



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

October 18 & 19, 2011

**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: October 18 & 19, 2011

PLACE: The Westgate Hotel
1055 Second Avenue
San Diego, CA 92101

WEBCAST: http://www.dca.ca.gov/publications/multimedia/webcast_current.shtml
(link to Webcast will not be available until 9:30 a.m. on October 18, 2011)

NOTE: Pharmacists and pharmacy technicians who attend in person the October 18th day 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.

Agenda items may be taken out of order to accommodate speakers and to maintain a quorum. The meeting may be cancelled without notice. 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. 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 18, 2011

Call to Order

9:30 a.m.

- I. **General Announcements**
- II. **Approval of the Full Board Meeting Minutes of July 26 & 27, 2011**
- III. **Approval of the Full Board Meeting Minutes of September 7, 2011**
- IV. **RECOGNITION AND CELEBRATION OF PHARMACISTS LICENSED FOR 50 YEARS IN CALIFORNIA**
- V. **LEGISLATION AND REGULATION COMMITTEE REPORT**

PART I – REGULATIONS

a. Approved by the Office of Administrative Law

- 1. Amend Title 16 Sections 1715, 1784, 1735.2, and 1751– Update of Self Assessment Forms for Pharmacies, Sterile Injectable Compounding Pharmacies, Hospitals and Wholesalers [45-day comment period: March 11 – April 25, 2011]
To take effect October 19, 2011
- 2. Amend Title 16 Section 1793.5 – Pharmacy Technician Application; Requirement for Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)
[45-day comment period: April 8 – May 23, 2011]
To take effect October 1, 2011

b. Board - Approved; Rulemaking File Being Prepared

- 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) *[45-day comment period: May 6-June 20, 2011]*
- 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) *[45-day comment period: May 6-June 20, 2011]*

c. Board - Approved; Undergoing Review by the Administration

- 1. Amend Title 16 CCR Section 1732.2 – Board Accredited Continuing Education
[45-day comment period: October 8-November 22, 2010; February 4-21, 2011]
- 2. Add Title 16 Section 1707.6 and to Amend Section 1707.2 Regarding Consumer Notices and Duty to Consult – Consumer Notice for Language Assistance Interpretive Services Provided in Pharmacies and the Ability to Request 12-Point Font on Prescription Drug Container Labels *[45-day comment period: May 27- July 11, 2011]*

d. Undergoing Initial 45-Day Comment Period

Amend 16 California Code of Regulations Section 1760, regarding the Board’s *Disciplinary Guidelines* and Integration of SB 1441 Standards for Substance Abuse Monitoring Programs
[45-day comment period: October 14 – November 28, 2011]

e. Board Approved – Under Development or Awaiting Notice (Update Only)

- 1. Proposed Amendments to § 1746 – Emergency Contraception Protocol
- 2. Proposed Amendments to § 1751.9 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

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

PART II – LEGISLATION

a. Board-Sponsored Legislation

SB 431 (Emmerson) Pharmacies: Regulation

- Sections 4104, 4105 and 4112 – Enforcement Enhancements

SB 943 (Senate Committee on Business, Professions & Economic Development) Omnibus

- Section 4200 – Pharmacist Examination

b. Legislation Impacting the Practice of Pharmacy or the Board’s Jurisdiction

1. Controlled Substances

- AB 507 (Hayashi) Pain Management

2. Reporting Requirements/Records

- AB 1280 (Hill) Ephedrine: Retail Sale
- SB 360 (DeSaulnier) Controlled Substance Utilization Review and Evaluation System
- SB 850 (Leno) Medical Records: Confidential Information

3. Healing Arts/DCA

- SB 541 (Price) Regulatory Boards: Expert Consultants

4. Other

- AB 389 (Mitchell) Bleeding Disorders: Blood Clotting Products
- AB 604 (Skinner) Needle Exchange Programs
- SB 41 (Yee) Hypodermic Needles and Syringes
- SB 514 (Simitian) Dextromethorphan: Sale to Minors Prohibited
- AB 1424 (Perea) Franchise Tax Board Holds

5. Additional Legislation Impacting the Board or Its Regulatory Jurisdiction

PART III – Legislation and Regulation Committee

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

VI. ENFORCEMENT COMMITTEE REPORT

There was no meeting of the Enforcement Committee this Quarter

- a. **Discussion about Compliance Monitoring for California Patient-Centered Requirements for Prescription Drug Containers as Authorized by Section 4076.5 of the California Business and Professions Code**
- b. **Board-Sponsored CE Scheduled for November 7 at Loma Linda University School of Pharmacy: a Joint Presentation with the Drug Enforcement Administration “Diversion of Controlled Substances, What Every Pharmacist Should Know to Prevent Diversion”**
- c. **Selection of Enforcement Committee Meeting Dates for 2012**
- d. **Review of Enforcement Statistics and Performance Standards of the Board**
- e. **First Quarterly Update of the Committee’s Strategic Performance Goals for 2010/11**

