



California State Board of Pharmacy

1625 N. Market Blvd, 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
Enforcement and Compounding Committee Meeting
June 1, 2016

DATE: June 1, 2016

TIME: 9:00 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 2 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 May 27, 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

9:00 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. Update by the University of California, San Diego on its Pilot Program to Permit Patients to Access Medications from an Automated Storage Device Not Immediately Adjacent to a Pharmacy
- b. Update on the CURES 2.0 Prescription Monitoring Program
- c. Consideration of the Proposed Regulation Relating to Reconciliation and Inventory Reports of Controlled Substances (Currently, to Add Title 16 California Code of Regulations Section 1715.65)
- d. Consideration of the Department of Consumer Affairs Contract and Audit of the DCA Diversion Program Provided by Maximus Health Services
- e. Consideration of the Food and Drug Administration's Required Class-Wide Safety Labeling Changes for Opioid Pain Medications
- f. Consideration of the Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain
- g. Proposal to Add Statutory Authority Relating to the Registration with the Board of Automated Delivery Systems for Dispensing of Medication
- h. Consideration of a Proposal to Conduct Inspections of All Pharmacies Every Four Years

IV. Compounding Matters

- a. Update on the Status of the Sterile Compounding Regulations, Title 16 California Code of Regulations, Sections 1735 et seq., and 1751 et seq.
- b. Presentation by the Office of Statewide Health Planning and Development Regarding Its Process for Reviewing Structural Modifications Needed in Healthcare Facilities
- c. Consideration of the Process for Pharmacies Seeking Waivers in Anticipation of the New Requirements in Title 16 California Code of Regulations, Sections 1735 et seq., and 1751 et seq.
- d. Consideration of The Pew Charitable Trust Reports: "Best Practices For State Oversight of Drug Compounding" and "National Assessment of State Oversight of Sterile Drug Compounding"
- e. Consideration of the Food and Drug Administration's Guidance Documents on Standards for Compounding Drugs Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act
 - 1) Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic

- Act
- 2) Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act
- 3) Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act
- f. Overview of Compounding Inspections Performed and Violations Noted

V. Meeting Dates for 2016

- August 31, 2016

ADJOURN

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