

California State Board of Pharmacy

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DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

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California State Board of Pharmacy Department of Consumer Affairs Notice of Public Board Meeting July 15 & 16, 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: July 15 & 16, 2009

PLACE: Radisson Hotel at Los Angeles Airport

6225 West Century Blvd. Los Angeles, CA 90045 (310) 670-9000

Note: Pharmacists and pharmacy technicians who attend the full day of the board meeting on Wednesday, July 15, 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

Wednesday, July 15, 2009

CALL TO ORDER 9:00 a.m.

General Announcements

- I. Approval of the Full Board Minutes of April 30, 2009 and May 1, 2009
- II. Enforcement Committee Report and Action
 - A. Presentation by Sharps Compliance, Inc.
 Mail Back Program for Unwanted Prescription Drugs
 - B. Update on the Status of Drug and Sharps Take Back Programs in California Pharmacies
 - C. Summary and Discussion of June 9, 2009 Meeting of the Enforcement Committee

- 1. Overview of the Board of Pharmacy's Complaint Investigation Processes
- 2. Discussion of the Board of Pharmacy's Citation and Fine Program Involving Medication Errors
- 3. Discussion of the Board of Pharmacy's Pharmacists Recovery Program
- 4. Discussion of the Actions of the Department of Consumer Affairs Health Care Boards to Develop Regulations Required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for Practitioner Recovery Programs
- 5. Presentations and Discussion on E-Prescribing Pilot Programs Underway in California by the California HealthCare Foundation and CalPERS
- 6. Discussion Regarding AB 718 (Emmerson), E-Prescribing Pilot Project
- 7. Demonstration of Technology Proposed for Future Pharmacy Use in California
- D. Strategic Plan Update for the Enforcement Committee for 2009/10 and Discussion of Future Activities of the Committee.
- E. Fourth Quarterly Report on Enforcement Committee Goals for 2008/09
- F. Public Comment

III. Licensing Committee Report and Action

A. Subcommittee to Evaluate Drug Distribution within Hospitals

- 1. Meeting Summary of the Meeting Held June 2, 2009
- 2. Discussion of the Board

B. Summary and Discussion of June 18, 2009 Meeting of the Licensing Committee

- 1. Emergency and Disaster Response Planning: Presentation on the H1N1 Emergency Response Activities in California by the California Department of Public Health (CDPH)
 - (a) CDPH Protocols for Distribution of Emergency Drug Supplies
 - (b) Gap Analysis for Improved Emergency Response in the Future
 - (c) Emergency Use Authorization by the FDA
 - (d) Emergency Response Plans for Fall 2009 Influenza Season
- 2. Becoming Licensed as a Pharmacy Technician in California: An Overview of Application Processing and Frequent Deficiencies
- 3. Release of the National Association of Boards of Pharmacy's Report of the Task Force on Standardized Pharmacy Technician Education and Training
- 4. Update: Psychometric Assessment of the PTCB and ExCPT Pharmacy Technician Exams
- 5. Discussion of the Reporting and Accounting of Intern Hours for California Pharmacy School Students
- 6. Private/Public Partnerships to Add Health Care Practitioners to California's Work Force
- 7. Obtaining a Pharmacy License in California: An Overview of the Process
- 8. Impact of State Furloughs on Processing Timelines and Work Flow of the Board
- 9. Pharmacies Refilling Orders for Other Pharmacies with Prescription Drugs Owned by Neither Pharmacy
- 10. Accreditation of Internet Pharmacies by the National Association of Boards of Pharmacy
- 11. Competency Committee Report
 - (a) Pharmacist Exam Performance Statistics for October 2008 April 2009 CPJE and NAPLEX Exam Administrations
 - (b) Comparison of Licensing Statistics with California's Pharmacist Licensure Examination Administered Prior to January 2004
 - (c) Job Analysis for the CPJE to Be Undertaken at the End of 2009
- 12. Meeting Summary of the Licensing Committee Meeting Held June 18, 2009
- C. Strategic Plan Update for the Licensing Committee for 2009/10 and Discussion of Future Activities of the Committee.
- D. Fourth Quarterly Report on Licensing Committee Goals for 2008/09
- **E. Public Comment**

Lunch

IV. Legislation and Regulation Committee Report and Action

1:00 p.m.

