



California State Board of Pharmacy

1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

NOTICE OF MEETING AND AGENDA

Public Board Meeting

April 23 & 24, 2014

Contact Person: Laura Hendricks
(916) 574-7918

This board meeting is open to the public and is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Laura Hendricks at (916) 574-7918, by emailing laura.hendricks@dca.ca.gov or sending a written request to the Board of Pharmacy, 1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834. Providing your request at least five business days before the meeting will help to ensure availability of the requested accommodation.

DATE: April 23 & 24, 2014

PLACE: Department of Consumer Affairs
First Floor Hearing Room
1625 North Market Blvd
Sacramento, CA 95834

WEBCAST: <http://www.dca.ca.gov/stream/audiocast.aspx>
(Link to Webcast will not be available until 11:00a.m. on April 23, 2014, and until 8:30 a.m. on April 24, 2014)

NOTE: Pharmacists and pharmacy technicians who attend in person the April 24th session of the Board Meeting may be awarded 6 hours of CE, in accordance with the board's CE policy. Sign in and sign out that day are required for the CE credit.

For verification of the meeting, call (916) 574-7918 or (916) 574-7900 or access the board's Web site at www.pharmacy.ca.gov.

Discussion and action may be taken on any item on the agenda. The board may discuss agenda items in any order on each day, unless noticed as "time certain." 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.

Agenda

Wednesday, April 23, 2014

Note: The Legislation and Regulation Committee Meeting will be held immediately before the board meeting from 8:00 a.m. – 11:00 a.m. in the First Floor Hearing Room.

Call to Order

12:00 p.m.

I. GENERAL ANNOUNCEMENTS

II. APPROVAL OF THE FULL BOARD MEETING MINUTES OF JANUARY 29-30, 2014

III. APPROVAL OF THE FULL BOARD MEETING MINUTES OF MARCH 17 & 18, 2014

IV. RECOGNITION AND CELEBRATION OF PHARMACISTS LICENSED FOR 50 YEARS IN CALIFORNIA

V. PUBLIC COMMENT ON 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 whether to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7(a)]

VI. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

Summary of the Organizational Development Committee meeting on April 14, 2014.

- a. Board and Committee Meeting Dates for the Remainder of 2014
- b. Board Meeting Dates for 2015
- c. Budget Update/Report
 1. Budget Report for 2013/14
 2. Budget Report for 2014/15
 3. Fund Condition Report
 4. Update on BreEZe
 5. Updates on Board Member Attendance, Reimbursement and Mail Votes
- d. Personnel Update

VII. EXECUTIVE OFFICER REPORT

- a. Update on Activities of the Medical Board of California –Kimberly Kirchmeyer, Executive Director
- b. Update on the Activities of the Executive Officer

- c. Update on Pharmacy/Medical Board Future Joint Forum on Appropriate Prescribing and Dispensing

VIII. LEGISLATION AND REGULATION COMMITTEE REPORT

The Legislation and Regulation Committee will meet on April 23, 2014.

a. Legislation Report

1. Legislation Recently Enacted

- AB 467 (Stone) Prescription Drug Collection and Distribution Program

2. Status of Board-Sponsored Provisions

- A. AB 2131 (Morrell) / SB 960 (Morrell) Pharmacy Licenses: Letters of Reprimand

- B. SB 1466 (Committee on Business, Professions, and Economic Development) Omnibus Provision Relating to Requirements for a Designated Representative

- C. Repeal of Pedigree Requirements

- D. Licensure Requirements for Third Party Logistics Providers

3. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

- A. AB 1535 (Bloom) Pharmacists: naloxone hydrochloride

- B. AB 1727 (Rodriguez) Prescription Drugs: collection and distribution program

- C. AB 2165 (Patterson) Professions and vocations: licenses

- D. AB 2605 (Bonilla) Pharmacy: sterile drug products

- E. SB 981 (Huff) Regulations: review process

- F. SB 1014 (Jackson) Pharmaceutical waste: home generated

- G. SB 1039 (Hernandez) Pharmacies: furnishing drugs

- H. SB 1258 (DeSaulnier) Controlled Substances: prescriptions: reporting

- I. AB 2603 (V. Manuel Perez) Controlled Substances: permissive lawful possession

