



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

California State Board of Pharmacy

Department of Consumer Affairs

February 1 & 2, 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: February 1 & 2, 2011

PLACE: **Please Note Location:**
First Floor Hearing Room
400 R Street
Sacramento, CA 95816



NOTE: Pharmacists and pharmacy technicians who attend the full day of the Board Meeting on Tuesday, February 1, 2011, may be awarded 6 hours of CE, in accordance with the Board's CE policy.

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) 574-7900 or access the Board's Web Site at www.pharmacy.ca.gov

The board's strategic plan organizes board activities into five committees of the board. Correspondingly, the board meeting agenda is organized around the committee reports as updates to the board on each committee's recent activities. 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.

DISCUSSION AND ACTION MAY BE TAKEN ON ANY ITEM LISTED ON THE AGENDA.

Agenda

Tuesday, February 1, 2011

OPEN SESSION:

CALL TO ORDER

9:00 a.m.

I. General Announcements

II. Approval of the Full Board Meeting Minutes of October 20 & 21, 2010

III. Licensing Committee Report and Action

Report of the Meeting Held December 2, 2010

- a. **Review and Possible Approval of Accreditation Agencies for Licensed Sterile Injectable Compounding Pharmacies**
 1. Accreditation Commission for Health Care, Inc. (ACHC)
 2. Community Health Accreditation Program (CHAP)
- b. **Update on the Board's Psychometric Evaluation for the ExCPT and PTCB Examinations**
- c. **Summary of a Discussion About a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas**
- d. **Update on the Board's Efforts to Implement 16 California Code of Regulations Section 1702, Mandatory Submission of Fingerprints for Pharmacists**
- e. **Discussion of the California Hospital Association's Repopulation After Hospital Evacuation Guidelines and Checklist**
- f. **Competency Committee Report**
- g. **Update on the Conversion to a New Content Outline for the California Practice Standards and Jurisprudence Examination for Pharmacists in April 2011.**
- h. **Licensing Statistics**
- i. **Workload and Processing Statistics**
- j. **Summary of the Meeting Held December 2, 2010**
- k. **Second Quarterly Report on the Committee's Goals for 2010/11**

IV. Recognition of Pharmacists Licensed with the Board for 50 Years

V. Legislation and Regulation Committee

There has been no meeting of the Legislation and Regulation Committee in the Last Quarter

Part 1 – 2011 LEGISLATION

a. Board-Sponsored Legislation

1. **2011 Omnibus Proposal to Amend Section 4200 – Remove Obsolete Reference to Previous Pharmacist Licensing Requirement**

Discussion and Action May Be Taken on Any Item on the Agenda

2. Section 4362 – Entry Into Pharmacists Recovery Program
3. Sections 4040.5, 4081 and 4126.5 – Proposal Regarding Return of Medicine via Reverse Distributors
4. Sections 4104, 4105 and 4112 – Enforcement Enhancements

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

1. SB 41 (Yee) – Disposal of Hypodermic Needles and Syringes
2. AB 36 (Hill) – Retail Sale of Ephedrine; Transmission of Sale Data to NPLEx

Part 2 – REGULATIONS

a. For Board Discussion and Possible Action

1. Staff Recommendations for Modification of Existing Proposed Text and Request for Reconsideration of Prior Board Directive to Modify and Adopt Changes to Title 16 CCR Section 1732.2 – Board Accredited Continuing Education
2. Staff Recommendations for Modification of Existing Proposed Text and Request for Reconsideration of Prior Board Directive to Initiate a Rulemaking to Amend Title 16 Section 1793.5 – Amend Pharmacy Technician Application and Require Applicants to Submit a Self-Query From the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)
3. Discussion and Possible Action to Initiate a Rulemaking to Amend Title 16 Sections 1715, 1784, 1735.2, and 1751– Update of Self-Assessment Forms for Pharmacies, Sterile Injectable Compounding Pharmacies, Hospitals and Wholesalers
4. Discussion and Possible Action to Initiate a Rulemaking to Add Title 16 Section 1707.6 and to Amend Section 1702 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

b. Board Adopted Regulations – Approved by OAL and Now in Effect

Title 16 California Code of Regulations Section 1707.5 – Patient-Centered Labels for Prescription Drug Containers; Requirements (*Effective January 1, 2011*)

c. Board Approved – Awaiting Notice

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)
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)

d. Board Approved – Under Development (*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

