



**California State Board of Pharmacy**

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
GOVERNOR EDMUND G. BROWN JR.

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**Notice of Meeting and Agenda  
Public Board Meeting  
April 21-22, 2015**

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**DATE:** April 21-22, 2015

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

**WEBCAST:** [http://www.pharmacy.ca.gov/meetings/current\\_webcasts.shtml](http://www.pharmacy.ca.gov/meetings/current_webcasts.shtml)  
(Link to Webcast will be available earliest at 10:00 a.m. on April 21, 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](http://www.pharmacy.ca.gov).

Meeting materials should be available on the board's Web site at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) by April 17, 2015.

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## Agenda

Call to Order

10:30 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. **Approval of January 27-28, 2015 and March 9, 2015 Meeting Minutes**

IV. **Recognition and Celebration of Pharmacists Licensed for 50 Years in California**

V. **Communication and Public Education Committee**

*The board will be presented a summary of the committee's efforts for review and action, as necessary.*

- a. Future Board Forum on Elements of Quality Patient Consultation and Instruction of Patient Consultation by California's Schools of Pharmacy
- b. Presentation on Approaches to Use of Social Media by the Board of Pharmacy
- c. Translation Surveys Conducted by Board Inspectors
- d. Proposed Regulation to Require Pharmacies to Develop Written Procedures for Providing Written Language Translations
- e. Redesign of the Board's Website in 2015
- f. Board's Newsletter ("Script")
- g. Media Activity
- h. Public Outreach Activities Conducted by the Board

VI. **Prescription Medication Abuse Subcommittee**

*The board will be presented a summary of the committee's efforts for review and action, as necessary.*

- a. CURES, California's Prescription Drug Monitoring Program
- b. Pharmacist's Corresponding Responsibility in Regards to Dispensing Prescription Medications
- c. Discussion and Possible Action to Require Continuing Education on Pain Management
- d. University of California, San Diego's Webinar and Other Activities Related to Prescription Drug Abuse
- e. Report on the Proposal to Prepare a Draft Report on the Subcommittee's Findings and Recommendations on the Opioid Epidemic
- f. Summary of Activities to Promote Prescription Drug Abuse Awareness Month, ACR 26 (Levine)
- g. Review of Articles Regarding Prescription Drug Abuse
- h. Public Outreach to Address Prescription Drug Abuse

VII. **Lunch**

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

VIII. **Enforcement and Compounding Committee**

*The board will be presented a summary of the committee's efforts for review and action, as necessary.*

**Part 1: Enforcement Matters**

- a. EMD Serono's Program to Permit Patients to Authenticate Medication via Checking a Serial Number on a Medication Container Against a Manufacturer's Data Base
- b. MatchRx's Model to Enable the Transfer of Prescription Medication in Short Supply Between Two Pharmacies
- c. University of California, San Diego's Request for Waiver of title 16, California Code of Regulations, Section 1706.5, to Permit a Pilot Program to Allow Patients to Access Medications from an Automated Storage Device Not Immediately Adjacent to a Pharmacy
- d. Drug Enforcement Administration's Regulations for the Take Back of Prescription Medication and Development of Regulations for Pharmacies and Reverse Distributors Who Take Back Prescription Medication from Patients
- e. Evaluation of title 16 California Code of Regulations, section 1744 Regarding Required Warning Labels on Prescription Container Labels
- f. Proposed Regulation for Pharmacies Aimed at Reducing Losses of Controlled Substances
- g. Carefusion's Drug Diversion Deterrent Reports Available with Its Automation Storage Cabinets
- h. Discussion of Proposed Regulations for Third-Party Logistics Providers; Proposed Amendments to 16 California Code of Regulations Sections 1780 -1786
- i. CURES Data on the Impact of the Federal Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II
- j. Discussion Regarding the Adoption of e-Prescribing
- k. Opportunity to Provide Comments on U.S. Food and Drug Administration Draft Guidance Documents
  1. Draft Guidance: For Entities Considering Whether to Register As Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act
  2. Draft Guidance for Industry: Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities
  3. Draft Guidance for Industry: Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application (BLA)
  4. Draft Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act
  5. Draft Memorandum of Understanding Between A State and the U.S. Food and Drug Administration Addressing Certain Distributions of Compounded Human Drug Products
- k. Enforcement Statistics
- l. Remaining Meeting Dates for 2015

**Part 2: Compounding Matters**

- a. Summary of the Report of Sterile Compounding Pharmacy Inspections Conducted

**IX. Discussion and Possible Action to Make Changes in Response to Comments 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**

**X. Board Member Officer Elections**

**XI. Closed Session**

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

Perform the Evaluation of the Executive Officer and to Consider Action Regarding the Compensation of the Executive Officer.

