

California State Board of Pharmacy

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STATE AND CONSUMERS AFFAIRS 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 29 and 30, 2008

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 Michelle Leech 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: October 29 and 30, 2008

PLACE: Radisson Hotel San Francisco Airport Bay Front

5000 Sierra Point Parkway Brisbane, CA 94005 (415) 467-4400

Note: Pharmacists and pharmacy technicians who attend the full day of the board meeting on Wednesday, October 29, 2008, 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's 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.

Agenda

Wednesday, October 29, 2008*

CALL TO ORDER 9:00 a.m.

General Announcements

I. Approval of the Full Board Minutes of July 23 and 24, 2008

II. Enforcement Committee and Workgroup on E-Pedigree

A. Report on the Meeting of October 6, 2008

- 1. WorkGroup on E-Pedigree
 - a. Overview of Provisions Enacted by SB 1307 (Ridley-Thomas, Chapter 713, Statutes of 2008)
 - b. Progress on the Implementation of Electronic Pedigrees Pursuant to the California Business and Professions Code Updates by GS1, Manufacturers, Wholesalers, Pharmacies and Their Associations to Implement Electronic Pedigrees
- 2. Enforcement Committee
 - a. E-Prescribing Forum Set for November 20, 2008
 - b. Presentation by Bob Pack Regarding the Controlled Substances Utilization Reports and Evaluation System (CURES) Moving to Provide Online, Near Real Time Reports to Practitioners in the Future

(*Times are approximate and subject to change)

Meeting Materials will be posted on the board's Web site at www.pharmacy.ca.gov by October 24, 2008

- c. Comments Submitted to the Federal Drug Enforcement Administration on Its Proposed Rule to Allow E-prescribing of Controlled Substances (Docket No. DEA 218: Electronic Prescriptions for Controlled Substances)
- d. Update on the Implementation of Drug Take Back Programs from Patients by California Pharmacies (SB 966, Simitian, Chapter 542, Statutes of 2007) and Presentation by the California Integrated Waste Management Board on Proposed Model Programs
- e. Discussion regarding the Role of Reverse Distributors in Picking Up Medical Waste and Returned Drugs
- f. Discussion of Sharps Take Back by Pharmacies
- g. Summary of Medication Errors Made by California Pharmacies 2007/08
- h. Discussion: Hospital Pharmacies' Control of Drugs within a Hospital and Proposal to Form a Subcommittee to Update Requirements for Hospital Pharmacies
- i. Minutes of the Meeting of October 6, 2008
- B. First Quarterly Report on Enforcement Committee Goals for 2008/09
- C. Enforcement Statistics 2008/09
- D. Public Comment

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

11:45 a.m.

Lunch

IV. Licensing Committee Report and Action

1:30 p.m.

A. Report on the Meeting of September 29, 2008

- 1. Emergency and Disaster Response Planning
 - a. California Department of Public Health: Request from San Diego County for Exemption to Distribute Prophylaxis Drugs to Emergency Response Staff Prior to a Declared Emergency
 - New Name for Emergency System for the Advanced Registration of Volunteer Health Professionals (ESAR-VHPS)
- 2. Patient Privacy Issues Arising from Abandonment of Records The Abandoned Records Project of the California Office of Privacy Protection
- 3. Update on the 2007 Compromise of the NAPLEX Examination
- 4. Fact Sheets on Application Procedures for Pharmacist Applicants
- 5. Licensing Unit Workload Adjustments Made to Accommodate Budget Restrictions
- 6. The Coalition on Shortages of Allied Health Professionals Formation of a Pharmacy Services Workgroup to Deal with Shortages of Pharmacists and Pharmacy Technicians
- 7. Update: Task Force to Evaluate Pharmacy Technician Qualifications
- 8. Veterinary Food Animal Drug Retailers Qualification Processes for Designated Representatives
- 9. Proposal to Award Continuing Education for Competency Committee Members for Specified Duties
- 10. Competency Committee Report
 - a. Update of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)
 - b. Report to the Legislature on the Impact of Requiring Those Who Fail the Pharmacist Licensure Examinations Four Times to Take 16 Units of Remedial Education (Business & Professions Code section 4200.1)
- 11. Minutes of the Licensing Committee Meeting Held September 29, 2008

