



California State Board of Pharmacy
1625 North Market Blvd., N219, Sacramento, CA 95834
Phone (916) 574-7900
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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: July 8, 2009
Time: 11:00 a.m. – 1:30 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 **11:00 a.m.**

A. REGULATIONS REPORT

1. Board Approved Regulations – Undergoing Administrative Review

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

2. 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

3. 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

4. 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. Board Sponsored Legislation

- a. **SB 819** (Senate Business, Professions & Economic Development Committee) – Omnibus Provisions (formerly contained in the enrolled version of SB 1779 [2008], vetoed).
 - Changes based on recodification of B&PC §4052
 - §733 – Dispensing Prescription Drugs and Devices
 - §4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Facilities
 - §4040 – Prescription; Content Requirements
 - §4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
 - §4060 – Controlled Substance; Prescription Required; Exceptions
 - §4076 – Prescription Container; Requirements for Labeling
 - §4111 – Restrictions on Prescriber Ownership
 - §4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
 - H&SC §11150 – Persons Authorized to Write or Issue a Prescription
 - General Omnibus Changes
 - §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**
- a. **AB 718** (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to electronically transmit data by 1/1/12
 - b. **AB 830** (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia recognized by the Centers of Medicare and Medicaid
 - c. **AB 931** (Fletcher) Emergency Supplies – Doses stored in an emergency supplies container
 - d. **AB 1370** (Solorio) “Best Before” date on a prescription label
 - e. **SB 43** (Alquist) Cultural and Linguistic Competency
 - f. **SB 389** (Negrete McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus
 - g. **SB 484** (Wright) Ephedrine Products / Schedule V
 - h. **SB 762** (Aanestad) Professions and Vocations; Healing Arts
- 3. Legislation That Failed Passage Deadline, May Become Two Year Bill**
- 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 877** (Emmerson) (*Intent language*)Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice
- d. **AB 1458** (Davis) Drugs: Adverse Effects Reporting
- e. **SB 26** (Simitian) Home-Generated Pharmaceutical Waste
- f. **SB 238** (Calderon) Prescription Drugs
- g. **SB 341** (DeSaulnier) California Department of Public Health. CDPH to contract with UC to study/evaluate the safety and effectiveness of prescription Drugs
- h. **SB 638** (Negrete McLeod) DCA regulatory boards; sunset reviews; operations; report requirements

4. 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)

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

D. 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

1:30 p.m.

Committee materials will be available on the board's Web site by July 3, 2009



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

To: Legislation and Regulation Committee

ATTACHMENT 1

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 16 CCR §1785 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.

Board staff does 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.

A copy of the language approved by the board is provided in ATTACHMENT 1.

c. Proposed Adoption of 16 CCR §1751.9 – 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.

A copy of the language approved by the board is provided in ATTACHMENT 1.

Attachment 1

**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 ~~and~~ 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.



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DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee
From: Staff
Subject: Board Approved Regulations Under Development

ATTACHMENT 2

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

16 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.

Former Committee Chair and Board Member Bob Graul served on the subcommittee to work with board staff and industry.

President Schell may wish to consider filling the subcommittee vacancy created when Mr. Graul's board term concluded.

2. 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 they are compensated for time and travel.

One of the core functions of the Competency Committee is to complete an on-line review of all test questions prior to exam 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).

Board staff will draft proposed regulation language for consideration by this committee at a future meeting.

Attachment 2

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



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

Date: July 8, 2009
To: Legislation and Regulation Committee
Subject: Legislation Sponsored by the Board of Pharmacy
SB 819 - 2009 Omnibus Provisions

ATTACHMENT 3

As of 6/30/09

Last Amendment: 6/22/09

Status: Since the board met in April 2009, the bill was amended three times. No provisions related to Pharmacy Law were affected by the amendments. However, an "urgency" clause was added on April 20, 2009. Should the bill be enacted, the provisions will become effective immediately.

Passed out of ASM Business and Professions on June 30, 2009
Referred to ASM Appropriations

At its 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 (2007-08) SB 1779 (Senate Committee on Business, Professions and Economic Development) which was vetoed by the Governor.

This year, the Senate Committee on Business, Professions & Economic Development sponsored SB 819, which contains many of the same provisions formerly contained in last session's SB 1779.

Four types of changes are addressed in SB 819:

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.

Attachment 3

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.

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

- Section 4022.5 – Designated Representative; Designated Representative-in-Charge
This section requires amendment to clarify the definition of “designated representative-in-charge” as well as the responsibilities of a licensee serving as such.
- Section 4036.5 – Pharmacist-in-Charge
A new section is needed to define the term “pharmacist-in-charge” as well as the responsibilities 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.
- 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 Facility – Intermediate Care Facility – Other Health Care Facilities
- Section 4040 – Prescription; Content Requirements
- Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- Section 4060 – Controlled Substance – Prescription Required, Exceptions
- Section 4076 – Prescription Container – Requirements for Labeling
- Section 4111 – Restrictions on Prescriber Ownership
- Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC 11150 – Persons Authorized to Write or Issue a Prescription

A copy of relevant pages of SB 819 as amended 6/22/09 are provided in ATTACHMENT 3.

BILL NUMBER: SB 819 AMENDED
BILL TEXT

AMENDED IN ASSEMBLY JUNE 22, 2009
AMENDED IN SENATE MAY 28, 2009
AMENDED IN SENATE MAY 5, 2009
AMENDED IN SENATE APRIL 20, 2009
AMENDED IN SENATE APRIL 13, 2009

INTRODUCED BY Committee on Business, Professions and Economic
Development (Negrete McLeod (chair), Aanestad, Corbett, Correa,
Flores, Oropeza, Romero, Walters, Wyland, and Yee)

MARCH 10, 2009

An act to amend Sections 27, 101, 128.5, 144, 146, 149, 683, 733, 800, 801, ~~801.01~~, 803, 2089.5, 2096, 2102, 2107, 2135, 2168.4, 2175, 2221, 2307, 2335, 2486, 2488, 2570.5, 2570.6, 2570.7, 2570.185, 2760.1, 3503, 3517, 3518, 3625, 3635, 3636, 3685, 3753.5, 4022.5, 4027, 4040, 4051, 4059.5, 4060, 4062, 4076, 4081, 4110, 4111, 4126.5, 4161, 4174, 4231, 4301, 4305, 4329, 4330, 4857, 4980.30, 4980.43, 4996.2, 4996.17, 4996.18, 5801, 6534, 6536, 6561, 7616, 7629, 8030.2, 8740, and 8746 of, to add Sections 2169, 2570.36, 4036.5, 4980.04, 4990.09, ~~5515.5~~ and 9855.15 to, and to repeal Sections 2172, 2173, 2174, 4981, 4994.1, 4996.20, 4996.21, and 6761 of, the Business and Professions Code, to amend Section 8659 of the Government Code, to amend Sections 8778.5, 11150, and 11165 of the Health and Safety Code, and to amend Section 14132.100 of the Welfare and Institutions Code, relating to professions and vocations, making an appropriation therefor, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

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

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

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 authorizes a person whose certificate has been surrendered, revoked, suspended, or placed on probation, as specified, to petition for reinstatement of the certificate or modification of the penalty if specified requirements are met. Under existing law, any person who meets certain eligibility requirements, including, but not limited to, the requirement that the person is academically eminent, as defined, may apply for a special faculty permit that authorizes the holder to practice medicine, without a physician's and surgeon's certificate, within the medical school itself and certain affiliated institutions.

This bill would revise the training requirements for a physician and surgeon's license, and would delete the requirement of passage of a clinical competency examination that is applicable to certain applicants. The bill would delete the provisions related to the appointment of examination commissioners, examinations being conducted in English and examination interpreters, the location of examinations, and examination notices. The bill would also delete the requirement that the board keep examination records on file for at least 2 years, and would instead require the board to keep state examination records on file until June 2070. The bill would revise the requirements for a petition for reinstatement or modification, as specified. The bill would require the holder of a special faculty permit to meet the same continuing medical education requirements as the holder of a physician's and surgeon's certificate and would also require a special faculty permit holder to show that he or she meets these requirements at the time of permit renewal.

Existing law provides for the licensure and regulation of podiatrists by the Board of Podiatric Medicine in the Medical Board of California. Existing law authorizes the Board of Podiatric Medicine to issue an order of nonadoption of a proposed decision or interim order of the Medical Quality Hearing Panel within 90 calendar days. Existing law requires an applicant for a certificate to practice podiatric medicine to meet specified application procedures.

This bill would instead authorize the Board of Podiatric Medicine to issue an order of nonadoption of a proposed decision or interim order of the Medical Quality Hearing Panel within 100 calendar days. The bill would revise the application procedures for a certificate to practice podiatric medicine, as specified.

(4) Existing law, the Occupational Therapy Practice Act, provides for the licensure of occupational therapists and the certification of occupational therapy assistants by the California Board of Occupational Therapy. Existing law requires an occupational therapist to document his or her evaluation, goals, treatment plan, and summary of treatment in the patient record. Existing law authorizes a limited permit to practice occupational therapy to be granted if specified education and examination requirements are met, but provides that if the person fails to qualify for or pass the first announced licensure examination, all limited permit privileges automatically cease upon due notice. Existing law requires an applicant applying for a license or certification to file with the board a written application provided by and satisfactory to the board, showing that he or she meets certain requirements, including, but not limited to, successful completion of an educational program's academic requirements approved by the board and accredited by the American Occupational Therapy Association's Accreditation Council for Occupational Therapy Education (ACOTE) and successful completion of a period of supervised fieldwork experience. Existing law also specifies the curriculum requirements for an education program for occupational therapists and occupational therapy assistants.

This bill would require an occupational therapy assistant to document in the patient record the services provided to the patient, and would require an occupational therapist or assistant to document and sign the patient record legibly. The bill would revise the provisions related to limited permit privileges to instead provide that a person's failure to pass the licensure examination during the initial eligibility period would cause the privileges to automatically cease upon due notice. The bill would require that the applicant successfully complete the educational program's academic requirements approved by the board and accredited by ACOTE, or accredited or approved by the American Occupational Therapy Association's (AOTA) predecessor organization, or approved by AOTA's Career Mobility Program. The bill would also revise those curriculum requirements for an educational program. The bill would authorize an applicant who is a graduate of an educational program and is unable to provide evidence of having met the curriculum requirements to demonstrate passage of a specified examination as evidence of having successfully satisfied the curriculum requirements. The bill would require an applicant who completed AOTA's Career Mobility Program to demonstrate participation in the program and passage of a specified examination as evidence of having successfully satisfied the educational program and curriculum requirements. The bill would revise the supervised fieldwork experience requirement. The bill would require a licensee to report to the board violations of the Occupational Therapy Practice Act by licensees or applicants for licensure and to cooperate with the board, as specified.

(5) Existing law, the Nursing Practice Act, provides for the licensure and regulation of nurses by the Board of Registered Nursing. Existing law authorizes a registered nurse whose license is revoked or suspended, or who is placed on probation, to petition for reinstatement of his or her license or modification of the penalty after a specified time period.

This bill would require a petition by a registered nurse whose

initial license application is subject to a disciplinary decision to be filed after a specified time period from the date upon which his or her initial license was issued.

(6) Existing law, the Physician Assistant Practice Act, provides for the licensure and regulation of physician's assistants by the Physician Assistant Committee of the Medical Board of California. Existing law authorizes the committee to grant interim approval to an applicant for licensure as a physician assistant.

This bill would delete that authority to grant interim approval and would make conforming changes.

(7) Existing law, the Naturopathic Doctors Act, provides for the licensure and regulation of naturopathic doctors by the Bureau of Naturopathic Medicine. Existing law requires licensees to obtain continuing education through specified continuing education courses. Existing law requires a licensee on inactive status to meet certain requirements in order to restore his or her license to active status, including paying a reactivation fee.

This bill would revise the standards for continuing education courses. The bill would delete the requirement that a licensee on inactive status pay a reactivation fee in order to restore his or her license to active status, and would instead require him or her to be current with all licensing fees.

Existing law authorizes the Director of Consumer Affairs to establish an advisory council related to naturopathic doctors composed of members who receive no compensation, travel allowances, or reimbursement of expenses.

This bill would delete the requirement that the members of the advisory council receive no compensation, travel allowances, or reimbursement of expenses.

(8) Existing law provides for the licensure and regulation of respiratory care practitioners by the Respiratory Care Board of California. Existing law authorizes the board to direct a practitioner or applicant who is found to have violated the law to pay the costs of investigation and prosecution.

This bill would also authorize the board to direct a practitioner or applicant who is found to have violated a term or condition of board probation to pay the costs for investigation and prosecution.

Existing law exempts certain healing arts practitioners from liability for specified services rendered during a state of war, state of emergency, or local emergency.

This bill would also exempt respiratory care practitioners from liability for the provision of specified services rendered during a state of war, state of emergency, or local emergency.

(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 applicants to provide certain boards and bureaus with a full set of fingerprints for the purpose of conducting criminal history record checks. Existing law requires licensees to file and the bureau to maintain certain information in each licensee's file, including whether the licensee has ever been removed as a fiduciary by a court for breach of trust committed intentionally, with gross negligence, in bad faith, or with reckless indifference, or demonstrated a pattern of negligent conduct, as specified.

This bill would require the bureau to disclose on the Internet information on its licensees and would require applicants to the bureau to comply with that fingerprint requirement. The bill would require licensees to file and the bureau to maintain information regarding whether the licensee has ever been removed for cause or resigned as a conservator, guardian, trustee, or personal representative, as well as various other details relating to that removal or resignation. The bill would also make a conforming change.

~~(13) Existing law, the Architects Practice Act, provides for the licensure and regulation of architects by the California Architects Board. Under existing law, the board is composed of 5 architect members and 5 public members. Existing law requires that each appointment to the board expire on June 30 of the 4th year following the year in which the previous term expired.~~

~~This bill would modify the term length for certain members of the board.~~

~~(14)~~

(13) Existing law provides a comprehensive scheme for the certification and regulation of interior designers. Under existing law, a stamp from an interior design organization certifies that an interior designer has passed a specified examination and that he or she has met certain other education or experience requirements, such as a combination of interior design education and diversified interior design experience that together total at least 8 years.

This bill would revise that provision by specifying that an interior designer may meet these requirements by having at least 8 years of interior design education, or at least 8 years of diversified interior design experience, or a combination of interior design education and diversified interior design experience that together total at least 8 years.

~~(15)~~

(14) Existing law provides for the registration of professional engineers and the licensure of land surveyors by the Board for Professional Engineers and Land Surveyors. Under existing law, in determining the qualifications of an applicant for registration or licensure, a majority vote of the board is required.

This bill would delete that majority vote requirement.

~~(16)~~

(15) Existing law, the Funeral Directors and Embalmers Law, provides for the licensure and regulation of funeral establishments and directors by the Cemetery and Funeral Bureau. Under existing law, every funeral establishment holding a funeral director's license on December 31, 1996, shall, upon application and payment of fees for renewal, be issued a funeral establishment license.

This bill would delete that provision.

~~(17)~~

(16) Existing law creates the Transcript Reimbursement Fund, with revenues in the fund to be available to provide shorthand reporting services to low-income litigants in civil cases. Existing law requires all unencumbered funds remaining in the Transcript Reimbursement Fund as of June 29, 2009, to be transferred to the Court Reporters' Fund, and repeals these provisions on January 1, 2011.

This bill would instead provide for the transfer of those unencumbered funds on January 1, 2011.

~~(18)~~

(17) The Electronic and Appliance Repair Dealer Registration Law provides for registration and regulation of service contractors by the Bureau of Electronic and Appliance Repair. Existing law makes it unlawful to act as a service contractor unless that person maintains a valid registration.

This bill would make it an infraction to violate that provision. The bill would also make conforming changes. By creating a new crime, the bill would impose a state-mandated local program.

~~(19)~~

(18) Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, pursuant to which medical benefits are provided to public assistance recipients and certain other low-income persons. Existing law provides that federally qualified health center services and rural health clinic services, as defined, are covered benefits under the Medi-Cal program, to be reimbursed, to the extent that federal financial participation is obtained, to providers on a per-visit basis. For those purposes, a "visit" is defined as a face-to-face encounter between a patient of a federally qualified health center or a rural health clinic and a "physician," which is defined to include a medical doctor, osteopath, podiatrist, dentist, optometrist, and chiropractor.

This bill would instead provide that the term "physician" includes a physician and surgeon, podiatrist, dentist, optometrist, and chiropractor.

~~(20)~~

(19) 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.

~~(21)~~

(20) This bill would declare that it is to take effect immediately as an urgency statute.

Vote: 2/3. Appropriation: yes. Fiscal committee: yes.
State-mandated local program: yes.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 27 of the Business and Professions Code is amended to read:

27. (a) Every entity specified in subdivision (b) shall provide on the Internet information regarding the status of every license issued by that entity in accordance with the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7

of Title 1 of the Government Code) and the Information Practices Act of 1977 (Chapter 1 (commencing with Section 1798) of Title 1.8 of Part 4 of Division 3 of the Civil Code). The public information to be provided on the Internet shall include information on suspensions and revocations of licenses issued by the entity and other related enforcement action taken by the entity relative to persons, businesses, or facilities subject to licensure or regulation by the entity. In providing information on the Internet, each entity shall comply with the Department of Consumer Affairs Guidelines for Access to Public Records. The information may not include personal information, including home telephone number, date of birth, or social security number. Each entity shall disclose a licensee's address of record. However, each entity shall allow a licensee to provide a post office box number or other alternate address, instead of his or her home address, as the address of record. This section shall not preclude an entity from also requiring a licensee, who has provided a post office box number or other alternative mailing address as his or her address of record, to provide a physical business address or residence address only for the entity's internal administrative use and not for disclosure as the licensee's address of record or disclosure on the Internet.

