



California State Board of Pharmacy
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www.pharmacy.ca.gov

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

Date: October 15, 2009

ATTACHMENT A-1a

To: Legislation and Regulation Committee

Subject: Legislation Sponsored by the Board of Pharmacy
SB 819 - 2009 Omnibus Provisions

As of 10/11/2009

Last Amendment: 9/12/09

Status: Signed by the Governor - - Chapter 308, Statutes of 2009

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 contained 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.

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.”

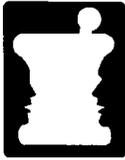
- Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy
This section requires amendment to clarify specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.
- Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
This 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 Chaptered are provided in ATTACHMENT A-1a.



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Date: October 15, 2009 **ATTACHMENT A-1b**

To: Legislation and Regulation Committee

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

Last Amendment: 8/17/09

Status: Signed by the Governor - - Chapter 307, Statutes of 2009

Recent amendments to SB 821 include omnibus provisions previously found in SB 820.

Both omnibus measures (SB 820 and SB 821) were amended in ASM B&P on July 6th. All pharmacy-related provisions were removed from SB 820, and they were placed in SB 821. Specifically, B&P sections 4200.3 and 4200.4 regarding the re-naming of the Office of Professional Examination Resources were placed in SB 821.

The remaining omnibus provisions in SB 821 remain unchanged from the prior version.

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.

A copy of the relevant pages of SB 821 as Chaptered are provided in ATTACHMENT A-1b.



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Date: October 15, 2009 **ATTACHMENT A-1c**
To: Legislation and Regulation Committee
From: Staff
Subject: Legislation Sponsored by the Board of Pharmacy
SB 470 (Corbett) - Elements of a Prescription Label

As of: October 11, 2009
Last Amendment: 4/30/09
Status: Signed by the Governor - - Chapter 590, Statutes of 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.

Attachment A-1c contains a copy of SB 470 as Chaptered.



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Date: October 15, 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 A-1d

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 A-1d.



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Date: October 15, 2009 **ATTACHMENT A-1e**

To: Legislation and Regulation Committee

From: Staff

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

As of: October 11, 2009

Introduced: September 2, 2009

Status: Signed by the Governor - - Chapter 270, Statutes of 2009

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.

In early September this bill was amended to extend the board's sunset date to 2013 as well as to extend the sunset date for several other DCA boards.

A copy of AB 1071 as Chaptered is provided in ATTACHMENT A-1e



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To: Legislation and Regulation Committee

ATTACHMENT A-2

From: Staff

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

Below is a summary of various legislative proposals signed by the Governor that impact the practice of pharmacy or the board's jurisdiction. ATTACHMENT A-2 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 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: Opposition removed after amendments

Status: Signed by the Governor - - Chapter 479, Statutes of 2009

b. 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: Signed by the Governor - - Chapter 491, Statutes of 2009

c. 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: Signed by the Governor - - Chapter 16, Statutes of 2009



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To: Legislation and Regulation Committee
From: Staff
Subject: Inactive or 2-Year Bills

Below is a summary of various legislative proposals that are either inactive or are 2-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 583 (Hayashi) Health Care Practitioners: Disclosure of Education and Office Hours (Last Amend: 7/8/09)

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

The board has not taken a position on this measure.

d. AB 877 (Emmerson) (Intent language) Healing Arts; DCA Committee Analysis; Scope of healing Arts Practice

This bill would require the Department of Consumer Affairs to appoint a scope of practice committee of five members, as specified, to perform occupational analyses and prepare written reports on bills seeking to substantively expand the scope of a healing arts practice. The bill would require that the reasonable cost of analysis and report be paid by the affected licensing board. The bill was placed on suspense and subsequently held under submission.

The board has not taken a position on this measure.

e. AB 1458 (Davis) Drugs: Adverse Effective Reporting

This bill requires health professionals, as defined, to report serious adverse drug events, as defined, to the federal Food and Drug Administration and would exempt violations from related criminal provisions. The measure was placed on the Assembly Appropriations suspense file 5/5/09.

The board has taken a "Support" position on the 5/5/09 version of the bill, stating "[the board] strongly believes that MedWatch provides an important consolidation point for collecting drug related misadventures, but reporting to this system on a voluntary basis has not resulted in adequate reporting."

f. SB 26 (Simitian) Home-Generated Pharmaceutical Waste

The board has closely monitored this measure for drug take-back. Amendments to sections 4040.5, 41266.5, and 4081 have been offered to the author to clarify the role of reverse distributors; define "dispenses" for purposes of drug take-back; specify that a pharmacy may furnish dangerous drugs to a integrated waste hauler, as defined, for the sole purpose of waste disposal of pharmaceutical waste returned to a pharmacy; and to specify the recordkeeping requirements of those drugs returned to a wholesaler or reverse distributor. The measure was placed on the Senate Appropriations Suspense File.

g. SB 238 (Calderon) Prescription Drugs

SB 238 amends the Confidentiality of Medical Information Act to allow a pharmacy, without the patient's authorization, to mail specified written materials to a patient regarding a prescribed course of treatment, only as specified. The latest amendment authorizes health care service enrollees to receive a 90-day supply of medication when so indicated on a prescription; and makes corresponding amendments to the Insurance Code related to the coverage of that 90-day supply. This measure failed passage from its first policy committee and is now a 2-year bill.

The board has not taken a position on this bill.

h. SB 341 (DeSaulnier) California Department of Public Health

This bill would require the California Department of Public Health (CDPH) to make every effort to enter into a contract with the University of California to establish a program to evaluate scientific literature related to the safety and effectiveness of prescription drugs

and to communicate that information to consumers and prescribers. The bill did not pass out of the house of origin by deadline.

The board has not taken a position on this measure.

i. **SB 389 (Negrete McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus (Last amend: 6/1/09)**

The bill would require applicants for a license and, commencing January 1, 2011, licensees who have not previously submitted fingerprints, who petition for reinstatement of a revoked, surrendered or canceled license, or for whom a record of the submission of fingerprints no longer exists, to successfully complete a state and federal level criminal offender record information search, as specified. The bill would also require a licensee to, as a condition of renewal of the license, notify the board on the license renewal form if he or she has been convicted, as defined, of a felony or misdemeanor since his or her last renewal, or if this is the licensee's first renewal, since the initial license was issued. SB 389 failed passage in the Assembly Committee on Public Safety, but was granted reconsideration.

