

Notice of Meeting and Agenda Public Board Meeting October 26 & 27, 2016

DATES October 26, 2016, at 9:30 a.m. **& TIMES:** October 27, 2016, at 9:00 a.m.

- PLACE: Holiday Inn San Jose Silicon Valley 1350 North First Street San Jose, CA 95122
- **WEBCAST:** October 26, 2016 https://www.youtube.com/watch?v=bPFDsHC1Tvw&feature=youtu.be October 27, 2016 - https://www.youtube.com/watch?v=BSCyj8MdY9Q&feature=youtu.be

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 <u>www.pharmacy.ca.gov</u>.

Meeting materials should be available on the board's website at <u>www.pharmacy.ca.gov</u> by October 21, 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 Debbie Damoth at (916) 574-7935, 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)).

<u>Agenda</u>

Call to Order

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. <u>Approval of the July 12, 2016, July 27-28, 2016, August 31, 2016, and September 22, 2016 Board</u> <u>Meeting Minutes</u>

IV. <u>Recognition and Celebration of Pharmacists Licensed In California for 50 Years</u>

V. Update from the Department of Consumer Affairs

VI. Executive Officer's Report

- a. Assembly Health Committee Informational Hearing "Understanding the Pharmaceutical Supply Chain: What is Driving Up the Cost of Drugs?"
- b. Discussion and Consideration of the Timeline for Reporting Immunizations into California's Department of Public Health CAIRS Data Base Pursuant to 16 CCR Section 1746.4
- c. Update from the Medical Board of California on Issues Affecting Both Boards
- d. NAPLEX and CPJE Examination Statistics

VII. <u>Discussion and Consideration of Proposed Regulations to Amend and Add Title 16 CCR sections 1702,</u> <u>1702.1, 1702.2 and 1702.5 related to Renewal Requirements</u>

VIII. <u>Discussion and Consideration of Proposed Regulations to Add Title 16 CCR sections 1776 et seq.</u> related to Prescription Drug Take-Back

IX. Communication and Public Education Committee

The board will be presented a summary of the committee's efforts at the September 8, 2016, meeting for discussion and action as necessary.

- a. Update and Discussion on the Development of a Revised Patient Consultation Survey Questionnaire
- b. Update and Discussion on Development of FAQs Received from ask.inspector@dca.ca.gov
- c. Discussion and Consideration of Naloxone Related Matters
 - 1. Communication to the California Healing Art Boards Regarding Naloxone
 - 2. Naloxone FAQs
 - 3. SB 833 (Committee on Budget and Fiscal Review, Health, Chapter 30, Statutes of 2016)
 - Discussion on Federal Legislation: US S. 524 Comprehensive Addiction and Recovery Act of 2016
 - i. Lali's Law
 - ii. Provisions regarding Partial Fills for Schedule II
- d. Discussion on the Development of FAQs for SB 493 Related Items
- e. Discussion on CE Courses Available for Naloxone, Self-Administered Hormonal Contraception and Nicotine Replacement Therapy under Protocols

- f. Update and Discussion on Resources Available on the Board's Website
- g. Discussion of a Board-Developed Billboard Message and Related Communication Materials
- h. Communication Plan for Consumers and Licensees
- i. Update and Discussion on the Forty-Fifth Annual Report of the Research Advisory Panel of California for 2015 Regarding Controlled Drugs Research
- j. Board Publications Review and Recommendations for Changes
 - 1. Counterfeit Prescription Drugs: Protect Yourself, Your Family and Your Pets
 - 2. Buying Prescription Medications Online: Are the Drugs you Buy Real or Fake?
- k. Update on The Script Newsletter
- I. Update on Media Activity
- m. Update on Public Outreach Activities Conducted by the Board
- n. Review and Discussion of the California Department of Public Health's Comparison Between the Centers for Disease Control and Prevention's *Guidelines for Prescribing Opioids for Chronic Pain* and the Medical Board of California's *Guidelines for Prescribing Controlled Substances for Pain*.
- o. Future Meeting Dates

X. Lunch

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

XI. Enforcement Committee Related Items

The board will be presented a summary of the committee's efforts at the August 31, 2016, meeting for discussion and action as necessary.

Part 1: Enforcement Matters

- 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 Possible Modifications to the Study Parameters - Update and Discussion and Consideration of Modifications to the Pilot Program, if Necessary.
- b. CURES 2.0 Prescription Monitoring Program and Use of CURES by Pharmacists Update and Discussion and Consideration of Next Steps, if Necessary
- c. Discussion and Consideration of Consumer Enrollment in Automated Refill Programs for Prescription Medications
- d. Discussion and Consideration of Statistics for Board Issued Citations and Fines
- e. Discussion and Consideration of Data Describing Medication Errors for Board Issued Citations and Fines
- f. Enforcement Statistics
- g. Future Committee Meeting Dates

Part 2: Compounding Matters

- a. [Not discussed at the August 31, 2016, Committee Meeting] Discussion and Consideration of Pharmacy Requests for Compliance Delays for Construction Pursuant to 16 CCR Sections 1735.6(f) and 1751.4(l), Including:
 - 1. Requests Received to Date
 - 2. Process for Reviewing Future Requests
- b. Discussion and Consideration of Statistics on Compounding Violations Identified by the Board (2014-2016).
- c. Discussion and Consideration of the Frequently Asked Questions about Sterile Compounding.
- d. Discussion and Consideration of Frequently Asked Questions about Venting in Compounding Pharmacies.

e. Articles in the News, Including Discussion and Consideration of "Fraud Concerns Grow as Spending on Handmade 'Compounded' Drugs Soar"

XII. Organizational Development Committee

- a. Budget Update/Report
 - 1. Fiscal Year 15/16 Final 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. Future Board Meeting Dates

XIII. Petitions for Reinstatement of Licensure or Other Reduction of Penalty

Date & Time Certain: October 27, 2016, 9 a.m.

