BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Notice of Meeting and Agenda Public Board Meeting July 25-26, 2017

DATES & Time: July 25, 2017, at 9:00 a.m.

July 26, 2017, at 8:30 a.m.

PLACE: Sheraton Park Hotel

1855 S. Harbor Blvd. Anaheim, CA 92802

WEBCAST: https://thedcapage.wordpress.com/webcasts/

(Webcast will be available earliest at 9:00 a.m. on July 25, 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 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 21, 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 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. 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. <u>Call to Order, Establishment of Quorum, and General Announcements</u>
- 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. January 24-25, 2017 Board Meeting Minutes Revisions to Previously Approved Minutes
- IV. May 3-4, 2017 Board Meeting Minutes
- V. Recognition and Celebration of Pharmacists Licensed In California for 50 Years
- VI. <u>Enforcement and Compounding Committee Related Items</u>

The board will be presented a summary of the committee's efforts at the June 2, 2017 and July 12, 2017, meetings, as well as updates, for discussion and action as necessary.

Part 1: Enforcement Matters

- a. Discussion and Consideration of Reporting Drug Losses Under State and Federal Laws
- b. Discussion and Consideration of Drug Diversion by Employees and Proposal to Mandate Reporting to Law Enforcement
- c. Update on the Development of the Continuing Education Training from the Board on Prescription Drug Abuse
- d. Discussion and Consideration of Safe Medication Transitions for Patients Upon Discharge
- e. Discussion and Consideration of Recalls by Drug Manufacturers at the Patient or Pharmacy Level
- f. Discussion and Consideration of Request for Wholesalers to Report Suspicious Drug Sales to the Board
- g. Discussion and Consideration of the California State Auditor Report on Home-Generated Sharps and Pharmaceutical Waste

Part 2: Compounding Matters

- h. Discussion and Consideration of Amendments to the Board's Compounding Regulations, California Code of Regulations, Title 16, Division 17, Articles 4.5 (Sections 1735-1735.8) and 7 (Sections 1751-1751.10)
 - 1. Committee's Recommended Changes
 - 2. Regulatory Amendments Requiring Emergency Adoption Procedure to Avoid Serious Harm to the Public Peace, Health, Safety, or General Welfare
 - 3. Regulatory Amendments Pursuant to Regular Rulemaking Procedure
- Discussion and Consideration of the Status of Waiver Requests for Compounding Construction Compliance Delays Pursuant to Title 16, California Code of Regulations, Sections 1735.6 and 1751.4 and the Process for Review and Appeals of such Requests

Part 3: General Committee Matters

- j. Enforcement Statistics
- k. Future Meeting Dates
- I. Minutes from the July 12, 2017 Enforcement and Compounding Committee Meeting

VII. Licensing Committee

The board will be presented a summary of the committee's efforts at the July 19, 2017, meeting, as well as updates, for discussion and action as necessary.

- a. Summary of Presentation by the Department of Health Care Services on Their Enrollment and Re-Enrollment Process of Fee-for-Service Health Care Providers in the Medi-Cal Program
- Discussion and Consideration of the Re-Take Waiting Period for the North American Pharmacist
 Licensure Examination (NAPLEX) and California Practice Standards and Jurisprudence Examination for
 Pharmacists (CPJE)
- c. Discussion and Consideration of Issuing Board Licenses Including Photos for Individual Licensees
- d. Discussion and Consideration of Pharmacy Technician Duties and Possible Changes to Such Duties
- e. Discussion and Consideration of Pharmacy Technician Ratios in California
- f. Discussion and Consideration of Application and Renewal Requirements for Pharmacy Technicians
- g. Update and Discussion on the Development of Board Provided Law and Ethics Continuing Education Courses
- h. Discussion and Consideration of Pharmacist Consultation in Various Pharmacy Settings
- i. Discussion and Consideration of the Center for Disease Control's Newly Released Guide for Pharmacists to Establish Collaborative Practice Agreements
- j. Licensing Statistics
- k. Future Committee Meeting Dates