At its July 2009 Board Meeting, and to be consistent with the board's public protection mandate, the board voted to "Support" the latest version (6/1/09) of the bill.

j. **SB 484 (Wright) – Ephedrine Products / Schedule V**

The California Office of the Attorney General sponsored SB 484 to place greater restrictions on the sale and reporting of sales of ephedrine / pseudoephedrine for the purpose of combating the manufacture and sale of methamphetamine in California, including the requirement that a prescription would be required for ephedrine and pseudoephedrine. The bill amends the Health & Safety Code to require that transactions, as specified, be reported to DOJ / CURES. The bill exempts from these reporting requirements any manufacture or wholesaler licensed by the board, as specified. The bill specifies criminal penalties for a person obtaining such substances without a prescription.

The board held a Support if Amended position of the 5/5/09 version, suggesting that ephedrine and pseudoephedrine be placed in controlled substance schedules III or IV. At its July 2009 Board Meeting, and to be consistent with the board's public protection mandate, the board voted to "Support" the latest version (5/12/09) of the bill.

k. **SB 638 (Negrete McLeod) DCA regulatory boards; sunset reviews; operations; report requirements**

This bill would redefine the sunset review process. The bill was held in Senate Rules and did not meet the deadline for bills to be passed out of the house of origin. The board's Executive Officer worked with the Senate Business, Professions and Economic Development committee to identify options to secure an extension of the board's sunset date. Following discussion, the committee voted to recommend that the board authorize the Executive Officer to have the Board of Pharmacy's sunset provisions addressed through a different legislative measure in order to extend the board's sunset date. Through those efforts, and through the amendment of the board's fee bill, AB 1071, the Board of Pharmacy's sunset provisions were extended to 2013.

Inactive or 2-Year Bills
Legislation and Regulation Committee
October 15, 2009

Staff will continue to monitor SB 638 when the Legislature reconvenes in January.



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ARNOLD SCHWARZENEGGER, GOVERNOR

Date: October 14, 2009 **ATTACHMENT B-1**

To: Legislation and Regulation Committee

Subject: Board Adopted Regulations – Recently Approved by the Office of Administrative Law

a. Amend 16 CCR §1773 and Adopt § 1773.5 – Establishment of an Ethics Course as an Optional Enforcement Component for Discipline

Amendments to 16 CCR §1773 and §1773.5 became effective on September 3, 2009.

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

The board determined the requirements, as necessary, based on testimony received during the October 2007 Board Meeting. During the meeting, the board received testimony from the Institute for Medical Quality (IMQ), the course provider for the Medical Board's ethics course. The board determined that a minimum of 14 direct contact hours is appropriate to allow for case presentations, group discussion and experiential exercises and role-playing to ensure sufficient time to discuss and evaluate situations. In addition, based on the recommendation of IMQ, the board's proposal also incorporates an additional 8 hours of time to allow the pharmacist to complete self-reflection on the decisions made that led to the violations and ultimate referral to the program and post-classroom instruction for up to one year. This self-reflection includes completing questions as part of a background assessment. The two post-course longitudinal studies ensure that the pharmacist has successfully internalized the necessary changes to prevent future violations resulting from unethical behavior.

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

authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to §1773 as filed and adopt §1773.5 of the proposed regulations with this modified text.

No comments were received during the 15-day comment period. At the end of the 15-day comment period, board staff compiled the rulemaking and transmitted it to the Office of Administrative Law. The Office of Administrative Law approved the regulatory action on August 4, 2009, and the new regulations became effective on September 3, 2009.



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ARNOLD SCHWARZENEGGER, GOVERNOR

Date: October 14, 2009

ATTACHMENT B-2

To: Legislation and Regulation Committee

Subject: Board Adopted Regulations – Undergoing Review by the Administration

a. Repeal Title 16 CCR Sections 1716.1 and 1716.2, Amend and Adopt Sections 1751 through 1751.8, and Adopt Sections 17.5 through 1735.8 – Pharmacies that Compound.

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

Draft regulation text was published at the end of August 2008, and a regulation hearing was held at the October 2008 Board Meeting. At the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing.

At its January 2009 Board Meeting, the board voted to pursue a 15-day comment period to exempt from some of the record keeping requirements detailed in Section 1735.3 those sterile products compounded on a one-time basis for administration within 2 hours, as specified. The modified text was noticed on February 26, 2009.

At the April 2009 Board Meeting, the board considered the comments received during the 45- and 15-day comment periods, along with a draft response to each. The board again considered modifications to proposed section 1735.3(a)(6) and subsequently voted to pursue a 2nd 15-day comment period to exempt from some of the record keeping requirements in proposed 1735.3(a)(6) those sterile products compounded on a one-time basis for administration within 24 hours, as specified. The 2nd 15-day comment period was noticed on May 4, 2009.

At the July 2009 Board Meeting the board considered the comments received during the 2nd 15-day comment period, as well as a draft response to each comment. The board then voted to approve the subcommittee's recommendation to adopt the regulation text as noticed on May 4, 2009, and to specify that the requirements would not go into effect for six months following approval by the

Office of Administrative Law to allow for implementation. The board further moved that staff will exercise enforcement discretion for an additional six months to allow for education and transition.

Staff compiled the final regulatory proposal and submitted it to the department. On August 20, 2009, the Director of the Department of Consumer Affairs pursuant to Business and Professions Code section 313.1(e)(1) extended the length of the notice period, and the regulatory proposal is currently under review by the department.



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DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: October 14, 2009

ATTACHMENT B-3

To: Legislation and Regulation Committee

Subject: Board Approved Regulations – Awaiting Notice

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

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

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting and, subsequently, was approved by the board at the October 2007 Board Meeting.

The Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program. 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 of Title 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 to 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 a qualifying licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists 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.

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

Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable 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. The proposed language was approved by the board at its July 2007 Board Meeting.

This regulation will specify the process and criteria that will be utilized to approve accreditation agencies for pharmacies that compound injectable sterile drug products.



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

Date: October 14, 2009

To: Legislation and Regulation Committee

Subject: Regulations Under Development

ATTACHMENT B-4

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

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

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

President Schell may wish to consider filling the subcommittee vacancy created when former board member Jim Burgard's term concluded. This subcommittee has not held any meetings.

