



Notice of Meeting and Agenda Public Board Meeting July 27-28, 2016

DATE: July 27-28, 2016

TIME: 9:00 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

(Webcast will be available earliest at 9:00 a.m. on July 27, 2016. 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 July 22, 2016.

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) 574-7918, 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 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. Approval of the February 24-25, 2016, June 7-8, 2016, June 8, 2016 and July 1, 2016 Board Meeting Minutes

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

V. Update from the Executive Director of the Medical Board of California on Issues Affecting Both Boards

VI. Licensing Committee

The board will be presented a summary of the committee's efforts at the June 22, 2016, meeting. The board will discuss and take action as necessary.

- a. Consideration of Possible Revisions to Regulation(s) Regarding Pharmacy Technician Training Programs (Title 16 CCR §1793.6)
- b. Consideration of the Duties of a Pharmacy Technician and Discussion on the Pharmacist to Pharmacy Technician Ratio In the Community Pharmacy Setting
- c. Consideration of Possible Revisions to Pharmacist Renewal Requirements and Content-Specific Continuing Education (Title 16 CCR §1732.5)
- d. Consideration of Ownership Structures for Pharmacies, including a Summary of a Presentation by the Office of the Attorney General Regarding Trusts and Possible Next Steps
- e. Licensing Statistics
- f. Future Committee Meeting Date for 2016

VII. Legislation and Regulation Committee

The board will be presented a summary of the committee's efforts at the July 12, 2016, meeting. The board will discuss and take action as necessary.

Part 1: Legislation for Discussion and Consideration

- a. Board-Sunset Legislation
 1. SB 1193 (Hill) California State Board of Pharmacy
 2. SB 1039 (Hill) Professions and Vocations
- b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction
 1. AB 45 (Mullin) Household Hazardous Waste
 2. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program
 3. AB 1386 (Low) Emergency Medical Care: Epinephrine Auto-Injectors
 4. AB 1748 (Mayes) Pupils: Pupil Health: Opioid Antagonist
 5. SB 482 (Lara) Controlled Substances: CURES Database
 6. SB 999 (Pavley) Health Insurance: Contraceptives: Annual Supply
 7. SB 1229 (Jackson) Pharmacies: Secure Drug Take-Back Bins

- c. Legislation Impacting Board Operations
 - 1. AB 12 (Cooley) State Government: Administrative Regulations: Review
 - 2. SB 952 (Anderson) Pharmacy Technicians: Licensure Requirements
 - 3. SB 1155 (Morrell) Professions and Vocations: Licenses: Military Service
- d. Legislative Items for Future Meeting

The board may discuss other items of legislation in sufficient detail to determine whether such items should be on a future board 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 Approved – Submitted for Administrative Review by the Department of Consumer Affairs or the Office of Administrative Law
 - 1. Proposed Regulations to Add Title 16 CCR sections 1730, 1730.1 and 1749 related to Advanced Practice Pharmacists
 - 2. Proposed Regulations to Add Title 16 CCR section 1730.2 related to Advanced Practice Pharmacists – Certification Programs
 - 3. Proposed Regulations to Add Title 16 CCR section 1746.4 related to Immunization (Vaccinations)
 - 4. Proposed Regulations to Amend Title 16 CCR section 1735 and 1751 et seq. related to Compounding
 - 5. Proposed Regulations to Add Title 16 CCR section 1746.5 related to Travel Medications
- b. Board Approved – Rulemaking File Being Prepared by Staff for Submission to the Department of Consumer Affairs or the Office of Administrative Law
 - 1. Proposed Regulations to Amend Title 16 CCR section 1760 related to the Board’s Disciplinary Guidelines
- c. Board Action to Initiate Rulemaking – Awaiting Notice
 - 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 Amend Title 16 CCR sections 1780-1785, et seq. related to Third Party Logistics Providers
- d. Board Action to Initiate Rulemaking – Comment Period Closed; Awaiting Further Action by Board/Licensing Committee
 - 1. Proposed Regulations to Amend Title 16 CCR section 1732.05, 1732.2 and 1732.5 related to Continuing Education

VIII. Lunch

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

IX. Discussion and Consideration of Proposed Regulations to Amend Title 16 CCR section 1703 related to Delegation of Certain Functions

X. Discussion and Consideration of Proposed Regulations to Amend Title 16 CCR section 1744 related to Drug Warnings

XI. Discussion and Consideration of Proposed Regulations to Amend Title 16 CCR section 1707.5 related to Patient-Centered Labels

XII. Discussion and Consideration of Proposed Regulations to Add Title 16 CCR sections 1776 et seq. related to Prescription Drug Take-Back

XIII. Closed Session

- a. Pursuant to Government Code section 11126(c)(3), the Board will Convene in Closed Session to Deliberate on Disciplinary Matters, Including 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

XIV. Reconvene Open Session

Recess for the Day

Thursday, July 28, 2016

XV. Call to Order and Establishment of Quorum

9:00 a.m.

