



California State Board of Pharmacy
1625 North Market Blvd., N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

Virginia Herold
(916) 574-7911

**California State Board of Pharmacy
Department of Consumer Affairs
Notice of Public Board Meeting
April 30 and May 1, 2009**

This board 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 board on each open agenda item.

DATE: April 30 and May 1, 2009

**PLACE: Department of Consumer Affairs
First Floor Hearing Room

1625 N. Market Boulevard
Sacramento CA 95834**

Note: Pharmacists and pharmacy technicians who attend the full day of the board meeting on Thursday, April 30, 2009, may be awarded 6 hours of CE, in accordance with the board's CE policy.

The board's strategic plan organizes board activities into five committees of the board. Correspondingly, the board meeting agenda is organized around the committee reports as updates to the board on each committee's recent activities. Action may be taken on any item on the agenda. An opportunity for public comment is provided at the end of each committee's report. All times are approximate and subject to change.

Time limitations for discussion and comment will be determined by the President.

Agenda

Thursday, April 30, 2008

CALL TO ORDER

9:00 a.m.

General Announcements

I. Approval of the Full Board Minutes of January 21 and 22, 2009

II. Legislation and Regulation Committee Report and Action

Part 1: Regulation Report and Action (Note: CCR as used below means California Code of Regulations)

Meeting Materials will be available on the board's Web site at www.pharmacy.ca.gov by April 27, 2009

A. Action to Repeal Title 16 CCR Sections 1716.1 and §1716.2, Amend and Adopt Sections 1751 through 1751.8, and Adopt Sections 1735 through 1735.8 – Pharmacies that Compound Medicine

B. Approved Regulations

Section 100 Changes

1. 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
2. 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

C. Board Approved Regulations – Undergoing Administrative Review

1. Proposed Adoption of 16 CCR §1760 – Disciplinary Guidelines
2. Proposed Amendment of 16 CCR §1773 and Adoption of 16 CCR §1773.5 – Ethics Course

D. Board Approved Regulations – Awaiting Notice

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

E. Regulations Under Development

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

Public Comment

Part 2. Legislative Report: Discussion and Action on Pending Legislation

A. Board Sponsored Legislation:

1. **SB 819 (Senate Business, Professions & Economic Development Committee) – Omnibus Provisions (formerly contained in the enrolled version of SB 1779 [2008], vetoed).**
 - (a) Changes Based on Recodification of B&PC §4052
 - (1) Dispensing Prescription Drugs and Devices -- §733
 - (2) Skilled Nursing Facility – Intermediate Care Facility – Other Health Facilities -- §4027
 - (3) Prescription; Content Requirements -- §4040
 - (4) Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist -- §4051
 - (5) Controlled Substances; Prescription Required; Exceptions -- §4060
 - (6) Prescription Container; Requirements for Labeling -- §4076
 - (7) Restrictions on Prescriber Ownership -- §4111
 - (8) Dispensing by Pharmacist Upon Order of Nurse Practitioner -- §4174
 - (9) Persons Authorized to Write or Issue a Prescription -- H&SC §11150
 - (b) General Omnibus Changes
 - (1) Who may order Dangerous Drugs or Devices; Exceptions -- §4059.5
 - (2) Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records; Current Inventory -- §4081
 - (3) Furnishing Dangerous Drugs by Pharmacy -- §4126.5
 - (4) Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee -- §4231
 - (5) Unprofessional Conduct -- §4301
 - (6) Controlled Substance Utilization Review and Evaluation System; Establishment; Operation; Funding; Reporting to Legislature -- H&SC §11165
 - (c) Omnibus Changes to Allow for the Use of Mobile Pharmacies
 - (1) Furnishing Dangerous Drugs During an Emergency -- §4062
 - (2) License Required; Temporary Permit Upon Transfer of Ownership -- §4110