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

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

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

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

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

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

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

Additionally, the board will award CE for:

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

Board staff is drafting regulation language for consideration at a future Legislation and Regulation Committee meeting.



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

Date: October 14, 2009

ATTACHMENT B-5

To: Legislation and Regulation Committee

Subject: Proposed Regulations to Implement Recently Enacted Legislation

a. Proposed Amendment of Title 16 CCR §1749 – Fee Schedule

Chapter 270, Statutes of 2009

Assembly Member Emmerson authored AB 1071 to update the board's fee schedule. The board approved an increase in fees in January 2009, following consideration of the results of an independent fee audit and to ensure the solvency of the board.

In September, the bill was amended to include provisions to extend the sunset date of the Board of Pharmacy and other specified boards within the Department. Following passage and concurrence of the amendments, the bill was enrolled and ultimately signed by the Governor on October 11, 2009.

Staff has drafted proposed text to update the board's fee schedule to implement the new fee schedule, which is effective January 1, 2010.

ATTACHMENT A-1a

**SB 819 (Senate Committee on Business, Professions and
Economic Development) – Omnibus**

Chapter 308, Statutes of 2009

Senate Bill No. 819

CHAPTER 308

An act to amend Sections 27, 101, 128.5, 144, 146, 149, 683, 733, 800, 801, 803, 1907, 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, 3635, 3636, 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, 5092, 5093, 5801, 6534, 6536, 6561, 7616, 7629, 8030.2, 8740, and 8746 of, to add Sections 2169, 2570.36, 2835.7, 4036.5, 4980.04, 4990.09, and 5094.6 to, to add and repeal Sections 5094.5 and 5094.7 of, to repeal Sections 2172, 2173, 2174, 4981, 4994.1, 4996.20, 4996.21, 5096.11, and 6761 of, and to repeal and amend Section 5094 of, the Business and Professions Code, to amend Section 8659 of the Government Code, to amend Sections 8778.5, 11150, and 11165 of the Health and Safety Code, and to amend Section 14132.100 of the Welfare and Institutions Code, relating to professions and vocations and making an appropriation therefor.

[Approved by Governor October 11, 2009. Filed with
Secretary of State October 11, 2009.]

LEGISLATIVE COUNSEL'S DIGEST

SB 819, Yee. 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, any of a list of specified state regulatory agencies 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 healing arts 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 healing arts boards to create and maintain a central file of the names of all persons who hold a

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 (l) 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.

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. 41. 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. 42. 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. 43. 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. 44. 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 3460.5, 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. 44.5. 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 Section 4052.1 or 4052.2.

(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to either 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. 45. 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. 46. 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. 47. 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. 48. 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. 49. 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. 49.5. 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 or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

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

(i) Prescriptions dispensed by a veterinarian.

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

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

(B) This paragraph applies to outpatient pharmacies only.

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

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

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

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either 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. 50. 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. 51. 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 of, or damage to, 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. 51.5. 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 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.

(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 of, or damage to, 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. 52. 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. 53. 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. 54. 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. 55. 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. 56. 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. 57. 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. 58. 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. 59. 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. 60. 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. 61. Section 4857 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

(6) As otherwise provided in this section.

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

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

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

SEC. 62. Section 4980.04 is added to the Business and Professions Code, to read:

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

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. 93. 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. 94. 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. 95. Section 14132.100 of the Welfare and Institutions Code is amended to read:

14132.100. (a) The federally qualified health center services described in Section 1396d(a)(2)(C) of Title 42 of the United States Code are covered benefits.

(b) The rural health clinic services described in Section 1396d(a)(2)(B) of Title 42 of the United States Code are covered benefits.

(c) Federally qualified health center services and rural health clinic services shall be reimbursed on a per-visit basis in accordance with the definition of "visit" set forth in subdivision (g).

(d) Effective October 1, 2004, and on each October 1, thereafter, until no longer required by federal law, federally qualified health center (FQHC) and rural health clinic (RHC) per-visit rates shall be increased by the Medicare Economic Index applicable to primary care services in the manner provided for in Section 1396a(bb)(3)(A) of Title 42 of the United States Code. Prior to January 1, 2004, FQHC and RHC per-visit rates shall be adjusted by the Medicare Economic Index in accordance with the methodology set forth in the state plan in effect on October 1, 2001.

(e) (1) An FQHC or RHC may apply for an adjustment to its per-visit rate based on a change in the scope of services provided by the FQHC or RHC. Rate changes based on a change in the scope of services provided by an FQHC or RHC shall be evaluated in accordance with Medicare reasonable cost principles, as set forth in Part 413 (commencing with Section 413.1) of Title 42 of the Code of Federal Regulations, or its successor.

(2) Subject to the conditions set forth in subparagraphs (A) to (D), inclusive, of paragraph (3), a change in scope of service means any of the following:

(A) The addition of a new FQHC or RHC service that is not incorporated in the baseline prospective payment system (PPS) rate, or a deletion of an FQHC or RHC service that is incorporated in the baseline PPS rate.

(B) A change in service due to amended regulatory requirements or rules.

(C) A change in service resulting from relocating or remodeling an FQHC or RHC.

(D) A change in types of services due to a change in applicable technology and medical practice utilized by the center or clinic.

(E) An increase in service intensity attributable to changes in the types of patients served, including, but not limited to, populations with HIV or AIDS, or other chronic diseases, or homeless, elderly, migrant, or other special populations.

ATTACHMENT A-1b

**SB 821 (Senate Committee on Business, Professions and
Economic Development) – Omnibus**

Chapter 307, Statutes of 2009

Senate Bill No. 821

CHAPTER 307

An act to amend Sections 139, 805, 1632.5, 1634.2, 2493, 2530.2, 2532.2, 2532.7, 2570.2, 2570.3, 2570.4, 2570.5, 2570.6, 2570.7, 2570.9, 2570.10, 2570.13, 2570.16, 2570.18, 2570.20, 2570.26, 2570.28, 2571, 2872.2, 3357, 3362, 3366, 3456, 3740, 3750.5, 3773, 4101, 4112, 4113, 4160, 4196, 4200.3, 4200.4, 4510.1, 4933, 4938, 4980.45, 4980.48, 4982, 4982.2, 4989.22, 4989.54, 4992.1, 4992.3, 4996.23, 4996.28, 4996.5, 4999.2, 5016, 5021, 5022, 5023, 5651, 7028.7, 7044, 7159, 7159.5, 7159.14, 7303.2, 7500.1, 7505.5, 7507.9, 7507.12, 7606, 7616, 7641, 7643, 7646, 7647, 7662, 7665, 7666, 7671, 7725.5, 7729, 9884.2, 9889.3, and 10146 of, to add Sections 2532.25, 2570.17, 4013, 4146, 4989.49, 4992.2, 4996.24, 7044.01, and 7507.115 to, to repeal Sections 821.5 and 821.6 of, and to repeal and add Section 7108.5 of, the Business and Professions Code, to amend Sections 44014.2, 44017.3, 44072.1, 44072.2, 44095, and 123105 of the Health and Safety Code, to amend Sections 28, 5201, and 24603 of the Vehicle Code, and to amend Section 3 of Chapter 294 of the Statutes of 2004, relating to consumer affairs.

