California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

Notice of Meeting and Agenda
Public Board Meeting
January 24 & 25, 2017

DATES & TIMES: January 24, 2017, at 10:00 a.m.
January 25, 2017, at 8:00 a.m.

PLACE: Hilton Glendale
100 West Glenoaks Blvd.
Glendale, CA 91202

WEBCAST: http://www.pharmacy.ca.gov/meetings/current_webcasts.shtml
(Webcast will be available earliest at 10:00 a.m. on January 24, 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 January 18, 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. 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

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 October 26-27, 2016, and December 14, 2016 Board Meeting Minutes

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

V. Update from the Department of Consumer Affairs

VI. Executive Officer's Report

a. Discussion and Consideration of Possible Board Comments on the FDA's Draft Guidance Documents:
   1. FDA's Draft Guidance, *Compounding And Repackaging of Radiopharmaceuticals by Outsourcing Facilities*
   2. FDA's Draft Guidance, *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities*
b. Final Guidance Documents Issued by the FDA:
   1. FDA Guidance, *Prescription Requirement Under Section 503A of the Federal Food, Drug and Cosmetic Act*
   2. Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act
   3. Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities
c. Discussion and Consideration of the Planned Decommissioning of CURES 1.0 by the California Department of Justice on March 5, 2017
d. Discussion and Consideration of a Planned Educational Forum Cohosted by the California State Board of Pharmacy and the Drug Enforcement Administration; Request for Authorization to Award Continuing Education Credits To Attendees

VII. Discussion and Consideration of the Proposed Regulation to Add Title 16 California Code of Regulations (CCR) Section 1715.65, Related to Inventory Reconciliation Report of Controlled Substances

VIII. Discussion and Consideration of the Proposed Regulation to Add Title 16 CCR Section 1746.5, Related to Travel Medications

IX. Discussion and Consideration of the Proposed Regulation to Amend Title 16 CCR Section 1760, Related to Disciplinary Guidelines

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

X. Enforcement and Compounding Committee Related Items

The board will be presented a summary of the committee's efforts at the January 4, 2017, meeting for discussion and action as necessary.

Part 1: Enforcement Matters

a. CURES 2.0 Prescription Monitoring Program: Presentation by California Department of Justice and Discussion of CURES System Components
b. 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 Not Immediately Adjacent to a Pharmacy
c. Disposal of Sharps in Pharmacy-Operated Drug Take Back Programs: Discussion and Consideration of Statutory and Regulatory Framework and Possible Changes
d. Automated Drug Delivery Systems (ADDS)
    1. Presentations Regarding Options and Features Currently Available
    2. Discussion and Consideration of Refilling of ADDS in Skilled Nursing Facilities
    3. Next Steps
e. Discussion and Consideration of Possible Regulations Regarding Patient Enrollment in Automated Refill Programs for Prescription Medications
f. Discussion and Consideration of the National Council of State Boards of Nursing (NCSBN) Nursys® e-Notify System
g. Discussion and Consideration of Possible Revision to Title 16 California Code of Regulations Section 1707, Relating to Off-Site Storage Waivers, to Address Licensees with Previous Records Violations.
h. Discussion and Consideration of Possible Amendment to New Business and Professions Code Section 4316 Regarding Cease and Desist Orders
i. Discussion and Consideration of the FDA's Article, *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry*
j. Discussion and Consideration of Beyond Use Labels in Institutional Settings

Part 2: Compounding Matters

a. Discussion and Consideration of Statistics for Board-Issued Citations and Fines for Compounding Violations.
b. Update and Discussion of Compounding Construction Waivers for New Requirements in Title 16 California Code of Regulations, Sections 1735 et. seq., and 1751 et. seq.
c. Discussion and Consideration of the United States Government Accountability Office Report to Congressional Committees, *Drug Compounding, FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported Challenges*
d. Review and Discussion of California Law Governing Compounding and Conflicts with USP Section 800
e. Presentation of Requirements for Sterile Compounding Master Formulas
f. Discussion and Consideration of the Proposed FDA 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*

Part 3: General Committee Matters

a. Enforcement Statistics
b. Future Committee Meeting Dates for 2017

XI. Organizational Development Committee

a. Budget Update/Report

1. Fund Condition Report
2. Budget for Fiscal Year 2016/17
3. DCA Distributed Costs Allocations, including BreEZe Costs

b. Board Member Reimbursement Information
c. Personnel Update
d. Future Meeting Dates
    1. Future Board Meeting Dates for 2017
    2. Automated Drug Delivery Device Demonstration Summit

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 Petitions, 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. The Board will Reconvene In Open Session

XIV. Licensing Committee

The board will be presented a summary of the committee's efforts at the January 10, 2017, meeting for discussion and action as necessary.

a. Discussion and Consideration of Certification Programs Developed to Satisfy Requirements for Licensure as an Advanced Practice Pharmacist Pursuant to Title 16, California Code of Regulations Section 1730.2
b. Discussion and Consideration of Possible Revisions to the Licensure Requirements for a Designated Representative in a Reverse Distributor, Including But Not Limited to Business and Professions Code Section 4053
c. Discussion and Consideration of a Statutory Proposal to Establish a Satellite Compounding Pharmacy Licensure Category
d. Discussion and Consideration of a Statutory Proposal to Establish Authority for County Emergency Medical Services Providers to Use Automated Drug Delivery Systems for Purposes of Restocking Ambulances
e. Licensing Statistics
f. Future Committee Meeting Dates
    1. Pharmacy Technician Summit - April 4, 2017
    2. Committee Meeting Dates for 2017

XV. Legislation and Regulation Committee

The board will be presented a summary of the committee's efforts at the January 24, 2017, meeting for discussion and action as necessary.

Part 1: Legislation for Discussion and Consideration Report

a. Board Sponsored Legislation
    Omnibus Provision to Amend B&PC 4013, Regarding Licensee Email Addresses
b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction
    1. AB 12 (Cooley) State Government: Administrative Regulations: Review

2. AB 29 (Nazarian) Pharmacy Benefits Managers
3. AB 40 (Santiago) CURES Database: Health Information Technology System
4. SB 17 (Hernandez) Prescription Drugs: Pricing: Notification
5. SB 27 (Morrell) Professions and Vocations: Licenses: Military Service
6. SB 70 (Bates) Health Care Professionals

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
Regulations Adding Title 16 CCR Sections 1730, 1730.1 and Amending Section 1749 Related to Advanced Practice Pharmacists

b. Board Adopted - Submitted for Administrative Review to the Department of Consumer Affairs or the Office of Administrative Law
1. Proposed Regulations to Amend Title 16 CCR Section 1744 Related to Drug Warnings
2. Proposed Regulations to Amend Title 16 CCR Section 1707.5 Related to Patient-Centered Labels
3. Proposed Regulations to Amend Title 16 CCR Sections 1732.05, 1732.2 and 1732.5 Related to Continuing Education
4. Proposed Regulations to Add Title 16 CCR Sections 1776 et seq. Related to Prescription Drug Take-Back
5. Proposed Regulations to Amend Title 16 CCR Section 1703 Related to Delegation of Certain Functions

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 and/or Add Title 16 CCR Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements

d. Board Approved to Initiate Rulemaking – Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency:
Proposed Regulations to Amend Title 16 CCR Section 1749 Related to the Board's Fee Schedule

e. 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 1780-1783, et seq. Related to Third-Party Logistics Providers
2. Proposed Regulation 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 Regulation 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 Regulation to Amend Title 16 CCR Section 1709 Related to Trust Ownership

Adjournment **Upon conclusion of business**