3. Pursuant to Government Code Section 11126(e) the Board Will Convene in Closed Session to Discuss Pending Litigation.

- *Berjikian, Vicken and Enna, v. Franchise Tax Board, Dept. of Motor Vehicles, Board of Pharmacy* (U.S. District Court, Central District of California; Case No. 213-cv-06301-DDP-JCG)
- *Nguyen, Tram Ngoc-Celia and Le, Hung Tuan v. California State Board of Pharmacy* (Orange County Superior Court, Case No. 30-2014-00751907-CU-NP-CJC)

## **XII. Reconvene Open Session**

### **Adjournment for the Day**

**Wednesday, April 22, 2015**

**Call to Order and Establishment of Quorum**

**8:30 a.m.**

## **XIII. Closed Session**

In the event the board does not complete the closed session items on the first day of the board meeting, it will reconvene to discuss any items listed in Agenda Item X above.

**Reconvene Open Session**

**9:00 a.m.**

## **XIV. Organizational Development Committee**

- a. Future Board Meeting Dates for 2015
- b. Budget Update/Report
  1. Budget Report for 2014/2015
  2. Fund Condition Report
  3. Discussion on Holding a Special One-Day Board Meeting
  4. Board Member Reimbursement and Mail Vote Information
- c. Personnel Update

## **XV. Review and Discussion of Office of the Attorney General Legal Opinion Relating to SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) Relating to Substance Abusing Healing Arts Licensees**

## **XVI. Licensing Committee**

*The board will be presented a summary of the committee's efforts for review and action, as necessary.*

- a. Status of Implementation of Recently Enacted Legislation Impacting Licensing Programs for the Board
- b. Department of Education's Acceptance of Additional Tests for Fulfillment of General Educational Development Certificate Equivalency
- c. Status of Board Sponsored Legislation to Change the Documentation Requirements for Pharmacy Practice Experience, (SB 590, Stone)
- d. NAPLEX Exam Content Outline
- e. Competency Committee Report
- f. Statistics Relating to Pharmacy Technician Application Denials

- g. Common Deficiencies for Pharmacy Technician Applications
- h. Common Deficiencies for Pharmacy Applications
- i. Licensing Statistics
- j. Future Committee Meeting Dates for 2015

**XVII. Lunch**

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

**XVIII. SB 493 Implementation Committee**

*The board will be presented a summary of the committee's efforts for review and action, as necessary.*

- a. Regulations Detailing Licensure Requirements for Advanced Practice Pharmacists
- b. Regulations to Implement the Protocol For Pharmacists Who Furnish Naloxone
- c. Review and Discussion About the Factsheet on Naloxone
  - 1. Emergency Rulemaking
  - 2. Formal Rulemaking
- d. Discussion and Identification of Materials Where Board Guidance Is Envisioned:
  - 1. Development of Proposed Requirements For Pharmacists Who Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices
  - 2. Development of Proposed Requirements For Pharmacists For Prescription Medications not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US
  - 3. Requirements For Pharmacists For Ordering and Interpreting Tests to Monitor and Manage Drug Therapies

**XIX. Legislation and Regulation Committee**

*Note: The Legislation and Regulation Committee will meet prior to the start of the board meeting on April 21, 2015.*

**Part 1: Legislation Report**

- a. Board-Sponsored Legislation
  - 1. AB 1073 (Ting) Prescription Drug Labels
  - 2. SB 590 (Stone) Intern Licenses
  - 3. SB 619 (Morrell) Outsourcing Facilities: Licensure
- b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction
  - 1. AB 45 (Mullin) Household Hazardous Waste
  - 2. AB 333 (Melendez) Healing Arts, Continuing Education
  - 3. AB 463 (Chiu) Pharmaceutical Cost Transparency Act of 2015
  - 4. AB 486 (Bonilla) Centralized Hospital Packaging Pharmacies: Medication Labels
  - 5. AB 611 (Dahle) Controlled Substances: Prescriptions: Reporting
  - 6. AB 623 (Wood) Abuse-Deterrent Opioid Analgesic Drug Products
  - 7. AB 684 (Bonilla) Pharmacy
  - 8. AB 750 (Low) Business and Professions: Licenses
  - 9. AB 788 (Chu) Prescriptions
  - 10. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program