[Approved by Governor October 11, 2009. Filed with
Secretary of State October 11, 2009.]

LEGISLATIVE COUNSEL'S DIGEST

SB 821, Committee on Business, Professions and Economic Development.
Consumer affairs: 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 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 Services.

(2) 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 "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.

(3) 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.

(4) 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.

(5) 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.

(6) 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 institution on or after January 1, 2008. The bill would make conforming changes to provisions related to the issuance of a required professional experience (RPE) temporary license, as specified.

(7) The Occupational Therapy Practice Act provides for the licensure and regulation of occupational therapists and occupational therapy assistants. Existing law prohibits an occupational therapy assistant from supervising an aide engaged in client-related tasks. Existing law also provides for minimizing the risk of transmission of blood-borne infectious diseases.

This bill would authorize occupational therapy assistants to supervise aides engaged in client-related tasks, and make conforming changes. The bill would delete obsolete certification terms and replace them with licensure references. The bill would provide for minimizing the risk of transmission of infectious diseases.

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

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

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

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

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

This bill would impose those requirements on occupational therapists.

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

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

results of the first examination, and 6 months pending the issuance of the initial license, as specified.

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

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

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

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

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

This bill would delete those transcript and letter fee provisions.

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

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

of the request, his or her license would be made inactive until the information is received.

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

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

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

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

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

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

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

This bill would modify the licensure provisions that apply to an applicant pending investigation of a complaint, and would add to those prohibited acts provisions related to drug use, telemedicine consent, subversion of an examination, impersonation, incompetence, and fraudulent advertising. The bill would define the term "advertising" for purposes of those provisions.

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

This bill would add to those prohibited acts provisions related to the subversion of an examination, access to certain psychological tests, and advertising. The bill would define the term “advertising” for purposes of those provisions. The bill would additionally modify the licensure provisions that apply to an applicant pending investigation of a complaint. The bill would modify provisions related to the supervision and employment of a marriage and family therapist interns or associate clinical social workers, as specified.

(16) Existing law appropriates specified sums from the State Dental Auxiliary Fund to the Committee on Dental Auxiliaries for operating expenses necessary to manage the dental hygiene licensing examination. Existing law requires the Dental Hygiene Committee of California to administer the dental hygiene licensing examination. Existing law also provides that on and after July 1, 2009, specified moneys are to be transferred from the State Dental Auxiliary Fund to the State Dental Hygiene Fund for purposes of carrying out certain provisions of the Dental Practice Act, including the payment of any encumbrances, related to dental hygienists, dental hygienists in alternative practice, and dental hygienists in extended functions.

This bill would specify that the moneys for operating the dental hygiene licensing examination are to be transferred to the Dental Hygiene Committee of California from the State Dental Hygiene Fund.

(17) 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. 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.

(18) 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. The bill would also make certain provisions that apply to tow trucks also apply to repossessioners' tow vehicles.

(19) 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 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.

(20) 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.

(21) 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 specified acts or omissions related to the business of the 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.

(22) 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.

(23) This bill would incorporate additional changes in Section 4160 of the Business and Professions Code proposed by AB 1071, to be operative if AB 1071 and this bill become effective on or before January 1, 2010, and this bill is enacted last.

(24) 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.

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

(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. 35. 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. 36. 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. 37. 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. 38. 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. 39. 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. 40. 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. 41. 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. 42. 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 required in an amount established by the board 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 licenseeholder or service by certified mail, return receipt requested, at the licenseeholder'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 licenseeholder be deemed to have a vested property right or interest in the license.

SEC. 43. 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. 44. 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 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 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. 45. 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 Services of the department.

SEC. 46. 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. 47. Section 4933 of the Business and Professions Code is amended to read:

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

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

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

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

SEC. 48. 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.

and mounted not lower than 15 inches above the roadway. The supplemental stoplamp on that side of a vehicle toward which a turn will be made may flash as part of the supplemental turn signal lamp.

A supplemental stoplamp may be mounted inside the rear window of a vehicle, if it is mounted at the centerline of the vehicle and is constructed and mounted so as to prevent any light, other than a monitorial indicator emitted from the device, either direct or reflected, from being visible to the driver.

(h) Any supplemental stoplamp installed after January 1, 1987, shall comply with Federal Motor Vehicle Safety Standard No. 108 (49 C.F.R. 571.108). Any vehicle equipped with a stoplamp that complies with the federal motor vehicle safety standards applicable to that make and model vehicle shall conform to that applicable safety standard unless modified to comply with the federal motor vehicle safety standard designated in this subdivision.

SEC. 109. Section 3 of Chapter 294 of the Statutes of 2004 is amended to read:

Sec. 3. The sum of one hundred thirty-eight thousand dollars (\$138,000) in the 2004–05 fiscal year, and the sum of two hundred sixty-four thousand dollars (\$264,000) in the 2005–06 fiscal year and subsequent fiscal years, is hereby appropriated from the State Dental Hygiene Fund to the Dental Hygiene Committee of California for operating expenses necessary to manage the dental hygiene licensing examination.

SEC. 110. Section 42 of this bill incorporates amendments to Section 4160 of the Business and Professions Code proposed by both this bill and AB 1071. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2010, (2) each bill amends Section 4160 of the Business and Professions Code, and (3) this bill is enacted after AB 1071, in which case Section 41 of this bill shall not become operative.

SEC. 111. 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.

ATTACHMENT A-1c

SB 470 (Corbett) – Prescription Label; Purpose

Chapter 590, Statutes of 2009

Senate Bill No. 470

CHAPTER 590

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

[Approved by Governor October 11, 2009. Filed with
Secretary of State October 11, 2009.]

