



California State Board of Pharmacy

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

Notice of Meeting and Agenda
Public Board Meeting
October 28-30, 2015

DATE: October 28-30, 2015

TIME: 10:00 a.m.

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

WEBCAST: http://www.pharmacy.ca.gov/meetings/current_webcasts.shtml
(Link to Webcast will not be available until 9:00 a.m. on October 28, 2015)

NOTE: Pharmacists and pharmacy technicians who attend in person may be awarded 6 hours of CE, in accordance with the Board's CE policy. Sign in and sign out on the day of the meeting will be required for the CE credit.

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

Meeting materials should be available on the board's Web site at www.pharmacy.ca.gov by October 23, 2015.

Agenda

Call to Order

10:00 a.m.

I. Call to Order and General Announcements

II. Public Comments 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)]

III. Approval of the September 15, 2015 and September 30, 2015 Board Meeting Minutes

IV. Recognition and Celebration of Pharmacists Licensed In California for 50 Years

V. Update from the Department of Consumer Affairs

VI. Licensing Committee

The board will be presented a summary of the committee's efforts at the September 10, 2015, meeting for review and action as necessary

- a. Pharmacy Technician Requirements Assessment
 1. Pharmacy Technician Accreditation Commission Information
 2. National Changes to the Pharmacy Technician Certification Board
- b. Pharmacy Technician Licensure Requirements and Practice and Possible Changes
- c. Pharmacy Technician Application Requirement Video
- d. North American Pharmacist Licensure Examination Changes
- e. Accreditation Council for Pharmacy Education Updates of Curriculum Requirements for Pharmacists
- f. Implementation of Pharmacy Curriculum Outcomes Assessment to Be Used by Schools of Pharmacy
- g. Competency Committee Report
- h. Pharmacy Application Requirements
- i. Status of Implementation of Legislation (AB 2605) Regarding Third-Party Logistics Providers
- j. Licensing Statistics
- k. Future Committee Meeting Dates

VII. Lunch

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

VIII. Organizational Development Committee

- a. Budget Update/Report
 1. Final Budget Report for 2014/2015
 2. Budget Report for 2015/2016
 3. Fund Condition Report
- b. DCA Fee Audit and Possible Statutory Changes to Board Fees
- c. Board's Current Strategic Plan and Progress
- d. Future Strategic Planning - Presentation on The Department's Strategic Planning Services
- e. Formation of a Committee to Hear Petitions for Reinstatements, Early Termination or Modification of Penalty
- f. Board's Mail Vote Policy and Procedures

- g. Presentation on the Disciplinary Process
- h. Policy Regarding Waivers of Statutory Provisions in a Declared Emergency and Possible Revisions
- i. Board Member Reimbursement and Mail Vote Information
- j. Personnel Update
- k. Future Board Meeting Dates

IX. Communication and Public Education Committee

The board will be presented a summary of the committee's efforts at the October 6, 2015, meeting for review and action as necessary

- a. Request for Waivers of Requirements for Patient-Centered Labels as Provided in California Business and Professions Code Section 4076.5(d) from: Coram CVS/Specialty Infusion Services
- b. Survey Questionnaire with Regard to Patient Consultation Released in July 2015 and Possible Revision for Future Use
- c. Request to Augment Information on the Board's Website Regarding the State's Emergency Contraception Protocol
- d. October is "Talk About Prescriptions Month"
- e. Redesign of the Board's Website
- f. .Pharmacy Domain and Options for the Board to Distribute Public Information
- g. Status of Final Report on the Activities of the Prescription Drug Abuse Subcommittee

