California State Board of Pharmacy
1625 North Market Blvd., N219, Sacramento, CA 95834
Phone (916) 574-7900
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www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING AND AGENDA
California State Board of Pharmacy
Department of Consumer Affairs
October 20 & 21, 2010

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 Carolyn Klein at (916) 574-7913, by emailing carolyn.klein@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 20 & 21, 2010

PLACE: UC San Diego
Health Sciences Education Center Auditorium
9500 Gilman Drive
La Jolla, CA 92093
(Map of campus, including parking areas for the public, follows at the end of the agenda)

Note: Pharmacists and pharmacy technicians who attend the full day of the board meeting on Wednesday, October 20, 2010, may be awarded 6 hours of CE, in accordance with the board's CE policy.

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.

Agenda

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

Wednesday, October 20, 2010

<u>OPEN SESSION:</u>

CALL TO ORDER **8:30 a.m.**

(Meeting Materials will be available on the board's website at www.pharmacy.ca.gov by October 14, 2010

I. General Announcements

II. Approval of the Full Board Meeting Minutes of July 28 and 29, 2010

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

IV. Executive Officer's Report

V. Organizational Development Committee Report and Action

a. Budget Update/Report
1. Final Budget Report for 2009/10
2. Budget Reports for 2010/11
3. Fund Condition Report
4. Budget Change Proposals for the 2010/11 Budget
5. Reimbursement to Board Members
6. BreEZe Progress
7. Board of Pharmacy Committee Membership Roster

b. Review and Comments on the Finalized Strategic Plan for 2010/11
c. Recognition Program of Pharmacists Who Have Been Licensed 50 Years
d. Personnel Update
e. First Quarterly Report on the Committee's Goals for 2010/11

VI. Communication and Public Education Committee Report and Action
There has been no meeting of the Communication and Public Education Committee During this Quarter

a. Review of Board of Pharmacy Video Developed by the Department of Consumer Affairs on Purchasing Drugs on the Internet
b. Update Report on *The Script*
c. Letter to Nonresident Pharmacies About Updates in California Pharmacy Law
d. Update on Public Outreach Activities
e. Progress Report on the Review of Consumer Education Materials
f. First Quarterly Report on Committee Goals for 2010/11

VII. Presentation from Manatt Health Solutions on Implementation Effects of Federal Healthcare Reform and Discussion by the Board

VIII. Recognition of Pharmacists Licensed with the Board for 50 Years **11:30 a.m.**

Lunch

IX. Licensing Committee Report **1:00 p.m.**
Report and Action from the October 5, 2010 Committee Meeting

a. Review and Action Regarding Review and Approval of Accreditation Agencies for Licensed Sterile Injectable Compounding Pharmacies
1. **Accreditation Commission for Health Care, Inc. (ACHC)**
2. **Community Health Accreditation Program (CHAP)**
3. **Joint Commission on Accreditation of Healthcare Organizations (JCAHO)**

b. **Proposal to Initiate Regulation Changes Regarding Application Requirements for Intern Pharmacists and Pharmacists to Require "Self-Query" Reports From the National Practitioner Data Bank -- Healthcare Integrity and Protection Data Bank (NPDB/HIPDB)**
c. **Proposal to Initiate Regulation Changes to Update the Pharmacy Technician Application and to Add an Application Requirement for Pharmacy Technicians to Require "Self-Query" Reports From the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB/HIPDB)**
d. **Request from PETNET Solutions for a Waiver of Security Requirements for Pharmacies to Permit Afterhours Maintenance of Equipment Without a Pharmacist Present**
e. **Discussion About a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas**
f. **Department of Consumer Affairs' Request that Health Care Boards Evaluate the Federal Healthcare Reform Act's Impact on Present and Future Licensees and their Licensing Acts**
g. **Competency Committee Report**
h. **Licensing Statistics 2010/11**
i. **Minutes of the October 5, 2010 Licensing Committee Meeting**
f. **First Quarterly Report on Committee Goals for 2010/11**

