



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

DATE: April 27-28, 2016

TIME: 9:00 a.m.

PLACE: Embassy Suites Anaheim Orange
400 N. State College Blvd.
Orange, CA 92868

WEBCAST: http://www.pharmacy.ca.gov/meetings/current_webcasts.shtml

(Webcast will be available earliest at 9:00 a.m. on April 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 Web site at www.pharmacy.ca.gov.

Meeting materials should be available on the board's Web site at www.pharmacy.ca.gov by April 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, and March 28, 2016, Board Meeting Minutes

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

V. Board Officer Elections

VI. Organizational Development Committee

- a. Budget Update/Report
 1. Budget Report
 2. Fund Condition Report
 3. Governor's Proposed Budget for 2017/18
- b. National Association of Boards of Pharmacy 2016 Annual Meeting in San Diego
- c. Board Member Reimbursement Information
- d. Personnel Update
- e. Future Board Meeting Dates
 1. Remaining Dates Established for 2016
 - June 7 & 8, 2016
 - July 27 & 28, 2016
 - October 26 & 27, 2016
 2. Proposed Dates for 2017
 - January 24 & 25, 2017
 - May 3 & 4, 2017
 - July 25 & 26, 2017
 - November 7 & 8, 2017
- f. Discussion and Consideration of Sunset Review Process and Actions
 1. Board Written Responses Provided in Response to Sunset Issues Identified by the Joint Committee
 2. Legislative Proposals Resulting from Sunset Review
 - Technical Changes to Statutes
 - Proposal to Add Section 4105.5 to the Business and Professions Code Relating to the Registration of Automated Delivery Systems
 - Proposal to Add Section 4083 to the Business and Professions Code Relating to Recall Notices for Compounded Drug Products
 3. Next Steps in Sunset Review
- g. Discussion and Consideration of Implementation of Assembly Bill 15 (Chapter 1, Statutes of 2015-16 Extraordinary Session) End of Life Option Act

VII. Proposed Regulations to Add Title 16 CCR sections 1776 et seq. related to Prescription Drug Take-Back

VIII. Legislation and Regulation Committee

Part 1: Legislation for Discussion and Consideration

- a. Board-Sunset Legislation
SB 1193 (Hill) California State Board of Pharmacy: Executive Officer
- 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 1977 (Wood) Health Coverage: Abuse-Deterrent Opioid Analgesics
 - 5. AB 2144 (Rodriguez) Pharmacy: Prescriptions
 - 6. AB 2592 (Cooper) Prescriptions
 - 7. SB 482 (Lara) Controlled Substances: CURES database
 - 8. SB 1217 (Stone) Healing Arts: Reporting Requirements: Professions Liability
 - 9. SB 1229 (Jackson and Stone) Home-Generated Pharmaceutical Waste: Secure Drug Take-Back Bins
 - 10. SB 1230 (Stone) Pharmacies: Compounding
 - 11. SB 1346 (Allen) Pharmacists: Drug Labeling: Medication Guides: Electronic Delivery
 - 12. SB 1454 (Stone) Pharmacy
- c. Legislation Impacting Board Operations
 - 1. AB 12 (Cooley) State Government: Administrative Regulations: Review
 - 2. SB 1155 (Morrell) Professions and Vocations: Licenses: Military Service
 - 3. SB 1195 (Hill) Professions and Vocations: Board Actions: Competitive Impact
- 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. Newly Effective Regulation
Title 16 CCR section 1746.1 related to Self-Administered Hormonal Contraception
- b. Board Approved – Submitted for Administrative Review by the Department of Consumer Affairs or the Office of Administrative Law
 - 1. Proposed Regulations to Amend Title 16 California Code of Regulations (CCR) Sections 1715 and 1784 related to Self-Assessment Forms for Community Pharmacies/Hospital Outpatient Pharmacies (17M-13), Hospital Pharmacies (17M-14), and Wholesalers (17M-26)
 - 2. Proposed Regulations to Add Title 16 CCR section 1746.4 related to Vaccinations
 - 3. Regulations to Amend Title 16 CCR section 1735 and 1751 et seq. related to Compounding
 - 4. Proposed Regulations to Add Title 16 CCR sections 1730, 1730.1 and 1749 related to Advanced Practice Pharmacists
 - 5. Proposed Regulations to Add Title 16 CCR section 1730.2 related to Advanced Practice Pharmacists – Certification Programs
- c. Board Approved – Comment Period Closed; Awaiting Action by Licensing Committee
 - 1. Proposed Regulations to Amend Title 16 CCR sections 1732.05, 1732.2, and 1732.5, related to Continuing Education
- d. Board Approved – Awaiting Notice
 - 1. Proposed Regulations to Amend Title 16 CCR section 1703 related to Authorities Delegated to the Executive Officer