(b) Each of the following entities within the Department of Consumer Affairs shall comply with the requirements of this section:

(1) The Acupuncture Board shall disclose information on its licensees.

(2) The Board of Behavioral Sciences shall disclose information on its licensees, including marriage and family therapists, licensed clinical social workers, and licensed educational psychologists.

(3) The Dental Board of California shall disclose information on its licensees.

(4) The State Board of Optometry shall disclose information regarding certificates of registration to practice optometry, statements of licensure, optometric corporation registrations, branch office licenses, and fictitious name permits of its licensees.

(5) The Board for Professional Engineers and Land Surveyors shall disclose information on its registrants and licensees.

(6) The Structural Pest Control Board shall disclose information on its licensees, including applicators, field representatives, and operators in the areas of fumigation, general pest and wood destroying pests and organisms, and wood roof cleaning and treatment.

(7) The Bureau of Automotive Repair shall disclose information on its licensees, including auto repair dealers, smog stations, lamp and brake stations, smog check technicians, and smog inspection certification stations.

(8) The Bureau of Electronic and Appliance Repair shall disclose information on its licensees, including major appliance repair dealers, combination dealers (electronic and appliance), electronic repair dealers, service contract sellers, and service contract administrators.

(9) The Cemetery and Funeral Bureau shall disclose information on its licensees, including cemetery brokers, cemetery salespersons, cemetery managers, crematory managers, cemetery authorities, crematories, cremated remains disposers, embalmers, funeral establishments, and funeral directors.

(10) The Professional Fiduciaries Bureau shall disclose information on its licensees.

(11) The Contractors' State License Board shall disclose information on its licensees in accordance with Chapter 9 (commencing with Section 7000) of Division 3. In addition to information related

to licenses as specified in subdivision (a), the board shall also disclose information provided to the board by the Labor Commissioner pursuant to Section 98.9 of the Labor Code.

(12) The Board of Psychology shall disclose information on its licensees, including psychologists, psychological assistants, and registered psychologists.

(c) "Internet" for the purposes of this section has the meaning set forth in paragraph (6) of subdivision (e) of Section 17538.

SEC. 2. Section 101 of the Business and Professions Code, as amended by Section 1 of Chapter 31 of the Statutes of 2008, is amended to read:

101. The department is comprised of:

- (a) The Dental Board of California.
- (b) The Medical Board of California.
- (c) The State Board of Optometry.
- (d) The California State Board of Pharmacy.
- (e) The Veterinary Medical Board.
- (f) The California Board of Accountancy.
- (g) The California Architects Board.
- (h) The Bureau of Barbering and Cosmetology.
- (i) The Board for Professional Engineers and Land Surveyors.
- (j) The Contractors' State License Board.
- (k) The Bureau for Private Postsecondary and Vocational Education.

- (l) The Structural Pest Control Board.
- (m) The Bureau of Home Furnishings and Thermal Insulation.
- (n) The Board of Registered Nursing.
- (o) The Board of Behavioral Sciences.
- (p) The State Athletic Commission.
- (q) The Cemetery and Funeral Bureau.
- (r) The State Board of Guide Dogs for the Blind.
- (s) The Bureau of Security and Investigative Services.
- (t) The Court Reporters Board of California.
- (u) The Board of Vocational Nursing and Psychiatric Technicians.
- (v) The Landscape Architects Technical Committee.
- (w) The Bureau of Electronic and Appliance Repair.
- (x) The Division of Investigation.
- (y) The Bureau of Automotive Repair.
- (z) The State Board of Registration for Geologists and

Geophysicists.

- (aa) The Respiratory Care Board of California.
- (ab) The Acupuncture Board.
- (ac) The Board of Psychology.
- (ad) The California Board of Podiatric Medicine.
- (ae) The Physical Therapy Board of California.
- (af) The Arbitration Review Program.
- (ag) The Hearing Aid Dispensers Bureau.
- (ah) The Physician Assistant Committee.
- (ai) The Speech-Language Pathology and Audiology Board.
- (aj) The California Board of Occupational Therapy.
- (ak) The Osteopathic Medical Board of California.
- (a) The Bureau of Naturopathic Medicine.
- (am) The Dental Hygiene Committee of California.
- (an) The Professional Fiduciaries Bureau.
- (ao) Any other boards, offices, or officers subject to its

jurisdiction by law.

SEC. 3. Section 128.5 of the Business and Professions Code is amended to read:

128.5. (a) Notwithstanding any other provision of law, if at the end of any fiscal year, an agency within the Department of Consumer

Affairs, except the agencies referred to in subdivision (b), has unencumbered funds in an amount that equals or is more than the agency's operating budget for the next two fiscal years, the agency shall reduce license or other fees, whether the license or other fees be fixed by statute or may be determined by the agency within limits fixed by statute, during the following fiscal year in an amount that will reduce any surplus funds of the agency to an amount less than the agency's operating budget for the next two fiscal years.

(b) Notwithstanding any other provision of law, if at the end of any fiscal year, the California Architects Board, the Board of Behavioral Sciences, the Veterinary Medical Board, the Court Reporters Board of California, the Medical Board of California, the Board of Vocational Nursing and Psychiatric Technicians, or the Bureau of Security and Investigative Services has unencumbered funds in an amount that equals or is more than the agency's operating budget for the next two fiscal years, the agency shall reduce license or other fees, whether the license or other fees be fixed by statute or may be determined by the agency within limits fixed by statute, during the following fiscal year in an amount that will reduce any surplus funds of the agency to an amount less than the agency's operating budget for the next two fiscal years.

SEC. 4. Section 144 of the Business and Professions Code is amended to read:

144. (a) Notwithstanding any other provision of law, an agency designated in subdivision (b) shall require an applicant to furnish to the agency a full set of fingerprints for purposes of conducting criminal history record checks. Any agency designated in subdivision (b) may obtain and receive, at its discretion, criminal history information from the Department of Justice and the United States Federal Bureau of Investigation.

(b) Subdivision (a) applies to the following:

- (1) California Board of Accountancy.
- (2) State Athletic Commission.
- (3) Board of Behavioral Sciences.
- (4) Court Reporters Board of California.
- (5) State Board of Guide Dogs for the Blind.
- (6) California State Board of Pharmacy.
- (7) Board of Registered Nursing.
- (8) Veterinary Medical Board.
- (9) Registered Veterinary Technician Committee.
- (10) Board of Vocational Nursing and Psychiatric Technicians.
- (11) Respiratory Care Board of California.
- (12) Hearing Aid Dispensers Advisory Commission.
- (13) Physical Therapy Board of California.
- (14) Physician Assistant Committee of the Medical Board of California.
- (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) The Professional Fiduciaries Bureau.

(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.

SEC. 5. Section 146 of the Business and Professions Code is amended to read:

146. (a) Notwithstanding any other provision of law, a violation of any code section listed in subdivision (c) or (d) is an infraction subject to the procedures described in Sections 19.6 and 19.7 of the Penal Code when either of the following applies:

(1) A complaint or a written notice to appear in court pursuant to Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code is filed in court charging the offense as an infraction unless the defendant, at the time he or she is arraigned, after being advised of his or her rights, elects to have the case proceed as a misdemeanor.

(2) The court, with the consent of the defendant and the prosecution, determines that the offense is an infraction in which event the case shall proceed as if the defendant has been arraigned on an infraction complaint.

(b) Subdivision (a) does not apply to a violation of the code sections listed in subdivisions (c) and (d) if the defendant has had his or her license, registration, or certificate previously revoked or suspended.

(c) The following sections require registration, licensure, certification, or other authorization in order to engage in certain businesses or professions regulated by this code:

- (1) Sections 2052 and 2054.
- (2) Section 2630.
- (3) Section 2903.
- (4) Section 3660.
- (5) Sections 3760 and 3761.
- (6) Section 4080.
- (7) Section 4825.
- (8) Section 4935.
- (9) Section 4980.
- (10) Section 4996.
- (11) Section 5536.
- (12) Section 6704.
- (13) Section 6980.10.
- (14) Section 7317.
- (15) Section 7502 or 7592.
- (16) Section 7520.
- (17) Section 7617 or 7641.
- (18) Subdivision (a) of Section 7872.
- (19) Section 8016.
- (20) Section 8505.
- (21) Section 8725.
- (22) Section 9681.
- (23) Section 9840.
- (24) Subdivision (c) of Section 9891.24.
- (25) Section 19049.

(d) Institutions that are required to register with the Bureau for Private Postsecondary and Vocational Education pursuant to Section 94931 of the Education Code.

(e) Notwithstanding any other provision of law, a violation of any of the sections listed in subdivision (c) or (d), which is an infraction, is punishable by a fine of not less than two hundred

fifty dollars (\$250) and not more than one thousand dollars (\$1,000). No portion of the minimum fine may be suspended by the court unless as a condition of that suspension the defendant is required to submit proof of a current valid license, registration, or certificate for the profession or vocation the absence of which was the basis for his or her conviction.

SEC. 6. Section 149 of the Business and Professions Code is amended to read:

149. (a) If, upon investigation, an agency designated in subdivision (e) 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 the agency to offer or perform those services, the agency may issue a citation under Section 148 containing an order of correction that requires the violator to do both of the following:

(1) Cease the unlawful advertising.

(2) Notify the telephone company furnishing services to the violator to disconnect the telephone service furnished to any telephone number contained in the unlawful advertising.

(b) This action is stayed if the person to whom a citation is issued under subdivision (a) notifies the agency in writing that he or she intends to contest the citation. The agency shall afford an opportunity for a hearing, as specified in Section 125.9.

(c) If the person to whom a citation and order of correction is issued under subdivision (a) fails to comply with the order of correction after that order is final, the agency shall inform the Public Utilities Commission of the violation and the Public Utilities Commission shall require the telephone corporation furnishing services to that person to disconnect the telephone service furnished to any telephone number contained in the unlawful advertising.

(d) The good faith compliance by a telephone corporation with an order of the Public Utilities Commission to terminate service issued pursuant to this section shall constitute a complete defense to any civil or criminal action brought against the telephone corporation arising from the termination of service.

(e) Subdivision (a) shall apply to the following boards, bureaus, committees, commissions, or programs:

- (1) The Bureau of Barbering and Cosmetology.
- (2) The Funeral Directors and Embalmers Program.
- (3) The Veterinary Medical Board.
- (4) The Hearing Aid Dispensers Advisory Commission.
- (5) The Landscape Architects Technical Committee.
- (6) The California Board of Podiatric Medicine.
- (7) The Respiratory Care Board of California.
- (8) The Bureau of Home Furnishings and Thermal Insulation.
- (9) The Bureau of Security and Investigative Services.
- (10) The Bureau of Electronic and Appliance Repair.
- (11) The Bureau of Automotive Repair.
- (12) The Tax Preparers Program.
- (13) The California Architects Board.
- (14) The Speech-Language Pathology and Audiology Board.
- (15) The Board for Professional Engineers and Land Surveyors.
- (16) The Board of Behavioral Sciences.
- (17) The State Board for Geologists and Geophysicists.
- (18) The Structural Pest Control Board.
- (19) The Acupuncture Board.
- (20) The Board of Psychology.
- (21) The California Board of Accountancy.
- (22) The Bureau of Naturopathic Medicine.
- (23) The Physical Therapy Board of California.

SEC. 7. Section 683 of the Business and Professions Code is amended to read:

683. (a) A board shall report, within 10 working days, 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 by the licensee, or placed in another category that prohibits the licensee from practicing his or her profession. The purpose of the reporting requirement is to prevent reimbursement by the state for Medi-Cal and Denti-Cal services provided after the cancellation of a provider's professional license.

(b) "Board," as used in this section, means the Dental Board of California, the Medical Board of California, the Board of Psychology, the State Board of Optometry, the California State Board of Pharmacy, the Osteopathic Medical Board of California, the State Board of Chiropractic Examiners, and the California Board of Occupational Therapy.

SEC. 8. Section 733 of the Business and Professions Code is amended to read:

733. (a) No licentiate shall obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other provision of law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this section, "reasonable accommodation"

and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (1) of Section 12940 of the Government Code.

(c) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022.

(d) The provisions of this section shall apply to the drug therapy described in Section 4052.3.

(e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third-party payer accepted by the licentiate or payment of any required copayment by the patient.

(f) The notice to consumers required by Section 4122 shall include a statement that describes patients' rights relative to the requirements of this section.

SEC. 9. Section 800 of the Business and Professions Code is amended to read:

800. (a) The Medical Board of California, the Board of Psychology, the Dental Board of California, the Osteopathic Medical Board of California, the State Board of Chiropractic Examiners, the Board of Registered Nursing, the Board of Vocational Nursing and Psychiatric Technicians, the State Board of Optometry, the Veterinary Medical Board, the Board of Behavioral Sciences, the Physical Therapy Board of California, the California State Board of Pharmacy, the Speech-Language Pathology and Audiology Board, the California Board of Occupational Therapy, and the Acupuncture Board shall each separately create and maintain a central file of the names of all persons who hold a license, certificate, or similar authority from that board. Each central file shall be created and maintained to provide an individual historical record for each licensee with respect to the following information:

(1) Any conviction of a crime in this or any other state that constitutes unprofessional conduct pursuant to the reporting requirements of Section 803.

(2) Any judgment or settlement requiring the licensee or his or her insurer to pay any amount of damages in excess of three thousand dollars (\$3,000) for any claim that injury or death was proximately caused by the licensee's negligence, error or omission in practice, or by rendering unauthorized professional services, pursuant to the reporting requirements of Section 801 or 802.

(3) Any public complaints for which provision is made pursuant to subdivision (b).

(4) Disciplinary information reported pursuant to Section 805.

(b) Each board shall prescribe and promulgate forms on which members of the public and other licensees or certificate holders may file written complaints to the board alleging any act of misconduct in, or connected with, the performance of professional services by the licensee.

If a board, or division thereof, a committee, or a panel has failed to act upon a complaint or report within five years, or has found that the complaint or report is without merit, the central file shall be purged of information relating to the complaint or report.

Notwithstanding this subdivision, the Board of Psychology, the Board of Behavioral Sciences, and the Respiratory Care Board of California shall maintain complaints or reports as long as each board deems necessary.

(c) The contents of any central file that are not public records under any other provision of law shall be confidential except that the licensee involved, or his or her counsel or representative, shall have the right to inspect and have copies made of his or her

proceeding before the board, the board or the administrative law judge may direct any practitioner or applicant found to have committed a violation or violations of law or any term and condition of board probation to pay to the board a sum not to exceed the costs of the investigation and prosecution of the case. A certified copy of the actual costs, or a good faith estimate of costs where actual costs are not available, signed by the official custodian of the record or his or her designated representative shall be prima facie evidence of the actual costs of the investigation and prosecution of the case.

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

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

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

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

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

~~SEC. 43.~~ SEC. 42. 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 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.

~~SEC. 44.~~ SEC. 43. 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 Section 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 Section 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 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. 45.~~ SEC. 44. 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. 46.~~ SEC. 45. 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 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 3640.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to either 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 (2) of subdivision (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. 47.~~ SEC. 46. 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 4052.1, 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. 48.~~ SEC. 47. 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 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.

~~SEC. 49.~~ SEC. 48. 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 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. 50.~~ SEC. 49. 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. 51.~~ SE C. 50. 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 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 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 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. 52.~~ SEC. 51. 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.

~~SEC. 53.~~ SEC. 52. 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. 54.~~ SEC. 53. 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 either Section 4052.1 or 4052.2.

~~SEC. 55.~~ SEC. 54. 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 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.

~~SEC. 56.~~ SEC. 55. 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. 57.~~ SEC. 56. 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 4052.1, 4052.2, or 4052.3.

~~SEC. 58.~~ SEC. 57. 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. 59.~~ SEC. 58. 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 dangerous drug or alcoholic beverage, or any combination of those substances.

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

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

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

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and 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.

~~SEC. 60.~~ SEC. 59. Section 4305 of the Business and Professions Code is amended to read:

4305. (a) 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.

(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 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.

~~SEC. 61.~~ SEC. 60. Section 4329 of the Business and Professions Code is amended to read:

4329. Any nonpharmacist who takes charge of or acts as 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. 62.~~ SEC. 61. 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 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. 63.~~ SEC. 62. 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:

requirements:

(a) (1) The board of trustees shall honor a written request of revocation by the trustor within 30 days upon receipt of the written request.

(2) Except as provided in paragraph (3), the board of trustees upon revocation of a special care trust may assess a revocation fee on the earned income of the trust only, the amount of which shall not exceed 10 percent of the trust corpus, as set forth in subdivision (c) of Section 2370 of Title 16 of the California Code of Regulations.

(3) If, prior to or upon the death of the beneficiary of a revocable special care trust, the cemetery authority is unable to perform the services of the special care trust fund agreement, the board of trustees shall pay the entire trust corpus and all earned income to the beneficiary or trustor, or the legal representative of either the beneficiary or trustor, without the imposition of a revocation fee.

(b) Notwithstanding subdivision (d) of Section 2370 of Title 16 of the California Code of Regulations, the board of trustees may charge an annual fee for administering a revocable special care trust fund, which may be recovered by administrative withdrawals from current trust income, but the total administrative withdrawals in any year shall not exceed 4 percent of the trust balance.