- B. Discussion of Licensure of Ambulatory Surgical Clinics by the Department of Public Health Under Health and Safety Code Section 1204 That Are Owned by Physicians
- C. Licensing Statistics 2008/09
- D. First Quarterly Report on Committee Goals for 2008/09
- E. Public Comment

V. Regulation Hearing

- A. Action to Amend 16 California Code of Regulations Section 1773 and Adopt Section 1773.5 Regarding Establishment of an Ethics Course as an Optional Enforcement Component for Discipline
- B. Discussion and Possible Action to Amend 16 California Code of Regulations Section 1773 and Adopt Section 1773.5 Regarding Establishment of an Ethics Course as an Optional Enforcement Component for Discipline

VI. Regulation Hearing 2:30 p.m.

- A. Action to Repeal 16 California Code of Regulations Sections 1716.1 and 1716.2, Adopt Sections 1735-1735.8 and Amend Sections 1751-1751.8 Regarding Requirements for Pharmacy Compounding and Sterile Injectable Compounding
- B. Discussion and Possible Action to Repeal 16 California Code of Regulations Sections 1716.1 and 1716.2, Adopt Sections 1735-1735.8 and Amend Sections 1751-1751.8 Regarding Requirements for Pharmacy Compounding and Sterile Injectable Compounding

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

4:00 p.m.

2:00 p.m.

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 and 11125.7(a)]

PUBLIC MEETING OF THE LEGISLATION AND REGULATION COMMITTEE* (see separate agenda) 4:05 p.m.

*A quorum of the Board may be present at this committee meeting. Board members who are not on the committee may observe, but may not participate as a committee member or vote.

Thursday, October 30, 2008

VIII. Closed Session 8:00 a.m.

- A. The board will convene in closed session pursuant to Government Code section 11126(c)(1) to discuss and evaluate the administration of the pharmacist licensure examination
- B. The board will move into closed session pursuant to Government Code section 11126(c)(3) to deliberate on disciplinary matters

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

- 1. Board Approved Regulations Undergoing Administrative Review
 - a. Amend Title 16 CCR Section 1760 Disciplinary Guidelines
- 2. Board Approved Regulations Awaiting Notice
 - a. Title 16 CCR section 1785 Self-Assessment of a Veterinary Food-Animal Drug Retailer
 - b. Title 16 CCR section 1780 Update the USP Standards Reference Material
 - c. Title 16 CCR section 1751.8 Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products
 - d. Title 16 CCR sections 1721 and 1723.1 Dishonest conduct during a Pharmacist's Licensure Examination/Confidentiality
- 3. Proposed Regulation Language for Board Discussion and Possible Action
 - a. Amend Title 16 CCR section 1715 Self-Assessment Forms for Community and Inpatient Pharmacies
 - b. Amend Title 16 CCR section 1784 Self-Assessment Form for Wholesalers

B. Legislative Report

- 1. Discussion and Action on Enacted Legislation
 - a. Board-Sponsored Legislation for 2008 SB 1307 (Ridley-Thomas)
 - b. Chaptered Bills Impacting the Board's Jurisdiction or Practice of Pharmacy
 - AB 1394 (Krekorian) Counterfeit: trademarks
 - SB 963 (Ridley-Thomas) Regulatory boards: operations
 - SB 1441 (Ridley-Thomas) Healing Arts Practitioners (substance abuse)
 - SB 377 (Aanestad) Highway signs: pharmacies and attractions
 - c. Vetoed Bills Impacting the Board's Jurisdiction or Practice of Pharmacy
 - SB 1779 (Board-Sponsored Omnibus Provisions)
 - Business and Professions Code Section 4062 Furnishing Dangerous Drugs During an Emergency
 - Section 4110 Temporary Permit Upon Transfer of Ownership
 - Pharmacist-in-Charge and Designated Representatives-in-Charge Amend Sections 4022.5, 4305, 4329, 4330; Add Section 4036.5
 - Who May Order Dangerous Drugs or Devices, Exceptions Amend Section 4059.5
 - Section 4081

 Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
 - Furnishing Dangerous Drugs by Pharmacy Amend Section 4126.5
 - Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee –
 Amend Section 4231
 - Health and Safety Code Section 11165 Controlled Substance Utilization Review and Evaluation System; Establishment; Operation; Funding; Reporting to Legislature
 - AB 501 (Swanson) Pharmaceutical Devices
 - AB 865 (Davis) State Agencies: Live Customer Service Agents
 - AB 1574 (Plescia) Surgical clinics: licensure
 - d. Bills That Failed Passage by the Legislature
 - AB 1436 (Hernandez) Nurse practitioners
 - AB 1587 (De La Torre) Personal Information: pharmacy
 - AB 1947 (Emmerson) Pharmacy technicians
 - AB 2756 (Duvall) Pharmacists: Furnishing Drugs During an Emergency
 - SB 1270 (Cedillo) Pharmacy: dangerous drug and devices pedigree

C. Legislation and Regulation Committee Report

- 1. Action on Legislative Proposals Recommended for Sponsorship by the Legislation and Regulation Committee During the Committee Meeting of October 29, 2008
- 2. Update of the Committee's Strategic Plan for 2008/09
- 3. First Quarterly Report on Committee Goals for 2007/08

D. Public Comment

X. Communication and Public Education Committee

A. Report of the Meeting of October 2, 2008

- 1. Summary of the Ongoing Discussion of Medication Errors and How to Prevent Them
- 2. Discussion of Comments Submitted in Response to Proposed Rule Changes to 45 CFR Part 88, Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law (Conscience Clauses), RIN 0991-AB48
- 3. Discussion Regarding Action to Implement SB 472, Patient-Centered Medication Container Labels
 - a. Report of Patient Surveys Undertaken
 - b. Discussion of Presentations and Agenda Planned for November 20, 2008 Forum
- 4. Update and Discussion Regarding the Consumer Fact Sheet Series with California Schools of Pharmacy Interns
- 5. Development of New Consumer Brochures by the Board
- 6. Request from Pharmacist Planning Service Inc. (PPSI) to Develop Consumer Brochures
- 7. Update on The Script
- 8. Update on Public Outreach Activities
- B. Minutes of the Meeting of the Communication and Public Education Committee of October 2, 2008
- C. First Quarterly Update on Committee Goals for 2008/09
- D. Public Comment

XI. Organizational Development Committee Report and Action

A. Report of the Meeting of October 20, 2008

- 1. Proposed Changes to Board Meeting Dates and locations for 2009
- 2. Status Update on Fee Audit
- 3. Budget Update/Report
 - a. Budget for 2007/08
 - b. Fund Condition Report
 - c. Reimbursement to Board Members
 - d. Ethics Course for Board Members Due
- 4. I-Licensing Progress
- 5. Recognition Program of Pharmacists Who Have Been Licensed for 50 Years

B. Personnel Update

- C. Professionals Achieving Consumer Trust Summit Joint Board Meeting in November 2008 with Other Departmental Boards and Bureaus
- D. First Quarterly Report on the Committee's Goals for 2008/09
- E. Public Comment

XII. Closed Session 12:00 noon

A. The board will convene in closed session pursuant to Government Code section 11126(c)(1) to discuss and evaluate the administration of the pharmacist licensure examination

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

ADJOURNMENT 1:30 p.m.