4. Other Legislation Being Tracked by Board Staff

- A. AB 1437 (Mullin) Medically important antimicrobials: nontherapeutic use

- B. AB 1743 (Ting) Hypodermic needles and syringes

- C. AB 2418 (Bonilla) Health care coverage: prescription drug refills

- D. SB 835 (Hill) Food animals: medically important antimicrobial drugs

5. Other Legislation Impacting the Board or Its Regulatory Jurisdiction

b. Regulation Report

1. Regulations Approved by the Office of Administrative Law

- Combined Rulemaking – Proposal to Amend Sections 1745 and 1769, and to add Section 1762 to Title 16 California Code of Regulations Related to Partial Fill of a Schedule II Prescription, Criteria for Rehabilitation, and to Define Unprofessional Conduct

2. Board-Approved – Recently Noticed
Update on Rulemaking to Amend Section 1707.5 of Title 16 California Code of Regulations Regarding Patient-Centered Labeling Requirements
3. Board-Approved – Undergoing Administrative Review
Fee Schedule –Proposal to Amend Title 16 California Code of Regulations Section 1749
4. Board-Approved – Awaiting Notice
 - A. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements
 - B. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1732.05, 1732.2, and 1732.5 related to Continuing Education
 - C. Proposal to Amend Title 16 California Code of Regulations Section 1703 Related to “Section 100” Regulatory Actions

IX. BOARD MEMBER OFFICER ELECTIONS

X. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters

ADJOURNMENT FOR THE DAY

THURSDAY, APRIL 24, 2014

RESUMPTION OF OPEN SESSION

8:30 a.m.

XI. ENFORCEMENT COMMITTEE REPORT

A report on the Enforcement and Compounding Committee meeting held on March 27, 2014

a. Enforcement Matters

1. Update on Implementation of AB 1136 (Levine, Chapter 304, Statutes of 2013) Regarding Warning Labels on Prescription Container Labels
2. Discussion and Possible Action on the Request from UCLA Health System, Ronald Reagan UCLA Medical Center, for a Waiver Under California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, Section 4128 et seq.
3. Discussion and Possible Action on the Availability to Provide Written Comments to the DEA on the Possible Rescheduling of Hydrocodone Combination Products from Schedule

III to Schedule II, 21 Code of Federal Regulations Part 1308 [Federal Register, Docket No. DEA-389]

4. Discussion on Availability to Submit Comments on the Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format; Establishment of a Public Docket, Federal Register, Food and Drug Administration [Docket No. FDA-2014-N-0200]
 5. Report on Alternative Process for Pharmacists to Become Registered to Access CURES
 6. Summary of Discussion and Possible Action Regarding Reported Losses of Controlled Substances in California
 7. Summary of Presentation on “What We Find When We (the Board of Pharmacy) Inspect Pharmacies”
 8. Summary of Demonstration by Omnicell Regarding Technology Currently in Use for Pharmacies Providing Automated Drug Delivery Systems in Health Care Facilities Licensed Under Health and Safety Code Section 1205 (c), (d) or (k)
 9. Enforcement Statistics
 10. Third Quarterly Report on the Committee’s Goals for 2013/14
- b. Compounding Matters
1. Summary of Discussion and Possible Action on the Board’s Proposed Compounding Regulations
 2. Update on Compounding Provisions Enacted by H.R. 3204, the Federal Drug Quality and Security Act and the Recent Meeting between the FDA and the States’ Boards of Pharmacy
 3. Review of Data Collected on Violations Found During Compounding Inspections in California
 4. Summary of Update on the National Shortage of IV Solutions

XII. PUBLIC COMMENT ON ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

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XIII. PRESCRIPTION MEDICATION ABUSE SUBCOMMITTEE REPORT

A report on the Prescription Medication Drug Abuse Subcommittee meeting held on February 18, 2014

- a. Summary of Presentation Made to Committee by the Placer County Task Force to Educate Parents, Teens, Educators, Law Enforcement, Medical and Pharmacy Professions About Prescription Drug Abuse

