



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

Public Board Meeting

October 29 & 30, 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 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: October 29-30, 2013

PLACE: Sheraton Garden Grove
12221 Harbor Blvd.
Garden Grove, CA 92840

WEBCAST: <http://www.dca.ca.gov/stream/audiocast.aspx>
(Link to Webcast will not be available until 9:30a.m. on October 29, 2013, and until 10:00 a.m. on October 30, 2013)

NOTE: Pharmacists and pharmacy technicians who attend in person the October 29th 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.

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.

Agenda

Tuesday , October 29, 2013

Call to Order

9:30 a.m.

I. GENERAL ANNOUNCEMENTS

II. APPROVAL OF THE FULL BOARD MEETING MINUTES OF JULY 30-31, 2013

III. BOARD MEETING DATES FOR 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 September 10, 2013.

a. Budget Update/Report

1. Final Budget Report for 2012/13
2. Budget Report for 2013/24
3. Fund Condition Report
4. Update on BreZE, DCA's New Computer System
5. Reimbursement to Board Members

b. Personnel Update

c. Discussion and Possible Action on Recommendation for Board Policy to Delegate Decisions Regarding Requests for Extensions of Time to Submit Arguments to the Board in Cases Under the Administrative Procedure Act to the Board President

d. Discussion and Possible Action to Initiate a Rulemaking to Amend Title 16 California Code of Regulations to Delegate to the Executive Officer the Authority to Initiate a Rulemaking to Adopt "Changes Without Regulatory Effect" (Title 1 California Code of Regulations Section 100 Changes)

VII. EXECUTIVE OFFICER REPORT

- a. Updated on Activities of the Medical Board of California – Ms. Kirchmeyer
- b. Update on Federal Legislation Relating to Track-and-Trace
- c. Discussion on Implementation of SB 493 (Chapter 469, Statutes of 2013, Hernandez)
- d. Discussion on Implementation of SB 294 (Chapter 565, Statutes of 2013, Emmerson)

VIII. LICENSING COMMITTEE REPORT

The Licensing Committee did not meet this quarter

- a. Competency Committee Report
- b. First Quarterly Report on the Committee's Goals for 2013/14
- c. Licensing Statistics for July 2013 – September 2013
- d. Examination Statistics for the California Practice Standards and Jurisprudence Examination for Pharmacists and the North American Pharmacy Licensure Examination

IX. ENFORCEMENT COMMITTEE REPORT

A report on the Enforcement and Compounding Committee meeting on September 10, 2013

a. Enforcement Matters

1. Review of Walgreens' New Business Model for Pharmacies
2. Summary of Presentation From the California Product Stewardship Council on Take Back Programs for Prescription Medications in California
3. Summary of Request from Da Vita Rx for Discussion Regarding Prescription Drugs Dispensed to Renal Clinics for Administration to Patients
4. Review and Discussion of Federal Government Accountability Office Report on the Difficulties of Regulating Internet Pharmacies
5. Role of a Pharmacist's Corresponding Responsibility in the Dispensing of Controlled Substances
6. First Quarterly Report on the Committee's Goals 2013/14
7. Enforcement Statistics for July 2013 – September 2013

b. Compounding Matters

1. Update on California Legislation on Sterile Compounding: Senate Bill 294 (Chapter 565, Statutes of 2013, Emmerson) and Assembly Bill 1045 (Chapter 302, Statutes of 2013, Quirk-Silva)
2. Update on Proposed Federal Legislation on Compounding
3. Subcommittee Recommendations to Amend California's Compounding Regulations in Title 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq.
4. Discussion and Possible Action to Initiate a Rulemaking to Amend California's Compounding Regulations in Title 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq.
5. Recalls of Compounded Drugs Throughout the United States

c. Future Meeting Dates

X. LUNCH

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

XI. E-PEDIGREE COMMITTEE REPORT

Report of the E-Pedigree Committee Meeting Held September 26, 2013

- a. Discussion and Possible Action Regarding 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)
- b. Update on Proposed Regulation on Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163.3
- c. Discussion Concerning Possible Regulation Requirements on the Certification Process to Comply with California's E-Pedigree Law
- d. Update on the Status of Proposed Regulations for the Use of Drop Shipments in an E-Pedigree System Pursuant to California Business and Professions Code Section 4163.1
- e. Future Meeting Dates

XII. REGULATION HEARING

TIME CERTAIN: 4:00 p.m.

Regulation Hearing Regarding a Proposal to Add Title 16 California Code of Regulations Section 1747.2 Regarding Electronic Pedigree Requirements for Drop Shipments

XIII. 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 1747.2 REGARDING Electronic Pedigree Requirements for Drop Shipments

XIV. CLOSED SESSION

- 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(a)(1) the Board Will Convene in Closed Session to Evaluate the Performance of the Board's Executive Officer

ADJOURNMENT FOR THE DAY

WEDNESDAY, OCTOBER 30, 2013

XV. CLOSED SESSION

8:30 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(a)(1) the Board Will Convene in Closed Session to evaluate the Performance of the Board's Executive Officer

RESUMPTION OF OPEN SESSION

9:30 a.m.

