



**California State Board of Pharmacy**

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[www.pharmacy.ca.gov](http://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

July 30-31, 2013

Contact Person: Laura Hendricks  
(916) 574-7918

This board 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.

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DATE: July 30-31, 2013

PLACE: Department of Consumer Affairs  
First Floor Hearing Room  
1625 North Market Boulevard  
Sacramento, Ca 95834

WEBCAST: <http://www.dca.ca.gov/stream/audiocast.aspx>  
(Link to Webcast will not be available until 12:00 a.m. on July 30, 2013, and until 8:30 a.m. on July 31, 2013)

*NOTE: Pharmacists and pharmacy technicians who attend in person the July 31<sup>th</sup> session of the Board Meeting may be awarded 6 hours of CE, in accordance with the Board's CE policy. Sign in and sign out that day are required for the CE credit.*

For verification of the meeting, call (916) 574-7918 or (916) 574-7900 or access the Board's Web site at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

Discussion and action may be taken on any item on the agenda. The board may discuss agenda items in any order on each day, unless noticed as "time certain." An opportunity for public comment is provided for each open agenda item and at the end of each committee's report. All times are approximate and subject to change. Time limitations for discussion and comment will be determined by the President.

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# Agenda

## **Tuesday , July 30, 2013**

*Note: The Legislation and Regulation Committee Meeting will be held immediately before the board meeting from 8:30 a.m. – 11:30 a.m. in the First Floor Hearing Room.*

### **Call to Order**

**12:30 p.m.**

#### **I. GENERAL ANNOUNCEMENTS**

#### **II. APPROVAL OF THE FULL BOARD MEETING MINUTES OF APRIL 24-25, 2013**

#### **III. BOARD MEETING DATES FOR 2013 AND 2014**

#### **IV. PUBLIC COMMENT 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)]*

#### **V. RECOGNITION AND CELEBRATION OF PHARMACISTS LICENSED FOR 50 YEARS IN CALIFORNIA**

#### **VI. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT**

Report of the Organizational Development Committee held July 27, 2013

##### a. Budget Update/Report

1. Budget Report for 2012/13
2. Budget Report for 2013/214
3. Fund Condition Report
4. Update on BreZE, DCA's New Computer System
5. Reimbursement to Board Members

##### b. Personnel Update

#### **VII. EXECUTIVE OFFICER REPORT**

##### a. Update on Activities of the Medical Board of California – Ms. Kirchmeyer

##### b. Items from the Executive Officer

1. Drug Diversion
2. Controlled Substance Utilization Review and Evaluation System (“CURES”)
3. Drug Shortages
4. New Configuration and name for the State and Consumer Services Agency

**VIII. REGULATION HEARING**

**TIME CERTAIN: 1:00 p.m.**

Regulation Hearing Regarding a Proposal to Amend Title 16 California Code of Regulations Section 1749 Regarding the Board's Fee Schedule

**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 1749 REGARDING THE BOARD'S FEE SCHEDULE**

**X. LICENSING COMMITTEE REPORT**

Report of the Licensing Committee Meeting held May 28, 2013

- a. Licensing Committee Meeting Dates for the Remainder of 2013
- b. Discussion and Possible Action to Initiate a Rulemaking to Require or Standardize the Reporting of Convictions and Discipline at the Time of Renewal for Pharmacists, Pharmacy Technicians and Designated Representatives, Proposed Amendment to 16 California Code of Regulations Section 1702 and Proposed Addition of 16 California Code of Regulations Sections 1702.1 and 1702.2
- c. Discussion and Possible Action to Initiate a Rulemaking to Require Site Licenses to Report Disciplinary Actions by Other Entities at Time of Renewal, Proposed Addition of 16 California Code of Regulations Section 1702.5
- d. Discussion and Possible Action on Request from Det Norske Veritas to Renew Board of Pharmacy Approval as an Accreditation Agency for Licensed Sterile Injectable Compounding Pharmacies
- e. Update on the Evaluation of the Pharmacy Technician Certification Board (PTCB) Exam and the Examination for the Certification of Pharmacy Technician (ExCPT) Exam.
- f. Review of the Board of Pharmacy's Emergency Response Plan
- g. Competency Committee Report
- h. Fourth Quarterly Report on the Committee's Goals for 2012/13
- i. Licensing Statistics for July 2012 – June 2013 and Three Year Comparison Data

**XI. DISCUSSION AND POSSIBLE ACTION TO ADOPT AS A BOARD PRECEDENTIAL DECISION UNDER GOVERNMENT CODE SECTION 11425.60 - PACIFICA PHARMACY; TRAN, THANG - BOARD OF PHARMACY CASE 3802**