LEGISLATIVE COUNSEL'S DIGEST

SB 470, 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, if requested by the patient. The bill would also require that every prescription container be correctly labeled to include that information if so indicated on the prescription.

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.

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 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 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.

(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.

O

ATTACHMENT A-1d

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

AMENDED IN ASSEMBLY APRIL 23, 2009

AMENDED IN ASSEMBLY APRIL 13, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 977

Introduced by Assembly Member Skinner

February 26, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

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

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

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

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

~~This bill would additionally authorize a pharmacist to initiate and administer influenza and pneumococcal immunizations to any person 7 years of age or older. The bill would require a pharmacist, prior to initiating and administering those immunizations, to complete a specified pharmacy-based immunization delivery training program. The bill~~

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

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

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

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

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

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

- 1 SECTION 1. *The California Pharmacists Association is hereby*
- 2 *requested to provide information to the respective chairpersons*
- 3 *of the Committees on Business and Professions and Health of the*
- 4 *Assembly and of the Committees on Business, Professions and*
- 5 *Economic Development and Health of the Senate on the status of*
- 6 *immunization protocols between independent pharmacists and*
- 7 *physicians.*
- 8 SECTION 1. ~~The Legislature finds and declares all of the~~
- 9 following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14
 15
 16 CORRECTIONS: _____
 17 Digest—Page 2—Vote key line.
 18 _____

ATTACHMENT A-1e

AB 1071 (Emmerson) – Pharmacy Fees; Sunset

Chapter 270, Statutes of 2009

Assembly Bill No. 1071

CHAPTER 270

An act to amend Sections 2001, 2020, 2460, 2701, 2708, 3010.5, 3014.6, 3685, 3710, 4001, 4003, 4110, 4127.8, 4160, 4400, and 5810 of, to add and repeal Section 3686 of, and to repeal Section 4127.5 of, the Business and Professions Code, relating to professions and vocations, and making an appropriation therefor.

[Approved by Governor October 11, 2009. Filed with
Secretary of State October 11, 2009.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1071, Emmerson. Professions and vocations.

(1) Existing law provides for the licensure and regulation of various healing arts licensees by various boards within the Department of Consumer Affairs, including, but not limited to, the Medical Board of California, the California Board of Podiatric Medicine, the Board of Registered Nursing, the State Board of Optometry, the Respiratory Care Board of California, and the California State Board of Pharmacy. Existing law requires or authorizes these boards, with the exception of the California Board of Podiatric Medicine, to appoint an executive director or officer. Under existing law, these provisions will become inoperative on July 1, 2010, and will be repealed on January 1, 2011.

Under this bill, these provisions would become inoperative and be repealed on January 1, 2013. The bill would also make nonsubstantive changes to similar provisions of the Naturopathic Doctors Act.

(2) 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.

(3) Existing law provides for the certification of interior designers, and repeals these provisions on January 1, 2010.

This bill would instead repeal these provisions on January 1, 2013.

(4) This bill would incorporate additional changes in Section 4110 of the Business and Professions Code proposed by SB 819, to be operative if

SB 819 and this bill become effective on or before January 1, 2010, and this bill is chaptered last.

(5) This bill would incorporate additional changes in Section 4160 of the Business and Professions Code proposed by SB 821, to be operative if SB 821 and this bill become effective on or before January 1, 2010, and this bill is chaptered last.

Appropriation: yes.

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

SECTION 1. Section 2001 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

(d) 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. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 2. Section 2020 of the Business and Professions Code is amended to read:

2020. (a) The board may employ an executive director exempt from the provisions of the Civil Service Act and may also employ investigators, legal counsel, medical consultants, and other assistance as it may deem necessary to carry into effect this chapter. The board may fix the compensation to be paid for services subject to the provisions of applicable state laws and regulations and may incur other expenses as it may deem necessary. Investigators employed by the board shall be provided special training in investigating medical practice activities.

(b) The Attorney General shall act as legal counsel for the board for any judicial and administrative proceedings and his or her services shall be a charge against it.

(c) 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. 3. Section 2460 of the Business and Professions Code is amended to read:

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

(b) 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. The repeal of this section renders the California Board of Podiatric Medicine subject to the review required by Division 1.2 (commencing with Section 473).

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

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

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

(c) 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. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 5. Section 2708 of the Business and Professions Code is amended to read:

2708. (a) The board shall appoint an executive officer who shall perform the duties delegated by the board and who shall be responsible to it for the accomplishment of those duties.

(b) The executive officer shall be a nurse currently licensed under this chapter and shall possess other qualifications as determined by the board.

(c) The executive officer shall not be a member of the board.

(d) 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. 6. Section 3010.5 of the Business and Professions Code is amended to read:

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

Six members of the board shall constitute a quorum.

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

(c) 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. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 7. Section 3014.6 of the Business and Professions Code is amended to read:

3014.6. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

(b) 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. 8. Section 3685 of the Business and Professions Code, as amended by Section 38 of Chapter 18 of the Fourth Extraordinary Session of the Statutes of 2009, is amended to read:

3685. (a) The repeal of this chapter renders the committee subject to the review required by Division 1.2 (commencing with Section 473).

(b) The committee shall prepare the report required by Section 473.2 no later than September 1, 2010.

SEC. 9. Section 3686 is added to the Business and Professions Code, to read:

3686. This chapter 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. 10. Section 3710 of the Business and Professions Code is amended to read:

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

(b) 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. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 11. Section 4001 of the Business and Professions Code is amended to read:

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

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

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

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

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

(f) In accordance with Sections 101.1 and 473.1, 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. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 12. Section 4003 of the Business and Professions Code is amended to read:

4003. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the Department of Consumer Affairs, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.

(e) In accordance with Sections 101.1 and 473.1, 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. 13. 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 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. 13.5. 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 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.

(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 of, or damage to, 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. 14. Section 4127.5 of the Business and Professions Code is repealed.

SEC. 15. 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 required in an amount established by the board 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. 16. 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 required in an amount established by the board 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. 16.5. 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 required in an amount established by the board 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.

SEC. 17. 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 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 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 two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).

(d) The fee for regrading an examination shall be 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 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 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).