X. <u>Enforcement Committee Report</u>

Report and Action from the September 14, 2010 Enforcement Committee Meeting

a. **Report on a Request from Omnicare to Modify Existing Requirements in Pharmacy Regulations:**
   1. **16 California Code of Regulations Section 1745 Regarding Partial Filling of Schedule II Prescriptions**
   2. **16 California Code of Regulations Section 1793.7 Regarding Requirements of a Pharmacy Employing Pharmacy Technicians**
b. **Questions and Answers About 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**
c. **Report and Action on an Update on California's Drug "Take Back" Programs from Patients and Comments Submitted to CalRecycle Pursuant to Requirements in SB 966 (Simitian, Statutes of 2007)**
d. **Report on the Presentation by Michael Lewis, Diversion Program Manager, Federal Drug Enforcement Administration, Los Angeles**
   1. **Drug Enforcement Administration's Regulations for the E-Prescribing of Controlled Substances**
   2. **National Drug Take-Back Day, September 25, 2010**
   3. **Drug Diversion of Controlled Substances in California**
e. **Presentation by Supervising Inspector Judi Nurse on Thefts of Drugs from Pharmacies**
f. **Discussion and Possible Action to Implement Components of the Department of Consumer Affairs Consumer Protection Enforcement Initiative**
g. **Discussion and Possible Action to Implement DCA's Recommendations of the Substance Abuse Coordination Committee, Pursuant to SB 1441, for the Pharmacists Recovery Program**
h. **Discussion about GS1's October 2010 Forum in San Francisco on Serialization and Track and Trace in the Pharmaceutical Supply Chain**
i. **Minutes of the Meeting of September 14, 2010**

Other Enforcement Issues Not Discussed During the Meeting of September 14, 2010

j. **Discussion and Possible Action on DEA's Policy Statement on the Role of Authorized Agents in Communicating Controlled Substances Prescriptions to Pharmacies, 21 CFR Part 1306 (Docket No. DEA 339S)**

k. **Discussion and Possible Action Regarding an Ad Hoc Task Force to Develop Guidelines on Implementing the DEA Electronic Prescribing Requirements for Controlled Substances**
l. **Discussion Regarding the Availability of Two Ethics Courses to Comply with 16 CCR Section 1773.5**
m. **Discussion Regarding the Board's Compliance with Reporting Disciplinary Actions to the National** *Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB/HIPDB)*
n. **Enforcement Statistics 2010-11**
o. **First Quarterly Report on Committee Goals for 2010/11**

XI. <u>Public Comment for Items Not on the Agenda/Agenda Items for Future Meetings</u>
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 Day

Thursday, October 21, 2010

XII. Report of the Legislation and Regulation Committee 8:30 a.m.
The Legislation and Regulation Committee Will Meet October 19, 2010 – See Separate Agenda, Attached

<u>LEGISLATION REPORT</u>

a. Board-Sponsored Legislation
SB 1489 Omnibus Provisions (Senate Committee on Business, Professions and Economic Development) – Chapter 653, Statutes of 2010
- General Omnibus Provisions
- Provisions to update references to the Department of Public Health
- Provision to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)
- Provisions to update references to the Department of Health Care Services

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction
1. <u>Chaptered</u>
Board of Pharmacy
AB 2104 (Hayashi, Chapter 374, Statutes of 2010) – Board of Pharmacy: DCA Approval of Appointment of EO
Licensing / General / Other
A. AB 2699 (Bass, Chapter 270, Statutes of 2010) – Licensure exemption: State of Emergency
B. SB 1172 (Negrete McLeod, Chapter 517, Statutes of 2010) – Diversion Programs
C. AB 1414 (Hill, Chapter 76, Statutes of 2010) – Controlled Substances: Apomorphine: Unscheduled
Sunset Review and Legislative Oversight Proposals
A. AB 1659 (Huber) – State Government, Agency Repeals
B. AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection
Distribution of Needles and Syringes
AB 1701 (Chesbro) – Hypodermic Needles and Syringes

Other Legislation Impacting the Board's Jurisdiction

A. SB 294 (Negrete McLeod) – Professions and Vocations: Regulation
B. SB 700 (Negrete McLeod, Chapter 505, Statutes of 2010) – Healing Arts: Peer Review

2. Vetoed
   A. AB 1858 (Blumenfield) – Hypodermic Needles and Syringes: Exchange Services
   B. AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies
   C. AB 2747 (Lowenthal) – Prisoners: Pharmacy Services
   D. SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products
   E. SB 1029 (Yee) – Hypodermic Needles and Syringes
3. Legislation That Failed Passage
   A. SB 1390 (Corbett) – Patient-Centered Prescription Labels
   B. AB 1455 (Hill) – Ephedrine; retail sale
   C. SB 1071 (DeSaulnier) – CURES
   D. SB 1106 (Yee) – Prescribers Dispensing of Samples
   E. AB 2551 (Hernandez) – Pharmacy Technician: Scholarship & Loan Repayment Program
   F. AB 1310 (Hernandez) – Healing Arts Database

c. Legislation for Sponsorship During 2011-12 Session

1. Previously-Approved Board-Sponsored Legislation for 2011/2012
   A. Section 4362 – Entry Into Pharmacists Recovery Program (Omnibus provision
   B. Sections 4040.5, 4081 and 4126.5 – Proposal Regarding Return of Medicine to Reverse Distributors
   C. Sections 4104, 4105 and 4112 – Enforcement Enhancements
2. Legislation for Consideration During 2011-2012 Legislative Session
   A. Section 4200 – Pharmacist Examination (Omnibus provision)
   B. Section 4301.1 – To Allow the Board to Suspend the License of a Pharmacist or Pharmacist Intern for a Felony Conviction for a Crime of Unprofessional Conduct