- (d) Omnibus Changes Specific to the PIC and Designated Representative in Charge Requirements
 - (1) Designated Representative; Designated Representative-in-Charge -- §4022.5
 - (2) Non-Resident Wholesaler; Requirements -- §4161
 - (3) Pharmacist-in-Charge; Notice to Board; Disciplinary Action -- §4305
 - (4) Nonpharmacists; Prohibited Acts -- §4329
 - (5) Proprietors; Prohibited Acts -- §4330
 - 2. **SB 820 (Senate Business, Professions & Economic Development Committee)**
New Omnibus Provisions
 - (a) Exam Process; Standards; Development; Reporting Requirements -- §4200.3
 - (b) Retaking Examinations; Set Limits; Requirements -- §4200.4
 - 3. **SB 821 (Senate Business, Professions & Economic Development Committee)**
New Omnibus Provisions specific to PIC and DRC Requirements
 - (a) Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board -- §4101
 - (b) Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation -- §4112
 - (c) Pharmacist-in-Charge; Approval; Responsibilities; Notifications -- §4113
 - (d) Wholesaler Licenses -- §4160
 - (e) Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed or Repacked -- §4196
 - 4. **SB 470 (Corbett) Prescription Labeling to Add “Purpose” -- Proposal to Amend B&PC §4040 and §4076**
 - 5. **AB 977 (Skinner) Pharmacists: Immunization Administration -- Proposal to Amend B&PC §4052 and §4052.8**
 - 6. **AB 1071 (Emmerson) Pharmacy Fees -- Proposal to Amend B&PC §4110, §4127.8, §4160, §4400, and §4127.5**
- B. Legislation Introduced Impacting the Practice of Pharmacy or the Board’s Jurisdiction**
- 1. **AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements**
 - 2. **AB 484 (Eng) Licensees Not in Compliance with Judgment or Order; Enforcement; Action on a License**
 - 3. **AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012**
 - 4. **AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid**
 - 5. **AB 877 (Emmerson) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice**
 - 6. **AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container**
 - 7. **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 (OSHDP)**
 - 8. **AB 1370 (Solorio) “Best Before” Date on a Prescription Label**
 - 9. **AB 1458 (Davis) Drugs: Adverse Effects Reporting**
 - 10. **SB 26 (Simitian) Home-Generated Pharmaceutical Waste**
 - 11. **SB 43 (Alquist) Cultural and Linguistic Competency**
 - 12. **SB 238 (Calderon) Medical Information**
 - 13. **SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs**
 - 14. **SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus**
 - 14. **SB 484 (Wright) Ephedrine Products to Schedule V**
 - 15. **SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews**
 - 16. **SB 762 (Aanestad) Professions and Vocations; Healing Arts**
- C. Other Legislation Introduced**
- 1. **AB 832 (Jones) Clinic Licensing**
 - 2. **AB 1094 (Conway) Disposal of Personal Information**
 - 3. **AB 1201 (Perez) – Immunizations -- Physician Reimbursement**

D. Summary of the Legislation and Regulation Committee Meeting Held April 16, 2009

E. Third Quarterly Report on Legislation/Regulation Committee Goals for 2008/09

F. Public Comment

Recognition of Pharmacists Licensed with the Board for 50 Years

11:30 a.m.

Lunch

III. Communication and Public Education Committee Report and Action

A. Report of the SB 472 Medication Label Subcommittee Meeting Held March 12, 2009

1. Review of Consumer Surveys Conducted by the Board of Pharmacy for SB 472
2. Review of Survey Results from a Joint Survey Developed by the California Pharmacy Foundation and the Board of Pharmacy for SB 472
3. Presentation of SB 853 (Escutia, Chapter 713, Statutes of 2003) Health Care Language Assistance
4. Patient-Focused Elements of Prescription Container Labels (California Business and Professions Code Section 4076)
5. Directions for Use Used on Prescription Labels
6. Meeting Summary From the Meeting of March 12, 2009

B. Update Report on *The Script*

C. Update on Public Outreach Activities

D. Third Quarterly Report on Committee Goals for 2008/09

E. Public Comment

IV. Licensing Committee Report and Action

A. Meeting Summary of the Subcommittee to Evaluate Drug Distribution within Hospitals, held March 2, 2009, and Discussion of the Board

B. Summary of March 24, 2009 Meeting of the Licensing Committee

1. Emergency and Disaster Response Planning: EMS Authority Looking for Pharmacists and Other Health Care Volunteers
2. Review of the Professional Competency Statement for Pharmacy
3. National Association of Boards of Pharmacy and Accreditation Council for Pharmacy Education's Confirmation of Appropriate Content for Continuing Education Provider Coursework
4. Request for Board Recognition of a School of Pharmacy with Precandidate Status with the Accreditation Council for Pharmacy Education Pursuant to 16 CCR § 1719 – Jefferson School of Pharmacy, Philadelphia, PA
5. Assembly Bill 418 (Emmerson): Pharmacy Technician Qualifications
6. ExCPT Examination For Pharmacy Technicians
7. Issue Statement on Pharmacy Workforce Shortage by the California Hospital Association Workforce Committee, December 1, 2008
8. US Department of Health and Human Services, Health Resources and Services Administration's Report: *The Adequacy of Pharmacist Supply: 2004-2030*
9. Experiences of an Employer Recruiting Foreign-Trained Pharmacists for Work in the United States
10. Pharmacy Access Partnership's Request to Establish a Hormonal Contraception Pilot in Pharmacies
11. Competency Committee Report and Examination Statistics for the CPJE and NAPLEX Exams
12. Meeting Summary of the Licensing Committee Meeting Held March 24, 2009