(g) The fee for a hypodermic license and renewal shall be 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 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 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-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 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 six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(2) For nonresident wholesalers who have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be 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 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 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 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 license where the 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 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, 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 license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325) for each license.

(r) 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 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-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).

SEC. 18. Section 5810 of the Business and Professions Code is amended to read:

5810. (a) This chapter shall be subject to the review required by Division 1.2 (commencing with Section 473).

(b) This chapter 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. 19. Section 13.5 of this bill incorporates amendments to Section 4110 of the Business and Professions Code proposed by this bill and SB 819. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2010, (2) each bill amends Section 4110 of the Business and Profession Code, and (3) this bill is enacted after SB 819, in which case Section 4110 of the Business and Professions Code, as amended by SB 819, shall remain operative only until the operative date of this bill, at which time Section 13.5 of this bill shall become operative, and Section 13 of this bill shall not become operative.

SEC. 20. Section 16.5 of this bill incorporates amendments to Section 4160 of the Business and Professions Code proposed by both this bill and SB 821. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2010, (2) each bill amends Section 4160 of the Business and Professions Code, and (3) this bill is enacted after SB 821, in which case Section 16 of this bill shall not become operative.

ATTACHMENT A-2

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

**AB 830 (Cook) – Drugs and Devices; References to Compendia
Chapter 479, Statutes of 2009**

**AB 931 (Fletcher) – Emergency Supplies Container
Chapter 491, Statutes of 2009**

**SB 762 (Aanestad) – Professions and Vocations; Healing Arts
Chapter 16, Statutes of 2009**

Assembly Bill No. 830

CHAPTER 479

An act to amend Sections 1367.21 and 1370.4 of the Health and Safety Code, to amend Sections 10123.195 and 10145.3 of the Insurance Code, and to amend Sections 14105.43 and 14133.2 of the Welfare and Institutions Code, relating to drugs and devices.

[Approved by Governor October 11, 2009. Filed with
Secretary of State October 11, 2009.]

LEGISLATIVE COUNSEL'S DIGEST

AB 830, Cook. Drugs and devices.

Existing law references various drug compendiums and compendia, including the United States Pharmacopoeia, for purposes of the Knox-Keene Health Care Service Plan Act of 1975, disability insurance, and for Medi-Cal.

This bill would revise these references to include references to a specified compendia, if recognized by the federal Centers for Medicare and Medicaid Services, as specified, or with respect to Medi-Cal, a compendia that is listed in a specified federal Medicaid provision of the federal Social Security Act.

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

SECTION 1. 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 any of the following:

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

(B) One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(i) The Elsevier Gold Standard's Clinical Pharmacology.

(ii) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(iii) The Thomson Micromedex DrugDex.

(C) 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. 2. 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 of 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) Either of the following reference compendia:

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

(B) The American Dental Association Accepted Dental Therapeutics.

(5) Any of the following reference compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(A) The Elsevier Gold Standard's Clinical Pharmacology.

(B) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(C) The Thomson Micromedex DrugDex.

(6) 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.

(7) 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. 3. 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 any of the following:

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

(B) One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(i) The Elsevier Gold Standard's Clinical Pharmacology.

(ii) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(iii) The Thomson Micromedex DrugDex.

(C) 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. 4. 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 of 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) Either of the following reference compendia:

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

(B) The American Dental Association Accepted Dental Therapeutics.

(5) Any of the following reference compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(A) The Elsevier Gold Standard's Clinical Pharmacology.

(B) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(C) The Thomson Micromedex DrugDex.

(6) 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.

(7) 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. 5. 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) 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:

(A) Any vaccine to protect against human immunodeficiency virus (HIV) infection.

(B) 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.

(C) 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 a compendia listed in Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8).

(D) 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. 6. 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 a compendia listed in Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8).

Assembly Bill No. 931

CHAPTER 491

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

[Approved by Governor October 11, 2009. Filed with Secretary of State October 11, 2009.]

LEGISLATIVE COUNSEL'S DIGEST

AB 931, 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.

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 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.

(c) Any limitations established pursuant to 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.

Assembly Bill No. 931

CHAPTER 491

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

[Approved by Governor October 11, 2009. Filed with Secretary of State October 11, 2009.]

LEGISLATIVE COUNSEL'S DIGEST

AB 931, 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.

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 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.

(c) Any limitations established pursuant to 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.

Senate Bill No. 762

CHAPTER 16

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

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

LEGISLATIVE COUNSEL'S DIGEST

SB 762, Aanestad. Professions and vocations: healing arts.

Existing law makes it unlawful for a city or county to prohibit a person, authorized by one of the agencies of the Department of Consumer Affairs to engage in a particular business, from engaging in that business, occupation, or profession or any portion thereof.

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

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

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

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

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

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

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

(c) Nothing in this section shall prohibit any city, county, or city and county from levying a business license tax solely for revenue purposes, nor any city or county from levying a license tax solely for the purpose of covering the cost of regulation.

ATTACHMENT B-1

Board Adopted Regulations – Approved by OAL

16 CCR §1773 and §1173.5

**Establishment of an Ethics Course as an Optional
Enforcement Component for Discipline**

Adopted Text

Amend Section 1773 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1773. Disciplinary Conditions of Probation of Pharmacist.

(a) Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of probation shall comply with the following conditions:

- (1) Obey all laws and regulations substantially related to the practice of Pharmacy;
- (2) Report to the Board or its designee quarterly either in person or in writing as directed; the report shall include the name and address of the probationer's employer. If the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made;
- (3) Submit to peer review if deemed necessary by the Board;
- (4) Provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board;
- (5) Inform all present and prospective employers of license restrictions and terms of probation. Probationers employed by placement agencies must inform all permittees in whose premises they work of license restrictions and terms of probation.
- (6) Not supervise any registered interns nor perform any of the duties of a preceptor;
- (7) *The period of probation shall not run during such time that the probationer is engaged in the practice of pharmacy in a jurisdiction other than California.*

(b) If ordered by the Board in an administrative action or agreed upon in the stipulated settlement of an administrative action, any registered pharmacist who is serving a period of probation shall comply with any or all of the following conditions:

- (1) Take and pass all or any sections of the pharmacist licensure examination and/or attend continuing education courses in excess of the required number in specific areas of practice if directed by the Board;
- (2) Provide evidence of medical or psychiatric care if the need for such care is indicated by the circumstances leading to the violation and is directed by the Board;
- (3) Allow the Board to obtain samples of blood or urine (at the pharmacist's option) for analysis at the pharmacist's expense, if the need for such a procedure is indicated by the circumstances leading to the violation and is directed by the Board;
- (4) If and as directed by the Board, practice only under the supervision of a pharmacist not on probation to the Board. The supervision directed may be continuous supervision, substantial supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for the protection of the public health and safety.
- (5) Complete an ethics course that meets the requirements of section 1773.5.

