



NOTICE OF MEETING AND AGENDA

Enforcement and Compounding Committee Meeting

August 31, 2016

DATE: August 31, 2016

TIME: 10:00 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 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 August 26, 2016.

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 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

10:00 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. Enforcement Matters

- a. University of California, San Diego's Pilot Program to Permit Patients to Access Medications From an Automated Storage Device Not Immediately Adjacent to the Pharmacy – 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.

IV. Compounding Matters

- a. Discussion and Consideration of Statistics on Compounding Violations Identified by the Board (2014 – 2016).
- b. Pending Compounding Regulations, Title 16 California Code of Regulations, 1735 et seq., and 1751 et seq.; Status Update and Discussion and Consideration of Next Steps, if necessary.
- c. Discussion and Consideration of the Proposed Process for Pharmacies Seeking Waivers From Structural Requirements in Title 16 California Code of Regulations, 1735 et seq., and 1751 et seq.
- d. Discussion and Consideration of the Draft Compounding Self-Assessment Form to Implement the Pending Compounding Regulations.
- e. Discussion and Consideration of Frequently Asked Questions about Sterile Compounding.
- f. Discussion and Consideration of Frequently Asked Questions about Venting in Compounding Pharmacies.
- g. Federal Food and Drug Administration's Draft Guidance Documents – Discussion and Consideration, including Whether to Submit Board Comments, regarding:
 1. Insanitary Conditions at Compounding Facilities
 2. Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act
 3. Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
 4. Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act

- h. Articles in the News, Including Discussion and Consideration of “Fraud Concerns Grow as Spending on Handmade ‘Compounded’ Drugs Soar”

ADJOURN

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