



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

NOTICE OF MEETING AND AGENDA

Public Board Meeting

July 17 -18, 2012

**Contact Person: Virginia Herold
(916) 574-7911**

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 Richard Hultgren at (916) 574-7934, by emailing richard.hultgren@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.

DATE: July 17-18, 2012

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

WEBCAST: <http://www.dca.ca.gov/stream/audiocast.aspx>

(Link to Webcast will not be available until 10:30 a.m. on July 17, 2012, and until 10 a.m. on July 18, 2012)

NOTE: Pharmacists and pharmacy technicians who attend in person the July 17th 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) 574-7934 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 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.

Note: The Communication and Public Education Committee will hold its quarterly public meeting immediately before this Board Meeting at 9:30 in the same meeting location. Please see the separate committee agenda, which follows the board meeting agenda below.

Agenda

Call to Order

10:30 a.m.

I. General Announcements

II. Approval of the Full Board Meeting Minutes of May 1 and 2, 2012

III. 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)]

IV. RECOGNITION AND CELEBRATION OF PHARMACISTS LICENSED FOR 50 YEARS IN CALIFORNIA

V. SUMMARY OF THE SUNSET REVIEW ISSUES IDENTIFIED BY THE SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT THAT WERE ADDRESSED BY THE BOARD DURING ITS MARCH HEARING

VI. LICENSING COMMITTEE REPORT

There was no meeting of the Licensing Committee in the past quarter.

- a. Implementation of Self Query Reports from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank for All Applications for Initial Licensure in California
- b. Competency Committee Report
- c. Reporting of Quarterly Data for Future Strategic Plan Reports on Committee Goals
- d. Fourth Quarterly Report on the Committee’s Goals for 2011/12

VII. LEGISLATION AND REGULATION COMMITTEE REPORT

Summary of the Meeting Held June 25, 2012

PART I – REGULATIONS

a. Approved

1. Add Title 16 Section 1727.2 – Requirements for Pharmacist Interns – To Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB) **Effective July 18, 2012**
2. Amend Title 16 Section 1728 – Requirements for Pharmacist Examination - Amend to Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB) **Effective July 18, 2012**

b. Discussion and Possible Action – Board Approved Regulations Previously Noticed

1. Proposed Amendments to Title 16, California Code of Regulations Section 1735.1 - 1735.3 and 1751.2 Related to Compounding Drug Products (*45-day comment period: March 9 – April 23, 2012*)
2. Proposed Amendments to Title 16, Section 1746 -- Emergency Contraception Protocol (*45-day comment period: January 6 – February 20, 2012*)

c. Board Approved Regulations – Awaiting Formal Public Notice

1. Proposed Addition of Section 1762 – Additional Grounds for Unprofessional Conduct
2. Proposed Addition of Section 1769 – Addition of Application Review to Criteria for Rehabilitation
3. Proposed Amendments to Section 1745 – Partial Filling of Schedule II Controlled Substance Prescriptions
4. Proposed Addition of Section 1751.9 – Standards for Agencies that Accredite Sterile Injectable Compounding Pharmacies
5. Proposed Amendments to Section 1732.2 – Board Accredited Continuing Education
6. Proposed Amendments to Section 1732.5 – Specification of Continuing Education Credit in Specific Content Areas
7. Proposed Amendment of Section 1732.05 to Update Accreditation Agencies for Continuing Education

d. Under Development

1. Proposed Amendments to Section 1780 – Update the USP Standards Reference Manual (Minimum Standards for Drug Wholesalers) [referred to subcommittee]
2. Proposed Amendments to Section 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer [referred to Licensing Committee]

e. Discussion and Possible Action to Initiate a Rulemaking to Amend California Code of Regulations, Title 16, Section 1760 -- Disciplinary Guidelines, and to Add a New Section Regarding Implementation of Uniform Standards for Substance Abusing Licensees