(c) Notwithstanding Section 8785, any person, partnership, or corporation who violates this section shall be subject to disciplinary action as provided in Article 6 (commencing with Section 9725) of Chapter 19 of Division 3 of the Business and Professions Code, or by a civil fine not exceeding five hundred dollars (\$500), or by both, as determined by the Cemetery and Funeral Bureau and shall not be guilty of a crime.

~~SEC. 88.~~ SEC. 87. Section 11150 of the Health and Safety Code is amended to read:

11150. No person other than a physician, dentist, podiatrist, or veterinarian, or naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of either Section 4052.1 or 4052.2 of the Business and Professions Code, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, a naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

~~SEC. 89.~~ SEC. 88. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the

Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

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

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

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

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

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

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

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

(5) Quantity of the controlled substance dispensed.

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

(7) Number of refills ordered.

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

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

~~SEC. 90.~~ SEC. 89. Section 14132.100

of the Welfare and Institutions Code is amended to read:

14132.100. (a) The federally qualified health center services



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

Date: July 8, 2009
To: Legislation and Regulation Committee
Subject: Legislation Sponsored by the Board of Pharmacy
SB 820 – 2009 Omnibus Provisions

ATTACHMENT 4

As of 6/30/09

Last Amendment: 6/22/09

Status: While the bill has been amended twice since the board met in April 2009, no provisions in Pharmacy law were modified.

Hearing: The bill is scheduled to be heard in the Assembly Committee on Business and Professions on June 30, 2009

In late 2008, board staff was advised that the Office of Examination Resources (OER) was being renamed to the Office of Professional Examination Resources.

SB 820 (Senate Committee on Business, Professions & Economic Development) makes conforming changes throughout the Business and Professions Code, including §4200.3 and §4200.4, to reflect this name change. The bill also makes other changes to Consumer Affairs professions and vocations.

A copy of relevant pages of SB 820, as amended 6/22/09, is provided in Attachment 4.

Attachment 4

BILL NUMBER: SB 820 AMENDED
 BILL TEXT

AMENDED IN ASSEMBLY JUNE 22, 2009
 AMENDED IN SENATE APRIL 21, 2009

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

MARCH 10, 2009

An act to amend Sections 139, 146, 1632.5, 1634.2, 2493, 4200.3, 4200.4, 4938, 5016, 5021, 5022, 5023, 5651, 7028.7, 7044, 7159, 7159.5, 7159.14, 7303.2, 7500.1, 7505.5, 7507.9, 7507.12, 7606, 7616, 7641, 7643, 7646, 7647, 7662, 7665, 7666, 7671, 7725.5, 7729, 9884.2, 9884.7, 9884.12, 9889.3, and 10146 of, to add Sections 5515.5, 7044.01 and 7507.115 to, and to to repeal Section 6763.1 of, repeal and add Section 7108.5 of, the Business and Professions Code, to amend ~~Sections 44017.3, 44072.1, and 44072.2 of the Health and Safety Code,~~ Sections 44014.2, 44017.3, 44072.1, 44072.2, and 44095 of the Health and Safety Code, and to amend Sections 28, 5201, and 24603 of the Vehicle Code, relating to consumer affairs.

LEGISLATIVE COUNSEL'S DIGEST

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

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

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

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 that 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, the Architects Practice Act, provides for the licensure and regulation of architects by the California Architects Board. Under existing law, the board is composed of 5 architect members and 5 public members. Existing law requires that each appointment to the board expire on June 30 of the 4th year following the year in which the previous term expired.

This bill would modify the term length for certain members of the board.

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 Professional Engineers Act, provides for the licensure and regulation of professional engineers by the Board for Professional Engineers and Land Surveyors within the department. Under existing law, in order to use the title "structural engineer," a person must successfully pass a written test incorporating a national examination for structural engineering by a nationally recognized entity approved by the board, and a supplemental California specific examination.

This bill would eliminate the requirement to successfully pass a California specific examination, so that only one board-prescribed examination is required.

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.

Under existing law, a person who violates the law by engaging in work as an owner-builder without a contractor's license or an exemption from licensure is prohibited from obtaining a contractor's license for a period of one year following the violation.

This bill would delete that prohibition.

Existing law, the Collateral Recovery Act, provides for the licensure and regulation of repossession agencies by the Bureau of Security and Investigative Services under the supervision and control of the Director of Consumer Affairs. The act defines "collateral" as any vehicle, boat, recreational vehicle, motor home, appliance, or other property that is subject to a security agreement. ~~The act prohibits a person from engaging in the activities of a repossession agency unless the person holds a valid agency license or is exempt from licensure, as specified.~~ Under the act, a person may be actively in charge of only one repossession office at a time. A violation of the act is a misdemeanor.

This bill would specify that the act also applies to trailers and

would authorize a person to be actively in charge of 2 repossession offices at a time. The bill would prohibit a licensee from appraising the value of any collateral. Because a violation of that prohibition would be a crime, the bill would impose a state-mandated local program.

Existing law sets forth a procedure for the removal, inventory, and storage of personal effects from repossessed collateral. Existing law allows a debtor to waive the preparation and presentation of an inventory in certain circumstances and authorizes a repossession agency to release those personal effects to someone other than the debtor when authorized by the debtor or legal owner. Existing law requires specified special interest license plates that remain the personal effects of the debtor to be removed from the collateral and inventoried and requires the destruction of those plates and notification to the Department of Motor Vehicles if the plates are not claimed by the debtor within 60 days.

This bill would authorize a debtor to make that waiver only with the consent of the licensee and would authorize the release of personal effects to someone other than the debtor only when authorized by the debtor. The bill would also authorize a licensee to retain those special interest license plates indefinitely for return to the debtor, as specified.

Existing law provides that whenever possession is taken of any vehicle by or on behalf of any legal owner under the terms of a security agreement or lease agreement, the person taking possession is required to notify specified law enforcement agencies within one hour after taking possession of the vehicle and by the most expeditious means available. Failure to provide that notice is an infraction.

This bill would require separate notifications for multiple vehicle repossessions. By changing the definition of a crime, the bill would impose a state-mandated local program.

Existing law, the Funeral Directors and Embalmers Law, provides for the licensure and regulation of embalmers and funeral directors by the Cemetery and Funeral Bureau. Existing law requires an applicant for an embalmer's license to, among other things, have successfully completed a course of instruction in a specified embalming school and to either furnish proof of completion of a high school course or evidence of licensure and practice for a certain period of time prior to application.

This bill would instead require the applicant to have graduated from a specified mortuary science program and to furnish official transcripts from that program. The bill would make other conforming changes.

Existing law requires the applicant to pass an examination including specified subjects and requires the bureau to examine applicants at least once annually.

This bill would require the applicant to pass the ~~funeral services~~ sciences section of a specified national examination and an examination on the state's laws and the rules and regulations of the bureau and would delete the requirement that the board examine applicants at least once annually. The bill would, until June 30, 2010, authorize an applicant who failed the examination previously administered by the bureau to retake that examination.

Existing law, the Real Estate Law, provides for the licensure and regulation of real estate brokers and salespersons by the Real Estate Commissioner. Existing law authorizes the commissioner to issue rules and regulations he or she deems necessary to regulate the method of accounting and to accomplish certain purposes related to

advance fees, as specified.

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

Existing law, the Automotive Repair Act, provides for the registration, licensure, and regulation of automotive repair dealers, lamp and brake adjusting stations, and smog check stations and technicians by the Bureau of Automotive Repair in the Department of Consumer Affairs and requires the Director of Consumer Affairs to validate an automotive repair dealer registration upon receipt of a specified form and fee. Existing law authorizes the director to refuse to validate or invalidate that registration for, among other things, a conviction for providing consideration to insurance agents for referrals. Under existing law, the director may deny, suspend, revoke, or take other disciplinary action against lamp and brake adjusting station or smog check station and technician applicants and licensees for, among other things, the conviction of a crime substantially related to the qualifications, functions, and duties of the licensee.

This bill would require the director to issue an automotive repair dealer registration upon receipt of a specified form and fee and would authorize the director to deny, suspend, revoke, or place on probation a registration for, among other things, conviction of a crime that is substantially related to the qualifications, functions, or duties of an automotive repair dealer. The bill would also authorize the director to deny, suspend, revoke, or take other disciplinary action against lamp and brake adjusting station and smog check station and technician applicants and licensees for the conviction of a crime substantially related to the qualifications, functions, or duties of that licensee.

Existing law establishes the vehicle inspection and maintenance (smog check) program, administered by the Department of Consumer Affairs and prescribes certain cost limits for repairs under the program. Existing law requires a smog check station where smog check inspections are performed to post a sign advising customers of those cost limits.

This bill would instead require the department to provide licensed smog check stations with a sign informing customers about their options when a vehicle fails a smog check inspection, as specified.

The bill would *revise provisions relating to repair assistance agreements and would make other technical, nonsubstantive changes.*

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

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

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

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 139 of the Business and Professions Code is amended to read:

139. (a) The Legislature finds and declares that occupational analyses and examination validation studies are fundamental components of licensure programs. It is the intent of the Legislature that the policy developed by the department pursuant to subdivision (b) be used by the fiscal, policy, and sunset review committees of

the Legislature in their annual reviews of these boards, programs, and bureaus.

(b) Notwithstanding any other provision of law, the department shall develop, in consultation with the boards, programs, bureaus, and divisions under its jurisdiction, and the Osteopathic Medical Board of California and the State Board of Chiropractic Examiners, a policy regarding examination development and validation, and occupational analysis. The department shall finalize and distribute this policy by September 30, 1999, to each of the boards, programs, bureaus, and divisions under its jurisdiction and to the Osteopathic Medical Board of California and the State Board of Chiropractic Examiners. This policy shall be submitted in draft form at least 30 days prior to that date to the appropriate fiscal, policy, and sunset review committees of the Legislature for review. This policy shall address, but shall not be limited to, the following issues:

(1) An appropriate schedule for examination validation and occupational analyses, and circumstances under which more frequent reviews are appropriate.

(2) Minimum requirements for psychometrically sound examination validation, examination development, and occupational analyses, including standards for sufficient number of test items.

(3) Standards for review of state and national examinations.

(4) Setting of passing standards.

(5) Appropriate funding sources for examination validations and occupational analyses.

(6) Conditions under which boards, programs, and bureaus should use internal and external entities to conduct these reviews.

(7) Standards for determining appropriate costs of reviews of different types of examinations, measured in terms of hours required.

(8) Conditions under which it is appropriate to fund permanent and limited term positions within a board, program, or bureau to manage these reviews.

(c) Every regulatory board and bureau, as defined in Section 22, and every program and bureau administered by the department, the Osteopathic Medical Board of California, and the State Board of Chiropractic Examiners, shall submit to the director on or before December 1, 1999, and on or before December 1 of each subsequent year, its method for ensuring that every licensing examination administered by or pursuant to contract with the board is subject to periodic evaluation. The evaluation shall include (1) a description of the occupational analysis serving as the basis for the examination; (2) sufficient item analysis data to permit a psychometric evaluation of the items; (3) an assessment of the appropriateness of prerequisites for admittance to the examination; and (4) an estimate of the costs and personnel required to perform these functions. The evaluation shall be revised and a new evaluation submitted to the director whenever, in the judgment of the board, program, or bureau, there is a substantial change in the examination or the prerequisites for admittance to the examination.

(d) The evaluation may be conducted by the board, program, or bureau, the Office of Professional Examination ~~Resources~~

Services of the department, the Osteopathic Medical Board of California, or the State Board of Chiropractic Examiners or pursuant to a contract with a qualified private testing firm. A board, program, or bureau that provides for development or administration of a licensing examination pursuant to contract with a public or private entity may rely on an occupational analysis or item analysis conducted by that entity. The department shall compile this information, along with a schedule specifying when examination

validations and occupational analyses shall be performed, and submit it to the appropriate fiscal, policy, and sunset review committees of the Legislature by September 30 of each year. It is the intent of the Legislature that the method specified in this report be consistent with the policy developed by the department pursuant to subdivision (b).

SEC. 2. Section 146 of the Business and Professions Code is amended to read:

146. (a) Notwithstanding any other provision of law, a violation of any code section listed in subdivision (c) or (d) is an infraction subject to the procedures described in Sections 19.6 and 19.7 of the Penal Code when:

(1) A complaint or a written notice to appear in court pursuant to Chapter 5c (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code is filed in court charging the offense as an infraction unless the defendant, at the time he or she is arraigned, after being advised of his or her rights, elects to have the case proceed as a misdemeanor, or

(2) The court, with the consent of the defendant and the prosecution, determines that the offense is an infraction in which event the case shall proceed as if the defendant has been arraigned on an infraction complaint.

(b) Subdivision (a) does not apply to a violation of the code sections listed in subdivisions (c) and (d) if the defendant has had his or her license, registration, or certificate previously revoked or suspended.

(c) The following sections require registration, licensure, certification, or other authorization in order to engage in certain businesses or professions regulated by this code:

- (1) Sections 2052 and 2054.
- (2) Section 2630.
- (3) Section 2903.
- (4) Section 3660.
- (5) Sections 3760 and 3761.
- (6) Section 4080.
- (7) Section 4825.
- (8) Section 4935.
- (9) Section 4980.
- (10) Section 4996.
- (11) Section 5536.
- (12) Section 6530.
- (13) Section 6704.
- (14) Section 6980.10.
- (15) Section 7317.
- (16) Section 7502 or 7592.
- (17) Section 7520.
- (18) Section 7617 or 7641.
- (19) Subdivision (a) of Section 7872.
- (20) Section 8016.
- (21) Section 8505.
- (22) Section 8725.
- (23) Section 9681.
- (24) Section 9840.
- (25) Subdivision (c) of Section 9891.24.
- (26) Section 19049.

(d) Institutions that are required to register with the Bureau for Private Postsecondary and Vocational Education pursuant to Section 94931 of the Education Code.

(e) Notwithstanding any other provision of law, a violation of any of the sections listed in subdivision (c) or (d), which is an

infraction, is punishable by a fine of not less than two hundred fifty dollars (\$250) and not more than one thousand dollars (\$1,000). No portion of the minimum fine may be suspended by the court unless as a condition of that suspension the defendant is required to submit proof of a current valid license, registration, or certificate for the profession or vocation which was the basis for his or her conviction.

SEC. 3. Section 1632.5 of the Business and Professions Code is amended to read:

1632.5. (a) Prior to implementation of paragraph (2) of subdivision (c) of Section 1632, the department's Office of Professional Examination ~~Resources~~ Services

shall review the Western Regional Examining Board examination to ensure compliance with the requirements of Section 139 and to certify that the examination process meets those standards. If the department determines that the examination process fails to meet those standards, paragraph (2) of subdivision (c) of Section 1632 shall not be implemented. The review of the Western Regional Examining Board examination shall be conducted during or after the Dental Board of California's occupational analysis scheduled for the 2004-05 fiscal year, but not later than September 30, 2005. However, an applicant who successfully completes the Western Regional Examining Board examination on or after January 1, 2005, shall be deemed to have met the requirements of subdivision (c) of Section 1632 if the department certifies that the Western Regional Examining Board examination meets the standards set forth in this subdivision.

(b) The Western Regional Examining Board examination process shall be regularly reviewed by the department pursuant to Section 139.

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

(d) As part of its next scheduled review by the Joint Committee on Boards, Commissions, and Consumer Protection, the Dental Board of California shall report to that committee and the department on the pass rates of applicants who sat for the Western Regional Examining Board examination, compared with the pass rates of applicants who sat for the state clinical and written examination administered by the Dental Board of California. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

SEC. 4. Section 1634.2 of the Business and Professions Code is amended to read:

1634.2. (a) An advanced education program's compliance with subdivision (c) of Section 1634.1 shall be regularly reviewed by the department pursuant to Section 139.

(b) An advanced education program described in subdivision (c) of Section 1634.1 shall meet the requirements of subdivision (a) of Section 12944 of the Government Code.

(c) The clinical residency program completion certification required by subdivision (c) of Section 1634.1 shall include a list of core competencies commensurate to those found in the board's examinations. The board, together with the department's Office of Professional Examination ~~Resources~~ Services, shall ensure the alignment of the competencies stated in the clinical residency program completion certification with the board's current occupational analysis. The board shall implement use of the clinical residency program completion certification form and use of the core competency list through the adoption of emergency regulations by January 1, 2008.

(d) As part of its next scheduled review after January 1, 2007, by the Joint Committee on Boards, Commissions and Consumer Protection, the board shall report to that committee and to the department the number of complaints received for those dentists who have obtained licensure by passing the state clinical examination and for those dentists who have obtained licensure through an advanced education program. The report shall also contain tracking information on these complaints and their disposition. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

SEC. 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~~ Services 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~~ Services

of the department or with an equivalent organization who shall certify at minimum once every five years that the examination process meets these national testing standards. If the department determines that the examination process fails to meet these standards, the board shall terminate its use of the North American Pharmacy Licensure Examination and shall use only the written and practical examination developed by the board.

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

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

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

(f) The board shall report to the Joint Committee on Boards, Commissions, and Consumer 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~~

Services 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~~ Services 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 ensure 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. 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



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

Date: July 8, 2009
To: Legislation and Regulation Committee
Subject: Legislation Sponsored by the Board of Pharmacy
SB 821 – 2009 Omnibus Provisions

ATTACHMENT 5

As of 6/30/09

Last Amendment: 6/15/09 (no amendments to Pharmacy provisions)
Amendment 5/20/09 – This version modified §4113(a) to specify the timeframe in which the board is notified upon change of a pharmacist-in-charge.