(c) When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

Add Section 1773.5 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1773.5 Ethics Course Required as Condition of Probation.

When directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course that meets the requirements of this section as a condition of probation, license reinstatement or as abatement for a citation and fine. Board approval must be obtained prior to the commencement of an ethics course.

a. The board will consider for approval an ethics course that at minimum satisfies the following requirements:

- (1) Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment.
- (2) Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution.
- (3) Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.
- (4) Methods of Instruction. The course shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.
- (5) Content. The course shall contain all of the following components:
 - (A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.
 - (B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of pharmacy in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.
 - (C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.

- (D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.
 - (E) Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.
 - (F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.
- (6) Class Size. A class shall not exceed a maximum of 12 participants.
- (7) Evaluation. The course shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation - and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.
- (8) Records. The course provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the board or its designee.
- (9) Course Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the board or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

ATTACHMENT B-2

Board Adopted Regulations – Undergoing Review by the Administration

Repeal 16 CCR §1716.1 and §1716.2

Amend and Adopt 16 CCR §§ 1751 through §1751.8

Adopt 16 CCR §§ 1735 through §1735.8

Pharmacies that Compound

Order of Adoption

Board of Pharmacy California Code of Regulations

To Repeal Division 17 of Title 16 CCR §1716.1 and §1716.2 and To Adopt Division 17 of Title 16 CCR §1735 and §1735.1 – §1735.8, and To Amend Division 17 of Title 16 CCR §1751 and §1751.1 -- §1751.8 Requirements for Compounding and Sterile Injectable Compounding

Repeal Section 1716.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.

As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:

- (a) "Reasonable quantity" means that quantity of an unapproved drug which:
 - (1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and
 - (2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.
- (b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.
- (c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.

Repeal Section 1716.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1716.2. Record Requirements—Compounding for Future Furnishing.

(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

- (1) The date of preparation.
- (2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.
- (3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

- ~~(4) The signature or initials of the pharmacist performing the compounding.~~
- ~~(5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.~~
- ~~(6) The name(s) of the manufacturer(s) of the raw materials.~~
- ~~(7) The quantity in units of finished products or grams of raw materials.~~
- ~~(8) The package size and the number of units prepared.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.~~

Article 4.5 Compounding

Add Section 1735 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735. Compounding in Licensed Pharmacies

- (a) “Compounding” means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
 - (1) Altering the dosage form or delivery system of a drug
 - (2) Altering the strength of a drug
 - (3) Combining components or active ingredients
 - (4) Preparing a drug product from chemicals or bulk drug substances
- (b) “Compounding” does not include reconstitution of a drug pursuant to a manufacturer’s direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.
- (c) “Compounding” does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.
- (d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.1. Compounding Definitions

- (a) “Integrity” means retention of potency until the expiration date noted on the label.
- (b) “Potency” means active ingredient strength within +/- 10% of the labeled amount.
- (c) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.
- (d) “Strength” means amount of active ingredient per unit of a compounded drug product.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.2. Compounding Limitations and Requirements

- (a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.
- (b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.
- (c) Pursuant to Business and Professions Code section 4052(a)(1), a “reasonable quantity” of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where “reasonable quantity” is that amount of compounded drug product that:
 - (1) is sufficient for administration or application to patients in the prescriber’s office, or for distribution of not more than a 72-hour supply to the prescriber’s patients, as estimated by the prescriber; and
 - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.
- (d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
 - (1) Active ingredients to be used.
 - (2) Inactive ingredients to be used.
 - (3) Process and/or procedure used to prepare the drug.
 - (4) Quality reviews required at each step in preparation of the drug.
 - (5) Post-compounding process or procedures required, if any.
 - (6) Expiration dating requirements.
- (e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.
- (f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.
- (g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.
- (h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This “beyond use date” of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability

studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

- (i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.
- (j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form 17m-39 rev. 10/07). That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of odd-numbered each year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.3. Records of Compounded Drug Products

- (a) For each compounded drug product, the pharmacy records shall include:
 - (1) The master formula record.
 - (2) The date the drug product was compounded.
 - (3) The identity of the pharmacy personnel who compounded the drug product.
 - (4) The identity of the pharmacist reviewing the final drug product.
 - (5) The quantity of each component used in compounding the drug product.
 - (6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.
Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
 - (7) The equipment used in compounding the drug product.
 - (8) A pharmacy assigned reference or lot number for the compounded drug product.
 - (9) The expiration date of the final compounded drug product.
 - (10) The quantity or amount of drug product compounded.
- (b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.
- (c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.
- (d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.4. Labeling of Compounded Drug Products

- (a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
- (b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
- (c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Add Section 1735.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.5. Compounding Policies and Procedures

- (a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.
- (b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
- (c) The policy and procedure manual shall include the following
 - (1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.
 - (2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
 - (3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
 - (4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
 - (5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.6. Compounding Facilities and Equipment

- (a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.
- (b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.
- (c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.7. Training of Compounding Staff

- (a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.
- (b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.
- (c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.8. Compounding Quality Assurance

- (a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.
- (b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.
- (c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

- (d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Article 7 Sterile Injectable Compounding

Amend Section 1751 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751. Sterile Injectable Compounding; Compounding Area.

- (a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.
- (b) The Any pharmacy doing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:
- (1) Clean Room and Work Station Requirements, shall be in accordance with Section 490A.3.1 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
 - (2) Walls, ceilings and floors shall be constructed in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
 - (3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.
 - (4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.
 - (5) The pharmacy shall be arranged in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
 - (6) A sink shall be included in accordance in with Section 490A.3.4 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
 - (7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.
- (c) Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127 and 4127.7, Business and Professions Code; and Section 18944, Health and Safety Code.

Re-number section 1751.3 to new section 1751.1 and amend section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.3. 1751.1. Sterile Injectable Recordkeeping Requirements.

