



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 November 8-9, 2017

DATES & Times: November 8, 2017, at 10:00 a.m.
November 9, 2017, at 8:30 a.m.

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

WEBCAST: <https://thedcapage.wordpress.com/webcasts/>
(Webcast will be available earliest at 10:00 a.m. on November 8, 2017. See notices below.)

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 website at www.pharmacy.ca.gov.

Meeting materials should be available on the board's website at www.pharmacy.ca.gov by November 3, 2017.

Important Notices 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) 574-7917, 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. Breaks will be taken each day 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 or technical difficulties. 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)).

Agenda

Call to Order

10:00 a.m.

I. Call to Order, Establishment of Quorum, 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. July 25-26, 2017 Board Meeting Minutes

IV. September 19, 2017 Teleconference Board Meeting Minutes

V. September 28, 2017 Board Meeting Minutes

VI. Recognition and Celebration of Pharmacists Licensed in California for 50 Years

VII. Update from the Department of Consumer Affairs

VIII. Legislation and Regulation Committee

The Legislation and Regulation Committee will convene a meeting immediately prior to the board meeting on November 8, 2017. The board will be presented a summary of the committee's efforts, as well as updates, for discussion and action as necessary.

Part 1: Legislation for Discussion and Consideration Report

- a. Board Sponsored Legislation
 - 1. Omnibus Provisions: SB 800 (Chapter 573, Statutes of 2017) Professions and Vocations, Including Changes to Pharmacy Law
 - 2. SB 351 (Chapter 623, Statutes of 2017) Hospital Satellite Compounding Pharmacy: License: Requirements
 - 3. SB 443 (Chapter 647, Statutes of 2017) Pharmacy: Emergency Medical Services Automated Drug Delivery System
 - 4. SB 510 (Chapter 649, Statutes of 2017) Pharmacies: Compounding
 - 5. SB 752 (Chapter 598, Statutes of 2017) Pharmacy: Designated Representative-Reverse Distributors
- b. Chaptered Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction with Board Established Positions
 - 1. AB 40 (Chapter 607, Statutes of 2017) CURES Database: Health Information Technology System
 - 2. AB 208 (Chapter 778, Statutes of 2017)) Deferred Entry of Judgment: Pretrial Diversion
 - 3. AB 401 (Chapter 548, Statutes of 2017) Pharmacy: Remote Dispensing Site Pharmacy: Telepharmacy: Shared Clinics
 - 4. AB 602 (Chapter 139, Statutes of 2017) Pharmacy: Nonprescription Diabetes Devices
 - 5. SB 17 (Chapter 603, Statutes of 2017) Prescription Drugs Costs
 - 6. SB 547 (Chapter 429, Statutes of 2017) Professions and Vocations

Part 2: Regulations for Discussion and Consideration

- c. Board Adopted - Approved by the Office of Administrative Law

Regulations to Amend and/or Add Title 16 CCR Sections 1702, 1702.1, 1702.2 and 1702.5, Related to Renewal Requirements

- d. Board Adopted - Submitted for Administrative Review to the Department of Consumer Affairs or the Office of Administrative Law
 - 1. Proposed Regulations to Amend Title 16 CCR Sections 1760, Related to the Board's Disciplinary Guidelines
 - 2. Proposed Regulations to Amend Title 16 CCR Sections 1749, Related to the Board's Fees
 - 3. Proposed Regulations to Add Title 16 CCR Sections 1715.65, Related to the Inventory Reconciliation Report of Controlled Substances
- e. Board Approved to Initiate Rulemaking - Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency, or Returned to Board Staff for Revisions Pursuant to Such Review:
 - 1. Proposed Emergency Regulations to Amend Title 16 CCR Section 1735.2, Related to Compounding Beyond Use Dates
 - 2. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783, et seq. Related to Third-Party Logistics Providers and Dangerous Drug Distributors
 - 3. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs
 - 4. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage
 - 5. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet
 - 6. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts
- f. Board Approved to Initiate Rulemaking – Board Staff Drafting Rulemaking Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency
 - 1. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs
 - 2. Proposed Regulations to Amend Title 16 CCR Sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4, Related to Compounding

Part 3: General Committee Matters

Future Meeting Dates

IX. Licensing Committee

The board will be presented a summary of the committee's efforts at the August 22, 2017, and October 27, 2017 meetings, as well as updates, for discussion and action as necessary.

