



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

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LEGISLATION AND REGULATION COMMITTEE

October 25, 2006
Sheraton Gateway San Francisco Airport Hotel
600 Airport Blvd.
Burlingame, CA 94010

3:30 p.m., or upon recess of the Board Meeting

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 Candy Place at telephone number (916) 574-7912, 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.

Agenda

**Times are approximate and are subject to change*

A. Call to Order **3:30 p.m., or upon recess of the Board Meeting**

B. Requests for Legislation and Regulatory Proposals for 2006

1. Proposed Legislation

- a. Adulterated or Counterfeit Drugs or Dangerous Devices – B&PC section 4084
- b. Wholesaler: Bonding Requirements – B&PC sections 4162 and 4162.5
- c. Citation and Fine for Repository and Distribution Programs for Dangerous Drugs – B&PC sections 4314 and 4315
- d. Temporary License Fees for Wholesalers - B&PC section 4160(f) and 4161(k)
- e. Intern Pharmacist License - B&PC section 4208

2. Proposed Regulations

Section 100 Change

Self Assessment Forms – 16 CCR section 1715

C. Public Requests for Future Legislation and Regulatory Proposals

The public is encouraged to bring to the meeting copies of proposed language, an explanation of the problem, and how the proposed language would correct the problem.

Adjournment

Committee materials will be available on the board's Web site by October 20, 2006.



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STATE AND CONSUMERS AFFAIRS AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

ARNOLD SCHWARZENEGGER, GOVERNOR

October 18, 2006

To: Legislation and Regulation Committee

From: Staff

Subject: Proposed Legislation for 2007

All of the following provisions should be omnibus provisions for 2007. Copies of the exact language follow.

- **Sections 4162 and 4162.5**
Extend bonding requirements for wholesalers from 2011 to 2015 to match the extension given to implement the e-pedigree requirements, restoring provisions in SB 1476 chaptered out by SB 1475.
- **Sections 4314 and 4315**
Allow the board to cite and fine licensees for violations of Health and Safety Code sections 150200-150206 which authorize a county to establish by local ordinance, a repository and distribution program for specified unused medications from skilled nursing homes to medically indigent patients served by government-owned pharmacies.
- **Section 4084**
To allow board inspectors to embargo a prescription drug when the inspector has probable cause that it is misbranded.
- **Sections 4160(f) – 4161(k)**
Revise section to specify temporary license fee of \$550. Current law does not specify the temporary fee.
- **Section 4208**
Revise requirements for intern licenses to allow the board the discretion to extend the duration of an intern license.

**Board of Pharmacy
2007 Omnibus Bill Proposed Language**

B&P 4162 & 4162.5 Wholesaler License Surety Bond Requirements

Amend Sections 4162 and 4162.5 of the Business and Professions Code to read:

4162. (a) (1) An applicant, that is not a government owned and operated wholesaler, for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten million dollars (\$10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars (\$25,000).

(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, shall not be required to post a surety bond as provided in paragraph (1).

(4) For licensees subject to paragraph (2), or (3), the board may require a bond up to one hundred thousand dollars (\$100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall remain in effect only until January 1, ~~2011~~ 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2011~~ 2015, deletes or extends those dates.

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars (\$10,000,000) or less in which the surety bond shall be twenty-five thousand dollars (\$25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars (\$100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(4) A person to whom an approved new drug application or a biologics license application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application or biologics license application, and is licensed or applies for licensure as a nonresident wholesaler, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, ~~2014~~ 2015, unless a later enacted statute, that is enacted before January 1, ~~2014~~ 2015, deletes or extends those dates.

B&P 4314 & 4315 Cite and Fine, Letter of Admonishment

Amend Sections 4314 and 4315 of the Business and Professions Code, to read:

4314. (a) The board may issue citations containing fines and orders of abatement for any violation of Section 733 or for any violation of this chapter or regulations adopted pursuant to this chapter, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections, and Health and Safety Code Sections 150200 through 150206.

