



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

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NOTICE OF MEETING and AGENDA
LEGISLATION AND REGULATION COMMITTEE

Date: October 21, 2009
Time: 3:00 p.m. – 5:30 p.m. or upon recess of board meeting
Location: Department of Consumer Affairs Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

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

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

Agenda

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

Call to Order **3:00 p.m.**

A. LEGISLATIVE REPORT

1. Board Sponsored Legislation

- a. **SB 819** (Senate Business, Professions & Economic Development Committee) – Omnibus Provisions (formerly contained in the enrolled version of SB 1779 [2008], vetoed).
 - Changes based on recodification of B&PC §4052
 - §733 – Dispensing Prescription Drugs and Devices

- §4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Facilities
 - §4040 – Prescription; Content Requirements
 - §4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
 - §4060 – Controlled Substance; Prescription Required; Exceptions
 - §4076 – Prescription Container; Requirements for Labeling
 - §4111 – Restrictions on Prescriber Ownership
 - §4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
 - H&SC §11150 – Persons Authorized to Write or Issue a Prescription
 - General Omnibus Changes
 - §4059.5 – Who may order Dangerous Drugs or Devices; Exceptions
 - §4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records; Current Inventory
 - §4126.5 – Furnishing Dangerous Drugs by Pharmacy
 - §4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
 - §4301 – Unprofessional Conduct
 - H&SC §11165 – Controlled Substance Utilization Review and Evaluation System; Establishment; Operation; Funding; Reporting to Legislature
 - Omnibus Changes to Allow for the Use of Mobile Pharmacies
 - §4062 – Furnishing Dangerous Drugs During an Emergency
 - §4110 – License Required; Temporary Permit Upon Transfer of Ownership
 - Omnibus Changes Specific to the PIC and DRC Requirements
 - §4022.5 – Designated Representative; Designated Representative-in-Charge
 - §4161 – Non-Resident Wholesaler; Requirements
 - §4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action
 - §4329 – Nonpharmacists; Prohibited Acts
 - §4330 – Proprietors; Prohibited Acts
- b. **SB 821** (Senate Business, Professions & Economic Development Committee) – New Omnibus Provisions specific to PIC and DRC Requirements
- §4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board
 - §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
 - §4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications
 - §4160 – Wholesaler Licenses
 - §4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed or Repacked
 - §4200.3 – Examination Process to be Reviewed Regularly; Required Standards
 - §4200.4 – Retaking National Examination After Failure; Waiting Period

- c. **SB 470** (Corbett) – “Purpose” bill. Proposal to amend B&P §4040 and §4076 re: prescription labeling.
- d. **AB 977** (Skinner) – Pharmacists: Immunization Administration. Proposal to amend B&PC §4052 and §4052.8
- e. **AB 1071** (Emmerson) Pharmacy Fees. Proposal to Amend B&PC §4110, §4127.8, §4160, §4400, and §4127.5

2. Legislation Introduced Impacting the Practice of Pharmacy or the Board’s Jurisdiction Enrolled or Chaptered

- a. **AB 830** (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia recognized by the Centers of Medicare and Medicaid
- b. **AB 931** (Fletcher) Emergency Supplies – Doses stored in an emergency supplies container
- c. **SB 762** (Aanestad) Professions and Vocations; Healing Arts

3. Legislation That Failed Passage Deadline, May Become Two Year Bill

- a. **AB 418** (Emmerson) Pharmacy Technicians – Education and CE Requirements
- b. **AB 484** (Eng) Licensees not in compliance with judgment or order; enforcement; action on a license
- c. **AB 583** (Hayashi) Health Care Practitioners: Disclosure of Education and Office Hours
- d. **AB 877** (Emmerson) (*Intent language*) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice
- e. **AB 1458** (Davis) Drugs: Adverse Effects Reporting
- f. **SB 26** (Simitian) Home-Generated Pharmaceutical Waste
- g. **SB 238** (Calderon) Prescription Drugs
- h. **SB 341** (DeSaulnier) California Department of Public Health. CDPH to contract with UC to study/evaluate the safety and effectiveness of prescription Drugs
- i. **SB 389** (Negrete McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus
- j. **SB 484** (Wright) Ephedrine Products / Schedule V
- k. **SB 638** (Negrete McLeod) DCA regulatory boards; sunset reviews; operations; report requirements

B. REGULATIONS REPORT

1. Board Adopted Regulations – Recently Approved by OAL

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

2. Board Adopted Regulations – Undergoing Review by the Administration

Title 16 CCR Repeal §1716.1 and §1716.2, Amend and Adopt sections 1751 through 1751.8 and Adopt sections 1735 through 1735.8 – Pharmacies that Compound

3. Board Approved Regulations – Awaiting Notice

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

4. Regulations Under Development

- a. Title 16 CCR Section 1780 – Update the USP Standards Reference Material
- b. Title 16 CCR Section 1732.2 – Continuing Education for Competency Committee Members

5. Proposed Regulations to Implement Recently Enrolled Legislation

- a. Proposed changes to Title 16 CCR Section 1749 to conform with provisions contained in AB 1071 (Emmerson) Pharmacy Fees
- b. Proposed adoption of provisions to implement provisions contained in AB 931 (Fletcher) Emergency Supplies

C. Proposal to Allow a Board Licensed Hospital Pharmacy to Package Unit Dose Medication and Compound for Inpatients of Hospitals with Common Ownership

1. Presentation by Scripps and Sharp Hospitals

2. Demonstration by Intelifill for Use in Preparing Hospital Medications

3. Demonstration by Amerisource Bergen on TrakRx System

D. Request for Legislative and Regulation Changes Submitted by the Public or Staff

The committee will consider future legislative and regulatory proposals. Stakeholders are encouraged to submit these proposals in writing to the committee before or during the meeting.

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

F. Public Comment for Items Not On the Agenda*

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

Adjournment

5:30 p.m.

Committee materials will be available on the board's Web site by October 15, 2009.