



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 10, 2014

Contact Person: Laura Hendricks
(916) 574-7918

Note: This is a combined meeting to discuss enforcement and compounding matters.

This committee 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 Ms. Hendricks at 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.

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

DATE: January 10, 2014
PLACE: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

This meeting may be cancelled without notice. For verification of the meeting, call (916) 574-7900 or access the Board's Web site at www.pharmacy.ca.gov.

Discussion and action may be taken on any item on the agenda. The committee may discuss agenda items in any order. Board members who are not on the committee may attend, but may not vote. Time limitations for discussion and comment will be determined by the committee chair.

Agenda

Call to Order

9:30 a.m.

I. Enforcement Matters

- a. Discussion on the Preemption of California's e-Pedigree Requirements, as Required by California Business and Professions Code Section 4034.1 and Enacted H.R. 3204, the Federal Drug Quality and Security Act
- b. Discussion on Federal Legislation that Eliminated Licensure of Third Party Logistics Providers as Wholesalers, Pursuant to the Enacted H.R. 32014, the Federal Drug Quality and Security Act
- c. Update on Implementation of AB 1136 (Levine) Chapter 304, Statutes of 2013 Regarding Warning Labels on Prescription Container Labels
- d. Request for Comments from the D.E.A. on the Possible Scheduling of Tramadol into Federal Schedule IV
- e. Request from Sharp Healthcare for a Waiver of 16 California Code of Regulations Section 1713(d) to Permit Expanded Use of Automated Prescription Dispensing Machines
- f. Request from MedAvail for a Waiver of 16 California Code of Regulations Section 1713(d) to Permit Expanded Use of Automated Prescription Dispensing Machines
- g. Request from Sharps Healthcare and Scripps Health San Diego for a Waiver of California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, Sections 4128 et seq.
- h. Request from K. Scott Guess, Pharm.D., RPh, to Present his Proposal for Safe, Effective Dispensing of Controlled Substances

II. Compounding Matters

- a. Update on Implementation of New California Sterile Compounding Laws: Senate Bill 294 (Emmerson) and Assembly Bill 1045 (Quirk-Silva) – *(Note: Currently Pending Proposed Regulation Changes to 16 CCR Sections 1735 et seq. and 1751 et seq. Will Not be Discussed at This Meeting)*
- b. Discussion Regarding Extension of Board Approval of Accreditation Agencies for Sterile Injectable Compounding Pharmacies until July 1, 2014:
 1. Accreditation Commission for Health Care, Inc. (ACHC) Currently Approved Through February 2014
 2. Community Health Accreditation Program (CHAP) Currently Approved Through February 2014
 3. Pharmacy Compounding Accreditation Board (PCAB) Currently Approved Through February 2014

4. American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP)
Currently Approved Through February 2014.
- c. Discussion on Compounding Provisions Enacted by H.R. 3204, the Federal Drug Quality and Security Act
- d. Recalls of Compounded Drugs Throughout the United States

III. Meeting Dates For 2014

V. Public Comment on Items Not on the Agenda/Agenda Items For Future Meetings

Note: The committee 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)]

ADJOURN

4:00 p.m.