



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

## Legislation and Regulation Committee

**Andrea Zinder, Board Member and Chair**  
**Tim Dazé, Board Member**  
**Robert Gaul, Board Member**  
**Ken Schell, PharmD, Board Member**

### LEGISLATION REPORT

#### 6. **BOARD SPONSORED LEGISLATION – FOR INFORMATION ONLY**

##### a. Omnibus Provisions

At the January 2007 Board Meeting, the board voted to include several of the following provisions as omnibus provisions for 2007. The language was recently incorporated into SB 1048, a committee bill containing omnibus provisions for several boards within the DCA.

- **Business and Professions Code Section 4068**  
Revise section to include schedule IV controlled substances to the CURES reporting requirements for hospitals.
- **Business and Professions Code Section 4084**  
To allow board inspectors to embargo a prescription drug when the inspector has probable cause that it is misbranded.
- **Business and Professions Code Section 4101**  
Amend B&P 4101 to change the term “exemptee” to “designated representative.”
- **Business and Professions Code Sections 4160(f) & 4161(k)**  
Revise section to specify temporary license fee of \$550. Current law does not specify the temporary fee.
- **Business and Professions Code 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.
- **Business and Professions Code Sections 4200 – 4200.2**  
Changes in the name of the exam to more accurately reflect the requirements described in B&P 4200.2. The new name will be the “California Practice Standards and Jurisprudence Examination for Pharmacists” (CPJE).
- **Business and Professions Code Section 4208**  
Revise requirements for intern licenses to allow the board discretion to extend the duration of an intern license.
- **Business and Professions Code 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.

A partial copy of the bill containing the board provisions is provided in attachment E-6.

## **7. LEGISLATION INTRODUCED IMPACTING THE PRACTICE OF PHARMACY OR THE BOARD'S JURISDICTION – FOR POSSIBLE BOARD ACTION**

### **7a. Active Bills with Positions Taken by the Board**

Provided in this packet are copies of bills impacting the practice of pharmacy or the board's jurisdiction. These bills were reviewed at the July 5, 2007 Legislation and Regulation Committee meeting. Below is a brief summary of each proposal as well as the board's current position. Bill analysis and copies of letters of support and opposition are also included in attachment E-7a. Copies of any amended bills and updated bill analysis will be provided at the board meeting.

#### 1. AB 110 (Laird) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects

This proposal would allow for the use of General Fund money to purchase needles for NEP programs.

Board Position: Support

#### 2. AB 249 (Eng) Licensees: Healing Arts: Settlement Agreements

This proposal would prevent all health care practitioners from including a "gag clause" in a civil action.

Board Position: Support

#### 3. AB 543 (Plescia) Ambulatory Surgical Centers: Licensure

This proposal would standardize the licensing requirements for ambulatory surgical centers.

Board Position: Support

#### 4. AB 1025 (Bass) Professions and Vocations: Licensure

This proposal would prohibit the board from denying an application for licensure or pursuing administrative action against a licensee for a conviction that has been set aside under certain circumstances.

Board Position: Oppose

#### 5. AB 1587 (De La Torre) Personal Information: Pharmacy

This bill was amended on July 16, 2007. This bill now is relating to recall elections for the City of Lynwood. As such neither a copy of the bill nor a bill analysis is provided in this packet.

#### 6. SB 472 (Corbett) Prescription Drugs: Labeling Requirements

This proposal would mandate that the board develop and adopt a patient-centered standardized prescription label.

Board Position: Support

7. SB 606 (Scott) Pharmaceutical Information: Clinical Trial Data

This proposal would require a pharmaceutical company that sells, delivers, offers for sale, or gives away pharmaceutical drugs within the state to make publicly available the results of every completed clinical trial, except a phase I trial or bioequivalence study, for that drug and an explanation of noncompletion for any clinical trial, except a phase I trial, that the company initiates or sponsors the initiation of, but does not complete.

Board Position: Support

8. SB 615 (Oropeza) Pharmacy Technicians: Scholarship and Loan Repayment Program

This proposal would establish a scholarship and loan repayment program for pharmacy technicians and require all pharmacy technicians as well as pharmacies to contribute \$10.00 at the time of renewal.

Board Position: Support

9. SB 963 (Ridley-Thomas) Regulatory Boards: Operations

This proposal would replace the sunset review process currently defined and create the Office Of Consumer Advocate within the DCA which will be responsible for among other things, oversight of board operations to ensure compliance with the board's public protection mandate.

Board Position: None

10. SB 966 (Simitian) Pharmaceutical Drug Disposal

This proposal would require retailers as defined to accept, then dispose of, returned unused medications.

Board Position: Oppose

**7b. Other Active Bills of Interest Impacting Board – For Information Only**

The bills listed below are included for information only as they may be of interest to the board or industry, but may not directly impact the practice of pharmacy or the board's jurisdiction. Copies of these bills are included in Attachment E-7b.

- a. AB 14 (Laird) Discrimination: Civil Rights Act of 2007
- b. AB 64 (Berg) Uniform Emergency Volunteer Health Practitioners Act
- c. AB 106 (Berg) Immunizations
- d. AB 329 (Nakanishi) Chronic Diseases: Telemedicine

## 7c. **Inactive Bills with Positions Taken by the Board**

### AB 501 (Swanson) Pharmaceutical Devices

This proposal would require a pharmaceutical manufacturer whose product is administered for home use through a prefilled syringe, prefilled pen needle, or other prefilled injection device to provide each person who uses the product with a container for the safe disposal of the used sharps from the syringe, pen needle, or other injection device. It would require the container to have a sticker with a specified warning and a toll free- telephone number that identifies safe disposal methods of the container.

### AB 851 (Brownley) Prescription Drugs: Informational Insert

This proposal would require the inclusion of a large font informational insert with all prescription medications that could adversely interact with alcohol and/or other prescribed or over-the-counter medications.

### AB 865 (Davis) State Agencies: Live Customer Service Agents

This proposal would require all state agencies to answer public telephone lines within 10 rings.

### AB 1276 (Karnette) Pharmacies: Prescription Containers: Labels

This proposal would require the prescription label to include the intended use for the medication if noted on the prescription by the prescriber.

### AB 1399 (Richardson) Pharmacies: Prescription Labels

This proposal would require a pharmacy to provide a prescription label that is readable by an assistive technology device if requested.

### AB 1436 (Hernandez) Nurse Practitioners: Scope of Practice

The bill would provide that a nurse practitioner is authorized to perform comprehensive health care services for which he or she is educationally prepared and competent to perform and to admit and discharge patients from health facilities in collaboration, as defined, with specified healing arts practitioners.

### SB 809 (Ashburn) Nurse Practitioners

This proposal would expand the scope of practice for nurse practitioners to include, among other things, the independent prescribing and dispensing of medications.

### SB 993 (Aanestad) Psychologists: Scope of Practice: Prescribing Drug

This proposal would expand the scope of practice for psychologists to include prescribing medications for specially trained and certified psychologists.

E-6

## Board Sponsored Legislation

- SB 1048 – Omnibus provisions

AMENDED IN ASSEMBLY JULY 12, 2007

AMENDED IN ASSEMBLY JUNE 27, 2007

**SENATE BILL**

**No. 1048**

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**Introduced by Committee on Business, Professions and Economic  
Development (Senators Ridley-Thomas (Chair), Aanestad,  
Corbett, Denham, Florez, Harman, Simitian, and Yee)**

March 22, 2007

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An act to amend Sections 337, 1701.1, 1725, 1750, 1750.1, 1750.2, 1750.3, 1750.4, 1751, 1752, 1752.1, 1752.2, 1752.5, 1752.6, 1753, 1753.1, 1754, 1756, 1757, 1770, 2177, 2225, 2313, 2335, 2397, 2416, 2497.5, 2570.7, 2717, 2732.05, 3057, 3527, 3634, 4068, 4084, 4101, 4160, 4161, 4162, 4162.5, 4200, 4200.1, 4200.2, 4208, 4314, 4315, 4980.01, 4980.38, 4980.40, 4980.44, 4980.54, 4980.57, 4980.80, 4980.90, 4982, 4984.1, 4984.4, 4989.36, 4989.42, 4989.54, 4992.3, 4996.4, 4996.6, 4996.18, and 4996.22 of, to add Sections 1672, 2471, 2570.8, 4984.01, 4984.72, 4992.10, and 4996.28 to, and to repeal and add Sections 3530, 4984.7, 4984.8, 4996.3, 4996.14, and 4997 of, the Business and Professions Code, and to amend Sections 11372, 12529, and 12529.5 of the Government Code, relating to healing arts, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1048, as amended, Committee on Business, Professions and Economic Development. Healing arts.

(1) Existing law, the Dental Practice Act, establishes the Dental Board of California and provides for the licensure and regulation of the practice of dentistry. The act makes the willful practice, attempt to practice, or advertisement to practice without appropriate authorization in circumstances causing harm, as specified, a misdemeanor offense.