Status: Since the board met in April 2009, SB 821 has been amended three times. Specific amendments to §4113 (5/20/09) are provided below.

Hearing: The bill is scheduled to be heard in the Assembly Committee on Business and Professions on July 7, 2009

The omnibus provisions contained in SB 821 were approved by the board at its October 2008 Board Meeting. Those provisions are as follows:

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.

To address opposition to the language in Section 4113, the board president authorized an amendment to the section.

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 relevant pages of SB 821 as amended 6/15/09 (Sections 32-38) are provided in Attachment 5.

Attachment 5

BILL NUMBER: SB 821 AMENDED
BILL TEXT

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

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

MARCH 10, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

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

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

This bill would include within the definition of "licentiate" a holder of a special faculty permit to practice medicine within a medical school. The bill would also delete the peer review provisions related to the obsolete diversion program.

(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.

Existing law requires an applicant for licensure as an audiologist to meet specified educational and curriculum standards, including possession of at least a master's degree in audiology.

This bill would revise the educational and curriculum standards for licensure as an audiologist, as specified, and instead require possession of a doctorate in audiology. The bill would apply those requirements to applicants who graduate from an approved educational

record pertaining to, the substances described in subdivision (a), in which event the record of the conviction is conclusive evidence thereof.

(e) Been committed or confined by a court of competent jurisdiction for intemperate use of or addiction to the use of any of the substances described in subdivisions (a), (b), and (c), in which event the court order of commitment or confinement is prima facie evidence of that commitment or confinement.

(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. 31. 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:

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

(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. 32. 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 its 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. 33. Section 4101 of the Business and Professions Code is amended to read:

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

(b) A designated representative or a pharmacist may take charge of, and act as, the designated representative-in-charge of a wholesaler or veterinary food drug-animal retailer 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. 34. 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) 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. 35. 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.

(b) 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.

(c) 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.

(d) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as the 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.

(e) 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. 36. 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. 37. 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) 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 the designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the 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.

(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.

(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.

SEC. 38. Section 4196 of the Business and Professions Code is amended to read:

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

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

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

similar functions relating to the veterinary food-animal drug retailer.

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

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

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

SEC. 39. 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. Provided that the application for licensure is received by the board no later than four months after completion of a board accredited psychiatric technician program and approval of the application, the board may issue an interim permit authorizing the applicant to practice all skills included in the permittee's basic course of study, pending the results of the first licensing examination, or for a period of nine months, whichever occurs first.

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

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

SEC. 40. Section 4933 of the Business and Professions Code is amended to read:

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



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

Date: July 8, 2009
To: Legislation and Regulation Committee
From: Staff
Subject: Legislation Sponsored by the Board of Pharmacy
SB 470 (Corbett) - Elements of a Prescription Label

ATTACHMENT 6

As of 7/3/09

Last Amendment: 4/30/09

Hearing: The bill passed out of ASM Business and Professions on June 30 and is now scheduled to be heard in ASM Appropriations on July 8, 2009

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

As introduced, the California Medical Association issued a "Support if Amended" letter and offered amendments which were accepted by the author (resulting in a 4/27/09 amendment).

The current version of the bill (4/30/09) amends the definition of "Prescription" in §4040(a)(E) to include the condition **or purpose** for which the drug was prescribed, *if requested by the patient or patients*. §4076(a)(10) is amended to include the condition **or purpose** for which the drug was prescribed if the condition or purpose is indicated on the prescription."

While board staff has worked to establish a broad base of support for this proposal, it was necessary to make the "condition or purpose" permissive so as to remove opposition and keep the bill moving through policy committee.

Board staff will continue to advocate for this proposal and will engage stakeholders who express concerns.

Attachment 6 contains a copy of SB 470 as amended 4/30/09.

Attachment 6

BILL NUMBER: SB 470 AMENDED
BILL TEXT

AMENDED IN SENATE APRIL 30, 2009
AMENDED IN SENATE APRIL 27, 2009

INTRODUCED BY Senator Corbett

FEBRUARY 26, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

SB 470, as amended, Corbett. Prescriptions.

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

This bill would instead require that every prescription include a legible, clear notice of the condition or purpose for which the drug is prescribed, ~~and would delete the requirement that a patient request the inclusion of that information if requested by the patient~~. The bill would also require that every prescription container be correctly labeled to include that information if so ~~included~~ indicated on the prescription ~~, and would provide a process for inclusion of that information on the label if it is not included on the prescription and is requested by the patient~~.

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

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

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

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

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. 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 or purpose 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.

(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 3640.5, 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 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) of subdivision (b) 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. 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 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 conducted orally or electronically.~~
 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 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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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: July 8, 2009
To: Legislation and Regulation Committee
From: Staff
Subject: Legislation Sponsored by the Board of Pharmacy
AB 977 (Skinner) – Immunization Proposal – 2-Year Bill

ATTACHMENT 7

As of 6/30/09

Last Amendment: 4/23/09

Status: AB 977 did not move out of policy committee by the statutory deadline

The board's immunization proposal, AB 977, is authored by Assembly Member Skinner. This measure, as introduced, proposed amendments to Business and Professions Code section 4052 and added 4052.8 to authorize a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP). However, the President of the Board approved amendments to allow a pharmacist to administer influenza and pneumococcal vaccinations or any other immunization pursuant to a protocol with a prescriber. Unfortunately the California Medical Association (CMA) continues to oppose the measure, even with the proposed amendments.

The most recent amendment (4/23/09) provides intent language (only) which requests that the California Pharmacists Association provide information to the respective chairpersons of the Assembly Committees on Business and Professions and Health; and to the Senate Committees on Business, Professions and Economic Development, and Health on the status of immunization protocols between independent pharmacists and physicians.

CPhA is developing a survey to disseminate regarding immunization protocols. The results of the survey will be provided at a future meeting.

A copy of AB 977 as amended 4/23/09 is provided in Attachment 7.

Attachment 7

BILL NUMBER: AB 977 AMENDED
BILL TEXT

AMENDED IN ASSEMBLY APRIL 23, 2009
AMENDED IN ASSEMBLY APRIL 13, 2009

INTRODUCED BY Assembly Member Skinner

FEBRUARY 26, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

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

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

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

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

~~This bill would additionally authorize a pharmacist to initiate and administer influenza and pneumococcal immunizations to any person 7 years of age or older. The bill would require a pharmacist, prior to initiating and administering those immunizations, to complete a specified pharmacy-based immunization delivery training program. The bill would also require a pharmacist initiating and administering immunizations to complete 3 hours of immunization-related continuing education coursework annually and to be certified in basic life support. The bill would require a pharmacist, at the time of administration of an immunization, to provide the patient with a Vaccine Information Statement and to provide the patient's physician with documentation of administration of the immunization. The bill would also require a pharmacist administering an immunization to maintain a specified immunization administration record, provide documentation of administration to the California Immunization Registry, report any adverse event and assure proper storage and handling of vaccines. The bill would authorize a pharmacist initiating and administering vaccines to initiate and administer epinephrine for severe allergic reactions. The bill would also require a pharmacist to obtain the consent of a parent or guardian before administering any immunization to a patient under 18 years of age.~~

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

~~The California Constitution requires the state to reimburse local~~

~~agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.~~

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

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

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

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

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

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

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

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

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

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

~~SEC. 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 or initiate and administer immunizations pursuant to 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. 3. Section 4052.8 is added to the Business and Professions Code, to read:~~

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

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

~~(2) Initiate and administer influenza or pneumococcal 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) A pharmacist shall obtain the consent of a parent or guardian before administering an immunization to a patient under 18 years of age.~~

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

~~(1) Provide the patient or the patient's agent with the appropriate Vaccine Information Statement, produced by the 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).~~

~~(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.~~

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

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

~~(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. 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.~~

_____ CORRECTIONS Digest--Page 2--Vote key
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: July 8, 2009
To: Legislation and Regulation Committee
From: Staff
Subject: Legislation Sponsored by the Board of Pharmacy
AB 1071 (Emmerson) - Pharmacy Fees

ATTACHMENT 8

As of 7/3/09

Introduced: 2/27/09

Hearing: AB 1071 is scheduled to be heard in SEN Appropriations on 7/6/09

AB 1071 (Emmerson), as introduced 2/27/09, 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.

This measure has passed through the Assembly unopposed and recently (6/29/09) passed from the Senate policy committee (Ayes 9. Noes 0.) to Senate Appropriations.

Staff continues to meet with legislative staff members and others to provide information and answer questions related to the board's proposal.

A copy of AB 1071 as introduced is provided in Attachment 8.

Attachment 8

BILL NUMBER: AB 1071 INTRODUCED
BILL TEXT

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:

SECTION 1. 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 required in an amount established by the board ~~at an amount not to exceed the annual fee for renewal of a permit to conduct a pharmacy~~ as specified in subdivision (a) of Section 4400. 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.

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

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

SEC. 3. Section 4127.8 of the Business and Professions Code 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).



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

To: Legislation and Regulation Committee

ATTACHMENT 9

From: Staff

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

Below is a summary of various legislative proposals 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 analyses and other relevant information. Staff will provide updates to the committee at the committee meeting of any changes to the measures.

a. AB 718 (Emmerson) Inland Empire Health Plan E-Prescribing Pilot Program

A recent (6/30) amendment to AB 718 creates the Inland Empire Health Plan E-Prescribing Pilot Program within the *Welfare and Institutions Code* (State Department of Health Care Services), thereby removing any impact to Pharmacy law. The bill continues to specify program requirements, including e-prescribing, to promote health care quality, and that the pilot program be funded by funds made available through the federal American Recovery and Reinvestment Act of 2009. The language incorporates by reference the definition of "electronic prescribing" as defined in B&P §4040(c).

Board Position: None

Status: SEN Committee on Business, Professions & Economic Development
Hearing: July 6, 2009

b. AB 830 (Cook) Drugs and devices

This bill replaces USP references in Pharmacy Law with "various drug compendia references with compendia approved by the federal Centers for Medicare and Medicaid Services." A copy of the board's letter to "Oppose Unless Amended" (6/24/09) is attached, wherein amendments were offered to address the board's concerns. Those amendments were accepted and we expect to see the amended version in print next week.

Board Position: Oppose Unless Amended (version 4/23/09)

Status: SEN Health – Hearing: July 9, 2009

c. AB 931 (Fletcher) Emergency Supplies

This bill would increase the number of oral dosage form and suppository dosage form drugs for storage within an emergency supplies container to a limit of 48. The current limit is 24. Recent amendments (6/17/09) provide limitations to psychotherapeutic drugs contained in that e-kit, as specified.

Board Position: None

Status: SEN Health. Hearing: July 8, 2009

d. AB 1370 (Solorio) "Best Before" date on a prescription label

As introduced, the 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. The bill was dropped by the author. It never moved out of policy committee and, thus, failed the deadline. Accordingly, no bill analysis or legislative text is provided.

e. SB 43 (Alquist)

A recent 'gut & amend' (6/30) results in *no impact* to Pharmacy Law or the board's jurisdiction. As such, no bill analysis or legislative text is provided.

f. 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.

Board Position: Support (as Introduced 2/26)
Status: ASM Public Safety: Hearing July 7, 2009

g. SB 484 (Wright) Ephedrine and pseudoephedrine

This bill requires that substances specified in H&S §11100(a) be reported to the Department of Justice (CURES), including specified ephedrine substances. Exempt from the requirement(s) is a pharmacy filling a valid prescription. In addition, H&S §11375.5 is amended to specify that anyone who obtains a substance in subsection (b) [i.e., ephedrine substances] without a prescription is guilty of an infraction or a misdemeanor. The bill was not passed out of ASM Public Safety on 6/30/09.

Board Position: Support (as introduced 2/26/09)
Status: ASM Public Safety (did not pass)

h. SB 762 (Aanestad) Professions and Vocations; Healing Arts

Provides that no city, county or city and 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 was obtained.

Board Position: Support
Status: Enrolled and to the Governor June 29, 2009, at 4:30 p.m.

Attachment 9

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 718

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

AUTHOR: Emmerson

SPONSOR: Reed Elsevier, Inc.

Board Position: None

SUBJECT: Inland Empire Health Plan e-Prescribing Pilot Program

EXISTING LAW:

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

THIS BILL WOULD:

State legislative intent to create

Add Section 4071.2 to the Business and Professions Code:

Adds Section 14087.521 to the Welfare and Institutions Code:

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

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

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

AUTHOR'S INTENT:

According to the sponsor, electronic prescribing would improve safety and efficiency in the practices of medicine and pharmacy, streamline the prescribing process, and enhance communication among health care professionals. Further, the sponsor states that electronically created and transmitted prescriptions can reduce and eliminate errors both at the physician's office at the point of prescribing, and at the pharmacy when a written or oral prescription is entered into the pharmacy's computer system. Further, the sponsor states that e-prescribing can help ensure that patients with multiple physicians are not being over prescribed or taking medications that are contradictory in nature and can ensure that only Medi-Cal approved medications are prescribed as a physician will be immediately notified if the medication is not on the formulary.

FISCAL IMPACT:

The board does not anticipate any fiscal impact.

COMMENTS:

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

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

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

SUPPORT/OPPOSITION:

Reed Elsevier, Inc.

HISTORY:

June 30 From committee chair, with author's amendments: Amend and re-refer to committee. Read second time, amended, and re-referred to Com. on B.P.&E.D.
June 26 From committee: Do pass, and re-refer to Com. on BP&ED. Re-referred (Ayes 11. Noes 0.) (June 25).
June 22 In committee. Hearing postponed by committee.
June 16 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH
June 11 In committee: Set, first hearing. Hearing canceled at the request of author.
June 4 Re-referred to Coms. On HEALTH and BP&ED

May 27 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on RLS.

May 21 Referred to Com. on RLS.

May 11 In Senate. Read first time. To Com. on RLS. For Assignment

May 11 Read third time, passed, and to Senate. (Ayes 78. Noes 0.)

Apr. 30 Read second time. To Consent Calendar.

Apr. 28 Set for hearing in ASM B & P

Apr. 22 From committee: Do pass, and re-refer to Com. On B & P. Re-referred (Ayes 17. Noes 0) (April 21)

Apr. 21 From committee chair, with author's amendments: Amend, and re-refer.

Apr. 14 Re-referred to Com. on HEALTH.

Apr. 13 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.

Mar. 26 Referred to Coms. on HEALTH and B. & P.

Feb. 27 From printer. May be heard in committee March 29.

Feb. 26 Read first time. To print.

BILL NUMBER: AB 718 AMENDED
BILL TEXT

AMENDED IN SENATE JUNE 30, 2009
AMENDED IN SENATE JUNE 16, 2009
AMENDED IN SENATE MAY 27, 2009
AMENDED IN ASSEMBLY APRIL 22, 2009
AMENDED IN ASSEMBLY APRIL 13, 2009

INTRODUCED BY Assembly Member Emmerson
(Coauthor: Senator Negrete
McLeod)

FEBRUARY 26, 2009

An act to add and repeal Section ~~4071.2 of the Business and Professions Code,~~ 14087.521 of the Welfare and Institutions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

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

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

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

This bill would, until January 1, 2013, create the Inland Empire Health Plan E-Prescribing Pilot Program and would require the program to promote health care quality and the exchange of health care information and to include specified components, including electronic prescribing, as defined. The bill would require the Inland Empire Health Plan, a joint powers agency, to select, through a competitive bid process, an entity ~~with~~ whose product has

specified certification to administer the program and would require this entity to submit a report to the Legislature, by January 1, 2012, regarding the goals and results of the program and whether the program should be extended, as specified. *The bill would provide that the above-described provisions shall be funded by funds made available by the federal American Recovery and Reinvestment Act of 2009.* By imposing a new requirement on a joint powers agency, the bill would impose a state-mandated local program.

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

This bill would provide that, if the Commission on State Mandates determines that the bill contains costs mandated by the state,

reimbursement for those costs shall be made pursuant to these statutory provisions.

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

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 14087.521 is added to the Welfare and Institutions Code , to read:

14087.521. (a) The Inland Empire Health Plan E-Prescribing Pilot Program is hereby created. For purposes of this section, "program" means the Inland Empire Health Plan E-Prescribing Pilot Program.

(b) The program shall be administered by an entity whose product has been certified by the Certification Commission for Health Information Technology, either as a stand-alone electronic prescribing product or service or as part of an electronic health record product or service. This entity shall be selected by the Inland Empire Health Plan through a competitive bid process.

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

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

(2) Current payer formulary information.

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

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

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

(6) Patient drug history.

(d) Electronic prescribing pursuant to the program shall not interfere with a patient's existing freedom to choose a pharmacy and shall not interfere with the prescribing decision at the point of care.

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

(1) The number of prescribers enrolled in the program who use electronic prescribing.

(2) The number of pharmacies participating in the program.

(3) The number and percentage of prescriptions sent electronically as a percentage of the overall number of prescriptions reimbursed by the plan.

(4) Expenditures on the program.

(5) Data on whether and to what extent the program achieved the following goals:

(A) Reduced medication errors.

(B) Reduced prescription fraud.

(C) Reduced health care costs, including, but not limited to, inpatient hospitalization, by reducing medication errors, increasing patient medication compliance, and identifying medication contraindications.

