



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
January 4, 2017

DATE: January 4, 2017

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 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 Kelli Williams at (916) 574-7729 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 December 29, 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 Kelli Williams at (916) 574-7729, 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. CURES 2.0 Prescription Drug Monitoring Program
 1. Presentation by the California Department of Justice, including Features for Pharmacists
 2. Discussion and Consideration 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 the 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. Presentation(s) Regarding Options and Features Currently Available
 2. Discussion and Consideration of Refilling of ADDS in Skilled Nursing Facilities
 3. Discussion and Consideration of Next Steps by the Committee or Board
- 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, Off-Site Storage Waivers, to Address Licensees With Previous Records Violations
- h. Discussion and Consideration of a Possible Amendment to New Business and Professions Code 4316 Regarding Cease and Desist Orders
- i. Discussion and Consideration of U.S. Department of Health and Human Services Food and Drug Administration'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

IV. 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 on Requirements for Sterile Compounding Master Formulas
- 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”

V. Enforcement Statistics

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

VI. Meeting Dates for 2017

- April 18, 2017
- July 12, 2017
- October 17, 2017

ADJOURN

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