1 (f) No petition shall be considered while the petitioner is under  
2 sentence for any criminal offense, including any period during  
3 which the petitioner is on court-imposed probation or parole. No  
4 petition shall be considered while there is an accusation or petition  
5 to revoke probation pending against the person. The committee  
6 may deny, without a hearing or argument, any petition filed  
7 pursuant to this section within a period of two years from the  
8 effective date of the prior decision following a hearing under this  
9 section.

10 (g) Nothing in this section shall be deemed to alter Sections 822  
11 and 823.

12 SEC. 40. Section 3634 of the Business and Professions Code  
13 is amended to read:

14 3634. A license issued under this chapter shall be subject to  
15 renewal biennially as prescribed by the bureau and shall expire  
16 unless renewed in that manner. The bureau may provide by  
17 regulation for the late renewal of a license.

18 SEC. 41. Section 4068 of the Business and Professions Code  
19 is amended to read:

20 4068. (a) Notwithstanding any provision of this chapter, a  
21 prescriber may dispense a dangerous drug, including a controlled  
22 substance, to an emergency room patient if all of the following  
23 apply:

24 (1) The hospital pharmacy is closed and there is no pharmacist  
25 available in the hospital.

26 (2) The dangerous drug is acquired by the hospital pharmacy.

27 (3) The dispensing information is recorded and provided to the  
28 pharmacy when the pharmacy reopens.

29 (4) The hospital pharmacy retains the dispensing information  
30 and, if the drug is a schedule II, schedule III, or schedule IV  
31 controlled substance, reports the dispensing information to the  
32 Department of Justice pursuant to Section 11165 of the Health and  
33 Safety Code.

34 (5) The prescriber determines that it is in the best interest of the  
35 patient that a particular drug regimen be immediately commenced  
36 or continued, and the prescriber reasonably believes that a  
37 pharmacy located outside the hospital is not available and  
38 accessible at the time of dispensing to the patient.

39 (6) The quantity of drugs dispensed to any patient pursuant to  
40 this section are limited to that amount necessary to maintain

1 uninterrupted therapy during the period when pharmacy services  
2 outside the hospital are not readily available or accessible, but  
3 shall not exceed a 72-hour supply.

4 (7) The prescriber shall ensure that the label on the drug contains  
5 all the information required by Section 4076.

6 (b) The prescriber shall be responsible for any error or omission  
7 related to the drugs dispensed.

8 SEC. 42. Section 4084 of the Business and Professions Code  
9 is amended to read:

10 4084. (a) When a board inspector finds, or has probable cause  
11 to believe, that any dangerous drug or dangerous device is  
12 adulterated, misbranded, or counterfeit, the board inspector shall  
13 affix a tag or other marking to that dangerous drug or dangerous  
14 device. The board inspector shall give notice to the person that the  
15 dangerous drug or dangerous device bearing the tag or marking  
16 has been embargoed.

17 (b) When a board inspector has found that an embargoed  
18 dangerous drug or dangerous device is not adulterated, misbranded,  
19 or counterfeit, a board inspector shall remove the tag or other  
20 marking.

21 (c) A board inspector may secure a sample or specimen of a  
22 dangerous drug or dangerous device. If the board inspector obtains  
23 a sample prior to leaving the premises, the board inspector shall  
24 leave a receipt describing the sample.

25 (d) For the purposes of this article, “counterfeit” shall have the  
26 meaning defined in Section 109905 of the Health and Safety Code.

27 (e) For the purposes of this article, “adulterated” shall have the  
28 meaning defined in Article 2 (commencing with Section 111250)  
29 of Chapter 6 of Part 5 of Division 104 of the Health and Safety  
30 Code.

31 (f) For the purposes of this article, “misbranded” shall have the  
32 meaning defined in Article 3 (commencing with Section 111330)  
33 of Chapter 6 of Part 5 of Division 104 of the Health and Safety  
34 Code.

35 SEC. 43. Section 4101 of the Business and Professions Code  
36 is amended to read:

37 4101. (a) A pharmacist who takes charge of, or acts as  
38 pharmacist-in-charge of a pharmacy or other entity licensed by  
39 the board, who terminates his or her employment at the pharmacy

1 or other entity, shall notify the board within 30 days of the  
2 termination of employment.

3 (b) A designated representative-in-charge of a wholesaler or  
4 veterinary food drug-animal retailer, who terminates his or her  
5 employment at that entity shall notify the board within 30 days of  
6 the termination of employment.

7 SEC. 44. Section 4160 of the Business and Professions Code  
8 is amended to read:

9 4160. (a) A person may not act as a wholesaler of any  
10 dangerous drug or dangerous device unless he or she has obtained  
11 a license from the board.

12 (b) Upon approval by the board and the payment of the required  
13 fee, the board shall issue a license to the applicant.

14 (c) A separate license shall be required for each place of business  
15 owned or operated by a wholesaler. Each license shall be renewed  
16 annually and shall not be transferable.

17 (d) The board shall not issue or renew a wholesaler license until  
18 the wholesaler identifies a designated representative-in-charge and  
19 notifies the board in writing of the identity and license number of  
20 that designated representative. The designated  
21 representative-in-charge shall be responsible for the wholesaler's  
22 compliance with state and federal laws governing wholesalers. A  
23 wholesaler shall identify and notify the board of a new designated  
24 representative-in-charge within 30 days of the date that the prior  
25 designated representative-in-charge ceases to be the designated  
26 representative-in-charge. A pharmacist may be identified as the  
27 designated representative-in-charge.

28 (e) A drug manufacturer premises licensed by the Food and  
29 Drug Administration or licensed pursuant to Section 111615 of  
30 the Health and Safety Code that only distributes dangerous drugs  
31 and dangerous devices of its own manufacture is exempt from this  
32 section and Section 4161.

33 (f) The board may issue a temporary license, upon conditions  
34 and for periods of time as the board determines to be in the public  
35 interest. A temporary license fee shall be five hundred fifty dollars  
36 (\$550) or another amount established by the board not to exceed  
37 the annual fee for renewal of a license to compound injectable  
38 sterile drug products. When needed to protect public safety, a  
39 temporary license may be issued for a period not to exceed 180  
40 days, subject to terms and conditions that the board deems

1 necessary. If the board determines that a temporary license was  
2 issued by mistake or denies the application for a permanent license,  
3 the temporary license shall terminate upon either personal service  
4 of the notice of termination upon the licenseholder or service by  
5 certified mail, return receipt requested, at the licenseholder's  
6 address of record with the board, whichever occurs first. Neither  
7 for purposes of retaining a temporary license, nor for purposes of  
8 any disciplinary or license denial proceeding before the board,  
9 shall the temporary licenseholder be deemed to have a vested  
10 property right or interest in the license.

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

12 SEC. 45. Section 4161 of the Business and Professions Code  
13 is amended to read:

14 4161. (a) A person located outside this state that ships, mails,  
15 or delivers dangerous drugs or dangerous devices into this state  
16 shall be considered a nonresident wholesaler.

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

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

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

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

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

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

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

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

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

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

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

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

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

22 (k) The board may issue a temporary license, upon conditions  
23 and for periods of time as the board determines to be in the public  
24 interest. A temporary license fee shall be five hundred fifty dollars  
25 (\$550) or another amount established by the board not to exceed  
26 the annual fee for renewal of a license to compound injectable  
27 sterile drug products. When needed to protect public safety, a  
28 temporary license may be issued for a period not to exceed 180  
29 days, subject to terms and conditions that the board deems  
30 necessary. If the board determines that a temporary license was  
31 issued by mistake or denies the application for a permanent license,  
32 the temporary license shall terminate upon either personal service  
33 of the notice of termination upon the licenseholder or service by  
34 certified mail, return receipt requested, at the licenseholder's  
35 address of record with the board, whichever occurs first. Neither  
36 for purposes of retaining a temporary license, nor for purposes of  
37 any disciplinary or license denial proceeding before the board,  
38 shall the temporary licenseholder be deemed to have a vested  
39 property right or interest in the license.

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

3 SEC. 46. Section 4162 of the Business and Professions Code  
4 is amended to read:

5 4162. (a) (1) An applicant, that is not a government-owned  
6 and operated wholesaler, for the issuance or renewal of a  
7 wholesaler license shall submit a surety bond of one hundred  
8 thousand dollars (\$100,000) or other equivalent means of security  
9 acceptable to the board payable to the Pharmacy Board Contingent  
10 Fund. The purpose of the surety bond is to secure payment of any  
11 administrative fine imposed by the board and any cost recovery  
12 ordered pursuant to Section 125.3.