(f) For purposes of this section, "electronic prescribing" shall have the same meaning as "electronic data transmission prescription" as defined in subdivision (c) of Section 4040 of the Business and Professions Code.

(g) This section shall be funded by funds made available by the federal American Recovery and Reinvestment Act of 2009 (Public Law 111-5).

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

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

~~4071.2. (a) The Inland Empire Health Plan E-Prescribing Pilot Program is hereby created. For purposes of this section, "program" means the Inland Empire Health Plan E-Prescribing Pilot Program.~~

~~(b) The program shall be administered by an entity with certification from the Certification Commission for Healthcare Information Technology. This entity shall be selected by the Inland Empire Health Plan through a competitive bid process.~~

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

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

~~(2) Current payer formulary information.~~

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

~~(4) Drug compendia approved by the Centers for Medicare and Medicaid Services.~~

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

~~(6) Patient drug history.~~

~~(d) Electronic prescribing pursuant to the program shall not interfere with a patient's existing freedom to choose a pharmacy and shall not interfere with the prescribing decision at the point of care.~~

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

~~(1) The number of prescribers enrolled in the program who use electronic prescribing.~~

~~(2) The number of pharmacies participating in the program.~~

~~(3) The number and percentage of prescriptions sent electronically as a percentage of the overall number of prescriptions reimbursed by the plan.~~

~~(4) Expenditures on the program.~~

~~(5) Data on whether and to what extent the program achieved the following goals:~~

~~(A) Reduced medication errors.~~

~~(B) Reduced prescription fraud.~~

~~(C) Reduced health care costs, including, but not limited to, inpatient hospitalization, by reducing medication errors, increasing patient medication compliance, and identifying medication contraindications.~~

~~(f) Notwithstanding Section 4321, a violation of this section~~

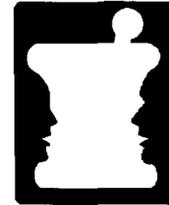
~~shall not be a crime.~~

~~(g) For purposes of this section, notwithstanding subdivision (c) of Section 4040, "electronic prescribing" means a prescription or prescription-related information transmitted between the point of care and the pharmacy using electronic media.~~

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

SEC. 2. If the Commission on State Mandates determines that this act contains costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 830

VERSION: As Amended: ~~April 1, 2009~~

Amended April 23, 2009

AUTHOR: Cook

SPONSOR: Medical Oncology Association of Southern California
(MOASC)

Association of Northern California Oncologists (ANCO)

BOARD POSITION:

OPPOSE UNLESS AMENDED

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 Pharmacopoeia

THIS BILL WOULD:

1. Would replace these references with ~~compendia~~ reference to a compendium 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~~ compendium 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 a federal compendium, or supplement thereof 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 has provided the author with a "Oppose Unless Amended" letter (6/24/09), in which the board conveys its concern with the replacement of "United States Pharmacopoeia" (USP) references with the diverse, broad term "compendium or supplement thereof approved by the

federal Centers for Medicare and Medicaid Services." The board offered suggested amendments to remove sections 2-13 of the bill which would restore current law.

The board established an "Oppose" position at its 4/30/09 Board Meeting; however, President Schell authorized an "Oppose Unless Amended" position prior to amendments being offered to the author.

HISTORY:

June 25 Re-referred to Com. on Health
June 4 Referred to Com. on RLS.
May 21 In Senate. Read first time. To Com. on RLS. For assignment.
May 21 Read third time, passed, and to senate. (Ayes 77. Noes 0. Page 1629)
May 18 Read second time. To Consent Calendar.
May 14 From committee: Do pass. To Consent Calendar. (May 13)
Apr. 27 Re-referred to committee on Appropriations
Apr. 23 Read second time and amended
Apr. 21 From committee: Amend, and do pass as amended, and re-refer to Com. on APPR. with recommendation: To Consent Calendar. (Ayes 19. Noes 0.) (April 14).
Apr. 2 Re-referred to Com. on HEALTH.
Apr. 1 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 23 Referred to Com. on HEALTH.
Feb. 27 From printer. May be heard in committee March 29.
Feb. 26 Read first time. To print.

BILL NUMBER: AB 830 AMENDED
 BILL TEXT

AMENDED IN ASSEMBLY APRIL 23, 2009
 AMENDED IN ASSEMBLY APRIL 1, 2009

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 *compendiums and compendia*, including the United States Pharmacopoeia, in various licensure, health care, and social services provisions.

This bill would replace these references with ~~compendia~~ a *compendium* 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~~ *compendium's* with ~~any compendia~~ a *compendium* approved by the federal Centers for Medicare and Medicaid Services. By changing the definition of a crime, this bill would impose a state-mandated local program.

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

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

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

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

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

13. The term "materia medica" as used in this code or in any initiative act referred to in this code, means those substances listed in a ~~compendia~~ *compendium* or supplement thereof approved by the federal Centers for Medicare and Medicaid Services, except substances covered by subdivision (a) of

Section 4052 and Section 4057.

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

4025. "Drug" means any of the following:

(a) Articles recognized in a ~~compendia~~ *compendium* 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 a ~~compendia~~ *compendium* 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 latest edition of a ~~compendia~~ *compendium* 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 either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

SEC. 6. Section 1370.4 of the Health and Safety Code is 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 contract.

(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 database 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) A ~~compendia~~ *compendium* 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 a ~~compendia~~ *compendium* 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 a ~~compendia~~ *compendium* 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 a ~~compendia~~ *compendium* 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 designated name and the drug or ingredient is an article recognized in a ~~compendia~~ *compendium* approved by the federal Centers for Medicare and Medicaid Services, then the official title in the 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 a ~~compendia~~ *compendium* 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 approved ~~compendia~~ *compendium*

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 a ~~compendia~~ *compendium* 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 approved ~~compendia~~ *compendium* 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 Homeopathic Pharmacopoeia of the United States and not to those of the approved ~~compendia~~ *compendium* .

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 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 a ~~compendia~~ *compendium* 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. 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 a ~~compendia~~ compendium 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 a

~~compendia~~ *compendium* 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 standards in a ~~compendia~~

compendium 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. 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 either of the following:

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

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

(b) It shall be the responsibility of the contracting prescriber to submit to the insurer documentation supporting compliance with the requirements of subdivision (a), if requested by the insurer.

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

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

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

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

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

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

(g) This section shall not apply to a policy of disability insurance that covers hospital, medical, or surgical expenses which is issued outside of California to an employer whose principal place of business is located outside of California.

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

(i) If an insurer denies coverage pursuant to this section on the basis that its use is experimental or investigational, that decision

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

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

SEC. 15. Section 10145.3 of the Insurance Code is amended to read:

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

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

(3) Either (A) the insured's contracting physician has recommended a drug, device, procedure, or other therapy that the physician certifies in writing is likely to be more beneficial to the insured than any available standard therapies, or (B) the insured, or the insured's physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the insured'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 insured 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 insurer to pay for the services of a noncontracting physician, provided pursuant to this subdivision, that are not otherwise covered pursuant to the contract.

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

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

(b) The insurer's decision to deny, delay, or modify experimental or investigational therapies shall be subject to the independent medical review process established under Article 3.5 (commencing with Section 10169) of Chapter 1 of Part 2 of Division 2, except that in lieu of the information specified in subdivision (b) of Section 10169.3, 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 insurer shall notify eligible insureds in writing of the opportunity to request the external independent review within five business days of the decision to deny coverage.

(2) If the insured'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 10169.3.

(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 insured than any available standard therapy, and the reasons that the expert recommends that the therapy should or should not be covered by the insurer, citing 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 database 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) A ~~compendia~~ *compendium* 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 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 a ~~compendia~~ *compendium* 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 a ~~compendia~~ *compendium* 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. 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 a ~~compendia~~ *compendium* 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. 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 either of the following:

(I) A ~~compendia~~ *compendium* approved by the federal Centers for Medicare and Medicaid Services.

(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. 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 either of the following:

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

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

June 24, 2009

The Honorable Paul Cook
Member, California State Assembly
State Capitol, Room 5164
Sacramento, CA 95814

RE: AB 830 (As amended April 23, 2009)

Dear Assemblymember Cook:

The California State Board of Pharmacy regrets to advise you that it opposes AB 830 unless it is amended. This bill identifies compendia used in diverse state codes, and would replace it with "compendium or supplement thereof approved by the federal Centers for Medicare and Medicaid Services."

First, let me state that the board thoroughly supports AB 830's intent to expand the options available to health care providers for treatment of patients with cancer. We also agree that all health care providers need to be reimbursed quickly, and any impediments to prompt payment need to be removed. We strongly support these goals.

However, we are concerned with replacement of the above phrase for "United States Pharmacopeia" (or simply USP) as currently specified throughout the California Business and Professions Code and Health and Safety Code. These code sections establish California's basic standards of quality and purity for pharmaceuticals.

The amendment we seek would be to remove sections 2-13 of the bill, which would restore these code sections to existing law. A mock-up of these changes into AB 830 is enclosed. We have no concern with the remaining sections of the bill.

We suggest these amendments because we are concerned that the broadening (or possible narrowing) of the reference to include (one or more) compendia and supplements approved by the CMS. Our concerns include: (a) It is not entirely clear whether the new language contemplates that only one compendium would be approved by CMS, or whether several compendia might be approved -- if the former, this could actually result in a narrowing of available drugs; (b) California would have no foreknowledge or supervision over which compendium or compendia might be approved by CMS; (c) California would be dependent on CMS not only for its determination(s) as to

The Honorable Paul Cook
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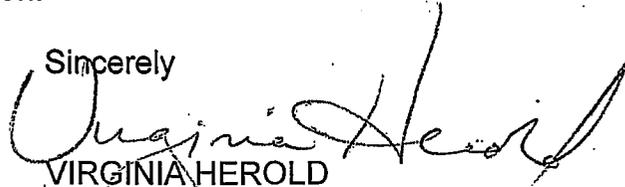
appropriate compendium/compendia, but also as to the timing of such approval(s); (d) California patients and providers would now have to consult state law, then the CMS list of approvals, followed by the compendium/compendia included on that list, before discovering appropriate drug information; (e) the list of approved compendium/compendia could change over time without any notice to California or its patients or providers; and (f) all of these factors introduce uncertainty into California law.

Finally, we received notice this morning that CMS has no such "approval" process in place for compendium/compendia (attached is a copy of an email from Craig Miner of CMS), so it is not clear whether the procedure proposed by AB 830 would accomplish the desired goals.

I will be happy to answer questions (574-7911) if I can be of assistance.

It was my pleasure to meet you and John Sobel this morning. And I again apologize for the timing of the notice of our opposition.

Sincerely



VIRGINIA HEROLD
Executive Officer

Enclosures: AB 830
Email String Containing Craig Miner's Assessment

AMENDED IN ASSEMBLY APRIL 23, 2009

AMENDED IN ASSEMBLY APRIL 1, 2009

CALIFORNIA LEGISLATURE—2009-10 REGULAR SESSION

ASSEMBLY BILL

No. 830

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

February 26, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

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

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

This bill would replace these references with *compendia a compendium* 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.

AB 830

— 2 —

This bill would replace the above drug *compendia compendium's* with any *compendia a compendium* approved by the federal Centers for Medicare and Medicaid Services. By changing the definition of a crime, this bill would impose a state-mandated local program.

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

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

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

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

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

3 13. The term "materia medica" as used in this code or in any
4 initiative act referred to in this code, means those substances listed
5 in a *compendia compendium* or supplement thereof approved by
6 the federal Centers for Medicare and Medicaid Services, except
7 substances covered by subdivision (a) of Section 4052 and Section
8 4057.

9 ~~SEC. 2. Section 4025 of the Business and Professions Code is~~
10 ~~amended to read:~~

11 ~~4025. "Drug" means any of the following:~~

12 (a) Articles recognized in a *compendia compendium* or
13 supplement thereof approved by the federal Centers for Medicare
14 and Medicaid Services.

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

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

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

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

23 4053. (a) Notwithstanding Section 4051, the board may issue
24 a license as a designated representative to provide sufficient and
25 qualified supervision in a wholesaler or veterinary food-animal
26 drug retailer. The designated representative shall protect the public

1 health and safety in the handling, storage, and shipment of
2 dangerous drugs and dangerous devices in the wholesaler or
3 veterinary food-animal drug retailer.

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

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

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

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

17 (A) Knowledge and understanding of California law and federal
18 law relating to the distribution of dangerous drugs and dangerous
19 devices.

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

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

23 (D) Knowledge and understanding of the standards relating to
24 the safe storage and handling of drugs in a *compendia compendium*
25 approved by the federal Centers for Medicare and Medicaid
26 Services.

27 (E) Knowledge and understanding of prescription terminology,
28 abbreviations, dosages and format.

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

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

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

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

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

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

6 4342. (a) The board may institute any action or actions as may
7 be provided by law and that, in its discretion, are necessary, to
8 prevent the sale of pharmaceutical preparations and drugs that do
9 not conform to the standard and tests as to quality and strength,
10 provided in the latest edition of a *compendia compendium* approved
11 by the federal Centers for Medicare and Medicaid Services or that
12 violate any provision of the Sherman Food, Drug and Cosmetic
13 Law (Part 5 (commencing with Section 109875) of Division 104
14 of the Health and Safety Code).

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

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

20 1367.21. (a) No health care service plan contract which covers
21 prescription drug benefits shall be issued, amended, delivered, or
22 renewed in this state if the plan limits or excludes coverage for a
23 drug on the basis that the drug is prescribed for a use that is
24 different from the use for which that drug has been approved for
25 marketing by the federal Food and Drug Administration (FDA),
26 provided that all of the following conditions have been met:

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

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

31 (B) The drug is prescribed by a participating licensed health
32 care professional for the treatment of a chronic and seriously
33 debilitating condition, the drug is medically necessary to treat that
34 condition, and the drug is on the plan formulary. If the drug is not
35 on the plan formulary, the participating subscriber's request shall
36 be considered pursuant to the process required by Section 1367.24.

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

39 (A) A *compendia compendium* approved by the federal Centers
40 for Medicare and Medicaid Services.

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 9 of
 36 Division 9 of the Welfare and Institutions Code) are exempt from
 37 the requirements of this section.
 38 SEC. 6. Section 1370.4 of the Health and Safety Code is
 39 amended to read:

1 1370.4. (a) Every health care service plan shall provide an
 2 external, independent review process to examine the plan's
 3 coverage decisions regarding experimental or investigational
 4 therapies for individual enrollees who meet all of the following
 5 criteria:
 6 (1) (A) The enrollee has a life-threatening or seriously
 7 debilitating condition.
 8 (B) For purposes of this section, "life-threatening" means either
 9 or both of the following:
 10 (i) Diseases or conditions where the likelihood of death is high
 11 unless the course of the disease is interrupted.
 12 (ii) Diseases or conditions with potentially fatal outcomes, where
 13 the end point of clinical intervention is survival.
 14 (C) For purposes of this section, "seriously debilitating" means
 15 diseases or conditions that cause major irreversible morbidity.
 16 (2) The enrollee's physician certifies that the enrollee has a
 17 condition, as defined in paragraph (1), for which standard therapies
 18 have not been effective in improving the condition of the enrollee,
 19 for which standard therapies would not be medically appropriate
 20 for the enrollee, or for which there is no more beneficial standard
 21 therapy covered by the plan than the therapy proposed pursuant
 22 to paragraph (3).
 23 (3) Either (A) the enrollee's physician, who is under contract
 24 with or employed by the plan, has recommended a drug, device,
 25 procedure or other therapy that the physician certifies in writing
 26 is likely to be more beneficial to the enrollee than any available
 27 standard therapies, or (B) the enrollee, or the enrollee's physician
 28 who is a licensed, board-certified or board-eligible physician
 29 qualified to practice in the area of practice appropriate to treat the
 30 enrollee's condition, has requested a therapy that, based on two
 31 documents from the medical and scientific evidence, as defined
 32 in subdivision (d), is likely to be more beneficial for the enrollee
 33 than any available standard therapy. The physician certification
 34 pursuant to this subdivision shall include a statement of the
 35 evidence relied upon by the physician in certifying his or her
 36 recommendation. Nothing in this subdivision shall be construed
 37 to require the plan to pay for the services of a nonparticipating
 38 physician provided pursuant to this subdivision, that are not
 39 otherwise covered pursuant to the plan contract.

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

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

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

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

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

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

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

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

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

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

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

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

20 (4) Compendia approved by the federal Centers
21 for Medicare and Medicaid Services.

22 (5) Findings, studies, or research conducted by or under the
23 auspices of federal government agencies and nationally recognized
24 federal research institutes, including the Federal Agency for Health
25 Care Policy and Research, National Institutes of Health, National
26 Cancer Institute, National Academy of Sciences, Health Care
27 Financing Administration, Congressional Office of Technology
28 Assessment, and any national board recognized by the National
29 Institutes of Health for the purpose of evaluating the medical value
30 of health services.

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

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

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

37 11014. "Drug" means (a) substances recognized as drugs in a
38 compendia *compendium* approved by the federal Centers for
39 Medicare and Medicaid Services; (b) substances intended for use
40 in the diagnosis, cure, mitigation, treatment, or prevention of

1 disease in man or animals; (c) substances (other than food) intended
2 to affect the structure or any function of the body of man or
3 animals; and (d) substances intended for use as a component of
4 any article specified in subdivision (a), (b), or (c) of this section.
5 It does not include devices or their components, parts, or
6 accessories.