VII. Presentation by United Parcel Service Regarding Durable Medical Equipment Supplies Being Dispensed to Patients Located Outside California, and the Type of License Required

VIII. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT

Summary of the Committee Meeting Held September 26, 2011

- a. Discussion and Possible Action to Consider Recommendations to Initiate a Rulemaking to Amend 16 California Code of Regulations Section 1746, Emergency Contraception Protocol Regulation
- b. Discussion and Possible Action to Add to the Board's Web Site the Developed Translations of Directions for Use on Patient Medication Containers as Required by 16 California Code of Regulations Section 1707.5
- c. Discussion on Existing Requirements for Patient-Centered Prescription Drug Container Labels
- d. Discussion Regarding USP's Guidance for Patient Prescription Container Labels
- e. Discussion Regarding the Future Design of New Notice to Consumers Posters (Pending 16 California Code of Regulations Section 1707.6)
- f. Discussion Surrounding a Proposal to Develop a Standardized Form for Pharmacies to Use to Request Refills
- g. Update on an Assessment of the Board's Public Education Materials
- h. Update on *The Script*
- i. Public Outreach Activities Conducted by the Board
- k. Minutes of the September 26, 2011 Meeting
- l. First Quarterly Update of the Committee's Strategic Performance Goals for 2011/12

IX. PETITION FOR REINSTATEMENT OF LICENSE

1:00 p.m.

- a. William Packer – Petition for Reinstatement of Pharmacist License
- b. Stephanie (Boyle) Werner -- Petition for Reinstatement of Pharmacy Technician License

X. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on the Petitions for Reinstatement.

XI. Oral Arguments Regarding NonAdoption of the Proposed Decision in the Matter of the Accusation Against Andrew Mark Sternberg, RPH 32370

3:00 p.m.

XII. CLOSED SESSION

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

ADJOURNMENT FOR THE DAY

XIII. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

There was no meeting of the Organizational Development Committee this quarter

- a. **Budget Update/Report**
 - 1. **Budget Report for 2011/12**
 - 2. **Fund Condition Report**
 - 3. **Final Budget Report for 2010/11**
 - 4. **Update on BreEze, DCA's Plans for a New Computer System**
 - 5. **Reimbursement to Board Members**
- b. **Recognition Program of Pharmacists Who Have Been Licensed 50 Years**
- c. **Personnel Update**
- d. **First Quarterly Report on the Committee's Goals for 2011/12**

XIV. REPORT OF THE COMPOUNDING REGULATION SUBCOMMITTEE

- a. **Presentation to the Board by Rita Shane, PharmD, regarding Compounding Practices in Hospital Pharmacies**
- b. **Discussion and Possible Action Regarding Proposed Modifications to Interpretations Involving Implementation of the Compounding Regulations and Modifications to the Text of Title 16 California Code of Regulations §1735 – §1735.8, and §1751 -- §1751.8**
- c. **Summary of the Meeting Held August 22, 2011**

XV. LICENSING COMMITTEE REPORT

Report of the Meeting held September 26, 2011

- a. **Review of Requests and Possible Board Action to Become a Board of Pharmacy Approved Accreditation Agency for Licensed Sterile Injectable Compounding Pharmacies:**
 - 1. **Pharmacy Compounding Accreditation Board (PCAB)**
 - 2. **American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP)**
- b. **Discussion and Possible Action to Pursue a Statutory Amendment to Business and Professions Code Section 4209 to allow for the Reporting of Intern Hours to the Board of Pharmacy by Other State Boards of Pharmacy**
- c. **Discussion About a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas**
- d. **Discussion Concerning DCA's Focus on Continuing Competency**
- e. **Office of Statewide Health Planning and Development's Manpower Assessment and Survey of Licensees**
- f. **Competency Committee Report**
- g. **Licensing Statistics**
- h. **Minutes of the Meeting Held September 26, 2011**
- i. **First Quarterly Report on the Committee's Goals for 2011/12**

XVI. DISCUSSION AND POSSIBLE ACTION TO ADOPT THE 2012-2017 STRATEGIC PLAN UPDATE FOR THE BOARD OF PHARMACY

XVII. EXECUTIVE OFFICER'S REPORT

- a. Discussion and Possible Action Regarding the Board's 2011 Sunset Review Process and Report for Submission to the Senate Committee on Business, Professions and Economic Development
- b. General Report of the Executive Officer

XVIII. 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)]

ADJOURNMENT