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

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

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

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

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

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

1 SEC. 47. Section 4162.5 of the Business and Professions Code  
2 is amended to read:

3 4162.5. (a) (1) An applicant for the issuance or renewal of a  
4 nonresident wholesaler license shall submit a surety bond of one  
5 hundred thousand dollars (\$100,000), or other equivalent means  
6 of security acceptable to the board, such as an irrevocable letter  
7 of credit, or a deposit in a trust account or financial institution,  
8 payable to the Pharmacy Board Contingent Fund. The purpose of  
9 the surety bond is to secure payment of any administrative fine  
10 imposed by the board and any cost recovery ordered pursuant to  
11 Section 125.3.

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

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

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

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

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

36 (d) This section shall become operative on January 1, 2006, and  
37 shall become inoperative and is repealed on, January 1, 2015,  
38 unless a later enacted statute, that is enacted before January 1,  
39 2015, deletes or extends those dates.

1 SEC. 48. Section 4200 of the Business and Professions Code  
2 is amended to read:

3 4200. (a) The board may license as a pharmacist an applicant  
4 who meets all the following requirements:

5 (1) Is at least 18 years of age.

6 (2) (A) Has graduated from a college of pharmacy or  
7 department of pharmacy of a university recognized by the board;  
8 or

9 (B) If the applicant graduated from a foreign pharmacy school,  
10 the foreign-educated applicant has been certified by the Foreign  
11 Pharmacy Graduate Examination Committee.

12 (3) Has completed at least 150 semester units of collegiate study  
13 in the United States, or the equivalent thereof in a foreign country.  
14 No less than 90 of those semester units shall have been completed  
15 while in resident attendance at a school or college of pharmacy.

16 (4) Has earned at least a baccalaureate degree in a course of  
17 study devoted to the practice of pharmacy.

18 (5) Has completed 1,500 hours of pharmacy practice experience  
19 or the equivalent in accordance with Section 4209.

20 (6) Has passed a written and practical examination given by the  
21 board prior to December 31, 2003, or has passed the North  
22 American Pharmacist Licensure Examination and the California  
23 Practice Standards and Jurisprudence Examination for Pharmacists  
24 on or after January 1, 2004.

25 (b) Proof of the qualifications of an applicant for licensure as a  
26 pharmacist, shall be made to the satisfaction of the board and shall  
27 be substantiated by affidavits or other evidence as may be required  
28 by the board.

29 (c) Each person, upon application for licensure as a pharmacist  
30 under this chapter, shall pay to the executive officer of the board,  
31 the fees provided by this chapter. The fees shall be compensation  
32 to the board for investigation or examination of the applicant.

33 SEC. 49. Section 4200.1 of the Business and Professions Code  
34 is amended to read:

35 4200.1. (a) Notwithstanding Section 135, an applicant may  
36 take the North American Pharmacist Licensure Examination four  
37 times, and may take the California Practice Standards and  
38 Jurisprudence Examination for Pharmacists four times.

39 (b) Notwithstanding Section 135, an applicant may take the  
40 North American Pharmacist Licensure Examination and the

1 California Practice Standards and Jurisprudence Examination for  
2 Pharmacists four additional times each if he or she successfully  
3 completes, at minimum, 16 additional semester units of education  
4 in pharmacy as approved by the board.

5 (c) The applicant shall comply with the requirements of Section  
6 4200 for each application for reexamination made pursuant to  
7 subdivision (b).

8 (d) An applicant may use the same coursework to satisfy the  
9 additional educational requirement for each examination under  
10 subdivision (b), if the coursework was completed within 12 months  
11 of the date of his or her application for reexamination.

12 (e) For purposes of this section, the board shall treat each failing  
13 score on the pharmacist licensure examination administered by  
14 the board prior to January 1, 2004, as a failing score on both the  
15 North American Pharmacist Licensure Examination and the  
16 California Practice Standards and Jurisprudence Examination for  
17 Pharmacists.

18 (f) From January 1, 2004, to July 1, 2008, inclusive, the board  
19 shall collect data on the applicants who are admitted to, and take,  
20 the licensure examinations required by Section 4200. The board  
21 shall report to the Joint Committee on Boards, Commissions, and  
22 Consumer Protection before September 1, 2008, regarding the  
23 impact on those applicants of the examination limitations imposed  
24 by this section. The report shall include, but not be limited to, the  
25 following information:

26 (1) The number of applicants taking the examination and the  
27 number who fail the examination for the fourth time.

28 (2) The number of applicants who, after failing the examination  
29 for the fourth time, complete a pharmacy studies program in  
30 California or another state to satisfy the requirements of this section  
31 and who apply to take the licensure examination required by  
32 Section 4200.

33 (3) To the extent possible, the school from which the applicant  
34 graduated and the school's location and the pass/fail rates on the  
35 examination for each school.

36 (g) This section shall remain in effect only until January 1, 2010,  
37 and as of that date is repealed, unless a later enacted statute, that  
38 is enacted before January 1, 2010, deletes or extends that date.

39 SEC. 50. Section 4200.2 of the Business and Professions Code  
40 is amended to read:

1 4200.2. When developing the Multi-State Pharmacy California  
2 Practice Standards and Jurisprudence Examination for Pharmacists,  
3 the board shall include all of the following:

4 (a) Examination items to demonstrate the candidate's proficiency  
5 in patient communication skills.

6 (b) Aspects of contemporary standards of practice for  
7 pharmacists in California, including, but not limited to, the  
8 provision of pharmacist care and the application of clinical  
9 knowledge to typical pharmacy practice situations that are not  
10 evaluated by the North American Pharmacy Licensure  
11 Examination.

12 SEC. 51. Section 4208 of the Business and Professions Code  
13 is amended to read:

14 4208. (a) At the discretion of the board, an intern pharmacist  
15 license may be issued for a period of:

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

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

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

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

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

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

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

1 (e) A person who has not completed the experience requirements  
2 necessary to be eligible for the licensure examination may have  
3 his or her intern license extended for a period of up to two years  
4 at the discretion of the board if he or she is able to demonstrate  
5 his or her inability to exercise the privileges of the intern license  
6 during the initial license period.

7 SEC. 52. Section 4314 of the Business and Professions Code  
8 is amended to read:

9 4314. (a) The board may issue citations containing fines and  
10 orders of abatement for any violation of Section 733, for any  
11 violation of this chapter or regulations adopted pursuant to this  
12 chapter, or for any violation of Division 116 (commencing with  
13 Section 150200) of the Health and Safety Code, in accordance  
14 with Sections 125.9, 148, and 4005 and the regulations adopted  
15 pursuant to those sections.

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

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

32 (d) Nothing in this section shall in any way limit the board from  
33 issuing a citation, fine, and order of abatement pursuant to Section  
34 4067 or Section 56.36 of the Civil Code, and the regulations  
35 adopted pursuant to those sections.

36 SEC. 53. Section 4315 of the Business and Professions Code  
37 is amended to read:

38 4315. (a) The executive officer, or his or her designee, may  
39 issue a letter of admonishment to a licensee for failure to comply  
40 with Section 733, for failure to comply with this chapter or

1 regulations adopted pursuant to this chapter, or for failure to  
2 comply with Division 116 (commencing with Section 150200) of  
3 the Health and Safety Code, directing the licensee to come into  
4 compliance.

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

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

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

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

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

23 (C) The office conference is intended to be an informal  
24 proceeding and shall not be subject to the provisions of the  
25 Administrative Procedure Act (Chapter 3.5 (commencing with  
26 Section 11340), Chapter 4 (commencing with Section 11370),  
27 Chapter 4.5 (commencing with Section 11400), and Chapter 5  
28 (commencing with Section 11500) of Part 1 of Division 3 of Title  
29 2 of the Government Code).

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

37 (E) Judicial review of the decision may be had by filing a  
38 petition for a writ of mandate in accordance with the provisions  
39 of Section 1094.5 of the Code of Civil Procedure within 30 days  
40 of the date the decision was personally served or sent by certified

1 mail. The judicial review shall extend to the question of whether  
2 or not there was a prejudicial abuse of discretion in the issuance  
3 of the letter of admonishment.

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

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

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

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

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

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

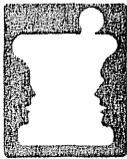
25 SEC. 54. Section 4980.01 of the Business and Professions  
26 Code is amended to read:

27 4980.01. (a) Nothing in this chapter shall be construed to  
28 constrict, limit, or withdraw the Medical Practice Act, the Social  
29 Work Licensing Law, the Nursing Practice Act, or the Psychology  
30 Licensing Act.

31 (b) This chapter shall not apply to any priest, rabbi, or minister  
32 of the gospel of any religious denomination when performing  
33 counseling services as part of his or her pastoral or professional  
34 duties, or to any person who is admitted to practice law in the state,  
35 or who is licensed to practice medicine, when providing counseling  
36 services as part of his or her professional practice.

37 (c) (1) This chapter shall not apply to an employee working in  
38 any of the following settings if his or her work is performed solely  
39 under the supervision of the employer:

40 (A) A governmental entity.



