



Notice of Meeting and Agenda Public Board Meeting May 3-4, 2017

DATES & TIMES: May 3 – 4, 2017, at 9:00 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 9:00 a.m. on May 3, 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 Debbie Damoth at (916) 574-7935 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 April 28, 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 Debbie Damoth at (916) 574-7935, by emailing debbie.damoth@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

9:00 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. **October 26-27, 2016, Board Meeting Minutes – Revisions to Previously Approved Minutes**

IV. **January 24-25, 2017, February 17, 2017 and March 30, 2017 Board Meeting Minutes**

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

VI. **Board Officer Elections**

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

VIII. **Executive Officer's Report**

- a. Semi-Annual Report of the *California Practice Standards and Jurisprudence Examination for Pharmacists* (CPJE) Examination Statistics
- b. Discussion and Consideration of NABP's Letter to Congress Regarding the Dispensing of Non-United States Food and Drug Administration Approved Medicines to Patients in the US from Online Pharmacies

IX. **Discussion and Consideration of Possible Regulations Regarding Patient Enrollment in Automated Refill Programs for Prescription Medications**

XI. **Organizational Development Committee**

- a. Budget Update/Report
 1. Fund Condition Report
 2. Budget Report for Fiscal Year 2016/17
 3. DCA Distributed Costs Allocations
- b. Board Member Reimbursement Information
- c. Board Member Attendance Information
- d. Personnel Update
- e. Future Meeting Dates
 1. Future Board Meeting Dates for 2017
 2. Future Board Meeting Dates for 2018
 3. Future Committee Meeting Dates for 2018

XII. **Enforcement and Compounding Committee Related Items**

The board will be presented a summary of the committee's efforts at the April 18, 2017, meeting, as well as updates, for discussion and action as necessary.

Part 1: Enforcement Matters

- a. Discussion and Consideration of the University of California, San Diego's Experimental Program/Research Study to Permit Patients to Access Medications From an Automated Drug Delivery System (ADDS) Without Compliance with All Provisions of Title 16, California Code of Regulations, Section 1713
- b. Update on CURES 2.0 Prescription Drug Monitoring Program
- c. Summary of a Presentation by Stericycle of a New Device for Destruction of Controlled Substances in Pharmacies
- d. Discussion and Consideration of the Use of Automated Drug Delivery Systems (ADDS)
 1. Options and Features Currently Available
 2. Refilling of ADDS in Skilled Nursing Facilities
 3. Next Steps by the Board
- e. Discussion and Consideration of a Proposed Regulation to Add Title 16 California Code of Regulations Section 1715.65 Related to Inventory Reconciliation of Controlled Substances
- f. Report on the March 11, 2017, Training Provided by the Board and DEA on CURES and Prescription Drug Abuse, and Possible Future Training
- g. Summary of the Report Submitted to the Assembly Budget Committee Regarding the Board's Prescription Drug Abuse Team

Part 2: Compounding Matters

- a. Report on Statistics Regarding Outcomes of Board of Pharmacy Compounding Inspections
- b. Discussion and Consideration of Waiver Requests for Compounding Construction Compliance Delays Pursuant to Title 16, California Code of Regulations, Sections 1735.6(f) and 1751.4(l) and the Process for Review and Appeals of such Requests
- c. Update on the Board's Progress in Implementing California Business and Professions Code Sections 4129, et seq., Regarding Licensure and Regulation of Outsourcing Facilities
- d. Discussion and Consideration of the United States Government Accountability Office's March 31, 2017, E-Supplement Report to Congressional Committees on *Drug Compounding: FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported Challenges*
- e. Presentation by Road Runner Pharmacy Regarding Compounding for Veterinary Prescriber Office Use
- f. Discussion and Consideration of the Proposed Food and Drug Administration Rule, *List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance with Section 503A of the Federal Food, Drug, and Cosmetic Act* and Proposed Lists
- g. Discussion and Consideration of the Food and Drug Administration Rule *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act –Guidance for Industry* and Proposed Lists
- h. Discussion and Consideration of the Food and Drug Administration Rule *Guidance for Industry Compounding Animal Drugs from Bulk Drug Substances* and Proposed Lists

Part 3: General Committee Matters

- a. Enforcement Statistics

XIII. Closed Session

- 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)
- d. Pursuant to Government Code section 11126(a)(1), the Board will Convene in Closed Session to Evaluate the Performance of the Board's Executive Officer
- e. The Board will Reconvene In Open Session

XIV. Presentation on the Board's Pharmacist Recovery Program

XV. Licensing Committee

- a. Summary of the Committee's Pharmacy Technician Summit on April 4, 2017
- b. Licensing Statistics

