



California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LEGISLATION AND REGULATION COMMITTEE
MINUTES**

DATE: October 24, 2007

LOCATION: San Jose Doubletree Hotel
2050 Gateway Place
San Jose, CA 95110

**BOARD MEMBERS
PRESENT:**

Andrea Zinder, Public Member, Chairperson
D. Timothy Dazé, Esq., Public Member

**BOARD MEMBERS
NOT PRESENT:**

Kenneth H. Schell, PharmD
Robert Graul, RPh

STAFF PRESENT:

Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General
Spencer Walker, DCA Staff Counsel
Anne Sodergren, Legislation and Regulation Manager
Karen Abbe, Public and Licensee Education Analyst

**BOARD MEMBERS
IN AUDIENCE:**

Stanley Goldenberg, RPh
Robert Swart, PharmD
Ruth Conroy, PharmD

CALL TO ORDER

Chairperson Zinder called the meeting to order at 5:10 p.m. Ms. Zinder advised that only two members of the Legislation and Regulation Committee were present, so there would not be a quorum for voting.

REQUESTS FOR LEGISLATIVE AND REGULATORY PROPOSALS FOR 2008

- **Previously Discussed Proposed Legislation**

- a. Immunizations by Pharmacists Pursuant to Published Recommendations of the Advisory Committee on Immunization Practices – Amendment to B&PC Section 4052 and Addition of Section 4052.8

Chairperson Zinder noted that this agenda item was considered during the Licensing Committee section of the board meeting. The board took action to support the proposed legislation to allow pharmacists to administer immunizations.

- b. Furnishing Dangerous Drugs During an Emergency – B&PC Section 4062

Ms. Sodergren noted that this agenda item was considered during the Licensing Committee portion of the meeting. This is a proposed amendment to B&PC Section 4062. The board voted to support the legislative proposal.

- c. Temporary Permit for Damaged Pharmacies – B&PC Section 4110

Ms. Sodergren noted that this agenda item also was considered during the Licensing Committee portion of the meeting. This is a proposed amendment to B&PC Section 4110. The board voted to support the legislative proposal at the meeting.

- **Proposed Legislation**

Ms. Sodergren noted that omnibus changes were recommended for technical changes as well as refining the definitions of pharmacist-in-charge (PIC) and designated representative-in-charge (DRIC), and to clarify reporting requirements when a change of PIC or DRIC occurs. Proposed language of the recommended changes was provided in the meeting materials.

Chairperson Zinder noted that because the committee lacked a quorum, these items would be brought to the January 2008 Board Meeting for a vote without a committee recommendation for action.

Section 4022.5 – Designated Representative; Designated Representative-in-Charge

This section requires amendment to clarify the definition of “designated representative-in-charge” as well as the responsibilities of a licensee serving as such.

Section 4036.5 – Pharmacist-in-Charge

A new section is needed to refine the term “pharmacist-in-charge” as well as the responsibilities of a pharmacist serving as such.

Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board.

This section requires amendment to clarify when a pharmacist-in-charge or designated representative-in-charge must notify the board that he/she ceased to serve in such a capacity.

Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications

This section requires amendment to clarify the procedures to be followed by a pharmacy when identifying a pharmacist-in-charge as well as the procedures to notify the board when a change in pharmacist-in-charge has occurred. In addition, this section allows for the use of an interim pharmacist-in-charge, for a period not greater than 120 days, when a pharmacy is unable to identify a permanent new pharmacist-in-charge within 30 days as required.

Section 4160 – Wholesaler Licenses

This section requires amendment to clarify the procedures to be followed by a wholesaler when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked

This section requires amendment to clarify the procedures to be followed by a veterinary food-animal drug retailer when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action

This section requires amendment to specify that failure to meet notification requirements will constitute grounds for disciplinary action.

Section 4329 – Nonpharmacists; Prohibited Acts

This section requires amendment to include the prohibition of a nonpharmacist from acting as a supervisor or pharmacist-in-charge.

Section 4330 – Proprietors; Prohibited Acts

This section requires amendment to clarify that any pharmacy owner that subverts or tends to subvert the efforts of a pharmacist-in-charge is guilty of a misdemeanor.

Additional Proposals for the Omnibus Bill:

In addition to the changes listed above, all of the following proposals are also recommended omnibus provisions for 2008.

Section 4059.5 Who May order Dangerous Drugs or Devices, Exceptions.

A technical change to this section is necessary to clarify that a designated representative must sign for and receive delivery of drugs by a wholesaler.

Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy

This section requires amendment to clarify specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee

This section requires amendment to expand the board's authority to also include the board's ability to automatically inactivate a pharmacist license when a pharmacist who certifies completion of the required CE as part of a renewal fails to provide proof either as part of an audit or investigation.

Section 4362 – Entry Into Pharmacists Recovery Program

This section requires amendment to specify the administrative co-pay participants pay.

H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature

This section requires amendment to require that a clinic that dispenses Schedule III and Schedule IV controlled substances must report to CURES weekly.

Business and Professions Code section 4052 was recodified into four sections in 2006. The B&PC and H&SC sections below reference 4052 and require update. The proposed language was provided in the committee materials.

- Section 733 – Dispensing Prescription Drugs and Devices
- Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
- Section 4040 – Prescription; Content Requirements
- Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- Section 4060 – Controlled Substance – Prescription Required, Exceptions
- Section 4076 – Prescription Container – Requirements for Labeling
- Section 4111 – Restrictions on Prescriber Ownership
- Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC 11150 – Persons Authorized to Write or Issue a Prescription

- **Proposed Regulations**

- a. Graduate of Foreign Pharmacy Schools (technical change) – 16 CCR Section 1720.1

This regulation defines the certification requirement for graduates of foreign pharmacy schools. This section requires amendment to correct the name of the certification. Specifically, the correct language shall refer to the Foreign Pharmacy Graduate Examination Committee. This should be a “section 100 change.”

- b. Implementation of Electronic Monitoring of Schedule II Prescriptions – 16 CCR Section 1715.5

This regulation defines the information that must be reported to CURES. This section currently references schedule II controlled substances and requires updating to reflect the expansion of CURES reporting requirements to include Schedule III and IV controlled substances.

PUBLIC REQUESTS FOR FUTURE LEGISLATION AND REGULATORY PROPOSALS

Philip Swanger, Director of Government Affairs for the California Society of Health-System Pharmacists (CSHP) presented a letter to the board dated October 23, 2007. The letter referred to a Task Force that is developing recommendations for the minimum levels of education, training, and testing for licensure of pharmacy technicians. Information from this task force will be provided to the board in the future.

ADJOURNMENT

Ms. Zinder adjourned the meeting at 5:34 p.m.