PART II – LEGISLATION

a. Board-Sponsored Legislation for 2012

SB 1575 (Senate Committee on Business, Professions and Economic Development)
Omnibus Proposals to Amend Section 4209 and to Add Section 4300.1

b. Regulation of Dangerous Drugs and Devices

1. **AB 389** (Mitchell) Bleeding Disorders: Blood Clotting Products
2. **AB 1442** (Wieckowski) Common Carriers to Transport Pharmaceutical Waste
3. **AB 2348** (Mitchell) Registered Nurses: Dispensing Oral Contraception in Clinics
4. **SB 419** (Simitian) Solid Waste: Home Generated Sharps
5. **SB 616** (DeSaulnier) CURES Program
6. **SB 1301** (Hernandez) Prescription Drugs: 90-Day Supply
7. **SB 1329** (Simitian) Prescription Drugs: Collection and Distribution Program

c. Sunset Review and Legislative Oversight

SB 1237 (Price) Sunset Extension to 2017

d. Licensing and Pharmacy Operations

1. **AB 377** (Solario) Hospital Central Fill Pharmacies
2. **AB 1588** (Atkins) Reservist Licensees: Fees and Continuing Education
3. **AB 1896** (Chesbro) Tribal Health Programs: Health Care Practitioners
4. **AB 1904** (Block) Military Spouses: Temporary License
5. **AB 2570** (Hill) Licensees: Settlement Agreements
6. **SB 1095** (Rubio) Pharmacy: Surgical Clinics
7. **SB 1481** (Negrete McLeod) Clinical Laboratories: Community Pharmacies

d. Other

1. **AB 2369** (Valadao) Prisoners: Pharmacy Services
2. **SB 1185** (Price) Centralized Intelligence Partnership Act (DCA)

e. Additional Legislation Impacting the Board or Its Regulatory Jurisdiction

PART III – LEGISLATION AND REGULATION COMMITTEE

Fourth Quarterly Report on the Committee’s Goals for 2011/12

- VIII. FOR INFORMATION: Presentation on a Proposed Amendment to the Alameda County Ordinance Code by Adding Chapter 6.53, Sections 6.53.010 through 6.53.120 to Require Any Person Who Produces a Drug Offered for Sale in Alameda County to Participate in an Approved Drug Stewardship Program for the Collection and Disposal of Unwanted Drugs from Residential Sources; Provide for Implementation, Enforcement, Fees, and Penalties; and Making Environmental Findings**

ADJOURNMENT FOR THE DAY

Wednesday, July 18, 2012

IX. CLOSED SESSION

8:00 a.m.

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

Call to Order -- RESUMPTION OF THE OPEN SESSION

10:00 a.m.

X. EXECUTIVE OFFICER’S REPORT

- a. **Presentation by Linda Whitney, Executive Director, Medical Board of California on Joint Projects of the Medical Board and the Board of Pharmacy**

Including:

- Update on the Pain Summit, a Board Co-Sponsored Conference with the Medical Board of California Scheduled for Late in 2012; Work on Securing the Continuation of CURES**
- b. **Update on the Proposal to Convene a One-Day Automation Technology Summit to Display Technology in Use or Proposed for Use in Pharmacies, Hospitals and Skilled Nursing Facilities in Conjunction with the October Board Meeting**

XI. ENFORCEMENT COMMITTEE REPORT

Discussion and Possible Action Items From the Meeting Held June 12, 2012

- a. Presentation and Discussion on the Use of the Pharmacist Assessment for Remediation Evaluation (PARE) Examination as an Optional Enforcement Tool to Assess Pharmacist Practice Deficiencies**

Discussion on the Implementation of California's Electronic Pedigree Requirements for Prescription Medication

