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

# Notice of Meeting and Agenda Public Board Meeting July 27-29, 2015

DATE: July 27-29, 2015

PLACE: Department of Consumer Affairs

1625 North Market Blvd. 1<sup>st</sup> Floor Hearing Room Sacramento, CA 95834

WEBCAST: <a href="http://www.pharmacy.ca.gov/meetings/current-webcasts.shtml">http://www.pharmacy.ca.gov/meetings/current-webcasts.shtml</a>

(Link to Webcast will be available earliest at 9:00 a.m. on July 28, 2015. Please see

additional notices below regarding availability.)

NOTE: Pharmacists and pharmacy technicians who attend in person on **July 28**<sup>th</sup> or **July 29**<sup>th</sup> 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.

NOTE: No CE will be awarded on July 27<sup>th</sup>.

For questions or verification of the meeting, call Laura Hendricks at (916) 574-7918 or access the board's Web site at <a href="www.pharmacy.ca.gov">www.pharmacy.ca.gov</a>.

Meeting materials may be available on the board's Web site at <a href="www.pharmacy.ca.gov">www.pharmacy.ca.gov</a> by July 24, 2015.

# **Agenda**

# Monday, July 27, 2015

Call to Order 12:30 p.m.

# I. <u>Call to Order, Establishment of Quorum and General Announcements</u>

# II. Closed Session

- a. Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters.
- Pursuant to Government Code section 11126(e), the board will convene in closed session to discuss pending litigation *Berjikian v FTB*, *Board of Pharmacy*, *and DMV* (State and Federal actions);
   US District Court, Central District of CA, LA Division, Case No Case 2:13-cv-06301-DDP-JCG;
   LA County Superior Court, Case No. BC514589).
- c. Pursuant to Government Code section 11126(e), the board will convene in closed session to discuss pending litigation 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)

# III. Reconvene Open Session

Adjourn for the Day

### **Tuesday, July 28, 2015**

#### Call to Order and Establishment of Quorum

8:30 a.m.

# **IV. 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 II above.

### **Reconvene Open Session**

(Earliest) 9:00 a.m.

# V. 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)]

#### VI. Approval of June 3-4, 2015 Meeting Minutes

#### VII. Recognition and Celebration of Pharmacists Licensed for 50 Years in California

# VIII. <u>Organizational Development Committee</u>

- a. Future Board Meeting Dates
- b. New Committee Assignments
- c. National Association of Boards of Pharmacy 112<sup>th</sup> Annual Meeting

- d. Budget Update/Report
  - 1. Budget Report for 2014/2015
  - 2. Budget Report for 2015/2016
  - 3. Fund Condition Report
  - 4. Fee Audit Update
  - 5. Board Member Reimbursement and Mail Vote Information
- e. Personnel Update

#### IX. Licensing Committee

- a. Consideration of Request to Recognize Chapman University School of Pharmacy Pursuant to Title 16, California Code of Regulations, Section 1719 for Purposes of Issuing Intern Licenses
- b. Competency Committee Report
- c. Licensing Statistics

# X. <u>Enforcement and Compounding Committee</u>

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

#### **Part 1: Enforcement Matters**

- a. Presentation by the Drug Enforcement Administration on its Requirements for the Take Back of Prescription Medications
- Discussion Regarding the 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
- c. Presentation by the Healthcare Distribution Management Association on Deadlines and Distributor and Pharmacy Readiness to Meet Requirements for Exchange of Transaction Information, Transaction Histories and Transaction Statements as Required by the Federal Drug Supply Chain Security Act of 2013
- d. Proposed Regulation for Pharmacies Aimed at Reducing Losses of Controlled Substances
- e. Data Reporting Rates of E-Prescribing in the US and California
- f. Proposed Regulations for Third-Party Logistics Providers; Proposed Amendments to Title 16 California Code of Regulations Sections 1780-1786
- g. Update on CURES 2.0
- h. Enforcement Statistics
- i. Remaining Meeting Dates for 2015

# **Part 2: Compounding Matters**

- a. Discussion of Critical IQ's Article on "Quality Standards for Large Scale Sterile Compounding Facilities"
- b. Update of SB 619 (Morrell) Licensure of Outsourcing Facilities
- c. Review and Discussion of the U.S. Food and Drug Administration's Draft Guidance Document on Guidance for Industry; Compounding Animal Drugs from Bulk Drug Substances
- d. Sterile Compounding Licensure Statistics