**California State Board of Pharmacy**

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

June 29, 2007

The Honorable Mark Ridley-Thomas  
California State Senate  
State Capitol, Room 4061  
Sacramento, CA 95814

SB 1048: Support (As amended June 28, 2007)

Dear Senator Ridley-Thomas:

The California Board of Pharmacy supports SB 1476 as amended June 28, 2007. The board is the sponsor of and supports changes contained in this bill involving pharmacy law that are important to the board.

This bill would:

1. Allow board inspectors to embargo a prescription drug when the inspector has probable cause that it is misbranded.
2. 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 (Statutes of 2006) chaptered out by SB 1475 (Statutes of 2006).
3. 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.
4. Specify a temporary license fee for a wholesaler as current law does not specify the amount of the temporary fee.
5. Revise requirements for intern licenses to allow the board the discretion to extend the duration of an intern license.
6. Replace the term "exemptee" with ""designated representative" when referring to the individual exempt from licensure as a pharmacist that may maintain control of a wholesaler or veterinary food-animal drug retailer.
7. Update Busienss and Professions Code code to conform with Health and Safety Code requirements that require the electronic reporting to the Controlled Substances Utilization Review and Evaluation System for Schedule II through IV controlled substances.

The Honorable Ridley-Thomas  
June 29, 2007  
Page Two

The board is grateful for the committee's sponsorship of the omnibus bill and while we do not anticipate any opposition to any of the proposed changes, the board will commit to working with any opposition, should it arise.

Thank you for your leadership. Please contact me if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Virginia Herold". The signature is fluid and cursive, with a large initial "V" and a long, sweeping tail.

VIRGINIA HEROLD  
Executive Officer

cc: Rebecca May, Consultant, Assembly Business & Professions Committee

## E-7a

# Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction

- Bill Analysis
- Copy of Language
- Correspondence

**CALIFORNIA STATE BOARD OF PHARMACY  
BILL ANALYSIS**



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**BILL NUMBER: AB 110**

**VERSION: As introduced January 5, 2007**

**AUTHOR: LAIRD**

**SPONSOR: Drug Policy Alliance Network  
San Francisco Aids Foundation**

**BOARD POSITION: SUPPORT**

**SUBJECT: Drug paraphernalia: clean needle and syringe exchange projects**

---

**EXISTING LAW:**

1. Permits a needle exchange program (NEP) in any city and county, county, or city upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.
2. Requires a city and county, or a county, or a city with or without a health department that authorizes a NEP, to authorize the exchange of clean hypodermic needles and syringes, as part of a network of comprehensive services, including treatment services.
3. Prohibits providers participating in an authorized NEP from being subject to criminal prosecution for possession of needles or syringes during participation in a NEP.
4. Requires local government, local public health officials, and law enforcement to be given the opportunity to comment on syringe exchange programs on an annual basis. Requires the public to be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare of syringe exchange programs are addressed and mitigated. Requires the health officer of the participating jurisdiction to present annually at an open meeting of the board of supervisors or city council a report detailing the status of NEPs including, but not limited to, relevant statistics on blood-borne infections associated with needle sharing activity. Requires law enforcement, administrators of alcohol and drug treatment programs, other stakeholders, and the public to be afforded ample opportunity to comment at this annual meeting, as specified.

## **THIS BILL:**

1. Makes a number of findings and declarations related to the continuing spread of acquired immune deficiency syndrome (AIDS) and blood-borne hepatitis, the relationship between injection drug use and HIV/AIDS and hepatitis, the reduction in the transmission of HIV and hepatitis resulting from NEPs, and the need for NEPs to purchase adequate supplies of sterile hypodermic needles in order to further reduce HIV and hepatitis transmission.
2. Permits a public entity that receives General Fund money from Department of Public Health (formerly DHS) for HIV prevention and education to use that money to support NEPs that are authorized by the public entity, as specified.
3. Permits the money to be used for, but not be limited to, the purchase of sterile hypodermic needles and syringes.
4. Requires funds allocated for the purchase of sterile hypodermic needles and syringes to be based upon epidemiological data as reported by the health jurisdiction in its local HIV prevention plan submitted to DPH.
5. Requires local health officers in jurisdictions with NEPs to include information on the use of public funds for NEPs in their annual report detailing the status of the project to the board of supervisors or city council.

## **AUTHOR'S INTENT**

According to the author, the U.S. government prohibits the use of federal funds to support the purchase of sterile hypodermic needles and syringes by Needle Exchange Programs (NEPs), and to date the state has not permitted the use of its funds for the purchase of sterile hypodermic needles and syringes. The ability of NEPs to purchase an adequate supply of sterile hypodermic needles and syringes is essential to California's ability to further reduce the transmission of HIV and other blood-borne diseases and relieve the public cost for the care and treatment of those diseases. The use of state General Funds to purchase clean needle and syringes for NEPs is not unprecedented. Eleven states currently expend these funds for this purpose (Connecticut, Hawaii, Massachusetts, New Mexico, New York, Oregon, Rhode Island, Vermont, Washington, and Wisconsin). This bill would substantially aid local efforts to reduce the rate of HIV transmission through injection drug use in California by authorizing the use of state funds for the purchase of clean hypodermic needles and syringes. Any funds that would be expended for clean needles and syringes come from existing appropriations for state HIV prevention funds. Accordingly, this bill does not increase funding and will, in effect, make counties prioritize how they will expend prevention funds. One of these choices may be to purchase needles and syringes, which could result in significant savings for state funded health programs.

## **PRIOR HISTORY/RELATED BILLS**

AB 547 (Berg and Richman) Chapter 692, Statutes 2005 - authorized clean NEPs in any city and county, county, or city upon the action of a county board of supervisors and the local health officer or health commission of that county; the city council, the mayor, and the local health officer of a city with a health department; or, the city council and the mayor of a city without a health department. No board position.

AB 1597 (Laird) of 2005 contained provisions substantially similar to this bill - Governor Schwarzenegger vetoed AB 1597, stating "authorizing the use of state funds to purchase syringes, without appropriate local controls, including mechanisms for input from local law enforcement, and protections against the use of state funds to supplant private or local resources is not prudent." No board position.

AB 2076 (Laird) of 2006 contained provisions substantially similar to this bill - held on the Assembly Floor after passing both houses of the Legislature. No board position.

## **FISCAL IMPACT:**

The board does not anticipate any fiscal impact. Any minor fiscal impact would be absorbable within existing resources.

## **SUPPORT AND OPPOSITION:**

### Support

AIDS Project Los Angeles  
America Federation of State, County and Municipal Employees  
AFL-CIO  
California Hospital Association  
California Opioid Maintenance Providers  
California State Association of Counties  
City of Moreno Valley  
Drug Policy Alliance Network  
Friends Committee on Legislation  
Lambda Letters Project  
San Francisco AIDS Foundation  
Santa Clara County Board of Supervisors  
Southern California HIV Advocacy Coalition

### Oppose

California Narcotic Officers' Association

History

**Dates      Actions**

- 07/11/07 July 11 Read second time. To third reading.
- 07/10/07 July 10 From committee: Do pass. (Ayes 9. Noes 6.) .
- 06/21/07 June 21 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 6. Noes 4.) .
- 06/14/07 June 14 Referred to Com. on HEALTH.
- 06/06/07 June 6 In Senate. Read first time. To Com. on RLS. for assignment.
- 06/05/07 June 5 Read third time, passed, and to Senate. (Ayes 44. Noes 35. Page 1871.)
- 06/01/07 June 1 From committee: Do pass. (Ayes 12. Noes 5.) (May 31). Read second time. To third reading.
- 03/28/07 Mar. 28 In committee: Set, first hearing. Referred to APPR. suspense file.
- 03/07/07 Mar. 7 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 12. Noes 5.) (March 6).
- 02/01/07 Feb. 1 Referred to Com. on HEALTH.
- 01/06/07 Jan. 6 From printer. May be heard in committee February 5.
- 01/05/07 Jan. 5 Read first time. To print.

Revised July 13, 2007

**ASSEMBLY BILL**

**No. 110**

---

**Introduced by Assembly Member Laird**  
**(Coauthors: Assembly Members Berg, Evans, Hancock, Jones, and Leno)**  
(Coauthors: Senators Kehoe and Kuehl)

January 5, 2007

---

An act to amend Section 121349.3 of, and to add Chapter 1.5 (commencing with Section 120780) to Part 4 of Division 105 of, the Health and Safety Code, relating to the use of state HIV prevention and education funds for distribution of needles and syringes.

LEGISLATIVE COUNSEL'S DIGEST

AB 110, as introduced, Laird. Drug paraphernalia: clean needle and syringe exchange projects.