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

- A. Action to Repeal Title 16 CCR §§1716.1 and 1716.2, Amend and Adopt §§1751 through 1751.8, and Adopt §§1735 through 1735.8 Pharmacies that Compound Medicine
- B. Board Approved Regulations Currently Undergoing Administrative Review
 - Proposed Amendment of 16 CCR §1773 and Adoption of 16 CCR §1773.5 Ethics Course
- C. Board Approved Regulations Currently Awaiting Notice
 - Title 16 CCR §1785 Self-Assessment of a Veterinary Food-Animal Drug Retailer
 - 2. Title 16 CCR §§1721 and 1723.1 Dishonest Conduct During a Pharmacist's Licensure Examination / Confidentiality
 - 3. Title 16 CCR §1751.9 Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products
- D. Regulations Under Development
 - 1. Title 16 CCR §1780 Update the USP Standards Reference Material
 - 2. Title 16 CCR §1732.2 Continuing Education for Competency Committee Members

Public Comment

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

- A. Board-Sponsored Legislation:
 - 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
- 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 583 (Hayashi) Health Care Practitioners: Disclosure of Education and Office Hours
- 2. AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions Requirement to Electronically Transmit Data by January 2012
- 3. AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid
- 4. AB 931 (Fletcher) Emergency Supplies Doses Stored in an Emergency Supplies Container
- 5. SB 389 (McLeod) FBI and State Fingerprinting Requirements for DCA Boards and Bureaus
- 6. SB 484 (Wright) Ephedrine Products to Schedule V
- 7. SB 762 (Aanestad) Professions and Vocations; Healing Arts

C. Inactive Bills

- 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 877 (Emmerson) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice
- 4. AB 1458 (Davis) Drugs: Adverse Effects Reporting
- 5. SB 26 (Simitian) Home-Generated Pharmaceutical Waste
- 6. SB 238 (Calderon) Medical Information
- 7. SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs
- 8. SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews

D. Other Legislation Introduced

- 1. AB 832 (Jones) Ambulatory Surgical Clinic Workgroup
- 2. AB 1094 (Conway) Disposal of Personal Information
- 3. AB 1201 (Perez) Immunizations -- Physician Reimbursement

E. Strategic Plan Update for the Legislation and Regulation Committee for 2009/10 and Discussion of Future Activities of the Committee.

- F. Summary of the Legislation and Regulation Committee Meeting Held on July 8, 2009
- G. Fourth Quarterly Report on Legislation/Regulation Committee Goals for 2008/09
- **H. Public Comment**

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

Note: The Board may not discuss or take action on any matter raised during this 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, 11125.7(a)]

VI. Closed Session

Pursuant to Government Code section 11126(e), the Board will convene in closed session to confer with and receive legal advice from counsel (Carol Marie Zalez-Simon v. California Board of Pharmacy, Los Angeles Sup.Ct.,Case No. BS116965)

Recess for Day

PUBLIC MEETING OF THE COMMUNICATION AND PUBLIC EDUCATION COMMITTEE (see separate agenda)

3:30 p.m.

FULL BOARD

Thursday July 16, 2009

VII. Communication and Public Education Committee Report and Action

8:30 a.m.

A. Report of the Public Education Committee Meeting Held July 15, 2009

- 1. Review of Consumer Surveys Conducted by the Board of Pharmacy for SB 472
- 2. Patient-Focused Elements of Prescription Container Labels (California Business and Professions Code Section 4076)
- 3. Directions for Use on Prescription Labels
- B. Discussion and Possible Action to Initiate Rulemaking to Adopt §1707.5 Relating to Patient-Centered Prescription Container Labels
- C. Update Report on The Script
- D. Update on Public Outreach Activities
- E. Strategic Plan Update for the Communication and Public Education Committee for 2009/10 and Discussion of Future Activities of the Committee.
- F. Fourth Quarterly Report on Committee Goals for 2008/09
- **G. Public Comment**

VIII. Organizational Development Committee Report and Action

A. Budget Update/Report

- 1. Governor's Executive Order to Furlough State Employees
- 2. Budget Report and Constraints for 2009/10
- 3. Budget Report for 2008/09
- 4. Fund Condition Report
- 5. Reimbursement to Board Members
- 6. BreEZe (I-Licensing) Progress

- B. Recognition Program of Pharmacists Who Have Been Licensed 50 Years
- C. Personnel Update
- D. Discussion of the Format of Future Board Meeting Agendas and Hearings.
- E. Strategic Plan Update for the Organizational Development Committee for 2009/10 and Discussion of Future Activities of the Committee.
- F. Approval of the Board of Pharmacy's Strategic Plan for 2009/10
- G. Election of Vice-President for 2009/10
- H. Fourth Quarterly Report on the Committee's Goals for 2008/09
- I. Public Comment

IX. Closed Session

Pursuant to Government Code section 11126(e), the Board will convene in closed session to confer with and receive legal advice from counsel (Carol Marie Zalez-Simon v. California Board of Pharmacy, Los Angeles Sup.Ct.,Case No. BS116965)

X. Petition for Reinstatement

11:30 a.m.

Jennifer West-Lackey

XI. 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 petition for reinstatement.

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

ADJOURNMENT 1:00 p.m.