# XI. <u>Lunch</u>

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

# XII. <u>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</u>

#### XIII. SB 493 Implementation Committee

- a. Consideration of Proposed Regulations Detailing Licensure Requirements for Advanced Practice Pharmacists
- b. Update on Pending Regulations
  - 1. Naloxone
  - 2. Self-Administered Hormonal Contraceptives
  - 3. Nicotine Replacement Products
  - 4. Immunizations
  - 5. Travel Medicine

### XIV. SB 1441 Uniform Standards Implementation Committee

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

- a. Review of SB 1441 Uniform Standards Relating to Substance Abusing Healing Arts Licensees
- b. Consideration of Proposed Changes to the Board's Disciplinary Guidelines and Title 16 California Code of Regulations Section 1760

### Adjournment for the Day

#### Wednesday, July 29, 2015

#### Call to Order and Establishment of Quorum

9:00 a.m.

### XV. Executive Officer's Report

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

# XVI. Discussion with the Deans of the California Schools of Pharmacy and the Accreditation Council for Pharmacy Education on the Training of Students in California Pharmacy Schools on Patient Consultation

# XVII. Communication and Public Education

- a. Update on the Redesign of the Board of Pharmacy's Web Site
- b. Update on the Script
- c. Board Prescription Drug Abuse Prevention Public Service Announcement Video Receives Excellence in State Government Award
- d. Update on Outreach Activities
- e. Update on Media Activity

# XVIII. Lunch

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

#### XIX. Legislation and Regulation Committee

# 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 486 (Bonilla) Centralized Hospital Packaging Pharmacies: Medication Labels
  - 3. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program
  - 4. SB 671 (Hill) Biological Products
- c. Legislation Impacting Board Operations
  - 1. AB 12 (Cooley) State Government: Administrative Regulations: Review
  - 2. AB 85 (Wilk) Open Meetings
  - 3. AB 1060 (Bonilla) Professions and Vocations: Licensure
  - 4. AB 1351 (Eggman) Deferred Entry of Judgment: Pretrial Diversion
  - 5. AB 1352 (Eggman) Deferred Entry of Judgment: Withdrawal of Plea
- 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. Board Approved Awaiting Administrative Review
  - 1. Proposal to Amend Title 16 California Code of Regulations (CCR) 1793.5 Pharmacy Technician Application
- b. Board Approved Recently Noticed
  - 1. Recommendation to Amend Title 16 CCR Sections 1784 and 1751 to Update Self-Assessment Forms 17M-13, 17M-14, and 17M-26
  - Discussion and Possible Action to Make Changes in Response to Comments or to Adopt or Amend Proposed Text at Title 16 CCR Section 1746.2 Nicotine Replacement Products
  - 3. Discussion and Possible Action to Make Changes in Response to Comments or to Adopt or Amend Proposed Text at Title 16 CCR Section 1746.3 Related to Naloxone Hydrochloride
  - 4. Discussion and Possible Action to Make Changes in Response to Comments or to Adopt or Amend Proposed Text at Title 16 CCR Section 1746.1 Related to Self-Administered Hormonal Contraception
- c. Board Approved Awaiting Notice
  - 1. Combined Rulemaking Proposal to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements
  - 2. Combined Rulemaking Proposal to Amend Title 16 CCR Sections 1732.05, 1732.2, and 1732.5 Related to Continuing Education
  - 3. Proposal to Amend Title 16 CCR Section 1703 Related to "Section 100" Regulatory Actions
  - 4. Proposal to Amend Title 16 CCR Section 1707.5(d) Related to Written Language Translations
  - 5. Proposal to Add Title 16 CCR Section 1730 Related to Advanced Practice Pharmacist

- 6. Proposal to Add Title 16 CCR Section 1746.4 Related to Immunizations
- 7. Proposal to Add Title 16 CCR Section 1746.5 Related to Travel Medications
- 8. Proposal to Amend Title 16 CCR Section 1744 Related to Drug Warnings

#### XX. Adjournment

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

#### **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. 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)).