X. Closed Session

- a. Pursuant to Government Code section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters
- b. Pursuant to Government Code Section 11126(e), the board may convene in closed session to Confer with, or Receive Advice From, Legal Counsel Regarding the Following Pending Litigation:
 - 1. *Berjikian v. FTB, Board of Pharmacy, and DMV* (State and Federal actions) (U.S. District Court, Central District of CA, LA Division, Case No. 2:13-cv-06301-DDP-JCG; LA County Superior Court, Case No. BC514589)
 - 2. *Roxsan Pharmacy and Shahla Keyvanfar Melamud v. Virginia Herold, Board of Pharmacy, et al.* (U.S. District Court, Central District of CA; Case No. CV15-05524)
 - 3. *Parallax Health Services v. Virginia Herold, Board of Pharmacy, et al.* (U.S. District Court, Central District of CA; Case No. CV15-05526)
- c. Pursuant to Government Code Section 11126(c)(1), the Board Will Convene in Closed Session to Consider the Preparation, Approval, Grading or Administration of One or More Licensing Examination(s)

XI. Reconvene Open Session

Adjournment for the Day

Thursday, October 29, 2015

XII. Call to Order and Establishment of Quorum

9:00 a.m.

XIII. Enforcement Committee

The board will be presented a summary of the committee's efforts at the September 9, 2015, meeting for review and action as necessary

Part 1: Enforcement Matters

- a. Update on the CURES 2.0 Prescription Monitoring Program
- b. Update on the University of California, San Diego on Its Pilot Program to Permit Patients to Access Medications from an Automated Storage Device not Immediately Adjacent to a Pharmacy
- c. Enforcement Options for Patient Consultation Violations
- d. Proposed Regulation for Pharmacies and Clinics Aimed at Reducing Losses of Controlled Substances
- e. Tracking of Automated Drug Delivery Devices in Use in California
- f. Enforcement Statistics

Part 2: Compounding Matters

- a. Medicare's Pharmacy Practice Expectations for Critical Access Hospitals
- b. Warnings about Becton-Dickinson Syringes and Loss of Medication Potency from the Food and Drug Administration and Institute for Safe Medication Practices
- c. Compounding for Prescriber Office Use
- d. Comments on the Food and Drug Administration's Guidance Document on Compounding Animal Drugs from Bulk Drug Substances
- e. Compounding Services Provided by Sterile Compounding Pharmacies and Outsourcing Facilities
- f. Review of Sterile Compounding Statistics Identified by the Board
- g. Future Committee Meeting Dates

XIV. Proposed Regulations to Amend Title 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq., Relating to Compounding

XV. Proposed Regulations for the Take Back of Prescription Medication

XVI. Consideration of Proposed Changes to the Board's Disciplinary Guidelines and Title 16 California Code of Regulations Section 1760

XVII. Sternberg v. California Board of Pharmacy

- a. Publication of Court of Appeal Case (California's 2nd District Court of Appeal Case No. B255862; Filed August 6, 2015)
- b. Making the Underlying Administrative Case Precedential (Board Case No. 3377; OAH No. 2010080067)

XVIII. Lunch

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

XIX. Legislation and Regulation Committee

Part 1: Legislation Report

- a. Board-Sponsored Legislation
 1. AB 1073 (Ting) Prescription Drug Labels
 2. SB 590 (Stone) Intern Licenses
 3. SB 619 (Morrell) Outsourcing Facilities: Licensure
- b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction
 1. AB 45 (Mullin) Household Hazardous Waste

2. AB 339 (Gordon) Health Care Coverage: Outpatient Prescription Drugs
 3. AB 486 (Bonilla) Centralized Hospital Packaging Pharmacies
 4. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program
 5. AB 679 (Allen) CURES
- c. Legislation Impacting Board Operations
1. AB 12 (Cooley) State Government: Administrative Regulations
 2. AB 85 (Wilk) Open Meetings
 3. AB 1351 (Eggman) Deferred Entry of Judgment: Pretrial Diversion
 4. AB 1352 (Eggman) Deferred Entry of Judgment: Withdrawal of Plea
- d. Other Pieces of Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction or Board Operations
- Examples include measures involving the regulation of prescription drugs and/or controlled substances; application, licensing and renewal requirements for board licensees; authorities granted to board licensees; measures adding, modify or removing requirements that impact the board and its operations or that of the Department of Consumer Affairs*

