



Notice of Meeting and Agenda Public Board Meeting February 6-7, 2018

DATES & Times: February 6, 2018, at 10:30 a.m.
February 7, 2018, at 9:00 a.m.

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

WEBCAST: <https://thedcapage.blog/webcasts/>
(Webcast will be available earliest at 10:30 a.m. on February 6, 2018. 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 February 2, 2018.

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. In accordance with the Bagley-Keene Open Meeting Act, all meetings of the Board are open to the public. In the event a quorum of the board is unable to attend the meeting, or the board is unable to maintain a quorum once the meeting is called to order, the members present may, at the president's discretion, continue to discuss items from the agenda and make recommendations to the full board at a future meeting. 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

10:30 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. **November 8-9, 2017 Board Meeting Minutes**

IV. **December 12, 2017 Board Meeting Minutes**

V. **January 11, 2018 Board Meeting Minutes**

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

VII. **Update from the Department of Consumer Affairs**

- a. Explanation of the "Pre-Notice Review" Process Conducted on Regulations
- b. Business Modernization Efforts
- c. Credit Card Payments for Boards Using the Legacy System
- d. Update on the New Fi\$cal System
- e. Update on the Board's Budget

VIII. **Legislation and Regulation Committee**

The Legislation and Regulation Committee will convene a meeting immediately prior to the board meeting on February 6, 2018. 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. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction
 1. AB 1659 (Low) Healing Arts Boards, Inactive Licenses
 2. AB 1751 (Low) Controlled Substances: CURES Database
 3. AB 1752 (Low) Controlled Substances: CURES Database
 4. AB 1753 (Low) Controlled Substances: CURES
 5. AB 710 (Wood) Cannabidiol

Part 2: Regulations for Discussion and Consideration

- b. Board Adopted - Approved by the Office of Administrative Law
 1. Regulations to Add Title 16 CCR Sections 1715.65, Related to the Inventory Reconciliation Report of Controlled Substances
 2. Regulations to Amend Title 16 CCR Sections 1760, Related to the Board's Disciplinary Guidelines
 3. Emergency Regulations to Amend Title 16 CCR Section 1735.2, Related to Compounding Beyond Use Dates
- c. Board Adopted - Submitted for Administrative Review to the Department of Consumer Affairs or the Office of Administrative Law - Proposed Regulations to Amend Title 16 CCR Sections 1749, Related to the Board's Fees
- d. 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 Regulations to Amend Title 16 CCR Sections 1780-1783, et seq., Related to Third-Party Logistics Providers and Dangerous Drug Distributors
 2. 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
 3. Proposed Regulations to Amend Title 16 CCR Section 1707, Related to Offsite Storage
 4. Proposed Regulations to Amend Title 16 CCR Section 1746.3, Related to the Naloxone Fact Sheet
 5. Proposed Regulations to Amend Title 16 CCR Section 1709, Related to Pharmacy Ownership, Management, and Control, Including Through Trusts
 6. Proposed Regulations to Add Title 16 CCR Sections 1717.5, Related to Automatic Refill Programs
 7. Proposed Regulations to Amend Title 16 CCR Sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4, Related to Compounding
- e. 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 Amend Title 16 CCR Section 1735.2, Related to the Compounding Self-Assessment Form 17M-39
 2. Proposed Regulations to Amend Title 16 CCR Sections 1715 and 1784, Related to Pharmacy and Wholesaler Self-Assessment Forms 17M-13, 17M-14 and 17M-26

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 January 16, 2018 meeting, as well as updates, meeting for discussion and action as necessary.

- a. Discussion and Consideration of Proposed Creation of an Advanced Hospital Pharmacy Technician (AHT) Licensing Program including Licensure Requirements, Authorized Duties and Changes to Inpatient Pharmacy
- b. Discussion and Consideration of Regulations Pursuant to Assembly Bill 401 (Chapter 548, Statutes of 2017) Relating to Pharmacy Technicians Working in a Remote Dispensing Site Pharmacy
- c. Discussion and Consideration of the Title 16, California Code of Regulations, Section 1706.2, Related to Abandonment of Application Files Licensing Statistics
- d. Discussion and Consideration of Patient Consultation Requirements for Mail Order Pharmacies or Nonresident Pharmacies
- e. Update on Implementation of Board-Provided Law and Ethics Continuing Education Courses
- f. Future Committee Meeting Dates

X. Communication and Public Education Committee

The board will be presented a summary of the committee's efforts at the January 31, 2018 meeting, as well as updates, for discussion and action as necessary.

