



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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**California State Board of Pharmacy
Department of Consumer Affairs
Notice of Public Board Meeting
October 21 & 22, 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.

DATE: October 21 & 22, 2009

**PLACE: Department of Consumer Affairs
Public Hearing Room – First Floor
1625 N. Market Boulevard
Sacramento, CA 95834**

Note: Pharmacists and pharmacy technicians who attend the full day of the board meeting on Wednesday or Thursday, October 21 or 22, 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 for each open agenda item and 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.

There will be a Legislation and Regulation Committee Meeting following the business section of the October 21, 2009 Board Meeting at 3 p.m. A separate agenda for the committee meeting follows the Board Meeting Agenda.

Agenda

DISCUSSION AND ACTION MAY BE TAKEN ON ANY ITEM LISTED ON THE AGENDA.

Wednesday, October 21, 2009

CALL TO ORDER

9:00 a.m.

General Announcements

- I. Approval of the Full Board Minutes of July 15 and 16, 2009**
- II. Approval of the Full Board Minutes of August 19, 2009**
- III. Ethical Decision Making for Regulators**
Presentation by DCA Senior Staff Counsel Kristy Schieldge

IV. Enforcement Committee Report and Action

Report of the Enforcement Committee Meeting Held September 16, 2009 and Recent Updates

A. Overview of Proposals to Strengthen the Enforcement Programs of the Health Care Boards of the Department of Consumer Affairs

1. Proposals of the Department of Consumer Affairs
2. Proposals of the California Business, Professions and Economic Development Committee
3. SB 294 -- 2009 Legislative Proposal of the Administration and Senate Business, Professions and Economic Development Committee
4. Enforcement Priorities of the Department of Consumer Affairs

B. Enforcement Program of the Board of Pharmacy and Proposals to Strengthen Board Operations

- Proposed Regulation for Pharmacists to Report on License Renewal Applications Prior Convictions and To Require Electronic Submission of Fingerprints for Pharmacists With No Prior History of Electronic Fingerprints On File

C. 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/Monitoring Programs

D. Implementation of the Board of Pharmacy's Ethics Regulation, 16 CCR Sections 1773 and 1773.5

E. Ongoing Discussion and Presentations About Prevention of Medication Errors

F. Other Items from the September 16, 2009 Meeting:

1. Discussion Regarding a Request to Use Pharmaceutical Manufacturer Patient Assistance Programs for Indigent Patients Receiving Care from County-Run Pharmacies
2. Presentation by Daichi Sankyo on Third Party Logistics Providers (Licensed Wholesalers) and Drug Manufacturers
3. Presentation of the 2008 Report of the Research Advisory Panel of California

G. Minutes of the September 16, 2009 Meeting

H. Update on the Status of Drug and Sharps Take Back Programs in California Pharmacies

I. Controlled Substances Utilization Review and Evaluation System (CURES) Implements Changes to Allow Pharmacies and Prescribers to Obtain Via the Internet Dispensing Histories of Patients

J. Enforcement Statistics 2009-10

K. First Quarterly Report on Enforcement Committee Goals for 2009/10

Public Comment

VI. Recognition of Pharmacists Licensed with the Board for 50 Years

11:00 a.m.

V. Licensing Committee Report and Action

There Has Been No Licensing Committee Meeting Held Since the July 2009 Board Meeting

A. Subcommittee to Evaluate Drug Distribution within Hospitals

1. Summary of the Meeting Held September 17, 2009
2. Draft Recall Procedures for Hospitals
3. Survey Results: Drug Distribution Within a Hospital
4. Discussion of the Board on Possible Future Activities of this Subcommittee

Lunch

B. Licensing Issues

1. Emergency and Disaster Response Planning: Presentation on the H1N1 Emergency Response Activities in California by the California Department of Public Health (CDPH)
2. Proposed Delegation to the Board President to Act Pursuant to California Business and Professions Code Section 4062 to Waive Statutory Requirements to Benefit Public the Safety in Response to a Declared Emergency or Disaster
3. Update: Psychometric Assessment of the PTCB and ExCPT Pharmacy Technician Exams
4. Reporting and Accounting of Intern Hours for California Pharmacy School Students
5. Impact of State Furloughs on Processing Timelines and Work Flow of the Board