XVI. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT

- a. Report of the Communication and Public Education Committee Meeting Held October 7, 2013
 1. Review and Discussion of the 42nd Annual Report of the Research Advisory Panel of California
 2. Discussion on Requests from California Pharmacies for Exemption from Title 16 California Code of Regulations Section 1707.6(e) to Use Alternate Notice of Interpreter Availability Posters
 3. Update on the Status of the Updated Emergency Contraception Fact Sheet, as Required by Title 16, California Code of Regulations Section 1707.5(e)
 4. Results of Assessment of California's Patient-Centered Labeling Requirements as Required by Title 16 California Code of Regulations Section 1707.5(e)
 5. Discussion and Possible Action to Initiate a Rulemaking to Amend Title 16 California Code of Regulations Section 1707.5
 6. Update on *The Script*
 7. Public Outreach Activities Conducted by the Board
 8. Update on the Development of Committee Goals for 2012-2017 to Fulfill the Board's Strategic Plan
- b. Report of Prescription Medication Abuse Subcommittee Held October 7, 2013
 1. Discussion on Proposed Mission Statement for the Subcommittee
 2. Review and Discussion of Statistics Documenting the Issue of Prescription Medication Abuse
 3. Discussion of Joint Efforts with the Medical Board of California to Address and Educate Licensees and the Public about Prescription Medication Abuse
 4. Discussion of the New CURES Program and Elements Needed in a Prescription Medication Monitoring Program for California
 5. Corresponding Responsibility of Pharmacists and the Board's Recent Precedential Decision in this Area
 6. Discussion on the Board of Pharmacy's Previously Published Health Notes on Pain, A Monograph for Pharmacy Practitioners
 7. Discussion about Public Education Efforts for Prescription Drug Abuse and Community Outreach
 8. Discussion about Public Outreach to Address Prescription Drug Abuse
 9. Future Meeting Dates

XVII. LEGISLATION AND REGULATION COMMITTEE REPORT

The Legislation and Regulation Committee did not meet this quarter.

a. LEGISLATION REPORT

1. Legislation Acted Upon in 2013

A. Board-Sponsored Legislation

- SB 294 (Emmerson) Compounded Sterile Drug Products , Chapter 565, Statutes of 2013

- SB 821 (Senate Omnibus) Chapter 473, Statutes of 2013
- SB 305 (Lieu) Healing Arts Boards: Records, Chapter 516, Statutes of 2013

B. Chaptered Legislation

- AB 512 (Rendon) Healing Arts Licensure Exemption, Chapter 111, Statutes of 2013
- AB 1045 (Quirk-Silva) Nonresident Sterile Compounding Pharmacies, Chapter 302, Statutes of 2013
- AB 1057 (Medina) Licenses: Military Service, Chapter 693, Statutes of 2013
- AB 1136 (Levine) Pharmacists: Drug Disclosures (Warning Labels), Chapter 304, Statutes of 2013
- SB 669 (Huff) Emergency Medical Care: Epinephrine Auto-Injectors, Chapter 725, Statutes of 2013
- SB 809 (DeSaulnier) CURES, Chapter 400, Statutes of 2013

C. Vetoed Legislation

- SB 205 (Corbett) Prescription Drugs: Labeling (Font Size)
- SB 598 (Hill) Biosimilars

2. Legislation for 2014

A. Status of Board-Sponsored Provisions

- Issuance of a Public Reprimand for Violations That Would Not Warrant License Denial or Issuance of a Probationary License
- Other Board-Approved Proposals for 2013-2014

B. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

- AB 467 (Stone) Prescription Drug Collection and Distribution Program
- SB 204 (Corbett) Prescription Drugs: Labeling (Translations)
- SB 306 (Torres) Automated Dispensing Machines
- SB 727 (Jackson) Medical waste: pharmaceutical product stewardship

3. Updates to Pharmacy Law

b. REGULATION REPORT

1. Recently Noticed Regulations

- #### A. Drop Shipment – Proposal to add Title 16 California Code of Regulations Section 1747.2

2. Board Approved - Undergoing Administrative Review (*Information Only*)

- #### B. Fee Schedule – Proposal to Amend Title 16 Section 1749
- #### C. Proposed Addition of a new Article 5.5, and new Sections 1747 and 1747.1 Related to Pedigree Requirements
- #### D. 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

3. Board Approved – Awaiting Notice

- #### E. Combined Rulemaking – Proposal to Amend Title 16 Sections 1732.2, 1732.5, 1732.05 Related to Continuing Education

F. Combined Rulemaking – Proposal to Amend Title 16 Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements

XVIII. LUNCH

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

XIX. PETITIONS FOR EARLY TERMINATION OF PROBATION

TIME CERTAIN: 1:00 p.m.

- a. Daryl Wolf, RPH 46273
- b. William Allen, RPH 54535

XX. PETITION FOR REINSTATEMENT

- a. Carol Zalez-Simon

XXI. 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 Early Termination of Probation
- b. 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.