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

9 109920. "Device" means any instrument, apparatus, implement,
10 machine, contrivance, implant, in vitro reagent, or other similar
11 or related article, including any component, part, or accessory, that
12 is any of the following:

13 (a) Recognized in a ~~compendia~~ *compendium* or supplement
14 thereof approved by the federal Centers for Medicare and Medicaid
15 Services.

16 (b) Intended for use in the diagnosis of disease or other
17 condition, or in the cure, mitigation, treatment, or prevention of
18 disease in humans or any other animal.

19 (c) Intended to affect the structure or any function of the body
20 of humans or any other animal and that does not achieve any of
21 its principal intended purposes through chemical action within or
22 on the body of humans or other animals and that is not dependent
23 upon being metabolized for the achievement of any of its principal
24 intended purposes.

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

27 109985. "Official compendium" means a ~~compendia~~
28 *compendium* or supplement thereof approved by the federal Centers
29 for Medicare and Medicaid Services.

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

32 111225. As used in this chapter, with respect to a drug or drug
33 ingredient, "established name" means either of the following:

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

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

1 If neither subdivision (a) or (b) of this section applies, the
2 common or usual name, if any, of the drug or of the ingredient is
3 the established name. When an article is recognized in a ~~compendia~~
4 *compendium* approved by the federal Centers for Medicare and
5 Medicaid Services and in the Homeopathic Pharmacopoeia under
6 different official titles, the official title used in the approved
7 ~~compendia~~ *compendium* shall apply unless it is labeled and offered
8 for sale as a homeopathic drug. If it is labeled and offered for sale
9 as a homeopathic drug, the official title used in the Homeopathic
10 Pharmacopoeia shall apply.

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

13 111235. Whenever a drug is recognized in both a ~~compendia~~
14 *compendium* approved by the federal Centers for Medicare and
15 Medicaid Services and the Homeopathic Pharmacopoeia of the
16 United States, it shall be subject to the requirements of the
17 approved ~~compendia~~ *compendium* unless it is labeled and offered
18 for sale as a homeopathic drug. If it is labeled and offered for sale
19 as a homeopathic drug, it shall be subject to the Homeopathic
20 Pharmacopoeia of the United States and not to those of the
21 approved ~~compendia~~ *compendium*.

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

24 111656.4. Section 4951 of the Business and Professions Code
25 shall not prohibit a home medical device retail facility from selling
26 or dispensing prescription devices if the department finds that
27 sufficient qualified supervision is employed by the home medical
28 device retail facility to adequately safeguard and protect the public
29 health. Each person applying to the department for this exemption
30 shall meet the following requirements to obtain and maintain the
31 exemption:

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

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

38 (2) He or she shall have a minimum of one year of paid work
39 experience related to the distribution or dispensing of dangerous
40 drugs or dangerous devices.

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

4 (A) Knowledge and understanding of state and federal laws
5 relating to the distribution of dangerous drugs and dangerous
6 devices.

7 (B) Knowledge and understanding of state and federal laws
8 relating to the distribution of controlled substances.

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

10 (D) Knowledge and understanding of the standards relating to
11 the safe storage and handling of drugs in a ~~compendium~~ *compendium*
12 approved by the federal Centers for Medicare and Medicaid
13 Services.

14 (E) Knowledge and understanding relating to the safe storage
15 and handling of home medical devices.

16 (F) Knowledge and understanding of prescription terminology,
17 abbreviations, and format.

18 (4) The department may, by regulation, require training
19 programs that include additional material.

20 (5) The department shall not issue an exemptee a license until
21 the applicant provides proof of completion of the required training
22 that the department determines is adequate to fulfill these
23 requirements.

24 (b) The licensed pharmacist or exemptee shall be on the premises
25 at all times that prescription devices are available for sale or fitting
26 unless the prescription devices are stored separately from other
27 merchandise and are under the exclusive control of the licensed
28 pharmacist or exemptee. A licensed pharmacist or an exemptee
29 need not be present in the warehouse facility of a home medical
30 device retail facility unless the department establishes that
31 requirement by regulation based upon the need to protect the
32 public.

33 (c) The department may require an exemptee to complete a
34 designated number of hours of coursework in department-approved
35 courses of home health education in the disposition of any
36 disciplinary action taken against the exemptee.

37 (d) Each premises maintained by a home medical device retail
38 facility shall have a license issued by the department and shall
39 have a licensed pharmacist or exemptee on the premises if
40 prescription devices are furnished, sold, or dispensed.

1 (e) A home medical device retail facility may establish locked
2 storage (a lock box or locked area) for emergency or after working
3 hours furnishing of prescription devices. Locked storage may be
4 installed or placed in a service vehicle of the home medical device
5 retail facility for emergency or after hours service to patients having
6 prescriptions for prescription devices.

7 (f) The department may by regulation authorize a licensed
8 pharmacist or exemptee to direct an employee of the home medical
9 device retail facility who operates the service vehicle equipped
10 with locked storage described in subdivision (e) to deliver a
11 prescription device from the locked storage to patients having
12 prescriptions for prescription devices. These regulations shall
13 establish inventory requirements for the locked storage by a
14 licensed pharmacist or exemptee to take place shortly after a
15 prescription device has been delivered from the locked storage to
16 a patient.

17 SEC. 13. Section 150204 of the Health and Safety Code is
18 amended to read:

19 150204. (a) A county may establish, by ordinance, a repository
20 and distribution program for purposes of this division. Only
21 pharmacies that are county-owned or that contract with the county
22 pursuant to this division may participate in this program to dispense
23 medication donated to the drug repository and distribution program.

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

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

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

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

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

36 (5) Ensuring the privacy of individuals for whom the medication
37 was originally prescribed.

38 (c) Any medication donated to the repository and distribution
39 program shall comply with the requirements specified in this

1 division. Medication donated to the repository and distribution
2 program shall meet all of the following criteria:

3 (1) The medication shall not be a controlled substance.
4 (2) The medication shall not have been adulterated, misbranded,
5 or stored under conditions contrary to standards set by a *compendia*
6 *compendium* approved by the federal Centers for Medicare and
7 Medicaid Services or the product manufacturer.

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

12 (d) Only medication that is donated in unopened, tamper-evident
13 packaging or modified unit dose containers that meet standards in
14 a *compendia compendium* approved by the federal Centers for
15 Medicare and Medicaid Services is eligible for donation to the
16 repository and distribution program, provided lot numbers and
17 expiration dates are affixed. Medication donated in opened
18 containers shall not be dispensed by the repository and distribution
19 program.

20 (c) A pharmacist shall use his or her professional judgment in
21 determining whether donated medication meets the standards of
22 this division before accepting or dispensing any medication under
23 the repository and distribution program.

24 (f) A pharmacist shall adhere to standard pharmacy practices,
25 as required by state and federal law, when dispensing all
26 medications.

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

- 29 (1) Dispensed to an eligible patient.
- 30 (2) Destroyed.
- 31 (3) Returned to a reverse distributor.

32 (h) Medication that is donated to the repository and distribution
33 program that does not meet the requirements of this division shall
34 not be distributed under this program and shall be either destroyed
35 or returned to a reverse distributor. This medication shall not be
36 sold, dispensed, or otherwise transferred to any other entity.

37 (i) Medication donated to the repository and distribution program
38 shall be maintained in the donated packaging units until dispensed
39 to an eligible patient under this program, who presents a valid
40 prescription. When dispensed to an eligible patient under this

1 program, the medication shall be in a new and properly labeled
2 container, specific to the eligible patient and ensuring the privacy
3 of the individuals for whom the medication was initially dispensed.
4 Expired medication shall not be dispensed.

5 (j) Medication donated to the repository and distribution program
6 shall be segregated from the pharmacy's other drug stock by
7 physical means, for purposes including, but not limited to,
8 inventory, accounting, and inspection.

9 (k) The pharmacy shall keep complete records of the acquisition
10 and disposition of medication donated to and dispensed under the
11 repository and distribution program. These records shall be kept
12 separate from the pharmacy's other acquisition and disposition
13 records and shall conform to the Pharmacy Law (Chapter 9
14 (commencing with Section 4000) of Division 2 of the Business
15 and Professions Code), including being readily retrievable.

16 (l) Local and county protocols established pursuant to this
17 division shall conform to the Pharmacy Law regarding packaging,
18 transporting, storing, and dispensing all medications.

19 (m) County protocols established for packaging, transporting,
20 storing, and dispensing medications that require refrigeration,
21 including, but not limited to, any biological product as defined in
22 Section 351 of the Public Health and Service Act (42 U.S.C. Sec.
23 262), an intravenously injected drug, or an infused drug, include
24 specific procedures to ensure that these medications are packaged,
25 transported, stored, and dispensed at their appropriate temperatures
26 and in accordance with standards in a *compendia compendium*
27 approved by the federal Centers for Medicare and Medicaid
28 Services and the Pharmacy Law.

29 (n) Notwithstanding any other provision of law, a participating
30 county-owned or county-contracted pharmacy shall follow the
31 same procedural drug pedigree requirements for donated drugs as
32 it would follow for drugs purchased from a wholesaler or directly
33 from a drug manufacturer.

34 ~~SEC. 14.~~ Section 10123.195 of the Insurance Code is amended
35 to read:

36 10123.195. (a) No group or individual disability insurance
37 policy issued, delivered, or renewed in this state or certificate of
38 group disability insurance issued, delivered, or renewed in this
39 state pursuant to a master group policy issued, delivered, or
40 renewed in another state that, as a provision of hospital, medical,

1 or surgical services, directly or indirectly covers prescription drugs
2 shall limit or exclude coverage for a drug on the basis that the drug
3 is prescribed for a use that is different from the use for which that
4 drug has been approved for marketing by the federal Food and
5 Drug Administration (FDA), provided that all of the following
6 conditions have been met:

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

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

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

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

17 (A) A compendia *compendium* approved by the federal Centers
18 for Medicare and Medicaid Services.

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

24 (b) It shall be the responsibility of the contracting prescriber to
25 submit to the insurer documentation supporting compliance with
26 the requirements of subdivision (a), if requested by the insurer.

27 (c) Any coverage required by this section shall also include
28 medically necessary services associated with the administration
29 of a drug subject to the conditions of the contract.

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

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

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

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

1 (f) The provision of drugs and services when required by this
2 section shall not, in itself, give rise to liability on the part of the
3 insurer.

4 (g) This section shall not apply to a policy of disability insurance
5 that covers hospital, medical, or surgical expenses which is issued
6 outside of California to an employer whose principal place of
7 business is located outside of California.

8 (h) Nothing in this section shall be construed to prohibit the use
9 of a formulary, copayment, technology assessment panel, or similar
10 mechanism as a means for appropriately controlling the utilization
11 of a drug that is prescribed for a use that is different from the use
12 for which that drug has been approved for marketing by the FDA.

13 (i) If an insurer denies coverage pursuant to this section on the
14 basis that its use is experimental or investigational, that decision
15 is subject to review under the Independent Medical Review System
16 of Article 3.5 (commencing with Section 10169).

17 (j) This section is not applicable to vision-only, dental-only,
18 Medicare or Champus supplement, disability income, long-term
19 care, accident-only, specified disease or hospital confinement
20 indemnity insurance.

21 SEC. 15. Section 10145.3 of the Insurance Code is amended
22 to read:

23 10145.3. (a) Every disability insurer that covers hospital,
24 medical, or surgical benefits shall provide an external, independent
25 review process to examine the insurer's coverage decisions
26 regarding experimental or investigational therapies for individual
27 insureds who meet all of the following criteria:

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

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

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

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

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

38 (2) The insured's physician certifies that the insured has a
39 condition, as defined in paragraph (1), for which standard therapies
40 have not been effective in improving the condition of the insured,

1 for which standard therapies would not be medically appropriate
2 for the insured, or for which there is no more beneficial standard
3 therapy covered by the insurer than the therapy proposed pursuant
4 to paragraph (3).

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

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

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

29 (b) The insurer's decision to deny, delay, or modify experimental
30 or investigational therapies shall be subject to the independent
31 medical review process established under Article 3.5 (commencing
32 with Section 10169) of Chapter 1 of Part 2 of Division 2, except
33 that in lieu of the information specified in subdivision (b) of
34 Section 10169.3, an independent medical reviewer shall base his
35 or her determination on relevant medical and scientific evidence,
36 including, but not limited to, the medical and scientific evidence
37 defined in subdivision (d).

38 (c) The independent medical review process shall also meet the
39 following criteria:

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

4 (2) If the insured's physician determines that the proposed
5 therapy would be significantly less effective if not promptly
6 initiated, the analyses and recommendations of the experts on the
7 panel shall be rendered within seven days of the request for
8 expedited review. At the request of the expert, the deadline shall
9 be extended by up to three days for a delay in providing the
10 documents required. The timeframes specified in this paragraph
11 shall be in addition to any otherwise applicable timeframes
12 contained in subdivision (c) of Section 10169.3.

13 (3) Each expert's analysis and recommendation shall be in
14 written form and state the reasons the requested therapy is or is
15 not likely to be more beneficial for the insured than any available
16 standard therapy, and the reasons that the expert recommends that
17 the therapy should or should not be covered by the insurer, citing
18 the insured's specific medical condition, the relevant documents,
19 and the relevant medical and scientific evidence, including, but
20 not limited to, the medical and scientific evidence as defined in
21 subdivision (d), to support the expert's recommendation.

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

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

27 (1) Peer-reviewed scientific studies published in or accepted
28 for publication by medical journals that meet nationally recognized
29 requirements for scientific manuscripts and that submit most of
30 their published articles for review by experts who are not part of
31 the editorial staff.

32 (2) Peer-reviewed literature, biomedical compendia and other
33 medical literature that meet the criteria of the National Institutes
34 of Health's National Library of Medicine for indexing in Index
35 Medicus, Excerpta Medicus (EMBASE), Medline and MEDLARS
36 database Health Services Technology Assessment Research
37 (HSTAR).

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

1 (4) *A-compendia compendium* approved by the federal Centers
2 for Medicare and Medicaid Services.

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

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

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

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

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

33 (a) In case of drugs: (1) if, when sold under or by a name
34 recognized in a *compendia compendium* approved by the federal
35 Centers of Medicare and Medicaid Services, it differs materially
36 from the standard of strength, quality, or purity laid down therein;
37 (2) if, when sold under or by a name not recognized in a
38 *compendia compendium* approved by the federal Centers of
39 Medicare and Medicaid Services, but which is found in some other
40 pharmacopocia or other standard work on materia medica, it differs

1 materially from the standard of strength, quality, or purity laid
2 down in such work; (3) if its strength, quality, or purity falls below
3 the professed standard under which it is sold.

4 (b) In the case of food: (1) if any substance or substances have
5 been mixed with it, so as to lower or depreciate, or injuriously
6 affect its quality, strength, or purity; (2) if any inferior or cheaper
7 substance or substances have been substituted wholly or in part
8 for it; (3) if any valuable or necessary constituent or ingredient
9 has been wholly or in part abstracted from it; (4) if it is an
10 imitation of, or is sold under the name of, another article; (5) if it
11 consists wholly, or in part, of a diseased, decomposed, putrid,
12 infected, tainted, or rotten animal or vegetable substance or article,
13 whether manufactured or not; or in the case of milk, if it is the
14 produce of a diseased animal; (6) if it is colored, coated, polished,
15 or powdered, whereby damage or inferiority is concealed, or if by
16 any means it is made to appear better or of greater value than it
17 really is; (7) if it contains any added substance or ingredient which
18 is poisonous or injurious to health.

19 SEC. 17. Section 47121 of the Public Resources Code is
20 amended to read:

21 47121. For the purposes of this article, the following terms
22 have the following meanings, unless the context clearly requires
23 otherwise:

24 (a) "Consumer" means an individual purchaser or owner of a
25 drug. "Consumer" does not include a business, corporation, limited
26 partnership, or an entity involved in a wholesale transaction
27 between a distributor and retailer.

28 (b) "Drug" means any of the following:

29 (1) Articles recognized in a *compendia compendium* or
30 supplement thereof approved by the federal Centers for Medicare
31 and Medicaid Services.

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

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

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

38 (c) "Participant" means any entity which the board deems
39 appropriate for implementing and evaluating a model program and
40 which chooses to participate, including, but not limited to,

1 governmental entities, pharmacies, veterinarians, clinics, and other
2 medical settings.

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

7 SEC. 18. Section 14105.43 of the Welfare and Institutions
8 Code is amended to read:

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

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

20 (i) Any vaccine to protect against human immunodeficiency
21 virus (HIV) infection.

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

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

30 (I) A compendia *compendium* approved by the federal Centers
31 for Medicare and Medicaid Services.

32 (II) Two articles from peer reviewed medical journals that
33 present data supporting the proposed use or uses as generally safe
34 and effective.

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

38 (3) The department shall add any drug deemed to be approved
39 pursuant to paragraph (1) to the Medi-Cal list of contract drugs or
40 allow the provision of the drug as a Medi-Cal benefit, subject to

1 utilization controls, pursuant to paragraph (2), only if the
2 manufacturer of the drug has executed a contract with the Centers
3 for Medicare and Medicaid Services which provides for rebates
4 in accordance with Section 1396r-8 of Title 42 of the United States
5 Code.

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

10 (c) If it is determined pursuant to subdivision (c) of Section
11 14105.39 that a drug to which subdivision (a) applies should not
12 be placed on the Medi-Cal list of contract drugs, that drug shall
13 no longer be deemed to be approved for addition to the list of
14 contract drugs pursuant to subdivision (a).

