



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

NOTICE OF MEETING AND AGENDA

Public Board Meeting

April 24-25, 2013

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 24 - 25, 2013

PLACE: DoubleTree by Hilton San Diego, Hotel Circle
1515 Hotel Circle South
San Diego, CA 92108

WEBCAST: [This meeting will not be webcast.](#)

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 24, 2013

Call to Order

9:30 a.m.

I. General Announcements

II. Approval of the Full Board Meeting Minutes of February 5 & 6, 2013

III. 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)]

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

V. BOARD MEETING DATES FOR 2014

VI. BOARD MEMBER OFFICER ELECTIONS

VII. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT

Report of the Communication and Public Education Committee Meeting on April 12, 2013

- a. Discussion on the Joint Forum to Promote Appropriate Prescribing and Dispensing held February 21 & 22, 2013, and Development of Related Consumer and Licensee Education Materials
- b. Update on the New Notice to Consumers Posters, Video Display Format Option for Notice to Consumers, and Notice of Interpreter Availability
- c. Discussion on Prescription Drug Labels
 1. United States Pharmacopeia Guidelines for Prescription Drug Labels
 2. Results of Consumer Surveys on Current CA Labeling Requirements
 3. Availability of Audible Prescription Labeling Systems
 4. Evaluation of Current CA Labeling Requirements
- d. Discussion on Research Advisory Panel's Annual Report for 2012
- e. Discussion on Continuing Education Credits for Joint Board of Pharmacy/DEA Presentations to Pharmacists on Preventing Drug Diversion and Abuse
- f. Update on Consumer Fact Sheet on Emergency Contraception in accordance with Title 16 California Code of Regulations Section 1746
- g. Update on *The Script*
- h. Update on Redesign of Board's Website
- i. Update on Board's Consumer Education Materials
- j. Public Outreach Activities Conducted by the Board
- k. Discussion on Proposed Committee Goals for 2012/17 to fulfill Board's Strategic Plan

VIII. LICENSING COMMITTEE REPORT

Report of the Licensing Committee Meeting on April 12, 2013

- a. Licensing Committee Meeting Dates for 2013
- b. Recommendations for Regulation Changes to Require or Standardize the Reporting of Convictions and Discipline at the Time of Renewal for Pharmacists, Pharmacy Technicians and Designated Representatives
- c. Recommendation for Regulation Changes to Require Site Licensees to Report Disciplinary Actions by Other Entities at Time of Renewal
- d. Proposed Amendments to California Business and Professions Code Section 4053 Regarding the Qualifying Experience of Designated Representatives
- e. Review of Request from Det Norske Veritas (DNV) to Renew Board of Pharmacy Approval as an Accreditation Agency for Licensed Sterile Injectable Compounding Pharmacies
- f. Update and Discussion on Implementation of BreEZe and Items Potential Impact on License Applications and Renewals
- g. Accreditation Reviews Planned During 2013 of California Schools by the Accreditation Council for Pharmacy Education
- h. Results from Continuing Education Audits
- i. Review of Statistics Regarding Discipline and License Denial of Pharmacy Technicians
- j. Competency Committee Report
- k. Licensing Statistics
- l. Third Quarterly Report on the Committee's Strategic Goals for 2012/13

IX. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

Report of the Organizational Development Committee on March 13, 2013

- a. Budget Update/Report
 - 1. Budget Report for 2012/13
 - 2. Fund Condition Report
 - 3. Update on BreEZe, DCA's New Computer System
 - 4. Reimbursement to Board Members
- b. Discussion and Possible Action to Initiate a Rulemaking to Amend Regulations Title 16 California Code of Regulations Section 1749, Fees
- c. Personnel Update
- d. Initiation of Evaluation of the Executive Officer
- e. Committee Assignments and Restructuring of Board Committees
- f. Discussion on Proposed Committee Goals for 2012/17 to fulfill Board's Strategic Plan

X. LUNCH

XI. LEGISLATION AND REGULATION COMMITTEE REPORT

Report of the Legislation and Regulation Committee on April 11, 2013

PART I – REGULATIONS

a. Regulations Approved by the Office of Administrative Law

Amend Title 16, Section 1746 – Emergency Contraception Protocol

b. Board Approved – Recently Noticed (Update)

Combined Rulemaking:

- Proposed Amendment of Section 1745 – Partial Filling of Schedule II Controlled Substance Prescriptions
- Proposed Addition of Section 1762 – Unprofessional Conduct
- Proposed Amendment of Section 1769 – Application Review / Criteria For Rehabilitation

c. Board Approved Regulations – Undergoing Administrative Review

Proposal to Add New Article 5.5 to Title 16 and Add Sections 1747 and 1747.1 – Pedigree Requirements

d. Board Approved – Awaiting Notice

Combined Rulemaking:

- Proposed Amendment of Section 1732.2 – Board Accredited Continuing Education
- Proposed Amendment of Section 1732.5 – Continuing Education; Specific Content
- Proposed Amendment of Section 1732.05 – Accreditation Agencies for Continuing Education
- Proposed Addition of Section 1751.9 – Accreditation Agencies for Pharmacies that Compound Sterile Injectable Drug Products

PART II – LEGISLATION REPORT

a. Board-Sponsored Legislation for 2013-2014

1. SB 294 (Emmerson) – Compounded Sterile Drug Products
2. Board Approved Proposals for 2013-2014
3. Board Proposal – Section 4046 “Correctional Pharmacy” Defined

b. Legislation Impacting the Practice of Pharmacy or the Board’s Jurisdiction

Regulation of Dangerous Drugs and Devices

1. AB 396 (Fox) Prescription Label – Condition or Purpose
2. AB 670 (Atkins) Therapeutic Equivalents
3. AB 1136 (Levine) Pharmacists: Drug Disclosures (Label)
4. AB 1139 (Lowenthal) Prescriptions: Biosimilar Products
5. SB 204 (Corbett) Prescription Drugs: Labeling
6. SB 205 (Corbett) Prescription Drugs: Labeling
7. SB 493 (Hernandez) Pharmacy Practice
8. SB 506 (Hill) Ephedrine: Retail Sale

9. SB 598 (Hill) Biosimilars
10. SB 669 (Huff) Emergency Medical Care: Epinedhrine Auto-Injectors
11. SB 809 (DeSaulnier) CURES

Enforcement

12. SB 62 (Price) Coroners: Reporting Requirements: Prescription Drug Use

Licensing

13. AB 186 (Maienschein) Professions and Vocations: Military Spouses: Temporary Licenses
14. AB 213 (Logue) Healing Arts: Licensure and Certification Requirements: Military Experience
15. AB 258 (Chavez) State Agencies: Veterans
16. AB 512 (Rendon) Healing Arts Licensure Exemption
17. AB 555 (Salas) Professions and Vocations: Military and Veterans
18. AB 1057 (Medina) Professions and Vocations: License: Military Experience

Pharmacy/Other

19. AB 299 (Holden) Health Care Service Plans / Insurer: Mail Order
20. SB 445 (Price) Pharmacies” Advertising: Controlled Substances
21. SB 727 (Jackson) Medical Waste: Pharmaceutical Product Stewardship Program
22. Other Legislation Impacting the Practice of Pharmacy

XII. 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 25, 2013

XIII. CLOSED SESSION

8:30 a.m.

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

Resumption of Open Session

10:00 a.m.

XIV. EXECUTIVE OFFICER REPORT

XV. ENFORCEMENT COMMITTEE REPORT

Report of the Enforcement Committee Meeting held March 14, 2013

- a. Request from Walgreens to Store Prescription Records Older than Five Years Outside of a Licensed Premises

- b. Summary of Request from Walgreens to Establish Kiosks in Workplace Clinics
- c. Summary of Request from Kaiser for a Temporary Waiver to Secure Prescription Blank Prescribing Requirements for Controlled Substances in a Closed Health Care System
- d. Discussion on Comments Submitted in Response to Department of Justice, Drug Enforcement Administration’s Notice of Proposed Rulemaking Related to Disposal of Controlled Substances [Docket No. DEA-316]
- e. Proposed Statutory Provisions to Prevent a Wholesaler From Purchasing Prescription Medication from a Pharmacy When the Pharmacy Did Not Purchase the Medication from the Wholesaler
- f. Discussion on the Implementation of California’s Electronic Pedigree Requirements for Prescription Medication
 - 1. Update on the Status of Proposed Regulations to Implement Serialized Numeric Identifiers, Grandfathering and Manufacturer Reporting of How the 50 Percent Threshold of Serialized Products on January 1, 2015 Has Been Determined (Proposals to Add Title 16, California Code of Regulations, Sections 1747 and 1747.1)
 - 2. Presentations and Questions from the Pharmaceutical Supply Chain on Their Readiness to Meet California’s Staggered E-Pedigree Implementation Schedule
 - 3. Discussion Concerning Elements for Possible Regulation Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163
 - 4. Discussion on the Certification Process to Comply with California’s E-Pedigree Law
 - 5. Discussion on the Use of Drop Shipments in an E-Pedigree System
- g. Institute of Medicine Report: Countering the Problem of Falsified and Substandard Drugs
- h. Third Quarterly Report on the Committee’s Goals for 2012/13
- i. Enforcement Statistics for July 2012 – March 2013

XVI. LUNCH

11:30 a.m.

XVII. PETITION FOR EARLY TERMINATION OF PROBATION

Time Certain: 12:30 p.m.

Michael Lenzner, RPH 33245
 Jim Palm, RPH 41806

XVIII. PETITION FOR REDUCTION OF PENALTY

Reza Abolahrar, RPH 47355

XIX. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on the Petitions for Early Termination of Probation or Reduction of Penalty and to Deliberate on Disciplinary Matters

ADJOURNMENT

4:30 p.m.