**XII. PETITIONS FOR REINSTATEMENT**

**TIME CERTAIN: 3:00 p.m.**

- a. Johnny Lang, RPH 50571
- b. Erin Maloney, RPH 46916

**XIII. PETITION FOR MODIFICATION OF PENALTY**

Warren Kingdon, RPH 28125

**XIV. CLOSED SESSION**

- a. Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters and the Petitions for Reinstatement and Modification of Penalty

- b. Pursuant to Government Code Section 11126(e), the Board Will Meet In Closed Session to Receive Advice from Counsel on Litigation (*Andrew M. Sternberg v. California State Board of Pharmacy, et al.*, Los Angeles County Superior Court, Case No. BS138984.)
- c. Pursuant to Government Code Section 11126(e), the Board Will Meet in Closed Session to Receive Advice from Counsel on Litigation (*Vicken O. Berjikian and Enna Berjikian v. Franchise Tax Board, Board of Pharmacy, et al.*, Los Angeles County Superior Court, Case No. BC514589.)
- d. Pursuant to Government Code Section 11126(a)(1) the Board Will Convene in Closed Session Evaluate the Performance of the Board’s Executive Officer

**ADJOURNMENT FOR THE DAY**

**WEDNESDAY, JULY 31, 2013**

**XV. CLOSED SESSION**

**8:00 a.m.**

- a. Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters
- b. Pursuant to Government Code Section 11126(e), the Board Will Meet In Closed Session to Receive Advice from Counsel on Litigation (*Andrew M. Sternberg v. California State Board of Pharmacy, et al.*, Los Angeles County Superior Court, Case No. BS138984.)
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**RESUMPTION OF OPEN SESSION**

**8:30 a.m.**

**XVI. E-PEDIGREE COMMITTEE REPORT**

Report of the E-Pedigree Committee Meeting Held June 24, 2013

- a. Next Meetings Scheduled of the E-Pedigree Committee
- b. Live Presentation by TechN’Arts Regarding the Operation and Technical Parameters of Turkey’s Serialized Tracking System for Prescription Medication
- c. Discussion on Comments Submitted by the Board of Pharmacy in Response to Federal Legislation in April 2013
- d. Update on the Status of Proposed Regulations to Implement Serialized Numeric Identifiers, Grandfathering and Manufacturer Reporting of How the 50 Percent Threshold of Serialized Products on January 1, 2015 (Proposals to Add Title 16, California Code of Regulations, Sections 1747 and 1747.1)
- e. Discussion on GS1 Healthcare US’s Implementation Guideline *Applying GS1 Standards to US Pharmaceutical Supply Chain Business Processes, Release 1.0*
- f. Update on Proposed Regulation on Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163.3

- g. Discussion Concerning Possible Regulation Requirements on the Certification Process to Comply with California's E-Pedigree Law
- h. Discussion and Possible Action to Initiate a Rulemaking on the Use of Drop Shipments in an E-Pedigree System Pursuant to California Business and Professions Code Section 4163.1

## **XVII. ENFORCEMENT AND COMPOUNDING COMMITTEE REPORT**

Report of the Enforcement Committee Meeting held June 4, 2013

### **a. Enforcement Matters:**

1. Enforcement and Compounding Committee Meeting Dates for the Remainder of 2013
2. Request from Sharp Healthcare on a Waiver of 16 California Code of Regulations Section 1713(d) to Permit Expanded Use of Automated Prescription Dispensing Machines
3. Request from California Society of Health-System Pharmacists to Discuss Drug Shortages
4. Update on the Implementation of Penal Code Section 11105 – Requirements to Provide Criminal Offender Record Information to an Applicant or Licensee When the Information Is Used as the Basis for a Licensing Decision
5. Discussion and Possible Action on the National Association of Boards of Pharmacy Report on Sales of Fake and Substandard Medications
6. Discussion on NABP's Announcement of the Development of Standards for the .*pharmacy* Generic Top Level Domain for Internet Pharmacy Web Sites
7. Fourth Quarterly Report on the Committee's Goals for 2012/13
8. Enforcement Statistics for July 2012- June 2013 and Three Year Comparison

### **b. Compounding Matters**

1. Discussion on Pending California Legislation on Sterile Compounding:  
Senate Bill 294 (Emmerson) and Assembly Bill 1045 (Quirk-Silva)
2. Discussion of Recent Federal Reports and Articles Relating to Compounding Pharmacies
  - a. *FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities?*
  - b. Office of Inspector General Memorandum Report: *High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them*, OEI-01-013-00150
  - c. ASHP Guidelines on Outsourcing Sterile Compounding Services
  - d. FDA's Guidance for FDA Staff and Industry – Marketed Unapproved Drugs, Compliance Policy Guide
  - e. U.S. Senate Health, Education, Labor and Pensions Committee Report: The Case for Clarifying FDA Authority: Large-Scale Drug Compounding and the Ongoing Risk to Public Health
  - f. Miscellaneous Articles
3. Proposed Federal Legislation on Compounding Introduced by the U.S. Senate (S. 959)
4. Discussion Regarding USP's 797 Standards and the Regulation Requirements of the Board of Pharmacy
5. Discussion Regarding "Batches"
6. Discussion of the Board of Pharmacy's Questions and Answers Document on Compounding