15 SEC. 19. Section 14133.2 of the Welfare and Institutions Code
16 is amended to read:

17 14133.2. (a) The director shall include in the Medi-Cal list of
18 contract drugs any drug approved for the treatment of cancer by
19 the federal Food and Drug Administration, so long as the
20 manufacturer has executed a contract with the Health Care
21 Financing Administration which provides for rebates in accordance
22 with Section 1396r-8 of Title 42 of the United States Code. These
23 drugs shall be exempt from the contract requirements of Section
24 14105.33.

25 (b) In addition to any drug added to the list of contract drugs
26 pursuant to subdivision (a), any drug that meets either of the
27 following criteria and for which the manufacturer has executed a
28 contract with the Health Care Financing Administration that
29 provides for rebates in accordance with Section 1396r-8 of Title
30 42 of the United States Code, shall be a Medi-Cal benefit, subject
31 to utilization controls, unless the contract requirements of Section
32 14105.33 have been complied with:

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

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

1 (A) A *compendia compendium* approved by the federal Centers
2 for Medicare and Medicaid Services.

3 (B) Two articles from peer reviewed medical journals that
4 present data supporting the proposed use or uses as generally safe
5 and effective.

6 SEC. 20. No reimbursement is required by this act pursuant to
7 Section 6 of Article XIII B of the California Constitution because
8 the only costs that may be incurred by a local agency or school
9 district will be incurred because this act creates a new crime or
10 infraction, eliminates a crime or infraction, or changes the penalty
11 for a crime or infraction, within the meaning of Section 17556 of
12 the Government Code, or changes the definition of a crime within
13 the meaning of Section 6 of Article XIII B of the California
14 Constitution.

O



"John Cronin"
<jcronin@fmglegal.com>
06/24/2009 07:02 AM

To <Virginia_Herold@dca.ca.gov>
cc
bcc
Subject FW: California Assembly Bill 830

History: This message has been forwarded.

From CMS. I'll send it in a reply to your e-mail this morning, too.

From: Miner, Craig (CMS/CDHPC) [mailto:Craig.Miner@CMS.hhs.gov]
Sent: Thursday, June 18, 2009 7:44 AM
To: jcronin@fmglegal.com
Cc: Saldana, Lucy L. (CMS/CMHPO)
Subject: FW: California Assembly Bill 830

Mr. Cronin,

It is unclear from the summary what is meant by "compendia approved by CMS" or the context for all the references to "USP" (does it mean USP/NF?).

CMS does not approve compendia but does recognize only specific compendia for purposes of determining "medically accepted indications" for coverage of off-label uses under Medicare Parts B and D, and Medicaid. Currently these compendia consist of AHFS, Drugdex, Clinical Pharmacology, and NCCN for off-label use of drugs and biologicals in anticancer chemotherapeutic regimens under Medicare Parts B and D. For non-cancer off-label uses covered under Part D and Medicaid, the compendia are limited to AHFS and Drugdex. Previously, USP-DI was recognized as a compendia for Part D and Medicaid but this publication is no longer available.

CMS does not use the USP/NF for determining medically accepted off-label uses.

I hope this is helpful

-Craig

Craig Miner RPh, JD

Medicare Drug Benefit and C & D Data Group

Center for Drug and Health Plan Choice

Centers for Medicare & Medicaid Services

7500 Security Blvd

Baltimore, MD 21244

410.786.7937

craig.miner@cms.hhs.gov \

From: Saldana, Lucy L. (CMS/CMHPO)
Sent: Tuesday, June 16, 2009 11:42 PM
To: Miner, Craig (CMS/CDHPC)
Subject: FW: California Assembly Bill 830

Hi Craig;

Would you be able to assist John Cronin on this issues? It sounds more like a Part B issues but not too sure.

Thanks,

Lucy

From: John Cronin [mailto:jcronin@fmglegal.com]
Sent: Tue 6/16/2009 7:32 PM
To: Saldana, Lucy L. (CMS/CMHPO)
Subject: California Assembly Bill 830

Lucy:

I'm writing on behalf of the California Pharmacists Association. I've attached an analysis of this bill that was prepared by the CA Board of Pharmacy. The bill replaces every reference to USP in the California statutes with language referencing "compendia approved by CMS." Our question is whether USP is among the compendia approved by CMS. I realize this may be outside your area of expertise, but if you can't provide an answer, please identify for me someone at CMS who could respond to this question.

Thanks for your help.

John A. Cronin, Pharm.D., J.D.

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- BOP Analysis of AB830.pdf

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 931

VERSION: Amended ~~March 26, 2009~~
Amended June 17, 2009

AUTHOR: Fletcher

SPONSOR: California Pharmacists Association

BOARD POSITION:

SUBJECT: Emergency Supplies

EXISTING LAW

1. The California Department of Public Health (CDPH) licenses and regulates health facilities, including, but not limited to, skilled nursing facilities and intermediate care facilities. (Title 22 CCR and H&SC §1261.5)
2. Existing Pharmacy Law provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the Board of Pharmacy and establishes requirements for the dispensing of dangerous drugs and dangerous devices. (B&PC Chapter 9, Division 2, Articles 1-24)
3. B&P Code §4119 authorizes a pharmacy to furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container (emergency kit, or e-kit) maintained in a facility in accordance with CDPH regulations.
4. H&SC §1261.5 limits the number of doses of any one drug (currently 4 doses), and limits the total number of dangerous drugs or dangerous devices in an emergency kit to 24.

THIS BILL WOULD

1. Amend §1261.5 of the Health and Safety Code to increase the total number of oral and suppository drugs stored in an emergency kit at specified facilities to from 24 to 48.
2. Provide that CDPH may limit to 16 (currently, four) the number of doses of each drug available in each emergency supply.
3. Provide for limitations and exceptions to psychotherapeutic drugs in an emergency supplies container, as specified.

AUTHOR'S INTENT

According to the sponsor, this bill would improve the quality of care for all patients in long term care facilities. Specifically, it would protect vulnerable populations like the

elderly, patients who are rehabilitating from a major medical event, and those who reside in Long-Term Care Facilities in rural areas in the event of emergencies.

By increasing the number of medications in an e-kit, doctors can provide a wider scope of treatment available to patients in an emergency situation. This change will also bring government policy up to date with modern medicine, which has made significant advancements in pharmaceutical treatments since the current limit was put in place fifteen years ago.

FISCAL IMPACT

The board will incur minimal fiscal impact to board operations which can be absorbed within existing resources.

COMMENTS

Emergency kit medications are approved by a Pharmacy and Therapeutics Committee, which is comprised of a facility's director of nurses, the medical director and the consultant pharmacist. E-kits generally include pain medications, antibiotics, and anti-anxiety medications for other conditions producing patient discomfort. The e-kit provides the first dose, and is NOT meant to refill a prescription. After a first dose is provided, a new prescription would still need to be filled by a pharmacy. The medications can also be used to start medication orders for patients in a disaster situation, when drugs cannot be readily accessed by a pharmacy (for example during an earthquake or flood).

Increasing the number of drugs available does not modify the security measures that are currently in place and working. E-kits are monitored by a pharmacist. Once the lock has been broken on the e-kit, the entire contents must be accounted for and replaced by a pharmacist within 72 hours.

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

PROPOSERS

California Pharmacists Association

OPPOSITION

None of file.

HISTORY:

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

- June 17 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
- June 11 In committee: Hearing postponed by committee.
- May 21 Referred to Com. on HEALTH.
- May 14 In Senate. Read first time. To Com. on RLS. for assignment.
- May 14 Read third time, passed, and to Senate. (Ayes 74. Noes 0. Page 1445.)
- May 7 Read second time. To third reading.
- May 6 From committee: Do pass. (Ayes 19. Noes 0.) (May 5).
- Mar 27 Hearing Set for 05/05/09 in ASM Health
- Mar. 27 Re-referred to Com. on HEALTH.
- Mar. 26 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
- Mar. 26 Referred to Com. on HEALTH.
- Feb. 27 From printer. May be heard in committee March 29.
- Feb. 26 Read first time. To print.

BILL NUMBER: AB 931 AMENDED
BILL TEXT

AMENDED IN SENATE JUNE 17, 2009
AMENDED IN ASSEMBLY MARCH 26, 2009

INTRODUCED BY Assembly Member Fletcher

FEBRUARY 26, 2009

An act to amend Section 1261.5 of the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

AB 931, as amended, Fletcher. Emergency supplies.

Existing law provides for the licensing and regulation by the State Department of Public Health of health facilities, including, but not limited to, skilled nursing facilities and intermediate care facilities.

Existing Pharmacy Law provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the California State Board of Pharmacy and establishes requirements for the dispensing of drugs.

Existing law authorizes a pharmacy to furnish dangerous drugs or devices to a licensed health facility for storage in a secure emergency pharmaceutical supplies container that is maintained within the facility under regulations of the department. Existing law limits the number of oral dosage form and suppository dosage form drugs for storage within this container to 24. It also authorizes the department to limit the number of doses of each drug available to a skilled nursing facility or intermediate care facility to not more than 4 doses of any separate drug dosage form in each emergency supply.

This bill would increase the storage container limit to 48, as specified. The bill would also increase the authorized dosage amount available to a skilled nursing facility or intermediate care facility.

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

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1261.5 of the Health and Safety Code is amended to read:

1261.5. (a) The number of oral dosage form or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c) or (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container, pursuant to Section 4119 of the Business and Professions Code, shall be limited to 48. The State Department of Public Health may limit the number of doses of each drug available to not more than ~~four~~ 16 doses of any separate drug dosage form in each emergency supply.

(b) Not more than four of the 48 oral form or suppository form drugs secured for storage in the emergency supplies container shall be psychotherapeutic drugs, except that the department may grant a

program flexibility request to the facility to increase the number of psychotherapeutic drugs in the emergency supplies container to not more than 10 if the facility can demonstrate the necessity for an increased number of drugs based on the needs of the patient population at the facility. In addition, the four oral form or suppository form psychotherapeutic drug limit shall not apply to a special treatment program service unit distinct part, as defined in Section 1276.9. The department shall limit the number of doses of psychotherapeutic drugs available to not more than four doses in each emergency supply. Nothing in this section shall alter or diminish informed consent requirements, including, but not limited to, the requirements of Section 1418.9.

~~(b)~~

(c) Any limitations established pursuant to ~~subdivision (a)~~ subdivisions (a) and (b) on the number and quantity of oral dosage or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c), (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container shall not apply to an automated drug delivery system, as defined in Section 1261.6, when a pharmacist controls access to the drugs.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: SB 389

VERSION: As Amended June 1, 2009

AUTHOR: Negrete McLeod

SPONSOR: Author Sponsored

RECOMMENDED POSITION: SUPPORT

SUBJECT: Professions and vocations: Fingerprint Requirements

EXISTING LAW:

1. Requires applicants to certain boards to provide a full set of fingerprints for the purpose of conducting criminal history record checks.
2. Authorizes a board to suspend or revoke a license on various grounds, including, but not limited to, conviction of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued.
3. Specifies the information to be disseminated by the Department of Justice as to the existence and content of a record of state or federal convictions and arrests, as specified. (PC 11105(p))
4. Authorizes the Department of Justice to distribute subsequent arrest notifications, as specified.

THIS BILL WOULD:

1. Require an applicant for licensure to successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice (DOJ) as provided.
2. Require each licensing agency to direct *an* applicant for a license *or petitions for reinstatement of a revoked, surrendered, or canceled license*, to submit the fingerprint images for the purpose of obtaining information as to the existence or content of a state or federal criminal record.
3. Require the DOJ to forward fingerprint images to the FBI and request federal criminal history information, which will be disseminated pursuant to statutory authorization by DOJ.
4. Require each agency to request subsequent arrest notification service from DOJ for each person for whom fingerprint images were submitted.
5. Require every licensee who has not previously submitted fingerprints or for whom a record of submission no longer exists to, as a condition of renewal, complete a state and federal criminal offender record information search.
6. Require all licensees, as a condition of renewal *or those who petition for reinstatement of a revoked, surrendered or canceled license*, to certify on the renewal application that he or she has complied with this record information search and require the licensee to retain proof for at least three years.
7. Prohibit the agency from renewing a license *or issuing a reinstatement of a revoked, surrendered, or canceled license* until the *the agency has received certification by the applicant that the renewal application* is complete.
8. Allow an agency to waive this requirement if the license is inactive, retired or if the licensee is actively serving in the military; however, the agency shall not activate a license until the criminal record information search, as specified, is completed.

9. ~~Require each agency to develop regulations to specify which owners, officers, directors, shareholders, members, agents, employees or other natural persons who are representative of a business entity licensed to complete a state and federal criminal offender record information search.~~
10. Specify that a licensee that falsely certifies completion of this search ~~may be~~ **shall be** subject to disciplinary action.
11. Require each agency to require a licensee, as a condition of renewal, to notify the board of a felony or misdemeanor since his or her last renewal, *or since the initial licensure if the license has not previously been renewed.*
12. Provides that certain provisions of the bill related to the State Contractors License Board become operative on a date specified, and at such time that an appropriation is made to fund the criminal history requirements contained within the measure.

AUTHOR'S INTENT:

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

FISCAL IMPACT:

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

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

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

Further, the board will incur programming costs to our CAS system to ensure appropriate implementation.

COMMENTS:

As part of the board's regulatory process, the board requires fingerprint background checks on all applicants. In addition, the board recently implemented a change to the renewal forms for all individual licensees requiring self-certification of criminal convictions or discipline imposed by other regulatory agencies as part of the renewal process. However, this bill goes beyond current board requirements, and will require the board to fingerprint approximately 80,000 existing licensees.

To implement these changes, the board will need some limited-term and permanent staff as specified above. Further, the board will need a listing from the DOJ of licensees currently on file

and the level of services provided for each. Absent such a list, the board will be required to manually pull the files for all of its licensees, to identify who will be affected by this proposal.

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

SUPPORT/OPPOSITION:

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

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

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

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

HISTORY:

2009

June 18 To Coms. on B. & P. and PUB. S.
June 3 In Assembly. Read first time. Held at Desk.
June 3 Read third time. Passed. (Ayes 37. Noes 1. Page 1178.) To Assembly.
June 1 From committee: Do pass as amended. (Ayes 12. Noes 0. Page 1070.) Read second time. Amended. To third reading.
May 22 Set for hearing May 28. (Suspense - for vote only.)
May 18 Placed on APPR suspense file.
May 8 Set for hearing May 18.
May 5 Read second time. Amended. Re-referred to Com. on APPR.
May 4 From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 7. Noes 0. Page 705.)
Apr. 24 Set for hearing April 28.
Apr. 21 From committee: Do pass, but first be re-referred to Com. on PUB. S. (Ayes 9. Noes 0. Page 580.) Re-referred to Com. on PUB. S.
Mar. 27 Set for hearing April 20.
Mar. 12 To Coms. on B., P. & E.D. and PUB. S.
Feb. 27 From print. May be acted upon on or after March 28.
Feb. 26 Introduced. Read first time. To Com. on RLS. for assignment. To print.

BILL NUMBER: SB 389 AMENDED
BILL TEXT

AMENDED IN SENATE JUNE 1, 2009
AMENDED IN SENATE MAY 5, 2009

INTRODUCED BY Senator Negrete McLeod

FEBRUARY 26, 2009

An act to amend Section 144 of, and to add Sections 144.5 and 144.6 to, the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

SB 389, as amended, Negrete McLeod. Professions and vocations.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law authorizes a board to suspend or revoke a license on various grounds, including, but not limited to, conviction of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued. Existing law requires applicants to certain boards to provide a full set of fingerprints for the purpose of conducting criminal history record checks.

This bill would make that fingerprinting requirement applicable to the Dental Board of California, the Dental Hygiene Committee of California, the Professional Fiduciaries Bureau, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, and the State Board of Chiropractic Examiners. The bill would require new applicants for a license ~~and,~~

and petitioners for reinstatement of a revoked, surrendered, or canceled license, to successfully complete a state and federal level criminal record information search. The bill would also require, commencing January 1, 2011, licensees who have not previously submitted fingerprints, or for whom a record of the submission of fingerprints no longer exists, to ~~successfully~~ complete the process necessary for a state and federal level criminal offender record information search, as specified. The bill would require licensees applying for licensure renewal to certify compliance with that requirement, as specified, and would subject a licensee to disciplinary action for making a false certification. The bill would also require a licensee to, as a condition of renewal of the license, notify the board on the license renewal form if he or she, or any member of the personnel of record of the licensee, has been convicted, as defined, of a felony or misdemeanor since ~~his or her~~ the last renewal, or if this is the licensee's first renewal, since the initial license was issued. The bill would provide that the Contractors' State License Board shall implement the provisions pertaining to renewal licenses on a specified schedule, after an appropriation is made for this purpose, utilizing its applicable fees.

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

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 144 of the Business and Professions Code is amended to read:

144. (a) Notwithstanding any other provision of law, an agency designated in subdivision (b) shall require an applicant for a license or a petitioner for reinstatement of a revoked, surrendered, or canceled license to furnish to the agency a full set of fingerprints for purposes of conducting criminal history record checks and shall require the applicant or petitioner to successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice as provided in subdivision (c) or as otherwise provided in this code.