Note: The Legislation and Regulation Committee Report Will Suspend Discussion at 10:15 a.m. to Permit the Presentation Below. Upon Completion of this Presentation, the Board will Resume with the Legislation and Regulation Committee Report.

XIII. Presentation by Libby Sagara and Patrick Robinson on E-Prescribing Efforts in California and the Work of the CaleRx Pharmacy Workgroup **10:15 a.m.**

REGULATION REPORT

Note: All section references are to Title 16 of the California Code of Regulations unless otherwise stated

a. Discussion and Possible Action to Initiate a Rulemaking to Adopt 1707.6. – Notices to Consumers, and Amend Section 1707.2 Notice to Consumers and Duty to Consult

b. Board Adopted Regulations – Approved by OAL
New Sections 1721 and 1723.1 in Division 17 of Title 16 of the Code of Regulations Regarding Dishonest Conduct During a Pharmacist's Licensure Exam/Confidentiality (effective 9/17/2010)

c. Board Adopted Regulations – Undergoing Administrative Review
Proposed Adoption of New Section 1707.5. in Title 16 of the California Code of Regulations – Requirements For Patient-Centered Prescription Drug Container Labels

d. Board Approved Regulations – Recently Noticed *(Update only)*
Proposed Amendments to § 1732.2. – Board Accredited Continuing Education

e. Proposed Regulations – Awaiting Board Approval to Notice

Proposed Amendments to §1728, §1728.2, and §1793.5., and Application Forms To Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB--HIPDB)

f. Regulations Under Development

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]

f. **Proposal to Initiate Rulemaking to Update 16 CCR Section 1715 Self Assessment of a Pharmacy by the Pharmacist-In-Charge and 16 CCR Section 1784 Self-Assessment by a Wholesaler by the Designated Representative-In-Charge**

g. Notification of Temporary Delay in Implementing New Section at Title 16 California Code of Regulations Section 1702—Fingerprint Submissions for Pharmacists

LEGISLATION AND REGULATION COMMITTEE REPORT AND ACTION

a. Request for Legislative and Regulation Changes Submitted by the Public or Staff
Stakeholders Are Encouraged to Submit Proposals in Writing to the Board Before or During the Meeting for Possible Consideration by the Board at a Future Meeting.