6. Competency Committee Report
 - (a) Pharmacist Exam Performance Statistics for April 2009 – October 2009 CPJE and NAPLEX Exam Administrations
 - (b) Job Analysis for the CPJE to Be Undertaken at the End of 2009

C. First Quarterly Report on Licensing Committee Goals for 2009/10

Public Comment

VII. 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))

Recess for Day

PUBLIC MEETING OF THE LEGISLATION AND REGULATION COMMITTEE **3 p.m.**
(See separate agenda following this Board Meeting Agenda)

FULL BOARD

Thursday, October 22, 2009

VIII. Closed Session **8 a.m.**

Full Board Closed Session:

Pursuant to Government Code section 11126(c)(3), the board will convene in closed session to deliberate on disciplinary matters, including a decision after remand (Carol Zalez-Simon, RPH 41523)

OPEN SESSION

IX. Legislation and Regulation Committee Report **9 a.m.**
Report of the Committee Meeting Held October 21, 2009

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

- A. Discussion and Possible Action to amend Title 16 CCR 1749 Board Fees**
- B. Board Approved Regulations -- Adopted**
 - Amendment of 16 CCR §1773 and Adoption of 16 CCR §1773.5 – Ethics Course for Pharmacists
- C. Board Approved Regulations – Currently Undergoing Administrative Review**
 - Pharmacies that Compound Medication – Repeal of Title 16 CCR §§1716.1 and 1716.2, Amend and Adopt §§1751 through 1751.8, and Adopt §§1735 through 1735.8
- D. Board Approved Regulations – Currently Awaiting Notice**
 1. 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
- E. 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, Enrolled and to the Governor:

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 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
3. **SB 470 (Corbett) Prescription Labeling to Add “Purpose” -- Proposal to Amend B&PC §§4040 and 4076**
4. **AB 1071 (Emmerson) Pharmacy Fees -- Proposal to Amend B&PC §§4110, 4127.8, 4160, 4400, and 4127.5, and Extend the Sunset Dates of the Board of Pharmacy and Specified Other Boards.**

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 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid
3. AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container
4. SB 762 (Aanestad) Professions and Vocations; Healing Arts

C. Two-Year or Inactive Bills

1. Sponsored by the Board: AB 977 (Skinner) Pharmacists: Immunization Administration -- Proposal to Amend B&PC §§4052 and 4052.8

Other:

2. AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements
3. AB 484 (Eng) Licensees Not in Compliance with Judgment or Order; Enforcement; Action on a License
4. AB 877 (Emmerson) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice
5. AB 1458 (Davis) Drugs: Adverse Effects Reporting
6. SB 26 (Simitian) Home-Generated Pharmaceutical Waste
7. SB 238 (Calderon) Prescription Drugs
8. SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs
9. SB 389 (Negrete McLeod) FBI and State Fingerprinting Requirements for DCA Boards and Bureaus
10. SB 484 (Wright) Ephedrine Products to Schedule V
11. SB 638 (Negrete McLeod) Regulatory Boards: Operations

D. Action on Proposed Legislative and Regulation Items Identified During the Legislation and Regulation Committee Meeting Held October 21, 2009

E. Summary of the Legislation and Regulation Committee Meeting Held on October 21, 2009

F. First Quarterly Report on Legislation/Regulation Committee Goals for 2009/10

Public Comment

X. Communication and Public Education Committee Report and Action

There Has Been No Meeting of the Communication and Public Education Committee During this Quarter

A. Discussion and Possible Action to Initiate Rulemaking to Adopt Proposed Section 1707.5 Relating to Patient-Centered Prescription Container Labels

B. Update Report on *The Script*

C. Update on Public Outreach Activities

D. First Quarterly Report on Committee Goals for 2009/10

Public Comment

XI. Organizational Development Committee Report and Action

A. Budget Update/Report

1. Governor's Executive Order to Furlough State Employees
2. Final Budget Report for 2008/09
3. Budget Report and Constraints for 2009/10
4. Fund Condition Report
5. Reimbursement to Board Members
6. Board Meeting Dates for 2010
7. BreEZe (I-Licensing) Progress

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

C. Personnel Update

D. First Quarterly Report on the Committee's Goals for 2009/10

Public Comment

XI. Closed Session

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

ADJOURNMENT

4:00 p.m.