XVI. Organizational Development Committee

- a. Budget Update/Report
 1. Fiscal Year/16 Budget Report
 2. Fund Condition Report
 3. Governor's Budget for Fiscal Year 2016/17
- b. Board Member Reimbursement Information
- c. Personnel Update
- d. Discussion and Consideration of the 2017-2021 Strategic Plan
- e. Fiscal Year 2016/17 Committee Rosters
- f. Future Board Meeting Dates
 1. Remaining Dates Established for 2016
 2. Proposed Dates for 2017

XVII. Executive Officer's Report

- a. Demonstration of the Board's New Website
- b. Report of the Board's Efforts to Assist Pharmacists in Meeting the CURES Registration Deadline as Required in SB 809, and Possible Next Steps
- c. Discussion and Consideration of Cooperating with Other Public Agencies in Issuing a CURES Survey
- d. Review of the NABP's .PHARMACY Program, Including its July 7, 2016, Executive Board Meeting
- e. Review of Demographic Data Available Describing California Licensed Pharmacists

XVIII. Enforcement Committee Related Items

The board will be presented a summary of the committee's efforts at the June 1, 2016, meeting. The board will discuss and take action as necessary.

Part 1: Enforcement Matters

- a. Discussion and Consideration of the University of California, San Diego's Pilot Program to Permit Patients to Access Medications from an Automated Storage Device Not Immediately Adjacent to a Pharmacy, Including Requests for Modifications to the Study Parameters
- b. Discussion and Consideration of the Proposed Regulation Relating to Reconciliation and Inventory Reports of Controlled Substances (Currently, to Add Title 16 California Code of Regulations Section 1715.65)
- c. Discussion and Consideration of the Department of Consumer Affairs Contract and Audit of the

DCA Diversion Program Provided by Maximus Health Services

- d. Discussion and Consideration of the Food and Drug Administration's Required Class-Wide Safety Labeling Changes for Opioid Pain Medications
- e. Discussion and Consideration of the Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain
- f. Discussion and Consideration of a Proposal to Add Statutory Authority Relating to the Registration with the Board of Automated Delivery Systems for Dispensing of Medication
- g. Consideration of a Proposal to Conduct Inspections of All Pharmacies Every Four Years

Part 2: Compounding Matters

- a. Update on the Status of the Sterile Compounding Regulations, Title 16 California Code of Regulations, Sections 1735 et seq., and 1751 et seq.
- b. Summary of the Presentation by the Office of Statewide Health Planning and Development Regarding Its Process for Reviewing Structural Modifications Needed in Healthcare Facilities
- c. Discussion and Consideration of the Process for Pharmacies Seeking Waivers In Anticipation of the New Requirements in Title 16 California Code of Regulations, Sections 1735 et seq., and 1751 et seq.
- d. Discussion and Consideration of The Pew Charitable Trust Reports: "Best Practices For State Oversight of Drug Compounding" and "National Assessment of State Oversight of Sterile Drug Compounding"
- e. Discussion and Consideration of the Food and Drug Administration's Guidance Documents on Standards for Compounding Drugs Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act
 - 1. Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act
 - 2. Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act
 - 3. Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act
- f. Overview of Compounding Inspections Performed and Violations Noted

Part 3: Administrative Matters

- a. Future Committee Meeting Dates
- b. Enforcement Statistics

XIX. Communication and Public Education Committee

The board will be presented a summary of the committee's efforts at the May 25, 2016, meeting. The board will discuss and take action as necessary.

- a. Update and Discussion on the Development of a Revised Patient Consultation Survey Questionnaire
- b. Discussion and Consideration on Current Patient Consultation Practices and Actions the Board Can Take to Educate Consumers and Licensees on Appropriate Patient Consultations
- c. Update and Discussion on Prescription Label Translations of Directions for Use
 - 1. Update on the Communication Plan
 - 2. Proposed Draft Regulation Language for Consideration
- d. Update on Development of FAQs Received From ask.inspector@dca.ca.gov
- e. Discussion and Consideration of Naloxone Related Matters
 - 1. Sample Naloxone Labels
 - 2. Communication to the California Healing Art Boards Regarding Naloxone
 - 3. Need for Naloxone FAQs
- f. Discussion and Consideration on SB 493 Implementation
 - 1. Immunization Protocol: Sample Administration Records for Immunizations
 - 2. Self-Administered Hormonal Contraception Matters: Documents Available to Memorialize Prescriptions Furnished by a Pharmacist as a Drug Order

3. Nicotine Replacement Therapy Matters: Discussion of The DCA Page: News from the Department of Consumer Affairs Blog Article – Pharmacists Can Help you Quit Smoking
- g. Discussion and Consideration on the Development of FAQs for SB 493 Related Items
- h. Update on CURES 2.0 and Communication to Licensees
- i. Update on Resources Available on the Board’s Website
- j. Discussion and Consideration of the United States Access Board’s Recommendations Related to Prescription Labels for Visually-Impaired and Elderly Patients
- k. Proposal to Develop a Consolidated List of Drug Take Back Locations for the Board’s Website
- l. Discussion on a Possible Regulatory Change to Require the Collection of Pharmacists’ Email Addresses
- m. Update on The Script Newsletter
- n. Update on Media Activity
- o. Update on Public Outreach Activities Conducted by the Board
- p. Review and Discussion of News or Journal Articles
- q. Future Meeting Dates

XX. Lunch

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

XXI. Closed Session

- a. Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters
- b. In the event that that the Board has not completed its closed session items under item XV above, it may return to that agenda item.

XXII. Reconvene Open Session

Adjournment

5:00 p.m. (or upon conclusion of business)