b. First Quarterly Report on Legislation/Regulations Committee Goals for 2010/11

XIV. 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)]

Lunch

XV. a. Petitions for Reinstatement **1:00 p.m.**

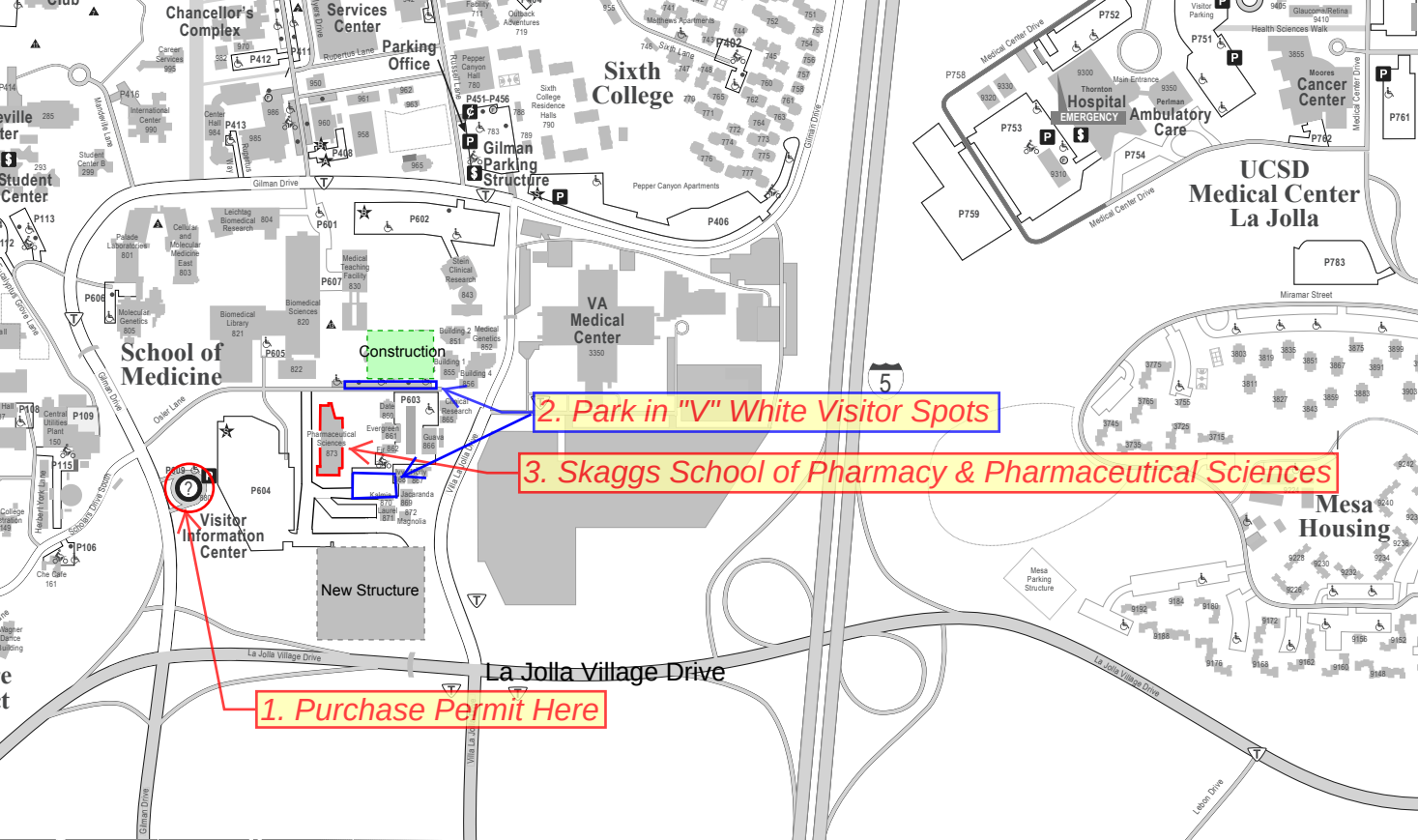
1. **Vee Quigley, RPH 24980**
2. **Raul Gutierrez, TCH 14159**

b. Petition for Early Termination of Probation
Robert Blackburn, RPH 30586

XVI. Closed Session **4:00 p.m.**

Pursuant to Government Code section 11126(c)(3), the Board will convene in closed session to deliberate on disciplinary decisions and the petitions for reinstatement.

ADJOURNMENT


Chancellor's Complex
Services Center
Parking Office
Sixth College
Gilman Parking Structure
Student Center
School of Medicine
Construction
VA Medical Center
Visitor Information Center
New Structure
La Jolla Village Drive
UCSD Medical Center La Jolla
Hospital
EMERGENCY
Ambulatory Care
Cancer Center
Mesa Housing
Gilman Drive
Medical Center Drive
Miramar Street
Lebon Drive
2. Park in "V" White Visitor Spots
3. Skaggs School of Pharmacy & Pharmaceutical Sciences
1. Purchase Permit Here

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NOTICE OF MEETING and AGENDA
LEGISLATION AND REGULATION COMMITTEE

Contact Person: Virginia Herold
(916) 574-7911

Date: **October 19, 2010**
Time: **2:00 p.m. – 5:00 p.m.**
Location: **UC San Diego**
Health Sciences Education Center Auditorium
9500 Gilman Drive
La Jolla, CA 92093
(Map of campus, including parking areas for the public, follows at the end of the agenda)

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Carolyn Klein at (916) 574-7913, at least five working days prior to the meeting.

Opportunities are provided to the public to address the committee on each open agenda item. Board members who are not on the committee may attend the meeting as observers. Action may be taken on any item on the agenda.

Agenda

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of continuing education (CE), in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order **2:00 p.m.**

A. LEGISLATION REPORT

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8. **Notification of Temporary Delay in Implementing New Section at Title 16 California Code of Regulation Section 1702 – Fingerprint Submissions for Pharmacists**

C. First Quarterly Report on Legislation / Regulations Committee Goals for 2010/2011

D. Request for Legislative and Regulation Changes Submitted by the Public or Staff
The committee will consider future legislative and regulatory proposals. Stakeholders are encouraged to submit these proposals in writing to the committee before or during the meeting.

E. Public Comment for Items Not On the Agenda*
*Note: The committee may not discuss or take action on any matter raised during the 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 and 11125.7(a).

Adjournment (Note: Adjournment time is approximate) 5:00 p.m.

Committee materials will be available on the board's Web site by October 13, 2010.