



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

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

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

Agenda

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

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

A. REGULATIONS REPORT

1. Approved Regulations

Section 100 Changes

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

2. Board Approved Regulations – Undergoing Administrative Review

- a. Proposed Adoption of 16 CCR §1760 – Disciplinary Guidelines
- b. Proposed Amendment of 16 CCR §1773 and Adoption of 16 CCR §1773.5 – Ethics Course

3. Board Approved Regulations – Previously Noticed

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

4. Board Approved Regulations – Awaiting Notice

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

5. Regulations Under Development

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

B. LEGISLATIVE REPORT

1. Legislation Impacting the Practice of Pharmacy or the Board’s Jurisdiction

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

- §4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
- §4301 – Unprofessional Conduct
- H&SC §11165 – Controlled Substance Utilization Review and Evaluation System; Establishment; Operation; Funding; Reporting to Legislature
- Omnibus Changes to Allow for the Use of Mobile Pharmacies
 - §4062 – Furnishing Dangerous Drugs During an Emergency
 - §4110 – License Required; Temporary Permit Upon Transfer of Ownership
- Omnibus Changes Specific to the PIC and DRC Requirements
 - §4022.5 – Designated Representative; Designated Representative-in-Charge
 - §4161 – Non-Resident Wholesaler; Requirements
 - §4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action
 - §4329 – Nonpharmacists; Prohibited Acts
 - §4330 – Proprietors; Prohibited Acts
- b. **SB 820** (Senate Business & Professions Committee) – New Omnibus Provisions
 - §4200.3 – Exam Process; standards; development; reporting requirements
 - §4200.4 – Retaking Examinations; Set Limits; Requirements
- c. **SB 821** (Senate Business & Professions Committee) – New Omnibus Provisions specific to PIC and DRC Requirements
 - §4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board
 - §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
 - §4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications
 - §4160 – Wholesaler Licenses
 - §4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed or Repacked
- d. **SB 470** (Corbett) – “Purpose” bill. Proposal to amend B&P §4040 and §4076 re: prescription labeling.
- e. **AB 977** (Skinner) – Pharmacists: Immunization Administration. Proposal to amend B&PC §4052 and §4052.8
- f. **AB 1071** (Emmerson) Pharmacy Fees. Proposal to Amend B&PC §4110, §4127.8, §4160, §4400, and §4127.5

2. Legislation Introduced Impacting the Practice of Pharmacy or the Board’s Jurisdiction – For Committee Consideration

- a. **AB 418** (Emmerson) Pharmacy Technicians – Education and CE Requirements
- b. **AB 484** (Eng) Licensees not in compliance with judgment or order; enforcement; action on a license
- c. **AB 718** (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to electronically transmit data by 1/1/12
- d. **AB 830** (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia recognized by the Centers of Medicare and Medicaid

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

3. Other Legislation Introduced (Of Interest or for Information Only)

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

C. Public Comment for Items Not On the Agenda*

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

Adjournment

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