- (a) Pharmacies compounding sterile injectable products for future use pursuant to section 1716.1 1735.2 shall, in addition to those records required by section 1716.2 1735.3, have make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.
- (b) In addition to the records required by section 1735.3 and subdivisions (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be maintained for at least three years made and kept by the pharmacy:
- (1) The training and competency evaluation of employees in sterile product procedures.
 - (2) Refrigerator and freezer temperatures.
 - (3) Certification of the sterile compounding environment.
 - (4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).
 - (5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
 - (6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.
- (c) ~~Pharmacies shall maintain records of validation processes as required by Section 1751.7~~
(b) for three years Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend Section 1751.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.2. Sterile Injectable Labeling Requirements.

In addition to existing labeling requirements to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

- (a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
- (b) Name and concentrations of ingredients contained in the sterile injectable product.
- (c) Instructions for storage and handling.
- (d) All cytotoxic agents shall bear a special label which states "Chemotherapy -Dispose of Properly."

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Re-number section 1751.02 to new section 1751.3 and amend section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.02. 1751.3. Sterile Injectable Policies and Procedures.

(a) ~~Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include, but not be limited to~~ Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:

- (1) Compounding, filling, and labeling of sterile injectable compounds.
- (2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
- (3) Equipment and supplies.
- (4) Training of staff in the preparation of sterile injectable products.
- (5) Procedures for handling cytotoxic agents.
- (6) Quality assurance program.
- (7) Record keeping requirements.

(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

(c) Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(d) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:

- (1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.
- (2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.
- (3) Policies and procedures must address at least the following:
 - (A) Competency evaluation.
 - (B) Storage and handling of products and supplies.
 - (C) Storage and delivery of final products.
 - (D) Process validation.
 - (E) Personnel access and movement of materials into and near the controlled area.
 - (F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).
 - (G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.
 - (H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.
 - (I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
 - (J) Sterilization.

(K) End-product evaluation and testing.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.01 to new section 1751.4 and amend section 1751.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.01. 1751.4. Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients.

- (a) No sterile injectable product shall be ~~prepared~~ compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.
- (b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.
- (c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.
- (d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.
- (e) Pharmacies preparing parenteral cytotoxic agents shall be do so in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

Repeal Section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.1. Laminar Flow Biological Safety Cabinet.

~~Pharmacies preparing parenteral cytotoxic agents shall be in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's~~

specifications. Certification records must be retained for at least 3 years.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Repeal Section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.3. Recordkeeping Requirements.

- (a) ~~Pharmacies compounding sterile injectable products for future use pursuant to section 1716.1 1735.2 shall, in addition to those records required by section 1716.2 1735.3, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~
- (b) ~~In addition to the records required by subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:
 - (1) ~~The training and competency evaluation of employees in sterile product procedures.~~
 - (2) ~~Refrigerator and freezer temperatures.~~
 - (3) ~~Certification of the sterile compounding environment.~~
 - (4) ~~Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).~~
 - (5) ~~Inspection for expired or recalled pharmaceutical products or raw ingredients.~~
 - (6) ~~Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.~~~~
- (c) ~~Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years.~~

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

Renumber section 1751.4 to new section 1751.5 and amend section 1751.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.4. 1751.5. Sterile Injectable Compounding Attire.

- (a) When preparing cytotoxic agents, gowns and gloves shall be worn.
- (b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:
 - (1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.
 - (2) Cleanroom garb must be donned and removed outside the designated area.
 - (3) Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
 - (4) Head and facial hair must be kept out of the critical area or be covered.
 - (5) Gloves made of low-shedding materials are required.

- (c) The requirements of this subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.5 to new section 1751.6 and amend section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.5, 1751.6. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.

- (a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.
- (b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.
- (c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.
- (d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.
- (e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:
- (1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:
 - (A) Aseptic technique.
 - (B) Pharmaceutical calculations and terminology.
 - (C) Sterile product compounding documentation.
 - (D) Quality assurance procedures.
 - (E) Aseptic preparation procedures.
 - (F) Proper gowning and gloving technique.
 - (G) General conduct in the controlled area.
 - (H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
 - (I) Sterilization techniques.
 - (J) Container, equipment, and closure system selection.
 - (2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Repeal Section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.6. Disposal of Waste Material.

~~Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.~~

~~Authority cited: Section 4005 Business and Professions Code. Reference: Section 4005 Business and Professions Code.~~

Amend 1751.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.7. Sterile Injectable Compounding Quality Assurance and Process Validation.

(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, ~~There shall be~~ a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

- (1) Cleaning and sanitization of the parenteral medication preparation area.
- (2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.
- (3) Actions to be taken in the event of a drug recall.
- (4) Written justification of the chosen expiration dates for compounded sterile injectable products.

(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials ~~are~~ must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

- (c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- (d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.9 to new section 1751.8 and amend section 1751.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.9. 1751.8. Sterile Injectable Compounding Reference Materials.

In any pharmacy engaged in compounding sterile injectable drug products, there shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Virginia Herold
Executive Officer

Date

ATTACHMENT B-3

Board Approved Regulations – Awaiting Notice

16 CCR §1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

16 CCR §1721 and §1723.1 – Dishonest Conduct During a Pharmacist's Licensure Examination; Confidentiality

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

Board of Pharmacy
Specific Language to Add Section 1785

Add Section 1785 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1785. Self-Assessment of a Veterinary Food-Animal Drug Retailer by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each veterinary food-animal drug retailer as defined under section 4041 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new veterinary food-animal drug retailer permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a veterinary food-animal drug retailer to a new address.

(c) The components of this assessment shall be on Form 17M-40 entitled "Veterinary Food-Animal Drug Retailer Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the licensed premises for three years after it is completed.

(e) The veterinary food-animal drug retailer is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4196 Business and Professions Code.

**Board of Pharmacy
Specific Language To
Amend 16 Cal.Code Reg §1721 and Amend 16 Cal.Code Reg §1723.1**

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

1721. Dishonest Conduct During Examination

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

Board of Pharmacy
Specific Language to Add Section 1751.8

Add Section 1751.8 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.8 – 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 or section 4127.2 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 standards-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 shall submit a report to the board listing all board-licensed facilities that have been accredited during the past 12 months.

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

(g) This approval shall be good for a period of three years. Three months before the end of the approval period, an approved accrediting agency must submit a reapplication to the board for continued recognition as an approved accrediting agency. The Board of Pharmacy shall take action on a completed application at a scheduled board meeting.