(1) Existing law, with certain exceptions, makes it a misdemeanor for a person to deliver, furnish, transfer, possess with intent to deliver, furnish, or transfer, or manufacture with the intent to deliver, furnish, or transfer, drug paraphernalia, knowing, or under circumstances where one reasonably should know, that it will be used to plant, propagate, cultivate, grow, harvest, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance. Existing law provides an exception to this general rule by authorizing a public entity, its agents, or employees to distribute hypodermic needles or syringes to participants in clean needle and syringe exchange projects authorized by the public entity pursuant to a declaration of a local emergency due to the existence of a critical local public health crisis.

1 and other injection equipment is linked to 20 percent of all reported  
2 AIDS cases in the state through 2003. State data suggests that over  
3 1,500 new syringe-sharing HIV infections occur annually.  
4 According to recent studies, researchers estimate that an American  
5 infected with HIV can expect to live about 24 years, on average,  
6 and that the cost of his or her health care during this time period  
7 is more than \$600,000.

8 (d) Injection drug users are also highly likely to become infected  
9 with hepatitis as a result of hypodermic needle and syringe sharing  
10 practices.

11 (e) The Legislature has responded to the spread of HIV and  
12 hepatitis among injection drug users by adopting Assembly Bill  
13 136 (Ch. 762, Stats. 1999), that permits localities to determine  
14 whether or not to operate clean needle and syringe exchange  
15 programs. As a result of that legislation, many localities are now  
16 operating these programs.

17 (f) These programs have been shown to significantly reduce the  
18 transmission of HIV and hepatitis among injection drug users,  
19 their sexual partners, and children. Moreover, these programs have  
20 been effective in moving individuals into substance abuse treatment  
21 programs and in reducing the number of used hypodermic needles  
22 and syringes disposed of in public places, which pose a threat to  
23 public health and safety.

24 (g) The United States government prohibits the use of federal  
25 funds to support the purchase of sterile hypodermic needles and  
26 syringes by clean needle and syringe exchange programs.  
27 Moreover, the state has not heretofore permitted the use of its funds  
28 for the purchase of sterile hypodermic needles and syringes,  
29 although current state policy allows state HIV prevention and  
30 education funds to be used for costs associated with authorized  
31 clean needle and syringe exchange programs, except for the  
32 purchase of sterile hypodermic needles and syringes.

33 (h) The ability of clean needle and syringe exchange programs  
34 to purchase an adequate supply of sterile hypodermic needles and  
35 syringes is essential to California's ability to further reduce the  
36 transmission of HIV and hepatitis and to relieve the public cost  
37 for the care and treatment of HIV disease and hepatitis.

38 SEC. 2. Chapter 1.5 (commencing with Section 120780) is  
39 added to Part 4 of Division 105 of the Health and Safety Code, to  
40 read:



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

April 24, 2007

The Honorable John Laird  
California State Assembly  
State Capitol, Room 6026  
Sacramento, CA 95814

AB 110: Support

Dear Assembly Member Laird:

I am pleased to inform you that the Board of Pharmacy supports your Assembly Bill 110 (as introduced on January 5, 2007) relating to sterile hypodermic needles and syringes.

The board supports needle exchange programs as a way to reduce the spread of infectious diseases that can be contracted through the sharing of contaminated needles.

The board is pleased to support AB 110.

Sincerely,

A handwritten signature in black ink, appearing to read "Virginia Herold".

Virginia Herold  
Executive Officer

**CALIFORNIA STATE BOARD OF PHARMACY  
BILL ANALYSIS**

---

**BILL NUMBER: AB 249**

**VERSION: As introduced February 1, 2007**

**AUTHOR: Eng**

**SPONSOR: Author**

**BOARD POSITION: Support**

**SUBJECT: Licensees: healing arts: settlement agreements**

---

**EXISTING LAW:**

1. Prohibits a physician or surgeon from including a provision in a civil settlement that prohibits the other party from contacting or cooperating with the Medical Board.
2. Prohibits a physician or surgeon from including a provision in a settlement for a civil action that requires the other party from filing a complaint with the Medical Board.
3. Prohibits a physician or surgeon from including a provision in a settlement that requires the other party to withdraw a complaint from the Medical Board.
4. Declares that such provisions is void as against public policy.
5. Specifies that a physician or surgeon who violates the section is subject to disciplinary action.

**THIS BILL WOULD:**

Expand the above prohibitions to apply to all licensees and entities or persons acting as an authorized agent of a licensee licensed under Division 2 of the Business and Professions Code.

**AUTHOR'S INTENT**

This bill is intended to close a loophole in current law that allows a healthcare professional licensed by the Department of Consumer Affairs (DCA) to prohibit a consumer who settles a civil suit from also filing a complaint or cooperating with the licensee's regulator. This bill is modeled on an existing statute that prohibits physicians and surgeons from including such clauses in civil settlements arising from his or her practice.

According to the author, "The state has created regulatory agencies to license healthcare professionals in order to protect patients, but those same healthcare practitioners can use gag clauses in malpractice settlements to prevent the licensing agency from finding out about their abuses. That makes absolutely no

sense. Licensed healthcare professionals should not be able to misuse the civil justice system to conceal evidence of misconduct from their regulators."

#### **PRIOR HISTORY/RELATED BILLS**

AB 320 (Correa) of 2004 would have prohibited all DCA licensed professionals from including a gag clause in a civil settlement. This bill was vetoed. The governor's message is as follows:

"I am returning Assembly Bill 320 without my signature as it further erodes the ability to do business in California by creating more uncertainty regarding litigation and litigation costs.

This bill prohibits all businesses and professions licensed under the DCA from inserting gag clauses in civil suits settled with customers.

When parties who are in dispute agree to settle, there should be some assurances that the dispute has been resolved in a satisfactory and final manner for both parties. Often settlements are reached when the cost of settlement is less than the cost of defense even if a party believes they have not erred; it often makes economic sense to settle.

Under this bill, a party who agrees to a civil settlement, could still file a complaint with a regulatory agency subjecting the licensee to double jeopardy. Even after the resolution of a civil suit, this bill could still require a licensee to a second adjudication before a regulatory body.

The policy implications of this bill does not further the goal of making California more business friendly, therefore, I cannot support this bill. The board had a support position on this bill."

AB 446 (Negrete McLeod) of 2005, would have prohibited all DCA licensed professionals from including a gag clause in a civil settlement. This bill was vetoed by the governor with the following message:

"I vetoed a similar bill last year because of the negative effect it would have had on the California economy. This bill further erodes the ability to do business in California by creating more uncertainty regarding litigation by prohibiting any licensee or professional overseen by the Department of Consumer Affairs from including in a civil settlement agreement a provision that prohibits the other party from contacting or filing a complaint with the regulatory agency. When parties who are in dispute agree to settle, there should be some assurances that the dispute has been resolved in a satisfactory and final manner for both parties."

The board had a support position on this bill.

AB 2260 (Negrete McLeod), Chapter 565, Statutes of 2006, prohibits physicians and surgeons licensed by the Medical Board from including a gag clause in a civil settlement agreement. The board did not take a position on this bill.

**FISCAL IMPACT:**

The board does not anticipate any major fiscal impact. Any minor fiscal impact could be absorbed within existing resources.

**SUPPORT AND OPPOSITION:**

Support

Board of Pharmacy  
Board of Registered Nursing  
California Nurses Association  
Center for Public Interest Law  
Citizens Commission on Human Rights, Los Angeles/Hollywood Chapter

Opposition

None on file

**HISTORY:**

<b>Dates</b>	<b>Actions</b>
07/05/07	July 5 Read second time. To third reading.
07/03/07	July 3 From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
06/12/07	June 12 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 5. Noes 3.)
05/09/07	May 9 Referred to Com. on B., P. & E.D.
05/03/07	May 3 In Senate. Read first time. To Com. on RLS. for assignment.
05/03/07	May 3 Read third time, passed, and to Senate. (Ayes 68. Noes 5. Page 1304.)
04/23/07	Apr. 23 Read second time. To third reading.
04/19/07	Apr. 19 From committee: Do pass. (Ayes 16. Noes 0.) (April 18).
03/27/07	Mar. 27 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 9. Noes 1.) (March 27).
03/06/07	Mar. 6 From committee: Do pass, and re-refer to Com. on JUD. Re-referred. (Ayes 10. Noes 0.) (March 6).
02/20/07	Feb. 20 Referred to Coms. on B. & P. and JUD.
02/02/07	Feb. 2 From printer. May be heard in committee March 4.
02/01/07	Feb. 1 Read first time. To print.

ASSEMBLY BILL

No. 249

---

Introduced by Assembly Member Eng

February 1, 2007

---

An act to add Section 809.10 to, and to repeal Section 2220.7 of, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 249, as introduced, Eng. Licensees: healing arts: settlement agreements.

Existing law prohibits a physician and surgeon from including or permitting to be included specified provisions in a settlement agreement arising from his or her practice regardless of whether the agreement is made before or after filing the civil action. Under existing law, a physician and surgeon who violates this requirement is subject to disciplinary action by the Medical Board of California.