- a. Summary of Presentation Regarding Prescription Drug Overdose Prevention and Corresponding Responsibility
- 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 Possible Options for Consumer and Pharmacist Education Regarding Safe Medication Transitions for Patients upon Discharge from Health Care Facilities 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 Creating Webinar Course to Satisfy Education Requirement for Pharmacists to Furnish Naloxone
- f. Discussion and Consideration of UC Berkeley Study of the Availability of Contraception Prescribed by Pharmacists in California
- g. Discussion and Consideration of FDA Proposal to Increase Consumer Protection from High-Risk Homeopathic Drugs
- h. Discussion and Consideration of FDA Guidance, “Evaluating Drug Effects on the Ability to Operate a Motor Vehicle”
- i. Discussion and Consideration of Journal of the American Pharmacists Association Article, “Enhancing the Educational Value of Direct-to-Consumer Advertising of Prescription Drugs”
- j. Discussion and Consideration of Annual Report of the Research Advisory Panel of California
- k. Discussion and Consideration of Granting Continuing Education Credit for Reading *The Script*
- l. Update and Discussion of Communication and Public Education Activities by Board Staff
- m. Future Committee Meeting Dates

XI. Enforcement and Compounding Committee Related Items

The board will be presented a summary of the committee’s efforts at the December 11, 2017 meeting, as well as updates, for discussion and action as necessary.

- a. Discussion and Consideration of Possible Board Policy Relating to Disclosure of Enforcement Actions Involving Board Members
- b. Discussion and Consideration of FDA Draft Guidance for Industry Relating to “Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier”
- c. Discussion and Consideration of “CURES 2.0 Survey of California Physicians’ and Pharmacists’ Experience with and Attitudes about CURES 2.0”
- d. Discussion and Consideration of Noncompliant California Security Prescription Forms
- e. Update on Emergency Regulations to Amend California Code of Regulations, Title 16 Section 1735.2, Related to Compounding Beyond Use Dates
- f. Discussion and Consideration of Draft Frequently Asked Questions Relating to Compounding Requirements, California Code of Regulations, Title 16, Sections 1735 et seq. and 1751 et seq.
- g. Discussion and Consideration of Requested Changes to Board Compounding Regulations, California Code of Regulations, Title 16, Sections 1735 et seq. and 1751 et seq., Including Presentation Regarding Beyond Use Date Testing
- h. Status Reports on Waivers Issued for Compounding Construction Compliance Delays Pursuant to California Code of Regulations, Title 16, Sections 1735.6 and 1751.4
- i. Enforcement Statistics
- j. Future Committee Meeting Dates

XII. Executive Officer’s Report

- a. Update on the Joint DEA and Board of Pharmacy Training Events
- b. Update on CURES
- c. Report on the National Association of Boards of Pharmacy’s Law Enforcement and Legislation Committee Meeting
- d. Report on the Federation of Associations of Regulatory Boards Meeting
- e. Discussion and Consideration of Newly Released FDA Guidance Documents

1. "Compounding Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of The Federal Food, Drug, and Cosmetic Act"
 2. FDA's "2018 Compounding Policy Priorities"
 3. "Compounding Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503B of The Federal Food, Drug, and Cosmetic Act"
 4. "Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biological License Application"
- f. Update to the Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) Examination Statistics and the North American Pharmacist Licensure Examination (NAPLEX)
 - g. Settlement of People v. Target Corp., Regarding Pharmacist Consultations
 - h. Future Sterile Compounding Training for Board Inspectors
 - i. Personnel Update

XIII. Organizational Development Committee

- a. Budget Update/Report
- b. Board Member Reimbursement and Attendance Information
- c. Future Board Meeting Dates

XIV. 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
- 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)

XV. Reconvene Open Session

Adjournment

Upon conclusion of business