7. Outcomes of Recent Sterile Compounding Inspections
8. Recalls of Compounded Drugs Throughout the United States

## **XVIII. LUNCH**

A Lunch Break will be Taken at Some Point During the Day's Meeting

## **XIX. LEGISLATION AND REGULATION COMMITTEE REPORT**

Report of the Legislation and Regulation Committee Meeting Held July 30, 2013

### a. LEGISLATION REPORT

#### Board-Sponsored Legislation for 2013

1. SB 294 (Emmerson) – Compounded Sterile Drug Products
2. SB 821 (Senate Committee on Business, Professions and Economic Development) Omnibus
3. SB 305 (Price) Healing Arts: Boards
4. Other Board-Approved Proposals for 2013-2014

#### Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

5. AB 1045 (Quirk-Silva) Nonresident Sterile Compounding Pharmacies
6. AB 1136 (Levine) Pharmacists: Drug Disclosures (Warning Label)
7. SB 204 (Corbett) Prescription Drugs: Labeling (Translations)
8. SB 205 (Corbett) Prescription Drugs: Labeling (Font Size)
9. SB 306 (Torres) Automated Dispensing Machines
10. SB 598 (Hill) Biosimilars
11. SB 669 (Huff) Emergency Medical Care: Epinephrine Auto-Injectors
12. SB 809 (DeSaulnier) CURES

#### Enforcement

13. SB 62 (Price) Coroners: Reporting Requirements: Prescription Drug Use

#### Licensing

14. AB 258 (Chavez) State Agencies: Veterans
15. AB 512 (Rendon) Healing Arts Licensure Exemption
16. AB 1057 (Medina) Professions and Vocations: License: Military Experience

#### Pharmacy / Other

17. SB 146 (Lara) Workers' Compensation: Medical Treatment: Billing
18. SB 445 (Price) Pharmacies: Advertising: Controlled Substances
19. Other Legislation Impacting the Practice of Pharmacy that Staff Becomes Aware of After this Notice is Posted

### b. REGULATION REPORT

#### Recently Noticed Regulations

1. Fee Schedule – Proposal to Amend Title 16 Section 1746
2. Combined Rulemaking - Proposal to Amend Sections 1745 and 1769, and to add Section 1762 to Title 16 California Code of Regulations Related to Partial Fill of Schedule II Prescriptions, Criteria for Rehabilitation, and to Define Unprofessional Conduct

Board Approved - Undergoing Administrative Review (Information Only)

3. Proposed Addition of a new Article 5.5, and new Sections 1747 and 1747.1 Related to Pedigree Requirements

Board Approved – Awaiting Notice

4. Combined Rulemaking – Proposal to Amend Title 16 Sections 1732.2, 1732.5, 1732.05 related to Continuing Education

Update on Self-Assessments

5. Section 100 Rulemaking to Revise Self-Assessment Forms

**XX. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT**

Report of the Communication and Public Education Committee Meeting Held July 16, 2013

- a. Discussion Regarding Recent Public Outreach Activities to Address Prescription Drug Abuse
  1. Public Continuing Education Training Sessions Provided by the California State Board of Pharmacy and the Los Angeles Field Division of the Drug Enforcement Administration: June 27 and July 25, 2013
  2. Four Public Continuing Education Training Sessions by the California State Board of Pharmacy and Federal Drug Enforcement Administration scheduled for August 2013
- b. Discussion Regarding the Implementation of 16 California Code of Regulations Section 1707.6 Notice to Consumers Poster, Video Display Format of Notice to Consumers Poster and Notice of Interpreter Availability
- c. Discussion Regarding Requests from California Pharmacies to Use Their Own Notice of Interpreter Availability Posters in Place of the Board's Notice Pursuant to the Waiver in 16 California Code of Regulations Section 1707.6(e)
- d. Review and Possible Approval of Updated Emergency Contraception Fact Sheet as Required by 16 California Code Regulations Section 1746
- e. Assessment of California's Patient-Centered Labels Regulation Requirements, Due by December 2013 as Required by California Code of Regulations Section 1707.5(e)
- f. Discussion and Possible Action on Committee's Goals for 2012/2017 to Fulfill the Board's Strategic Plan
- g. Update on *The Script*
- h. Review of the Board's New Consumer Education Materials
- i. Report on Media Activity During the Fourth Quarter of FY 2012/13
- j. Public Outreach Activities Conducted by the Board During the Fourth Quarter of FY 2012/13

**XXI. CLOSED SESSION**

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- d. Pursuant to Government Code Section 11126(a)(1) the Board Will Convene in Closed Session Evaluate the Performance of the Board's Executive Officer

**ADJOURNMENT**

**5:00 p.m.**