



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
March 9, 2015

DATE: March 9, 2015

PLACE: Department of Consumer Affairs
1625 North Market Blvd.
1st Floor Hearing Room
Sacramento, CA 95834

WEBCAST: http://www.pharmacy.ca.gov/meetings/current_webcasts.shtml
(Link to Webcast will be available earliest at 10:00 a.m. on March 9, 2015. Please see additional notices below regarding availability.)

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 March 6, 2015.

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. Discussion and Possible Action to Make Changes in Response to Comments Received During the 15 Day Comment Period, or to Adopt or Amend Proposed Text at Title 16, California Code of Regulations, Section 1735, et seq., and 1751, et seq., Relating to Pharmacy Compounding

IV. Legislative Proposal to Establish a Separate Licensure Category for Outsourcing Facilities

V. Discussion and Possible Action to Initiate a Rulemaking to Add Title 16, California Code of Regulations, Section 1746.1 Regarding Requirements for Pharmacists Who Furnish Self-Administered Hormonal Contraceptives

VI. Discussion and Possible Action to Add Title 16, California Code of Regulations, Section 1730 Regarding Requirements for Advanced Practice Pharmacists

VII. Title 16, California Code of Regulations, Section 1746.3: Protocol for Pharmacists Who Furnish Naloxone – Update and Next Steps

VIII. Opportunity to Provide Comments on U.S. Food and Drug Administration Draft Guidance Documents

- a. Draft Guidance: For Entities Considering Whether to Register As Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act
- b. Draft Guidance for Industry: Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities
- c. Draft Guidance for Industry: Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application (BLA)
- d. Draft Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act
- e. Draft Memorandum of Understanding Between A State and the U.S. Food and Drug Administration Addressing Certain Distributions of Compounded Human Drug Products

IX. Organizational Development Committee

- a. Fee Audit Update
- b. New Legal DCA Counsel
- c. Update of BreEZe, DCA's New Application and Licensing Computer System
- d. Procedures for Evaluation of the Performance of the Board's Executive Officer

X. Lunch

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

XI. Closed Session

Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters.

XII. Reconvene Open Session

XIII. Adjournment

4:00 p.m.

Important Notice 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 Laura Hendricks at (916) 574-7918, by emailing laura.hendricks@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 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. 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. 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)).*