- b. The Presence of Counterfeit Avastin and Altuzan Found in California Physician Offices and Clinics**
- c. Dysfunction in California's Supply of Prescription Medication Discovered During Board of Pharmacy Investigations**
- d. Board of Pharmacy's Letters to Federal Representatives and Senators on Elements Needed in any Proposal for Federal Legislation**
- e. Colloquy from Senators Enzi and Harkin in Support of Retaining Protections in California Law in Future Federal Requirements for Tracking Prescription Medications Through Pharmaceutical Supply Chain**
- f. Presentations from Supply Chain Companies**
 - 1. Live Presentation to the Board by Robert Celeste, Director, Healthcare, GS1 US**
 - 2. Other Companies, Associations and Other Entities Wishing to Address the Board on E-Pedigree Issues**
 - 3. Summary of Other Presentations Made During the Enforcement Committee Meeting on Their Readiness to Meet California's Staggered E-Pedigree Implementation Schedule**
- g. Discussion Regarding Proposed Regulation Requirements Specifying a Unique Identification Number for Prescription Medication Pursuant to California's E-Pedigree Requirements**
- h. Discussion and Possible Action to Initiate a Rulemaking to Adopt Proposed Section 1747 to Title 16, California Code of Regulations -- Requirements Specifying a Unique Identification Number for Prescription Medication Pursuant to California's E-Pedigree Requirements**
- i. Discussion Regarding Proposed "Grandfathering" Provisions for Non-Pedigreed Dangerous Drugs Pursuant to Section 4163.2 of the Business and Professions Code**
- j. Discussion and Possible Action to Initiate a Rulemaking to Adopt Proposed Section 1747.1 to Title 16, California Code of Regulations – Establishing "Grandfathering" Provisions for Prescription Drugs in California Commerce After Activation of e-Pedigree Requirements**
- k. Discussion Concerning Elements for Inference as Provided by California Business and Professions Code Section 4163.3**
- l. Minutes of the Meeting Held June 12, 2012**

OTHER ENFORCEMENT ITEMS NOT DISCUSSED DURING THE ENFORCEMENT COMMITTEE MEETING:

- m. Board of Pharmacy's Letter to Federal Representatives and Senators on Proposed PDSA Amendments for Possible Inclusion in Pending 2012 Prescription Drug User Fee (Re-Authorization) Act
- n. Enforcement Statistics
- o. Fourth Quarterly Report on the Committee's Goals for 2011/12

XII. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT

The Communication and Public Education Committee Met on July 17, 2012, Immediately Before the Start of this Board Meeting

- a. Discussion on the Design of New Notice to Consumers Posters (as Required by Title 16 California Code of Regulations Section 1707.6)
- b. Discussion about the Video Display Format Option for Notice to Consumers (as Required by Title 16 California Code of Regulations Section 1707.6)
- c. Discussion on the Format for Notice of Interpreter Availability (as Required by Title 16 California Code of Regulations Section 1707.6)
- d. Discussion on Securing Consumer Comments on the Board's Regulation Requirements for Patient-Centered Labels and Translations for Limited English Speaking Individuals
- e. Update on an Assessment of the Board's Public Education Materials
- f. Update on *The Script*
- g. Public Outreach Activities Conducted by the Board
- h. Fourth Quarterly Report on the Committee's Goals for 2011/12

XIII. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

There was no meeting of the Organizational Development Committee in the past quarter.

- a. Budget Update/Report
 - 1. Budget Report for 2011/12
 - 2. Fund Condition Report
 - 3. Budget Report for 2012/13
 - 4. Update on BreZE, DCA's New Computer System
 - 5. Reimbursement to Board Members
- b. Update on the Recognition Program of Pharmacists Who Have Been Licensed 50 Years
- c. Personnel Update
- d. Fourth Quarterly Report on the Committee's Goals for 2011/12

XIV. CLOSED SESSION

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

Resumption of Open Session

XV. PETITION FOR EARLY TERMINATION OF PROBATION

Time Certain: 12:30 p.m.

- a. Shauna Weaver, RPH 49557
- b. Annette Patterson, RPH 42732
- c. Valerie Gaurano, RPH 38852

XVI. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on the Petitions for Early Termination of Probation and to Deliberate on Disciplinary Matters

ADJOURNMENT

5:30 p.m.