Part 2: Regulation Report

- a. Board Approved – Awaiting Review by Control Agencies
- Note: Board approved language can be found on the Board's website:
http://www.pharmacy.ca.gov/laws_regs/regulations.shtml
1. Amendment of Title 16 California Code of Regulations (CCR) section 1793.5 Related to Pharmacy Technician Application
 2. Amendment of Title 16 CCR sections 1715 and 1784 to Update Self-Assessment Forms 17M-13, 17M-14 and 17M-26
 3. Addition of Title 16 CCR Section 1746.1 Related to Self-Administered Hormonal Contraception
 4. Addition of Title 16 CCR Section 1746.2 Related to Nicotine Replacement Products
 5. Addition of Title 16 CCR Section 1746.3 Related to Naloxone Hydrochloride (Non-Emergency)
- b. Board Approved – Recently Noticed
1. Proposal to Add Title 16 CCR Section 1730 Related to Advanced Practice Pharmacist
 2. Proposal to Add Title 16 CCR Section 1746.4 Related to Vaccinations
 3. Proposal to Add Title 16 CCR Section 1746.5 Related to Travel Medications
 4. Proposal to Amend Title 16 CCR Section 1744 Related to Drug Warnings
 5. Proposal to Add Title 16 CCR Section 1715.65 Related to Reconciliation and Inventory
 6. Proposal to Amend Title 16 CCR Section 1760 Related to Disciplinary Guidelines
- c. Board Approved – Awaiting Notice
1. Proposal to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements
 2. Proposal to Amend Title 16 CCR Sections 1732.05, 1732.2 and 1732.5 Related to Continuing Education
 3. Proposal to Amend Title 16 CCR Section 1703 Related to "Section 100" Regulatory Actions
 4. Proposal to Amend Title 16 CCR Section 1780-1786 Related to Third-Party Logistics Providers
 5. Proposal to Amend Title 16 CCR Section 1707.5(a)(1)(B) Related to Patient-Centered Labels for Generics
 6. Proposal to Amend Title 16 CCR Section 1707.5(d) Related to Translation Services

XX. Closed Session

In the event that that the Board has not completed its closed session items under item X above, it may return to that agenda item.

XXI. Reconvene Open Session

Adjournment for the Day

Friday, October 30, 2016

XXII. Call to Order and Establishment of Quorum

9:00a.m.

XXIII. Petitions for Early Termination or Modification of Probation

- a. Eugenia Tom, TCH 18794
- b. Alice Watchorn, TCH 116919
- c. James Greenlee, RPH 48842

XXIV. Closed Session

- a. 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.
- b. The Board may return to agenda item X above if that item is not completed.

XXV. Adjournment

(Estimate) 1:00 p.m.

Note: The SB 493 Committee will meet immediately following the conclusion of the Board Meeting

Important Notice to the Public:

The 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.

Discussion and action may be taken on any item on the agenda. The time and order of agenda items are subject to change at the discretion of the Board President. In accordance with the Bagley-Keene Open Meeting Act, all meetings of the Board are open to the public. The Board plans to webcast this meeting on its website at www.pharmacy.ca.gov. Webcast availability cannot, however, be guaranteed due to limited resources. The meeting will not be cancelled if webcast is not available. If you wish to participate or to have a guaranteed opportunity to observe, please plan to attend at a physical location. Adjournment, if it is the only item that occurs after a closed session, may not be webcast.

**Government Code section 11125.7 provides the opportunity for the public to address each agenda item during discussion or consideration by the Board or prior to the Board taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issues before the board, but the Board President may, at his or her discretion, apportion available time among those who wish to speak. Individuals may appear before the Board to discuss items not on the agenda; however, the Board can neither discuss nor take official action on these items at the time of the same meeting (Government Code sections 11125, 11125.7(a)).*