



California State Board of Pharmacy

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

NOTICE OF MEETING AND AGENDA
Enforcement and Compounding Committee Meeting
April 18, 2017

DATE: April 18, 2017

TIME: 9:30 a.m.

PLACE: DCA Headquarters, First Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

NOTE: Pharmacists and pharmacy technicians who attend in person may be awarded two hours of continuing education (CE) credit, 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 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 14, 2017.

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 email 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 Committee Chairperson and may be taken out of order. In accordance with the Bagley-Keene Open Meeting Act, all meetings of the board are open to the public.

**Government Code Section 11125.7 provides the opportunity for the public to address each agenda item during discussion or consideration by the committee or prior to the committee taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issues before the committee, but the Committee Chairperson may, at his or her discretion, apportion available time among those who wish to speak. Individuals may appear before the committee to discuss items not on the agenda; however, the committee 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

9:30 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. Enforcement Matters

- a. University of California, San Diego's Pilot Program to Permit Patients to Access Medications From an Automated Drug Delivery System Not Immediately Adjacent to the Pharmacy
 1. Discussion and Consideration of the Final Report from the Pilot Program
 2. Discussion and Consideration of Possible Future Action Based on the Pilot Program
- b. Discussion and Consideration of CURES 2.0 Prescription Drug Monitoring Program
- c. Presentation by Stericycle of a New Device for Destruction of Controlled Substances in Pharmacies
- d. Discussion and Consideration of the Use of Automated Drug Delivery Systems (ADDS) – Follow up from the February 2017 Board Meeting
 1. Options and Features Currently Available
 2. Refilling of ADDS in Skilled Nursing Facilities
 3. Next Steps by the Committee or Board
- e. Discussion and Consideration of a Proposed Regulation to Add Title 16 California Code of Regulations Section 1715.65 Related to Inventory Reconciliation of Controlled Substances
- f. Discussion and Consideration of March 11, 2017, Training Provided by the Board and DEA on CURES and Prescription Drug Abuse, and Possible Future Training
- g. Report Submitted to the Assembly Budget Committee Regarding the Board's Prescription Drug Abuse Team

IV. Compounding Matters

- a. Discussion and Consideration of Statistics Regarding Outcomes of Board of Pharmacy Compounding Inspections
- b. Discussion and Consideration of Waiver Request for Compounding Construction Compliance Delays Pursuant to Title 16 California Code of Regulations, Sections 1735 et. seq., and 1751 et. seq.
 1. Update
 2. Process for Review of Requests
- c. Update on the Board's Progress in Implementing California Business and Professions Code sections 4129, et seq., regarding Licensure and Regulation of Outsourcing Facilities
- d. Discussion and Consideration of the United States Government Accountability Office's March 31, 2017, E-Supplement Report to Congressional Committees on *Drug Compounding: FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported*

Challenges

- e. Presentation by Road Runner Pharmacy Regarding Compounding for Veterinary Prescriber Office Use
- f. Discussion and Consideration of the Proposed Food and Drug Administration 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” and Proposed Lists
- g. Discussion and Consideration of the Food and Drug Administration Rule “Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act –Guidance for Industry” and Proposed Lists
- h. Discussion and Consideration of the Food and Drug Administration Rule “Guidance for Industry Compounding Animal Drugs from Bulk Drug Substances” and Proposed Lists

V. Enforcement Statistics

- a. Citations and Fines
- b. Medication Errors
- c. Other Enforcement Statistics

VI. Future Meeting Dates for 2017

- July 12, 2017
- October 17, 2017

ADJOURN

4:00 p.m. (or upon conclusion of business)