2. Proposed Regulations to Amend and/or Add Title 16 CCR section 1702, 1702.1, 1702.2, and 1702.5, related to Renewal Requirements
3. Proposed Regulations to Amend Title 16 CCR sections 1780 – 1784, et seq, related to Third Party Logistics Providers

IX. Lunch

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

X. Proposed Regulations to Amend Title 16 CCR section 1760 related to Board's Disciplinary Guidelines

XI. Proposed Regulations to Add Title 16 CCR section 1746.5 related to Travel Medications

XII. Proposed Regulations to Amend Title 16 CCR section 1744 related to Drug Warnings

XIII. Proposed Regulations to Amend Title 16 CCR section 1707.5 related to Patient-Centered Labels

XIV. Presentation on the North Carolina State Board of Dental Examiners v. Federal Trade Commission United States Supreme Court Ruling

XV. 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(a), the Board will Convene in Closed Session to Perform the Evaluation of the Executive Officer
- c. Pursuant to Government Code section 11126(e), the Board will Convene in Closed Session to Discuss Pending Litigation

XVI. Reconvene Open Session

Adjournment for the Day

Thursday, April 28, 2016

XVII. Call to Order and Establishment of Quorum

9:00 a.m.

XVIII. Development of Guidance Document for Pharmacies Implementing Self-Administered Hormonal Contraception Provisions

XIX. Discussion and Consideration of Statement Released by the Endocrine Society Related to Compounding Bioidentical Hormones in Endocrinology Practice

XX. Proposed Regulations to Add Title 16 CCR section 1715.65 related to Reconciliation and Inventory of Controlled Substances

XXI. Enforcement Committee Related Items

The board will be presented a summary of the committee's efforts at the March 2, 2016, meeting for review and action as necessary.

Part 1: Enforcement Matters

- a. Update on 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
- b. Discussion and Update to the Board's Procedures to Waive Requirements During a Declared Emergency Pursuant to Business and Professions Code section 4062
- c. Data Describing Duty Inspector Activities
- d. Automated Dispensing Machines – Available Drug Diversion Tools, Assessing Features Available, Training Provided to Pharmacy and Health Facility Staff. Summary of Presentations by:
 1. Kaiser Permanente
 2. BD CareFusion/Pyxis & Rx Auditor
 3. Omnicell/Aesyent
 4. Cerner Automated Cabinets
 5. Talyst
- e. Discussion on the Proposed Reconciliation and Inventory Report of Controlled Substances Regulation, Proposal to Add Title 16 California Code of Regulations Section 1715.65
- f. Enforcement Statistics

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 Presentation on FDA-Approved Alternative Testing Technologies to Assess Sterility and Potency in Compounded Medications in Use by Drug Manufacturers

Administrative Matters

- c. Future Committee Meeting Dates
 - June 1, 2016
 - August 31, 2016

XXII. Communication and Public Education Committee

- a. Update on the Redesign of the Board's Website
- b. Update on Communication to Licensees about CURES 2.0
- c. Update on The Script Newsletter
- d. Update on Media Activity
- e. Update on Public Outreach Activities Conducted by the Board
- f. Future Committee Meeting Dates
 - May 25, 2016
 - July 6, 2016

XXIII. Lunch

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

XXIV. Licensing Committee

The board will be presented a summary of the committee's efforts at the March 30, 2016, meeting for review and action as necessary.

- a. Discussion of Pharmacy Technician Licensure Requirements and Practice
 1. Overview of Pharmacy Technician Discipline and Applicant Denials

2. Presentation by the Pharmacy Technician Certification Board (PTCB)
 3. Comparison of the PTCB and ExCPT Certifications
 4. Discussion and Consideration of Possible Requirements for Applicants Enrolling in a Pharmacy Technician Training Programs
 5. Pharmacy Technician Duties, Functions and Licensure Requirements. The Board may discuss the licensure requirements, functions, roles and responsibilities of the pharmacy technician as well as possible changes.
- b. Discussion and Consideration of Senate Bill 952, Anderson (Pharmacy Technicians: Licensure Requirements)
 - c. Demonstration of the Video Instructions for Pharmacy Technician Applications
 - d. Consideration of Proposal to Allow Automated Dispensing Machines to Replenish Medications Administered by Fire Departments and Other Emergency Medical Services Personnel
 - e. Discussion and Consideration of Ownership Structures for Pharmacies, including Trusts
 - f. Discussion and Consideration of Allowing Pharmacists to be Shareholders, Officers or Directors of Professional Corporations, Medical or Otherwise, Pursuant to the Moscone-Knox Professional Corporation Act
 - g. Licensing Statistics
 - h. Competency Committee Report Including Semi-Annual CPJE Examination Statistics
 - i. Future Committee Meeting Dates for 2016
 - May 26, 2016
 - September 1, 2016

XXV. 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.

XXVI. Reconvene Open Session

Adjournment for the Day

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