This bill would continue to impose that prohibition on physicians and surgeons and would additionally impose it on other healing arts practitioners and would also make them subject to disciplinary action.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. Section 809.10 is added to the Business and
- 2 Professions Code, to read:
- 3 809.10. (a) No person who is licensed, certified, or registered
- 4 by a board under this division, nor an entity or person acting as an
- 5 authorized agent of that person, shall include or permit to be

1 included any of the following provisions in an agreement to settle  
2 a civil dispute, whether the agreement is made before or after the  
3 commencement of a civil action:

4 (1) A provision that prohibits the other party in that dispute  
5 from contacting or cooperating with the department or board.

6 (2) A provision that prohibits the other party in that dispute  
7 from filing a complaint with the department or board.

8 (3) A provision that requires the other party in that dispute to  
9 withdraw a complaint from the department or board. This type of  
10 provision is void as against public policy.

11 (b) A licensed, certified, or registered person who violates this  
12 section is subject to disciplinary action by the appropriate board.

13 SEC. 2. Section 2220.7 of the Business and Professions Code  
14 is repealed.

15 ~~2220.7. (a) A physician and surgeon shall not include or permit  
16 to be included any of the following provisions in an agreement to  
17 settle a civil dispute arising from his or her practice, whether the  
18 agreement is made before or after filing the action:~~

19 ~~(1) A provision that prohibits another party to the dispute from  
20 contacting or cooperating with the board.~~

21 ~~(2) A provision that prohibits another party to the dispute from  
22 filing a complaint with the board.~~

23 ~~(3) A provision that requires another party to the dispute to  
24 withdraw a complaint he or she has filed with the board.~~

25 ~~(b) A provision described in subdivision (a) is void as against  
26 public policy.~~

27 ~~(c) A physician and surgeon who violates this section is subject  
28 to disciplinary action by the board.~~



**California State Board of Pharmacy**

1625 N Market Blvd. N219, Sacramento, CA 95834

Phone (916) 574-7900

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

ARNOLD SCHWARZENEGGER, GOVERNOR

April 24, 2007

The Honorable Mike Eng  
California State Assembly  
State Capitol, Room 6025  
Sacramento, CA 95814

AB 249: Support

Dear Assembly Member Eng:

I am pleased to inform you that the Board of Pharmacy supports your Assembly Bill 249 (as introduced February 1, 2007) relating to "gag" clauses.

This bill expands on the requirements detailed in AB 2260 (Negrete McLeod, Chapter 565, Statutes of 2006), which prohibits physicians and surgeons licensed by the Medical Board from including a gag clause in a civil settlement agreement. The board supports the prohibition of gag clauses in the resolution of civil matters as it inhibits the board's ability to carry out its mandate of public protection.

The board is pleased to support AB 249.

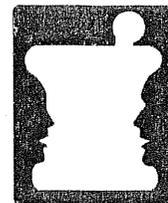
Sincerely,

A handwritten signature in black ink, appearing to read "Virginia Herold".

Virginia Herold  
Executive Officer

CALIFORNIA STATE BOARD OF PHARMACY  
BILL ANALYSIS

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BILL NUMBER: AB 543

VERSION: As Amended July 16, 2007

AUTHOR: Plescia

SPONSOR: CA Ambulatory Surgery Assoc.

BOARD POSITION: Support

SUBJECT: Ambulatory surgical centers: licensure

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**EXISTING LAW:**

1. Defines a surgical clinic as a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours.
2. Provides that no surgical clinic licensed pursuant to Section 1204 of the Health and Safety Code may purchase drugs at wholesale unless licensed by the California State Board of Pharmacy.
3. Defines the licensing requirements for the board to issue a clinic license to an ambulatory surgery center.

**THIS BILL WOULD:**

1. Modify the licensing requirements for a board issued clinic license for surgical clinic to include:
  - licensure by the Department of Public Health (DPH) under 1204 and 1212.5 of the Health and Safety Code
  - accreditation by an approved agency or
  - certification to participate in the Medicare Program.(This board issued license would allow the clinic to purchase drugs at wholesale for administration or dispensing as well as commingle medications.)
2. Require the board to inspect a board licensed surgical clinic that is accredited by an agency or certified to participate in the Medicare Program within 120 days of the issuance of the license and at least on an annual basis thereafter.
3. Require a board licensed surgical clinic to complete a self-assessment within 30 days of issuance of the license and at least 30 days before each license renewal.
4. Develop standard licensing requirements surgical clinics licensed by the Department of Public Health (DPH) to include:
  - Compliance with Medicare conditions of coverage for ambulatory surgical centers as required in the Code of Federal Regulations

- Limit surgical procedures to those that do not result in extensive blood loss, do not require major or prolonged invasion of body cavities, do not directly involve major blood vessels, and are not emergency or life threatening in nature.
  - Establishing and implementing policies and procedures consistent with Medicare conditions as set forth in the Code of Federal Regulations.
5. Require the DPH to perform initial inspections of a surgical clinic within 45 days of application approval as well as periodic inspections at least once every three years.
  6. Allow for the DPH to contract with licensed physicians and surgeons to serve as surveyors to perform the inspections.
  7. Require the DPH to establish a training program for inspection personnel.
  8. Exempts accredited surgical clinics, those certified to participate in the Medicare Program as those exempt from state licensure pursuant to 1206 of the Health and Safety Code for the provisions listed in 4 – 7.

#### **AUTHOR'S INTENT**

The sponsor states that this bill is intended to define operation staffing and procedural standards for surgical clinics licensed by the Department of Public Health.

#### **PRIOR HISTORY/RELATED BILLS**

AB 2308 (Plescia) of 2006 – This bill was vetoed by the governor. The veto message stated. "While I recognize the need for the Department of Health Services to develop clear licensing standards for surgical clinics, I am unable to support Assembly Bill 2308 because it does not establish such standards, but rather statutorily mandates creation of another advisory committee and provides an unrealistic timeframe to operate within. I am directing the Department of Health Services to work with stakeholders to develop standards that will effectively promote quality care in these facilities and to pursue legislation, as needed, to provide licensing standards for surgical clinics in a timely manner."

The board had no position on this bill.

#### **FISCAL IMPACT:**

The sponsor believes that 400 or more additional locations would qualify under the new criteria for licensure as a drug clinic by the board. The board anticipates the need for a part-time office technician to process new applications should all eligible facilities choose to pursue licensure with the board. In addition, the board would require an additional inspector to complete initial and annual inspections of those surgical license specified.

## COMMENTS:

Current law allows the board to issue a clinic license only to an entity licensed by H&S Code section 1204. However there is no requirement that a surgical center must be licensed by the DHS to operate. The unintended consequence is that approximately 400 – 500 ambulatory surgical centers do not qualify for licensure as a clinic by the board, but would under this bill.

There are currently four approved accreditation agencies:

- American Association for Accreditation of Ambulatory Surgery Facilities Inc. (AAAASF)
- Accreditation Association for Ambulatory Health Care (AAAHC)
- Joint Commission of Accreditation of Healthcare Organizations (JCAHO)
- The Institute for Medical Quality (IMQ)

With the approval of the Board President, board staff offered an amendment to the bill that would require board inspectors to complete initial as well as annual inspections of board licensed clinics that are not also licensed by the DPH. This mandate is necessary to ensure the proper handling and dispensing of the common drug supply given that no other regulatory agency will be completing inspections on these licensed sites.

Additionally, the amendments will require all board licensed surgical centers to complete a self-assessment on an annual basis.

These amendments were incorporated in the July 16, 2007 version of the bill.

## HISTORY:

### Dates Actions

- 07/16/07 July 16 Read second time, amended, and re-referred to Com. on APPR.  
07/12/07 July 12 From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 9. Noes 0.)  
07/02/07 July 2 Re-referred to Com. on B., P. & E.D.  
06/28/07 June 28 From committee: Do pass, and re-refer to Com. on RLS. Re-referred. (Ayes 9. Noes 0.)  
06/14/07 June 14 Referred to Coms. on HEALTH and RLS.  
06/05/07 June 5 In Senate. Read first time. To Com. on RLS. for assignment.  
06/04/07 June 4 Read third time, passed, and to Senate. (Ayes 79. Noes 0. Page 1802.)  
06/01/07 June 1 From committee: Do pass. (Ayes 17. Noes 0.) (May 31). Read second time. To third reading.  
05/02/07 May 2 In committee: Set, first hearing. Referred to APPR. suspense file.  
04/18/07 Apr. 18 Re-referred to Com. on APPR.  
04/17/07 Apr. 17 Read second time and amended.  
04/16/07 Apr. 16 From committee: Amend, and do pass as amended, and re-refer to

Com. on APPR. with recommendation: To Consent Calendar. (Ayes 17.  
Noes 0.) (April 10).