(b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.

(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.

(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with Section 733 or for failure to comply with this chapter or regulations adopted pursuant to this chapter, or Health and Safety Code Sections 150200 through 150206, directing the licensee to come into compliance.

(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.

(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.

(B) Prior to or at the office conference, the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.

(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(d) The letter of admonishment shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available a copy of the letter of admonishment and corrective action plan, if any, for at least three years from the date of issuance of the letter of admonishment.

(f) Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

B&P 4084 Adulterated or Counterfeit Drug or Dangerous Device

Amend Section 4084 of the Business and Professions Code, to read:

- B&P 4084.** (a) When a board inspector finds, or has probable cause to believe, that any dangerous drug or dangerous device is adulterated, misbranded, or counterfeit, the board inspector shall affix a tag or other marking to that dangerous drug or dangerous device. The board inspector shall give notice to the person that the dangerous drug or dangerous device bearing the tag or marking has been embargoed.
- (b) When a board inspector has found that an embargoed dangerous drug or dangerous device is not adulterated, misbranded, or counterfeit, a board inspector shall remove the tag or other marking.
- (c) A board inspector may secure a sample or specimen of a dangerous drug or dangerous device. If the board inspector obtains a sample prior to leaving the premises, the board inspector shall leave a receipt describing the sample.
- (d) For the purposes of this article "counterfeit" shall have the meaning defined in Section 109905 of the Health and Safety Code.
- (e) For the purposes of this article "adulterated" shall have the meaning defined in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.
- (f) For the purposes of this article "misbranded" shall have the meaning defined in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

B&P 4160 Wholesaler License Required

Amend Section 4160 & 4161 of the Business and Professions Code, to read:

- 4160.** (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.
- (b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.
- (c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.
- (d) The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.
- (e) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(f) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. ~~A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a wholesaler. A temporary license fee shall be \$550 or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the license holder or service by certified mail, return receipt requested at the license holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary license holder be deemed to have a vested property right or interest in the license.~~

(g) This section shall become operative on January 1, 2006.

4161 a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.

(b) A nonresident wholesaler shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. ~~A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a nonresident wholesaler. A temporary license fee shall be \$550 or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the license holder or service by certified mail, return receipt requested at the license holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary license holder be deemed to have a vested property right or interest in the license.~~

(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

B&P 4208 Intern Pharmacist License

Amend Section 4208 of the Business and Professions Code, to read:

4208. (a) At the discretion of the board, an intern pharmacist license may be issued for a period of:

(1) One to six years to a person who is currently enrolled in a school of pharmacy recognized by the board.

(2) Two years to a person who is a graduate of a school of pharmacy recognized by the board and who has applied to become licensed as a pharmacist in California.

(3) Two years to a foreign graduate who has met educational requirements described in paragraphs (1) and (2) of subdivision (a) of Section 4200.

(4) One year to a person who has failed the pharmacist licensure examination four times and has reenrolled in a school of pharmacy to satisfy the requirements of Section 4200.1.

(b) The board may issue an intern pharmacist license to an individual for the period of time specified in a decision of reinstatement adopted by the board.

(c) An intern pharmacist shall notify the board within 30 days of any change of address.

(d) An intern pharmacist whose license has been issued pursuant to paragraph (1) or paragraph (4) of subdivision (a) shall return his or her license, by registered mail, within 30 days of no longer being enrolled in a school of pharmacy. The intern pharmacist license will be canceled by the board. Notwithstanding subdivision (c), an intern pharmacist license may be reinstated if the student reenrolls in a school of pharmacy recognized by the board to fulfill the education requirements of paragraphs (1) to (4), inclusive, of subdivision (a) of Section 4200.

(e) Persons who has not completed experience requirements necessary to be eligible for the licensure examination may have their intern license extended for a period of up to two years at the discretion of the board.