(b) Subdivision (a) applies to the following:

- (1) California Board of Accountancy.
- (2) State Athletic Commission.
- (3) Board of Behavioral Sciences.
- (4) Court Reporters Board of California.
- (5) State Board of Guide Dogs for the Blind.
- (6) California State Board of Pharmacy.
- (7) Board of Registered Nursing.
- (8) Veterinary Medical Board.
- (9) Registered Veterinary Technician Committee.
- (10) Board of Vocational Nursing and Psychiatric Technicians.
- (11) Respiratory Care Board of California.
- (12) Hearing Aid Dispensers Bureau.
- (13) Physical Therapy Board of California.
- (14) Physician Assistant Committee of the Medical Board of California.
- (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) 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.
- (29) Professional Fiduciaries Bureau.
- (30) California Board of Podiatric Medicine.
- (31) Osteopathic Medical Board of California.
- (32) State Board of Chiropractic Examiners.

(c) Except as otherwise provided in this code, each agency listed in subdivision (b) shall direct applicants for a license or a petitioner for reinstatement of a revoked, surrendered, or canceled 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 record of state or federal convictions and state or federal arrests and also information as to the existence and content of a record of state or federal arrests for which the Department of Justice establishes that the person is free on bail or on his or her recognizance pending trial or appeal. 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 licensee 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~~ complete the process necessary for a state and federal level criminal offender record information search to be 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.~~

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

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

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

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

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

(c) Failure to provide the certification required by subdivision (b) renders an application for license 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 record of state or

federal convictions and state or federal arrests and also information as to the existence and content of a record of state or federal arrests for which the Department of Justice establishes that the person is free on bail or on his or her recognizance pending trial or appeal. 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~~ shall 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)~~
(f) 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. ~~(b)~~ shall be subject to disciplinary action.

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

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

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

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

(2) If this section becomes operative with respect to the Contractors' State License Board after July 1, 2012, the license

renewal period commencement dates specified in subparagraphs (A), (B), and (C) of paragraph (1) shall be delayed one year at a time until this section becomes operative with respect to the Contractors' State License Board.

(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~~ notify the agency on the license renewal form if he or she, or any member of the personnel of record of the licensee, has been convicted, as defined 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.~~ since the license was last renewed, or since the license was initially issued if it has not been previously renewed.

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

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 484

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

AUTHOR: Wright

SPONSOR: Attorney General's Office

SUBJECT: Ephedrine and Pseudoephedrine

EXISTING LAW:

Under existing law, ephedrine and pseudoephedrine are over-the-counter drugs. In 2006, the federal "Combat Methamphetamine Epidemic Act of 2005" was signed into law. This law requires restrictive sale conditions for over-the-counter sales of products containing ephedrine, pseudoephedrine and phenylpropanolamine (these compounds are used in many cough, cold and allergy products). However, ephedrine and pseudoephedrine also are precursor ingredients used illegally to produce methamphetamine or amphetamine. The federal sales restrictions include daily sales limits, monthly purchase limits, placement of products out of direct customer access, sales logbooks, customer identification at point of sale and employee training.

THIS BILL WOULD:

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

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

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

Thus, a prescription (and presumably at some point, a prescriber's office visit) would be required before a consumer could purchase ephedrine or pseudoephedrine.

AUTHOR'S INTENT:

Ephedrine and pseudoephedrine are over-the-counter drugs. Despite the 2006 sales restrictions implemented by the federal government, the AG's Office believes that additional restrictions are needed for sales of these products.

Methamphetamine production is a serious law enforcement issue – it is highly addictive, and the production of which creates serious public safety and environmental problems.

COMMENTS:

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

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

Committee Discussion:

The Legislation and Regulation Committee discussed this bill at its public meeting held April 16, 2009. At that time, Kent Shaw, Assistant Chief of the California Bureau of Narcotic Enforcement, California Department of Justice provided information to the committee regarding the increase in methamphetamine labs in California, and those that "smurf" pseudoephedrine purchased from retail outlets in California. Through this legislation, the Attorney General's Office (the sponsor) moves to add pseudoephedrine to Schedule V (thus making it available from a pharmacy). Mr. Shaw provided information related to precursors and the various methods of manufacture of methamphetamine and urged the committee's support of this legislation.

The Committee discussed possible impacts the bill may have on pharmacies, the potential for pharmacy errors, and if alternative products (to pseudoephedrine) are available to those without medical insurance.. Public comment was received by Cookie Quandt representing Longs Drugs, stating that Longs is a proponent of making pseudoephedrine a scheduled drug. Lynn Rolston stated the California Pharmacists Association (CPhA) is in support of this initiative. She sought clarification on why the bill is seeking to add pseudoephedrine to Schedule V as opposed to a schedule that would be tracked through CURES. Mr. Shaw stated that successfully requiring a prescription for this drug is the primary and most achievable challenge.

Executive Officer Virginia Herold discussed the purchase of pseudoephedrine via mail-order. She proposed the consideration of a sunset date of five years.

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

HISTORY:

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

- May 4 From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 6. Noes 1. Page 705.)
- Apr. 13 Set for hearing April 28.
- Mar. 12 To Com. on PUB. S.
- Feb. 27 From print. May be acted upon on or after March 28.
- Feb. 26 Introduced. Read first time. To Com. on RLS. for assignment. To print.



California State Board of Pharmacy

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

May 11, 2009

The Honorable Roderick D. Wright
California State Senate
State Capitol, Room 2048
Sacramento, CA 95814

RE: SB 484 (As Amended May 5, 2009): Support if Amended

Dear Senator Wright:

The California State Board of Pharmacy is pleased to advise you that it supports your SB 484, which would require a prescription for ephedrine and pseudoephedrine to be provided to patients by pharmacies.

The board supports this measure as a means to reduce the production of methamphetamine in California. We are aware that is modeled after a similar law in Oregon that has reduced the production of methamphetamine in that state.

However, the board suggests that SB 484 be amended to require that ephedrine and psuedoephedrine be placed in controlled substance schedule III or IV -- principally because California already has a monitoring system in place, operated by the California Department of Justice, which tracks all schedule II, III, and IV controlled drugs that are dispensed to patients. California's Controlled Substance Utilization Review and Evaluation System (CURES) allows law enforcement and regulatory agencies to identify diversion and resultant abuse of reported substances. Placing ephedrine and psuedoephedrine in schedule III or IV will immediately allow use of an existing monitoring system that will greatly aid law enforcement in receiving optimum benefits from requiring a prescription for these drugs. Also, schedule III and IV drugs can be orally prescribed, so patients can readily receive refill authorizations for these medically necessary drugs where warranted by their prescribers.

The Board of Pharmacy seeks to protect and promote the health and safety of Californians through the appropriate use of pharmaceuticals. The board believes that requiring a prescription for ephedrine and pseudoephedrine, as defined in SB 484, is an important step in this mission.

If you have any questions, please contact me at (916) 574-7912.

Sincerely,

A handwritten signature in black ink that reads "Virginia Herold".

Virginia Herold
Executive Officer

cc: Assistant Chief Kent Shaw
California Bureau of Narcotic Enforcement

BILL NUMBER: SB 484 AMENDED
BILL TEXT

AMENDED IN SENATE MAY 12, 2009
AMENDED IN SENATE MAY 5, 2009

INTRODUCED BY Senator Wright
(Coauthor: Senator Florez)

FEBRUARY 26, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

SB 484, as amended, Wright. Ephedrine and pseudoephedrine.

(1) Existing law classifies controlled substances into 5 schedules, with the most restrictive limitations placed on controlled substances classified in Schedule I, and the least restrictive limitations placed on controlled substances classified in Schedule V. A controlled substance in any of the schedules may be possessed or dispensed only upon a lawful prescription, as specified. Existing law does not classify ephedrine, pseudoephedrine, and specified related drugs within any of these 5 schedules, but provides that it is a crime, punishable as specified, for a person in this state who engages in specified transactions involving those drugs to fail to submit a report to the Department of Justice of all of those transactions, or to fail to submit an application to, and obtain a permit for the conduct of that business from, the Department of Justice, as specified.

This ~~bill would classify ephedrine, pseudoephedrine, and specified related drugs as Schedule V controlled substances, able to be possessed or dispensed only upon a lawful prescription. The~~ bill would provide, in addition, that any person who obtains ~~any of these~~ ephedrine, pseudoephedrine, and specified related drugs without a prescription, as specified, shall be guilty of an infraction or a misdemeanor. The bill would make conforming changes to related provisions. By creating new crimes or revising the penalties for existing crimes involving ephedrine, pseudoephedrine, and specified related drugs, this bill would impose a state-mandated local program.

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

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

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

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

~~SECTION 1. Section 11058 of the Health and Safety Code is amended to read:~~

~~11058. (a) The controlled substances listed in this section are included in Schedule V.~~

~~(b) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.~~

~~(c) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:~~

~~(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.~~

~~(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.~~

~~(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.~~

~~(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.~~

~~(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.~~

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

~~(d) Buprenorphine.~~

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

~~SEC. 2. SECTION 1.~~ Section 11100 of the Health and Safety Code is amended to read:

11100. (a) Any manufacturer ~~or wholesaler~~, 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~~, 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 ~~and~~ or federal Drug Enforcement Administration (DEA) registration number, the address of the business, and a full description of how the substance is to be used, and (B) proper identification from the purchaser. The manufacturer ~~or wholesaler~~, 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, 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.

~~(3)~~

(4) Any analytical research facility that is registered

with the federal Drug Enforcement Administration of the United States Department of Justice.

~~(4)~~

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

~~(5)~~

(6) Any sale, transfer, furnishing, or receipt of a product specified in ~~subdivision (c) of Section 11058~~

Section 11375.5 pursuant to prescription shall not be subject to the 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.

~~(6)~~

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

~~(7)~~

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

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

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

(g) (1) ~~Except as otherwise provided, it~~
It is unlawful for any manufacturer ~~or wholesaler~~
, wholesaler, retailer, or other person or
entity in this state 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 (c), it~~ It is
unlawful for any person under 18 years of age to possess a substance
specified in subdivision (a).

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

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

(h) 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 any product specified in ~~subdivision (e) of Section 11058 per five~~ Section 11375.5 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~~ include being a distributor of any product specified in ~~subdivision (e) of Section 11058 are limited to the sale of those products~~

Section 11375.5 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.

(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.~~ SEC. 2. Section 11106 of the Health and Safety Code is amended to read:

11106. (a) (1) (A) Any manufacturer ~~or wholesaler~~, wholesaler, retailer, or 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) A permit shall be required for the sale, transfer, furnishing, or obtaining of preparations in solid or liquid dosage form containing any product as specified in ~~subdivision (e) of Section 11058.~~ Section 11375.5.

(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 permit holder.

(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.

(1) (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.~~ SEC. 3. Section 11375.5 is added to the Health and Safety Code, to read:

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

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

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

~~(c)~~

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

~~(d)~~

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

~~SEC. 5.~~ 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.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: SB 762

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

AUTHOR: Aanestad

SPONSOR:

RECOMMENDED POSITION: NONE

SUBJECT: Professions and Vocations: healing arts

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

EXISTING LAW:

States that no city or county shall prohibit a person, authorized by one of the agencies in the Department of Consumer Affairs from engaging in the business for which the license has been obtained.

THIS BILL WOULD:

1. Clarify that no city or county shall prohibit a person, or group of persons from engaging in the business for which the license has been obtained.
2. Specify that no city, county, or city and county shall prohibit a healing arts professional from engaging in any activity that falls within the professionally recognized scope of practice of the licensee. Clarify that the provisions of the section become effective January 1, 2010.
3. Clarify that the above will not prohibit any city, county or city and county from levying a business license tax solely for revenue purposes, nor any city or county from levying a license tax solely for the purposes of covering the cost of regulation.
4. Specifies that the provisions of the bill shall not be construed to prevent a city, county, or city and county from adopting or enforcing any local ordinance governing zoning, business licensing, or reasonable health and safety requirements for establishments or businesses of a healing arts professional licensed under Division 2.

AUTHOR'S INTENT:

FISCAL IMPACT:

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

COMMENTS:

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

HISTORY:

June 29 Enrolled. To Governor at 4:30 p.m.
June 25 In Senate. To enrollment.
June 25 Read third time. Passed. (Ayes 59. Noes 6. Page 2260.) To Senate.
June 17 Read second time. To third reading.
June 16 From committee: Do pass. (Ayes 9. Noes 0.) (Hearing date: June 16.)
May 28 To Com. on B. & P.
May 14 In Assembly. Read first time. Held at Desk.
May 14 Read third time. Passed. (Ayes 31. Noes 6. Page 887.) To Assembly.
May 5 Read second time. Amended. To third reading.
May 4 From committee: Do pass as amended. (Ayes 7. Noes 3. Page 676.)
Apr. 13 Set for hearing April 27.
Mar. 19 To Com. on B., P. & E.D.
Mar. 2 Read first time.
Feb. 28 From print. May be acted upon on or after March 30.
Feb. 27 Introduced. To Com. on RLS. for assignment. To print.



California State Board of Pharmacy

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

May 12, 2009

The Honorable Sam Aanestad
California State Senate
State Capitol, Room 3063
Sacramento, CA 95814

RE: SB 762 (Amended May 5, 2009) – Support

Dear Senator Aanestad:

The California State Board of Pharmacy is pleased to support SB 762, as amended, to ensure that no person or group of persons licensed by the board be prohibited by a city, county or city and county from engaging in the profession for which they have been authorized.

As a regulatory agency charged with public protection, the board strongly believes that it is inappropriate for a city or county to limit the scope of services a professional can provide. These services have been fully vetted and deemed appropriate.

If you have any questions, please contact me at (916) 574-7912.

Sincerely,

A handwritten signature in cursive script that reads "Virginia Herold".

Virginia Herold
Executive Officer

Senate Bill No. 762

Passed the Senate May 14, 2009

Secretary of the Senate

Passed the Assembly June 25, 2009

Chief Clerk of the Assembly

This bill was received by the Governor this _____ day
of _____, 2009, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

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

LEGISLATIVE COUNSEL'S DIGEST

SB 762, Aanestad. Professions and vocations: healing arts.

Existing law makes it unlawful for a city or county to prohibit a person, authorized by one of the agencies of the Department of Consumer Affairs to engage in a particular business, from engaging in that business, occupation, or profession or any portion thereof.

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

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

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

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

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

(1) This subdivision shall not be construed to prohibit the enforcement of a local ordinance in effect prior to January 1, 2010, related to any act or procedure that falls within the professionally

recognized scope of practice of a healing arts professional licensed under Division 2 (commencing with Section 500).

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

(c) Nothing in this section shall prohibit any city, county, or city and county from levying a business license tax solely for revenue purposes, nor any city or county from levying a license tax solely for the purpose of covering the cost of regulation.

Approved _____, 2009

Governor



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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 That Failed Passage Deadline, May Become Two-Year Bill

Below is a summary of various legislative proposals that failed the passage deadline. These measures may become two-year bills. Staff will continue to monitor these measures and update the committee of any changes.

- 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. This measure was last amended on 4/13/09, but failed to pass policy committee before the statutory deadline. Board Position: Support (4/30/09)

- b. AB 484 (Eng) Licensees not in compliance with judgment or order; enforcement; action on a license
Current law requires every board to provide the Franchise Tax Board (FTB) with specified information upon request from the FTB. This measure, instead, requires that governmental entities who issue professional licenses provide specific information to the Franchise Tax Board for every licensee. The bill further requires, that if a licensee fails to pay taxes for which a state lien has been recorded, to send a notice of suspension to the applicable governmental agency and the licensee. Administrative remedies now available to licensees remain. The sponsor (FTB) asserts that 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 measure is an attempt to suspend one's licensing status because of unpaid tax liabilities. This measure failed to pass policy committee and did not meet the deadline for bills to be passed out of the house of origin (J.R. 61(a)(8)). Board Position: Support

- c. AB 877 (Emmerson) (Intent language) Healing Arts; DCA Committee Analysis; Scope of healing Arts Practice
This bill declared intent to establish within the Department of Consumer Affairs a committee to perform occupational analysis on any legislative proposal which seeks to expand the scope of practice of a healing arts practice. The most recent amendment (4/14/09) requires the applicable board for which the occupational analysis was being conducted, bear the cost of that analysis and written report. The bill was held under submission in ASM Appropriations and did not meet the deadline for bills to be passed out of the house of origin (J.R. 61(a)(8)). Board Position: None

- d. AB 1458 (Davis) Drugs: Adverse Effective Reporting
This bill requires pharmacists and other licensed health professions to report to the Federal Drug Administration's MedWatch adverse drug events, as defined. The most recent amendment (5/5/09) specified definitions for "Licensed health professional" (to include a pharmacist) and "Serious adverse drug events."
The bill was placed on the ASM Appropriations Suspense File and failed passage by the deadline.
Board Position: Support (4/15/09 version)
- e. 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.
The bill stalled in SEN Appropriations.
Board Position: Oppose Unless Amended
- f. SB 238 (Calderon) Prescription Drugs
The bill amends various provisions of the Civil, Health & Safety, and Insurance Code related to the prescription, dispensing and insurance coverage of 90-day supplies of prescription medication, as specified.
The bill was never heard in SEN Health (first policy committee).
- g. SB 341 (DeSaulnier) California Department of Public Health
CDPH to contract with UC to study / evaluate the safety and effectiveness of prescription drugs, to be implemented only by federal or private funds, or both.
The bill was held in submission in SEN Appropriations.
- h. SB 638 (Negrete McLeod) DCA regulatory boards; sunset reviews; operations; report requirements
The bill passed from SEN BP&ED to SEN Committee on Rules.