03/29/07 Mar. 29 Re-referred to Com. on HEALTH.

03/28/07 Mar. 28 From committee chair, with author's amendments: Amend, and re-  
refer to Com. on HEALTH. Read second time and amended.

03/01/07 Mar. 1 Referred to Com. on HEALTH.

02/22/07 Feb. 22 From printer. May be heard in committee March 24.

02/21/07 Feb. 21 Read first time. To print.

Revised July 17, 2007

AMENDED IN SENATE JULY 16, 2007  
AMENDED IN ASSEMBLY APRIL 17, 2007  
AMENDED IN ASSEMBLY MARCH 28, 2007  
CALIFORNIA LEGISLATURE—2007—08 REGULAR SESSION

**ASSEMBLY BILL**

**No. 543**

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**Introduced by Assembly Member Plescia  
(Coauthor: Assembly Member Jones)**

February 21, 2007

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~~An act to amend Sections 2472 and 4190 of the Business and Professions Code, to amend Sections 1204, 1206, 1214.1, 1226, 1226.5, 1233, 1242, and 1248.1 of, and to add Section 1212.5 to, the Health and Safety Code, and to amend Section 139.3 of the Labor Code, relating to health clinics.~~  
*An act to amend Section 4190 of the Business and Professions Code, and to add Section 1212.5 to the Health and Safety Code, relating to health clinics.*

LEGISLATIVE COUNSEL'S DIGEST

AB 543, as amended, Plescia. ~~Ambulatory surgical centers~~ *Surgical clinics*: licensure.

Existing law, with certain exceptions, provides for the licensure and regulation of health facilities and clinics, including specialty clinics, by the State Department of ~~Health Services~~ *Public Health*. Existing law defines a specialty clinic to include a surgical clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. A violation of these provisions is a crime. ~~Effective July 1, 2007, these duties will be transferred to the State Department of Public Health.~~

~~This bill would redesignate a surgical clinic as an ambulatory surgical center for purposes of these licensure and regulatory requirements and would make various conforming changes.~~

This bill would require, on or after January 1, 2008, any person, firm, association, partnership, or corporation desiring a license for ~~an ambulatory surgical center~~ *a surgical clinic, except specified surgical clinics and ambulatory surgical centers*, in addition to other prescribed licensing requirements, to meet prescribed operational, staffing, and procedural standards. The bill would require the department to perform initial inspections of ~~an ambulatory surgical center~~ *a surgical clinic* within 45 calendar days of the date of an application *approval*, and to perform periodic inspections at least once every 3 years thereafter. ~~The bill would specify that, on and after January 1, 2008, surgical clinics that have licenses issued prior to that date, shall not be subject to those additional requirements for ambulatory surgical centers until January 1, 2013. The bill would prohibit the department from issuing any new surgical clinic licenses on or after January 1, 2008.~~

The bill would require the department, until January 1, 2015, contingent upon an appropriation in the annual Budget Act, to establish a program for the training of ambulatory surgical center inspection personnel, and *would require the department* to prepare a comprehensive report on the training program, as provided. By imposing new licensure requirements on ~~ambulatory surgical centers~~ *surgical clinics*, a violation of which would be a crime, the bill would impose a state-mandated local program.

*Existing law provides that a surgical clinic may not operate and is not entitled to the benefits of specified provisions of the Pharmacy Law without a license issued by the California State Board of Pharmacy. Existing law authorizes the board to inspect a clinic at any time.*

*This bill would, instead, provide that a surgical clinic that is licensed by the State Department of Public Health, accredited by an accreditation agency, or certified to participate in the Medicare Program is not entitled to the above-described benefits without a license issued by the board. It would also specify inspection requirements for the accredited or certified surgical clinic's.*

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1     SECTION 1. Section 4190 of the Business and Professions  
2     Code is amended to read:

3     4190. (a) Notwithstanding any provision of this chapter, a  
4     surgical clinic, ~~as defined in~~ *licensed pursuant to* paragraph (1) of  
5     subdivision (b) of Section 1204 *and Section 1212.5* of the Health  
6     and Safety Code, *accredited by an accreditation agency as defined*  
7     *in Section 1248 of the Health and Safety Code, or certified to*  
8     *participate in the Medicare Program under Title XVIII (42 U.S.C.*  
9     *Sec. 1395 et seq.) of the federal Social Security Act,* may purchase  
10    drugs at wholesale for administration or dispensing, under the  
11    direction of a physician, to patients registered for care at the clinic,  
12    as provided in subdivision (b). The clinic shall keep records of the  
13    kind and amounts of drugs purchased, administered, and dispensed,  
14    and the records shall be available and maintained for a minimum  
15    of three years for inspection by all properly authorized personnel.

16    (b) The drug distribution service of a surgical clinic shall be  
17    limited to the use of drugs for administration to the patients of the  
18    surgical clinic and to the dispensing of drugs for the control of  
19    pain and nausea for patients of the clinic. Drugs shall not be  
20    dispensed in an amount greater than that required to meet the  
21    patient's needs for 72 hours. Drugs for administration shall be  
22    those drugs directly applied, whether by injection, inhalation,  
23    ingestion, or any other means, to the body of a patient for his or  
24    her immediate needs.

25    (c) ~~No surgical clinic shall operate without a license issued by~~  
26    ~~the board nor shall it~~ be entitled to the benefits of this section until  
27    it has obtained a license from the board. A separate license shall  
28    be required for each clinic location. A clinic shall notify the board  
29    of any change in the clinic's address on a form furnished by the  
30    board.

31    (d) Any proposed change in ownership or beneficial interest in  
32    the licensee shall be reported to the board, on a form to be furnished  
33    by the board, at least 30 days prior to the execution of any  
34    agreement to purchase, sell, exchange, gift or otherwise transfer

1 any ownership or beneficial interest or prior to any transfer of  
2 ownership or beneficial interest, whichever occurs earlier.

3 (e) *The board shall inspect a surgical clinic that is accredited*  
4 *by an accreditation agency or is certified to participate in the*  
5 *Medicare Program as specified in subdivision (a), but is not*  
6 *licensed pursuant to Sections 1204 and 1212.5 of the Health and*  
7 *Safety Code, within 120 days of the issuance of a clinic licensed*  
8 *pursuant to this article, and at least annually thereafter.*

9 (f) *Every surgical clinic issued a license pursuant to this article*  
10 *shall complete a self-assessment within 30 days of opening and at*  
11 *least 30 days before each license renewal pursuant to this article.*  
12 *The completed self-assessment form shall be retained at the*  
13 *licensed premises for a period of three years.*

14 SEC. 2. *Section 1212.5 is added to the Health and Safety Code,*  
15 *to read:*

16 1212.5. (a) *In addition to other licensing requirements of this*  
17 *chapter, any person, firm, association, partnership, or corporation*  
18 *desiring a license for a surgical clinic shall meet the following*  
19 *standards:*

20 (1) *Comply with the Medicare conditions of coverage for*  
21 *ambulatory surgical centers, as set forth in Subpart C of Part 416*  
22 *of Title 42 of the Code of Federal Regulations, including*  
23 *interpretive guidelines issued by the Centers for Medicare and*  
24 *Medicaid Services as it pertains to Subpart C of Part 416 of Title*  
25 *42 of the Code of Federal Regulations.*

26 (2) *Limit surgical procedures to those that:*

27 (A) *Do not result in extensive blood loss.*

28 (B) *Do not require major or prolonged invasion of body cavities.*

29 (C) *Do not directly involve major blood vessels.*

30 (D) *Are not emergency or life threatening in nature.*

31 (3) *Establish and implement policies and procedures consistent*  
32 *with the Medicare conditions of coverage set forth in Subpart C*  
33 *of Part 416 of Title 42 of the Code of Federal Regulations,*  
34 *including interpretive guidelines issued by the Centers for*  
35 *Medicare and Medicaid Services as it pertains to Subpart C of*  
36 *Part 416 of Title 42 of the code of Federal Regulations, including,*  
37 *but not limited to:*

38 (A) *Physician services policies and procedures, including*  
39 *surgical and anesthesia services.*

40 (B) *Nursing services policies and procedures.*

1 (C) *Infection control policies and procedures.*

2 (D) *Pharmaceutical services policies and procedures.*

3 (E) *Housekeeping services policies and procedures that include*  
4 *provisions for maintenance of a safe and clean environment.*

5 (F) *Laboratory and radiology services.*

6 (G) *Patient health records policies and procedures, which shall*  
7 *be developed with the assistance of a person skilled in records*  
8 *maintenance and preservation.*

9 (H) *Personnel policies and procedures.*

10 (b) *Notwithstanding subdivision (c) of Section 1228, the*  
11 *department shall perform initial inspections of a surgical clinic*  
12 *within 45 calendar days of the date the completed application is*  
13 *received and approved by the department. Periodic inspections*  
14 *shall occur at least once every three years thereafter.*