XVI. Legislation and Regulation Committee

The board will be presented a summary of the committee's efforts at the April 12, 2017, meeting, 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 (Hill) Professions and Vocations, Including Changes to Pharmacy Law
 - 2. SB 351 (Roth) Hospital Satellite Compounding Pharmacy: License: Requirements
 - 3. SB 443 (Hernandez) Pharmacy: Emergency Medical Services Automated Drug Delivery System
 - 4. SB 510 (Stone) Pharmacies: Compounding
 - 5. SB 752 (Stone) Pharmacy: Designated Representative-Reverse Distributors
- b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction with Recommended or Current Positions
 - 1. AB 12 (Cooley) State Government: Administrative Regulations: Review
 - 2. AB 40 (Santiago) CURES Database: Health Information Technology System
 - 3. AB 182 (Walderon) Heroin and Opioid Public Education (HOPE)
 - 4. AB 208 (Eggman) Deferred Entry of Judgment: Pretrial Diversion
 - 5. AB 315 (Wood): Pharmacy Benefits Management
 - 6. AB 602 (Bonta) Pharmacy: Nonprescription Diabetes Devices
 - 7. AB 703 (Flora) Professions and Vocations: Licenses: Fee Waivers
 - 8. AB 835 (Dababneh) Consumer Affairs: Licenses: Prohibited Acts
 - 9. AB 845 (Wood) Cannabidiol: Prescriptions in Accordance with Federal Law
 - 10. AB 912 (Oberholte) Small Business: California Small Business Regulatory Fairness Act
 - 11. SB 17 (Hernandez) Prescription Drugs: Pricing: Notification
 - 12. SB 27 (Morrell) Professions and Vocations: Licenses: Military Service
 - 13. SB 641 (Lara) Controlled Substances Utilization Review and Evaluation System: Privacy
 - 14. SB 716 (Hernandez) California Board of Pharmacy: Pharmacy Technician Member
- c. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction, Measures without Recommendations or Current Positions
 - 1. AB 241 (Dababneh) Personal Information: Privacy: State and Local Agency Breach
 - 2. AB 265 (Wood) Prescription Drugs: Prohibition on Price Discount
 - 3. AB 401 (Aguiar-Curry) Pharmacy: Remote Dispensing Site Pharmacy: Telepharmacy
 - 4. AB 444 (Ting) Medical Waste: Home-Generated Sharps Waste

5. AB 710 (Wood) Department of Consumer Affairs: Boards: Meetings
6. AB 767 (Quirk-Silva) Master Business License Act
7. AB 827 (Rubio) Department of Consumer Affairs: Task Force: Foreign-Trained Professionals
8. AB 1048 (Arambula) Health Care: Pain Management and Schedule II drug prescriptions
9. AB 1589 (Salas) Pharmacy: Pharmacist Supervision: Technicians
10. SB 212 (Jackson) Medical Waste
11. SB 419 (Portantino) Oxycodone: Prescriptions
12. SB 528 (Stone) Pharmacy: Automated Drug Dispensing Systems
13. SB 555 (Morrell) Regulations: 5-Year Review and Report
14. SB 572 (Stone) Healing Arts Licensees: Violations: Grace Period

c. Legislative Items for Future Meeting

The committee may discuss other items of legislation in sufficient detail to determine whether such items should be on a future committee meeting agenda and/or whether to hold a special meeting of the board to discuss such items pursuant to Government Code section 11125.4.

Part 2: Regulations for Discussion and Consideration

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

1. Regulations Amending Title 16 CCR Section 1744 Related to Drug Warnings
2. Regulations Amending Title 16 CCR Section 1707.5 Related to Patient-Centered Labels
3. Regulations Amending Title 16 CCR Sections 1732.05, 1732.2 and 1732.5 Related to Continuing Education

b. Board Adopted - Submitted for Administrative Review to the Department of Consumer Affairs or the Office of Administrative Law

1. Proposed Regulations to Amend and/or Add Title 16 CCR Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements
2. Proposed Regulations to Add Title 16 CCR Sections 1776 et seq. Related to Prescription Drug Take-Back
3. Proposed Regulations to Amend Title 16 CCR Section 1703 Related to Delegation of Certain Functions
4. Proposed Regulations to Add Title 16 CCR Section 1746.5 Related to Travel Medications

c. Board Adopted – Rulemaking File Being Prepared by Staff for Submission and Review by the Department of Consumer Affairs or the Office of Administrative Law:

Proposed Regulations to Amend Title 16 CCR Section 1760 Related to the Board’s Disciplinary Guidelines

d. Board Approved to Initiate Rulemaking – Open Comment Period

Proposed Regulations to Amend Title 16 CCR Section 1749 Related to the Board’s Fee Schedule

e. Board Approved to Initiate Rulemaking – Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency:

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

5. 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 Amend Title 16 CCR Section 1707 Related to Offsite Storage
 2. Proposed Regulations to Amend Title 16 CCR Section 1735 and 1751 Related to Compounding

XVII. Communication and Public Education Committee

The board will be presented a summary of the committee's efforts at the March 23, 2017, meeting, as well as updates, for discussion and action as necessary.

- a. Summary of Presentation and Proposal from Chapman University School of Pharmacy for Patient-Focused Labeling Changes to California Law
- b. Summary of Presentation by Office for Civil Rights of U.S. Department of Health and Human Services on Final Rule Implementing Section 1557 of the Affordable Care Act (ACA) Regarding Nondiscrimination in Health Programs and Activities
- c. Update on NABP Request to Boards of Pharmacy Regarding Labeling Requirements for Emergency-Use Medications
- d. Discussion and Consideration of Naloxone Matters
 1. Update on Federal Legislation: US S. 524 – Comprehensive Addiction and Recovery Act of 2016 (CARA) – Provisions Regarding Partial Fills for Schedule II
 2. Discussion Regarding Availability of Naloxone at Pharmacies in Specific Communities, including Los Angeles County
 3. Request from Walgreens to Use In-House Fact Sheet for Patients Receiving Naloxone
- e. Update on Board-Developed Public Service Billboard Message and Related Communication Materials
- f. Summary of Discussion of Efforts by Drug Manufacturers to Stop Illegal Sales of Non-FDA Approved Products
- g. Update on Communication Plan for Reaching Consumers and Licensees
 1. Update on *The Script* Newsletter
 2. Update on Media Activity
 3. Update on Public Outreach Activities Conducted by the Board

Adjournment

Upon conclusion of business