C. Third Quarterly Report on Licensing Committee Goals for 2008/09

D. Public Comment

V. Organizational Development Committee Report and Action

A. Budget Update/Report

1. Governor's Executive Order to Furlough State Employees
2. Budget for 2008/09
3. Fund Condition Report
4. Reimbursement to Board Members
5. I-Licensing Progress

B. Discussion of the 2008 Audit Report Regarding the Independent Review of the Board's Fee Structure by Sjoberg Evashenck Consulting, Inc.

C. Recognition Program of Pharmacists Who Have Been Licensed 50 Years

D. Personnel Update

E. Professionals Achieving Consumer Trust Summit Scheduled for January 2010

F. Board Meetings Scheduled for 2010

G. Third Quarterly Report on the Committee's Goals for 2008/09

Public Comment

VI. Election of Board Officers for 2009-10

VII. Public Comment for Items Not on the Agenda/Agenda Items for Future Meetings

Recess for Day

Friday, May 1, 2009

VIII. Overview: The Board's Role in the Disciplinary Process

8:00 a.m.

Presentation and Discussion Led by Senior Staff Counsel Kristy Schieldge

IX. Enforcement Committee Report and Action

Part 1: Workgroup on E-Pedigree

A. Review and Action on Items from the Meeting Held March 9, 2009

1. Review of the Board's Comments Submitted Regarding the FDA's Proposed Guidance for Industry on Standards for Securing the Drug Supply Chain -- Standardized Numerical Identification of Prescription Drug Packages
2. FDA's Proposed Guidance for Industry on Unique Device Identification Systems
3. Review of Presentations Made to the Workgroup to Implement Electronic Pedigree Requirements -- Presentations by:
 - Federal Food and Drug Administration
 - Congressman Buyer's Office
 - GS1
 - Oracle

Public Comment

Part 2: Enforcement Committee Matters

A. Internet Pharmacies Dispensing of Controlled Substances: DEA Implements Ryan Haight Online Pharmacy Consumer Protection Act of 2008 as an Interim Rule, Comments Sought on Implementation 21 CFR Part 1300, 1301, 1304 et al., Docket No. DEA-3221

B. Discussion of Policies Involving Home Generated Pharmaceutical Waste Take Back by Pharmacies

1. Model Guidelines for Home Generated Pharmaceutical Waste Approved by the California Integrated Waste Management Board (February 2009)
2. Senate Bill 26 (Simitian)
3. Comments Submitted by the Board to the Federal Drug Enforcement Administration on Disposal of Controlled Substances by Persons Not Registered with the DEA – Docket No. DEA-316 A

- C. Update on Activities to Implement E-Prescribing in California
- D. Review of the Presentation on California's Controlled Substance Utilization Review and Evaluation System (CURES), a presentation and question and answer session led by Department of Justice, Bureau of Narcotics Enforcement
- E. Update Regarding Arrests and Criminal Convictions of Board Applicants and Licensees
- F. Department of Consumer Affairs' Policies Regarding Pursuit of Interim Suspension Orders
- G. Minutes of the Enforcement Committee Meeting of March 9, 2009
- H. Enforcement Statistics 2008-2009
- I. Third Quarterly Report on Enforcement Committee Goals for 2008/09

Public Comment

X. Closed Session

The board will move into closed session pursuant to Government Code section 11126(c)(3) to deliberate on disciplinary matters.

XI. Petition for Early Termination of Probation

10:00 a.m.

Anne Cabrera

XII. Closed Session

At the close of the hearing, the board will move into closed session pursuant to Government Code section 11126(c)(3) to deliberate on the request for early termination of probation.

The board will also conclude deliberations on disciplinary matters pursuant to Government Code section 11126(c)(3).

ADJOURNMENT

1:00 p.m.