Discussion and Action May Be Taken on Any Item on the Agenda

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 3: -- General

Second Quarterly Report on the Committee's Goals for 2010/11

VI. Organizational Development Committee

There was no meeting of the Organizational Development Committee this quarter

- a. **Presentation on the BreEZe Project and an Interim Solution to Allowing Online Renewals of Licenses by Debbie Balaam, Chief Information Officer, Department of Consumer Affairs**
- a. **Budget Update/Report**
 1. Budget Report for 2010/11
 2. Budget Constraints and Reductions to Reduce the State Budget Deficit
 3. Fund Condition Report
 4. Budget Change Proposals for the 2011/12 Budget
 5. Reimbursement to Board Members
 6. Board of Pharmacy Committee Membership Roster
- b. **Selection of a Board Meeting Date for One Day in April**
- c. **Future Development of a Strategic Plan for 2011/12 to 2016/17**
- d. **Recognition Program of Pharmacists Who Have Been Licensed 50 Years**
- e. **Transition Issues of Governor Brown's Administration**
- f. **Personnel Update**
- g. **Second Quarterly Report on the Committee's Goals for 2010/11**

VII. Public Comment for 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)]

Recess for the Day

Wednesday, February 2, 2011

CALL TO ORDER

8:30 a.m.

Discussion and Action May Be Taken on Any Item on the Agenda

VIII. Communication and Public Education Committee Report and Action

a. Report of the Meeting Held January 10, 2011

1. Update of the State's Emergency Contraception Protocol Regulation (16 California Code of Regulations Section 1746.) and Consumer Fact Sheet
2. Discussion of the 39th Annual Report of the Research Advisory Panel of California
3. Public Education Campaign for Patient-Centered Prescription Drug Container Labels
4. Development of Consumer Education Videos for the Board's Web Site
5. Update on Consumer Fact Sheet Series with California Schools of Pharmacy Interns
6. Discussion: Balancing Providing Important Consumer Information Versus Consumer Indifference to Reading Extensive Important Warnings in Public Education Materials
7. Suggestions from Pharmacists Planning Service on a Redesigned Notice to Consumers
8. Update on the Committee's Assessment of the Board's Public Education Materials
9. Public Education Materials Under Development and Proposed for the Future
10. Update on *The Script*
11. Update on Public Outreach Activities
12. Minutes of the January 10, 2011 Committee Meeting Summary

b. Second Quarterly Report on the Committee's Goals for 2010/11

IX. Report of the Director of the Department of Consumer Affairs

X. Enforcement Committee Report and Action

a. Report of the Meeting Held December 6, 2010

1. Discussion of Requests for Exemptions from 16 California Code of Regulations Section 1707.5 Label Requirements for Prescription Drug Containers as Authorized by Section 4076.5 (SB 1489, Negrete-McLeod, Chapter 653, Statutes of 2010) for Infusion Pharmacies and Skilled Nursing
2. Discussion Regarding Reporting Financial Settlements to the Board Under Sections 801-804 of the California Business and Professions Code
3. Update on the Board's Efforts to Implement Components of the Department of Consumer Affairs Consumer Protection Enforcement Initiative
4. Proposed Amendment to 16 California Code of Regulations Section 1762, Regarding Submission of Records to the Board
5. Discussion and Possible Action to Implement DCA's Recommendations of the Substance Abuse Coordination Committee, Pursuant to SB 1441, for the Pharmacists Recovery Program
6. Discussion Regarding Proposed Modifications to the Board's *Disciplinary Guidelines*
7. Questions and Answers on the Board's Implementation of 16 California Code of Regulations Sections 1735.-1735.8., Pharmacies That Compound, and Sections 1751-1751.8, Pharmacies That Compound Sterile Injectable Medications
8. Discussion Regarding Whether Patients Should Be Allowed to Take Their Multi-Dose Medications Home Upon Discharge From a Hospital
9. Provision of the First Ethics Course Pursuant to 16 California Code of Regulations Section 1773.5
9. Review and Discussion of Enforcement Statistics and Performance Standards of the Board
10. Summary of Meeting of December 6, 2010

Discussion and Action May Be Taken on Any Item on the Agenda

- b. Request from University Specialty Pharmacy to Renew its Board Waiver From 16 California Code of Regulations Section 1713(b) to Provide Synagis Prescription Medicine to Home Health Patients
- c. Discussion and Review of Proposed Written Guidance to Pharmacies and Prescribers on the Transmission and Receipt of Electronic Controlled Substances Prescriptions Pursuant to the Drug Enforcement Administration's Interim Final Rule
- d. Review and Comments on CalRecycle's Report to the Legislature on the Evaluation of Home-Generated Pharmaceutical Programs in California, Revised January 19, 2011
- e. Possible Board Comments to the DEA on Parameters for the Take Back of Unwanted Prescription Medication From Patients for Destruction
- f. Transition Issues Surrounding the New Vendor for California's CURES Program
- g. Second Quarterly Report on the Committee's Goals for 2010/11

XI. Executive Officer's Report

XII. Public Comment for Items Not on the Agenda/Agenda Items for Future Meetings

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XIII. Petition for Reinstatement

1:00 p.m.

Mary French

XIV. Closed Session

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

ADJOURNMENT