11. AB 1351 (Eggman) Deferred Entry of Judgment: Pretrial Diversion
  12. AB 1352 (Eggman) Deferred Entry of Judgment: Withdrawal of Plea
  13. SB 396 (Hill) Health and Care Facilities, Outpatient Settings and Surgical Clinics
  14. SB 423 (Bates) Pharmaceutical Waste: Over-the-Counter Drugs and Nutritional Supplements
  15. SB 587 (Stone) Pharmacy Compounding
  16. SB 671 (Hill) Biological Products
- c. Legislation Impacting Board Operations
1. AB 85 (Wilk) Open Meetings
  2. AB 410 (Obernalte) Documents Submitted to Legislative Committees
  3. AB 507 (Olsen) Department of Consumer Affairs: BreEZe System: Annual Report
  4. AB 797 (Steinorth) Regulations: Effective Dates and Legislative Review
  5. AB 1060 (Bonilla) Professions and Vocations: Licensure
- d. Other Pieces of Legislation Impacting the Practice of Pharmacy, the Board’s Jurisdiction or Board Operations
- Examples include measures involving the regulation of prescription drugs and/or controlled substances; application, licensing and renewal requirements for board licensees; authorities granted to board licensees; measures adding, modify or removing requirements that impact the board and its operations or that of the Department of Consumer Affairs

**Part 2: Regulation Report**

- a. Newly Effective Regulations: Update on Title 16 California Code of Regulations Section 1707.5 Regarding Patient-Centered Labeling Requirements
- b. Currently Noticed: Proposal to Amend Title 16 California Code of Regulations Sections 1784 and 1751 to Update Self-Assessment Forms 17M-13, 17M-14, 17M-26 and 17M-35
- c. For Board Action: Proposal to Amend Title 16 California Code of Regulations Section 1793.5 Pharmacy Technician Application
- d. Board Approved – Awaiting Notice:
  1. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements
  2. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1732.05, 1732.2, and 1732.5 Related to Continuing Education
  3. Proposal to Amend Title 16 California Code of Regulations Section 1703 Related to “Section 100” Regulatory Actions
  4. Proposal to Add Title 16 California Code of Regulations Section 1746.1 Related to the Protocol for Pharmacists Who Furnish Self-Administered Hormonal Contraceptives
  5. Proposal to Add Title 16 California Code of Regulations Section 1746.2 Related to the Protocol for Pharmacists Who Furnish Nicotine Replacement Products

**XX. Executive Officer’s Report**

- a. Medical Board Update
- b. General Board Update
- c. Duty Inspector Update

**Important Notice to the Public:**

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*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](mailto: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](http://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)).*

## IN-PERSON APPLICATION INSTRUCTIONS FOR PDMP/CURES

In order to help pharmacists obtain access to the PDMP/CURES system by the January 1, 2016 deadline, pharmacists can submit their applications in person with CA Board of Pharmacy staff as follows:

### 1) Pre-register online

Complete the registration application at <http://www.oag.ca.gov/cures-pdmp>.

**Note:** If you do not have a Drug Enforcement Administration Registration number, please enter "CA1234567" when it is requested.

### 2) Print the registration confirmation

Upon completion of the online registration, immediately print your registration confirmation. This confirmation page is the user application form which must be submitted in person to Board of Pharmacy staff with copies of all supporting documents (see below).

**Note:** The signature and date by the applicant on the confirmation page must be witnessed by Board of Pharmacy staff.

#### Supporting documents required:

- a. Copy of pharmacist license;
- b. Copy of government issued photo identification (such as driver's license or passport);
- c. If you possess one, a copy of the Drug Enforcement Administration Registration

### 3) Reply to E-mail Verification within 72 hours

After completing the online pre-registration, applicants will receive an email requesting verification of their email address. Applicants must complete the email verification within 72 hours of receipt of the notice.

**Note:** Be sure to check your junk email box if you do not receive the verification email.

### 4) Applicants must submit the application package in person to Board of Pharmacy staff

**Note:** A confirmation will be emailed to you by the Department of Justice once your registration is processed.

#### **Application Package Checklist**

- Application Form/Registration Confirmation Page
- Copy of pharmacist license
- Copy of government-issued identification
- Copy of Drug Enforcement Administration registration, (if applicable)

#### **Additional Instruction**

- Email verification (within 72 hours)