- a. Discussion and Consideration of Licensing Requirements of an Advanced Pharmacy Technician (APT)
- b. Discussion and Consideration of the Duties an APT May Perform in a Traditional Community Pharmacy Setting and Proposed Pharmacy Requirements for Patient Care Services
- c. Discussion and Consideration of the Employment of APTs in a Closed-Door Pharmacy Which Provides Pharmacy Services for Patients of Skilled Nursing and Long-Term Care Facilities and Proposed Pharmacy Requirement for Patient Care Following Discharge
- d. Discussion and Consideration of the Employment of APTs in Inpatient Hospital Pharmacies and Proposed Hospital Pharmacy Requirements for Patient Care Following Discharge
- e. Discussion and Consideration of Application and Renewal Requirements for Pharmacy Technicians
- f. Licensing Statistics
- g. Future Committee Meeting Dates

X. Discussion and Consideration of Proposed Regulations to Amend Title 16 CCR Section 1735.2 Related to the Compounding Self-Assessment Form 17M-39 and Proposed Regulations to Amend Title 16 CCR Sections 1715 and 1784 to Update Self-Assessment Forms 17M-13, 17M-14 and 17M-26

XI. Communication and Public Education Committee

The board will be presented a summary of the committee's efforts at the September 20, 2017 meeting, as well as updates, for discussion and action as necessary.

- a. Discussion and Consideration of a Proposal by Chapman University School of Pharmacy Group to Require a Warning Label on Prescription Containers for Chemotherapy Medications
- b. Discussion and Consideration of a Proposal for a Public Service Billboard Message and Related Communications Materials on Drug Abuse
- c. Discussion and Consideration of Safe Medication Transitions for Patients upon Discharge from Health Care Facilities, Consumer and Pharmacist Educational Opportunities, and Any Necessary Statutory or Regulatory Changes
- d. Discussion and Consideration of Educational Materials Regarding Drug Take-Back Collection Receptacles and Providing Public Access to Such Information
- e. Discussion and Consideration of Requests to Use Non-Board Versions of Naloxone Fact Sheet and Notice to Consumers
- f. Discussion and Consideration of the National Association of Boards of Pharmacy (NABP) Report on Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: August 2007
- g. Update and Discussion of Communication and Public Education Activities by Board Staff
- h. Future Meeting Dates

XII. Enforcement and Compounding Committee Related Items

The board will be presented a summary of the committee's efforts at the September 15, 2017 meeting, as well as updates, for discussion and action as necessary.

- a. Discussion and Consideration of the Discrepancies Between the State and Federal Controlled Substance Schedules and its Impact on Healthcare Services and Potential Changes to Impact Laws and Regulations
- b. Discussion and Consideration of Proposed 2018 Board Sponsored Legislation Regarding CURES
- c. Discussion and Consideration of Board Policy to Conduct Inspections of All Pharmacies Every Four Years
- d. Discussion and Consideration of Possible Statutory or Regulatory Changes to Expand the Use of Automated Drug Delivery Systems (ADDS)
- e. Discussion and Consideration of the University of California San Diego's Experimental Program Regarding Access to Medications from an Automated Drug Delivery System (ADDS) (Pursuant to California Code of Regulations, Title 16, Section 1706.5)
- f. Status Report on Waivers Issued for Compounding Construction Compliance Delays Pursuant to California Code of Regulations, Title 16, Sections 1735.6 and 1751.4
- g. Enforcement Statistics
- h. Future Committee Meeting Dates

XIII. Executive Officer's Report

- a. Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) Examination Statistics and the North American Pharmacist Licensure Examination (NAPLEX)

- b. Response to FDA’s Guidance for Industry titled: “Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy”
- c. Update on the Executive Officer’s Engagement at the Federal Level
- d. Update on Opioid Training Provided to Board’s Inspection Staff and Other Healing Arts Investigators
- e. Update on the Joint DEA and Board of Pharmacy Training Events
- f. Federal Reevaluation of the Distribution of Controlled Substances
- g. Board’s Response to the State of Emergency Declared by Governor Edmund G. Brown Due to Multiple Wildfires
- h. Personnel Update

XIV. Organizational Development Committee

- a. Discussion and Consideration of Proposal to Amend BPC Section 4400 to Require Collection of Application and Renewal Fees for Government-Owned Facilities
- b. Budget Update/Report
 - 1. Final Budget Report for Fiscal Year 2016/2017
 - 2. Budget Report for Fiscal Year 2017/18
 - 3. Fund Condition Report
- c. Board Member Reimbursement Information
- d. Board Member Attendance Information
- e. Future Meeting Dates
 - 1. Future Board Meeting Dates for 2017
 - 2. Future Board Meeting Dates for 2018

XV. Other Closed Session Matters

- a. Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters, Proposed Decisions, Stipulated Decisions, Defaults, and Any Other Disciplinary Matters.
- b. Pursuant to Government Code Section 11126(e), the Board Will Convene in Closed Session to Discuss Pending Litigation

XVI. Reconvene Open Session

Adjournment

Upon conclusion of business