- a. Asher Kashanchi, RPH 56942
- b. Entirelypets Pharmacy, PHY 50832

XIV. <u>Closed Session</u>

- a. Pursuant to Government Code section 11126(c)(3), the Board will Convene in Closed Session to Deliberate on Disciplinary Matters, Including the Above Petition, 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. The Board Will Recovene In Open Session

XV. Licensing Committee

The board will be presented a summary of the committee's efforts at the September 27, 2016, meeting for discussion and action as necessary.

- a. Discussion on Implementation of Provisions Contained in Senate Bill 1193 (Chapter 484, Statutes of 2016)
 - 1. Incorporate Trusts as an Entity Authorized to Obtain Licensure, Proposal to Amend CCR section 1709, Names of Owners and Pharmacist In Charge
 - 2. Licensure of Outsourcing Facilities
 - 3. Email Notification List Requirement
- b. Discussion and Consideration of Possible Revisions to the Board's Fee Schedule (Title 16 CCR §1749) to Implement the Provisions Contained in Senate Bill 1039 (Chapter 799, Statutes of 2016)
- c. Discussion and Consideration of Next Steps Necessary to Implement Senate Bill 952 Relating to Pharmacy Technician Licensure Requirements (SB 952, Chapter 150, Statutes of 2016) Including Proposal to Add Section 1793.65 to Title 16 CCR.
- d. Discussion and Consideration of Amendment to Title 16, CCR section 1780 et seq., to include Operational Requirements for Third-Party Logistics Providers
- e. Presentation by the Office of Statewide Health Planning and Development (OSHPD) on the Health Professions Education Foundation
- f. Discussion and Consideration of Pharmacist Examination Matters
 - 1. The National Association of Boards of Pharmacy's Change in Policy Relating to the 91-Day Waiting Period for Candidates that Fail the NAPLEX
 - 2. Evaluation of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

- g. Consideration of Request from Marshal B. Ketchum University, College of Pharmacy, for Recognition by the Board of Pharmacy Under Title 16, California Code of Regulations Section 1719 for Purposes of Issuing Intern Licenses
- h. Licensing Statistics
- i. Future Committee Meeting Date for 2016

XVI. Legislation and Regulation Committee

The board will be presented a summary of the committee's efforts at the October 26, 2016, meeting for discussion and action as necessary.

Part 1: Legislation for Discussion and Consideration Report

- a. Board-Sunset Legislation
 - 1. SB 1193 (Hill, Chapter 484, Statutes of 2016) California State Board of Pharmacy
 - 2. SB 1039 (Hill, Chapter 799, Statutes of 2016) Professions and Vocations
- b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction
 - 1. AB 1069 (Gordon, Chapter 316, Statutes of 2016) Prescription Drugs: Collection and Distribution Program
 - 2. AB 1114 (Eggman, Chapter 602, Statutes of 2016) Medi-Cal: Pharmacist Services
 - 3. AB 1386 (Low, Chapter 374, Statutes of 2016) Emergency Medical Care: Epinephrine Auto-Injectors
 - 4. AB 1748 (Mayes, Chapter 557, Statutes of 2016) Pupils: Pupil Health: Opioid Antagonist
 - 5. SB 482 (Lara, Chapter 708, Statutes of 2016) Controlled Substances: CURES Database
 - 6. SB 952 (Anderson, Chapter 150, Statutes of 2015) Pharmacy Technicians: Licensure Requirements
 - 7. SB 999 (Pavley, Chapter 499, Statutes of 2016) Health Care Coverage: Contraceptives: Annual Supply
 - 8. SB 1229 (Jackson, Chapter 238, Statutes of 2016) Pharmacies: Secure Drug Take-Back Bins
- c. 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 Adopted Approved by the Office of Administrative Law
 - 1. Regulations to Add Title 16 CCR section 1730.2 related to Advanced Practice Pharmacists Certification Programs
 - 2. Regulations to Add Title 16 CCR section 1746.4 related to Immunizations (Vaccinations)
 - 3. Regulations to Amend Title 16 CCR section 1735 and 1751 et seq. related to Compounding
- b. Board Adopted Submitted for Administrative Review to the Department of Consumer Affairs or the Office of Administrative Law
 - 1. Proposed Regulations to Add Title 16 CCR sections 1730, 1730.1 and Amend section 1749 related to Advanced Practice Pharmacists
 - 2. Proposed Regulations to Add Title 16 CCR section 1746.5 related to Travel Medications
 - 3. Proposed Regulations to Amend Title 16 CCR section 1760 related to the Board's Disciplinary Guidelines
 - 4. Proposed Regulations to Amend Title 16 CCR section 1744 related to Drug Warnings
 - 5. Proposed Regulations to Amend Title 16 CCR section 1707.5 related to Patient-Centered Labels
 - 6. Proposed Regulations to Amend Title 16 CCR section 1732.05, 1732.2 and 1732.5 related to Continuing Education

- c. Board Adopted Rulemaking File Being Prepared by Staff for Submission to the Department of Consumer Affairs or the Office of Administrative Law
 - Proposed Regulations to Amend Title 16 CCR section 1703 related to Delegation of Certain Functions
- Board Approved to Initiate Rulemaking Open Comment Period Proposed Regulations to Add Title 16 CCR section 1715.65 related to Inventory Reconciliation Report of Controlled Substances
- e. Consideration and Discussion of Proposed Regulations to Amend Title 16 CCR sections 1715 and 1784 to Update Self-Assessment Forms 17M-13 (rev. 10/16), 17M-14 (rev. 10/16) and 17M-26 (rev.10/16)

Adjournment

Upon conclusion of business