VIII. Legislation and Regulation Committee

The board will be presented a summary of the committee's efforts at the June 27, 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 Board Established Positions
 - 1. AB 40 (Santiago) CURES Database: Health Information Technology System
 - 2. AB 182 (Walderon) Heroin and Opioid Public Education (HOPE)
 - 3. AB 208 (Eggman) Deferred Entry of Judgment: Pretrial Diversion
 - 4. AB 315 (Wood) Pharmacy Benefits Management
 - 5. AB 401 (Aguiar-Curry) Pharmacy: Remote Dispensing Site Pharmacy: Telepharmacy
 - 6. AB 602 (Bonta) Pharmacy: Nonprescription Diabetes Devices
 - 7. AB 845 (Wood) Cannabidiol: Prescriptions in Accordance with Federal Law
 - 8. SB 17 (Hernandez) Prescription Drugs: Pricing: Notification
 - 9. SB 528 (Stone) Pharmacy: Automated Drug Delivery Systems
 - 10. SB 547 (Hill) Professions and Vocations
 - 11. SB 641 (Lara) Controlled Substances Utilization Review and Evaluation System: Privacy
 - 12. SB 716 (Hernandez) California Board of Pharmacy: Pharmacy Technician Member
- c. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction Currently being Watched
 - 1. AB 265 (Wood) Prescription Drugs: Prohibition on Price Discount

- 2. AB 444 (Ting) Medical Waste: Home-Generated Sharps Waste
- 3. AB 710 (Wood) Department of Consumer Affairs: Boards: Meetings
- 4. AB 827 (Rubio) Department of Consumer Affairs: Task Force: Foreign-Trained Professionals
- 5. AB 1048 (Arambula) Health Care: Pain Management and Schedule II Drug Prescriptions
- 6. SB 212 (Jackson) Medical Waste
- 7. SB 715 (Newman) Department of Consumer Affairs: Removal of Board Members
- 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

- e. Board Adopted Approved by the Office of Administrative Law
 - 1. Regulations Amending Title 16 CCR Section 1703 Related to Delegation of Certain Functions
 - 2. Regulations Adding Title 16 CCR Section 1776 et seq. Related to Prescription Drug Take-Back
 - 3. Regulations Adding Title 16 CCR Section 1746.5 Related to Travel Medications
- f. 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 Amend Title 16 CCR Sections 1760 Related to the Board's Disciplinary Guidelines
- g. 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:
 - 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
 - 6. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage
 - 7. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet
- h. 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 Sections 1735 et seq. and 1751 et seq. Related to Compounding
 - 2. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

Part 3: General Committee Matters

Future Meeting Dates

X. Closed Session for Examination Matters

- a. 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)
- b. The Board Will Reconvene in Open Session

XI. Executive Officer's Report

- a. Discussion and Consideration of FDA Draft Guidance, "Product Identifier Requirements Under the Drug Supply Chain Security Act Compliance Policy"
- b. Update on CURES

XII. Organizational Development Committee

- a. Budget Update/Report
 - 1. Fund Condition Report
 - 2. Budget Report for Fiscal Year 2016/17
- b. Board Member Reimbursement Information
- c. Board Member Attendance Information
- d. Personnel Update
- e. Discussion and Possible Action to Increase the Exempt Salary Category Level for the Position of Executive Officer
- f. Future Meeting Dates
 - 1. Future Board Meeting Dates for 2017
 - 2. Future Board Meeting Dates for 2018
- XIII. <u>Discussion and Consideration of the University of California, San Diego's Pilot Program to Permit Patients to Access Medications from an Automated Drug Delivery System (ADDS) Not Immediately Adjacent to the Pharmacy, Including Medications Requiring Consultation by a Pharmacist</u>
- XIV. Update from the Department of Consumer Affairs
- XV. <u>Discussion and Consideration of the Proposed Regulation to Amend Title 16 CCR Section 1749, Related to Fees</u>
- XVI. <u>Discussion and Consideration of the Proposed Regulations to Add Title 16 CCR Section 1715.65,</u>
 Related to Inventory Reconciliation Report of Controlled Substances

XVII. Other 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(a), the Board May Convene in Closed Session to Discuss the Evaluation of the Executive Officer
- d. The Board Will Reconvene in Open Session

Adjournment

Upon conclusion of business