- b. Information on April 26, 2014 DEA Sponsored Prescription Drug Disposal Day
- c. Summary of Discussion with Mike Small, California Department of Justice, Administrator, CURES Program Regarding Processes to Facilitate the Enrollment of Pharmacists in CURES
- d. Report on the Discussion and Identification of Effective Ways to Educate Pharmacists about Prescription Drug Abuse and Corresponding Responsibility
- e. Summary of Discussion on Pharmacists' Scope of Practice and Consultations for Opioid Dispensing
- f. Report on the Discussion of Activities to Promote March 2014 as Prescription Drug Awareness Month, Pursuant to Senate Concurrent Resolution 8 (DeSaulnier, Chapter 26, Statutes of 2013)
- g. Report on Review of Public Outreach Materials Developed and Shared by Southern California Community Groups
- h. Report on Review of Industry-Produced Educational Materials for the Public and Licensees
- i. Report on the Review of Articles Documenting the Issues of Prescription Medication Abuse
- j. Report on Public Outreach to Address Prescription Drug Abuse

XIV. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

A report on the Communication and Public Education Committee meeting held on April 1, 2014.

- a. Report on the Presentation to the Committee by Mpack Systems on New Product Design for Pharmacy Prescription Containers
- b. Update on the Committee's Assessment of California's Patient-Centered Labeling Requirement
- c. Report on the Availability of Options for Prescription Labels for Visually Impaired Patients
- d. Information on the Proposal by the Federal Food and Drug Administration on "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products"
- e. Update on *The Script*
- f. Updated on the Board's Public Service Announcement and Video Developed on Prescription Drug Abuse
- g. Summary of Review of Board's Consumer Education Materials on Counterfeit Drugs and a Newsletter Article for the Medical Board's Newsletter
- h. Update on Media Activity
- i. Update on the Outcome of the Public Continuing Education Training Session by the California State Board of Pharmacy and the Federal Drug Enforcement Administration Held January 31, 2014, in Sacramento
- j. Report on the Public Outreach Activities Conducted by the Board
- k. Third Quarterly Report on the Committee's Goals for 2013/14

XV. LICENSING COMMITTEE

A report on the Licensing Committee meetings held on February 12, 2014 and March 19, 2014.

- a. Summary of Presentation Made to Committee on the Duties and Operations of Third Party Logistics Providers in the Pharmaceutical Supply Chain
- b. Summary of Presentation Made to Committee on an Update of Major ACPE Programs and Activities
- c. Summary of Presentation Made to Committee on Requirements for Intern Experience in ACPE Approved School of Pharmacy Curricula
- d. Summary of Presentation by the California Schools of Pharmacy on the Intern Experience Earned by Students in California Schools of Pharmacy and the Reporting of Intern Hours to the California Board of Pharmacy
- e. Discussion and Possible Action to Update the Pharmacist Interns Hour Requirements from Business and Professions Code section 4209 and 16 California Code of Regulations Section 1728 and the Intern Hours Affidavit Form 17A-29
- f. Summary of Update on Discussion Regarding Application Questions Relating to “Prior Convictions”
- g. Summary of Presentation Made to Committee on Qualifications to Become an Advanced Practice Pharmacist
- h. Update on the Implementation Schedule for SB 493 (Hernandez, Chapter 469, Statutes of 2013) Relating to Advanced Practice Pharmacist
 1. Summary of Presentation Regarding Development of Certification Programs and Existing Certification Programs by Board of Pharmacy Specialties
 2. Update on Development of Application and Renewal Requirements for Advance Practice Pharmacist
 3. Summary of Discussion on the Development of Other Certification Programs
- i. Summary of Discussion on Requirements for Pharmacists who Furnish Self-Administered Hormonal Contraceptives and the Development of Draft Protocols
- j. Summary of Discussion on the Requirements for Pharmacists who Initiate and Administer Immunizations Pursuant to Recommended Immunization Scheduled by the Federal Advisory Committee of Immunization Practices
- k. Summary of Discussion on the Requirements for Pharmacists Who Furnish Nicotine Replacement Products and Development of Draft Protocols
- l. Competency Committee Report
- m. Licensing Statistics
- n. Third Quarterly Report on the Committee’s Goals for 2013/14

XVI. LUNCH

A lunch break will be taken at some point during the day’s meeting.

XVII. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters

ADJOURNMENT

5:00 p.m.