15 (c) *The department may contract with licensed physicians and*  
16 *surgeons to serve as surveyors to perform inspections of surgical*  
17 *clinics for compliance with the licensure requirements of this*  
18 *chapter and in a manner that is consistent with department*  
19 *inspections pursuant to Section 1279.*

20 (d) *Contingent upon an appropriation in the annual Budget Act,*  
21 *the department shall until January 1, 2015, establish a program*  
22 *for training of surgical clinic inspection personnel. The goal of*  
23 *this program shall be to provide a sufficient number of qualified*  
24 *persons to facilitate the timely performance of the department's*  
25 *duties and responsibilities relating to initial and periodic licensing*  
26 *inspections of surgical clinics, in order to ensure compliance with*  
27 *this chapter.*

28 (e) (1) *The department shall prepare a comprehensive report*  
29 *on the training program setting forth its goals, objectives, and*  
30 *structure. The report shall assess processing time for initial and*  
31 *periodic licensing inspections of surgical clinics and include*  
32 *information on all of the following:*

33 (A) *The number of surgical clinic inspection personnel to be*  
34 *trained annually.*

35 (B) *A timeline for completion of training.*

36 (C) *A process for gathering information to evaluate the training*  
37 *programs efficiency that includes dropout and retention rates.*

38 (D) *A mechanism to annually assess the need for the training*  
39 *program to continue.*

1 (2) The report required by paragraph (1) shall be submitted to  
2 the Joint Legislative Budget Committee no later than July 1, 2008,  
3 and no later than July 1 of each year thereafter, through July 1,  
4 2014.

5 (f) (1) This section shall not apply to any surgical clinic that  
6 is any of the following:

7 (A) Accredited by an accreditation agency as defined in Section  
8 1248.

9 (B) Certified to participate in the Medicare Program under  
10 Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social  
11 Security Act.

12 (C) Exempt from state licensure pursuant to Section 1206.

13 (2) An entity exempt from the requirements of this section  
14 pursuant to paragraph (1) may, at its option, apply for licensure  
15 as a surgical clinic.

16 SECTION 1. ~~Section 2472 of the Business and Professions~~  
17 ~~Code is amended to read:~~

18 ~~2472. (a) The certificate to practice podiatric medicine~~  
19 ~~authorizes the holder to practice podiatric medicine.~~

20 ~~(b) As used in this chapter, "podiatric medicine" means the~~  
21 ~~diagnosis, medical, surgical, mechanical, manipulative, and~~  
22 ~~electrical treatment of the human foot, including the ankle and~~  
23 ~~tendons that insert into the foot and the nonsurgical treatment of~~  
24 ~~the muscles and tendons of the leg governing the functions of the~~  
25 ~~foot.~~

26 ~~(c) A doctor of podiatric medicine may not administer an~~  
27 ~~anesthetic other than local. If an anesthetic other than local is~~  
28 ~~required for any procedure, the anesthetic shall be administered~~  
29 ~~by another licensed health care practitioner who is authorized to~~  
30 ~~administer the required anesthetic within the scope of his or her~~  
31 ~~practice.~~

32 ~~(d) (1) A doctor of podiatric medicine who is ankle certified~~  
33 ~~by the board on and after January 1, 1984, may do the following:~~

34 ~~(A) Perform surgical treatment of the ankle and tendons at the~~  
35 ~~level of the ankle pursuant to subdivision (c).~~

36 ~~(B) Perform services under the direct supervision of a physician~~  
37 ~~and surgeon, as an assistant at surgery, in surgical procedures that~~  
38 ~~are otherwise beyond the scope of practice of a doctor of podiatric~~  
39 ~~medicine.~~



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

ARNOLD SCHWARZENEGGER, GOVERNOR

May 1, 2007

The Honorable George Plescia  
California State Assembly  
State Capitol, Room 3141  
Sacramento, CA 95814

AB 543: Support

Dear Assembly Member Plescia:

I am pleased to inform you that the Board of Pharmacy supports your Assembly Bill 543 (as amended on April 17, 2007) relating to licensing of ambulatory surgery centers.

Current law allows the board to issue a clinic license only to an entity also licensed by the Department of Health Services. Current law does not require an ambulatory surgery center however to be licensed by the DHS to operate. The unintended consequence is that approximately 400 – 500 ambulatory surgical centers are not currently licensed by the DHS and therefore do not qualify for board licensure as a clinic.

This bill will expand the board's ability to issue clinic licenses to ambulatory surgery centers that are currently not licensed by the Department of Health Services but are either certified to participate in the Medicare Program or accredited by an accreditation agency as defined. This board-issued clinic license would allow such clinics to purchase drugs at wholesale as well as commingle medications, instead of requiring separate drug supplies owned by each prescriber or a drug supply wholly owned by the professional director or some single prescriber.

The board is pleased to support AB 543.

Sincerely,

A handwritten signature in cursive script that reads "Virginia Herold".

Virginia Herold  
Executive Officer

**CALIFORNIA STATE BOARD OF PHARMACY  
BILL ANALYSIS**

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**BILL NUMBER: AB 1025**

**VERSION: As amended July 5, 2007**

**AUTHOR: Bass**

**SPONSOR: National Employment Law Project**

**BOARD POSITION: Oppose**

**SUBJECT: Professions and vocations: Licensure**

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**EXISTING LAW:**

1. Allows the board to deny a license on the grounds that an applicant has done any of the following:
  - Been convicted of a crime including a plead or verdict of guilty or a conviction following a plead of nolo contendere
  - Done any act involving dishonesty, fraud, deceit with the intent to substantially benefit himself or another, or substantially injure another
  - Done any act which if done by a licentiate of the business or profession in question would be grounds for suspension or revocation of a license
2. Prohibits the board from denying a license solely on the basis that he or she has been convicted of a felony if he or she has obtained a certification of rehabilitation or that he or she has been convicted of misdemeanor if he or she has met all applicable requirements of the criteria of rehabilitation as developed by the board
3. Allows the board to deny a license on the grounds that the applicant knowingly makes a false statement of fact required to be relevant in the application
4. Specifies the procedures the board must comply with to deny an application for licensure
5. Authorizes the board to suspend or revoke a license on the grounds that the licensee has been convicted of a crime if the crime is substantially related to the duties of the license
6. Details the board's requirement to notify the licensee of the revocation or suspension

**THIS BILL WOULD:**

1. Prohibit the board from denying an application solely on the basis that he or she has been convicted of a felony if either of the following apply:

- The applicant has obtained a certificate of rehabilitation
  - The felony conviction has been dismissed pursuant to Section 1203.4 of the Penal Code, which creates a presumption of rehabilitation unless the board provides substantial evidence to the contrary to the applicant documenting the substantial relationship to the duties for the license being sought.
2. Prohibit the board from denying an application solely on the basis that he or she has been convicted of a misdemeanor if either of the following apply:
    - The applicant has met all applicable requirements of the criteria of rehabilitation developed by the board
    - The misdemeanor conviction has been dismissed pursuant to either 1203.4 or 1203.4a of the Penal Code, which creates a presumption of rehabilitation unless the board provides substantial evidence to the contrary to the applicant documenting the substantial relationship to the duties for the license being sought
  3. Permit the board to deny a license on the grounds that the applicant knowingly made a false statement of fact to be revealed in the application.
  4. require the DCA to report annually the number of denials of licenses based solely on dismissed felony or misdemeanor convictions.
  5. Requires the board to include with a notice of denial a copy of the criminal record relied upon in making the denial determination. This information shall not be modified or altered and shall be provided in such a manner as to protect the confidentiality and privacy of the applicant's criminal history record, as the criminal record shall not be made available by the board to any employer.
  6. Require the board to record and maintain the name of the applicant, the applicant's address and the date the criminal history was provided to the applicant. This information must be available upon request by the Department of Justice or the Federal Bureau of Investigation.
  7. Prohibit the board from suspending or revoking a license based solely on any criminal conviction that has been dismissed pursuant to Section 1203.4 or 1203.4a of the Penal Code since that dismissal creates a presumption of rehabilitation unless the board provides substantial evidence to the contrary to the applicant documenting the substantial relationship to the duties for the license obtained.
  8. Require the DCA to prepare an annual report that documents the number of suspensions and revocations of licenses based solely on dismissed criminal convictions.
  9. Requires that if a suspension or revocation of a license is due at least in part to the ex-licensee's criminal history, the board shall provide a copy of the ex-licensee's criminal record. This information shall be unaltered and provided in such a manner as to protect the confidentiality and privacy of the applicant's criminal history record, as the criminal record shall not be made available by the board to any employer.

10. Require the board to record and maintain the name of the ex-licensee, the ex-licensee's address and the date the criminal history was provided to an ex-licensee. This information must be available upon request by the Department of Justice or the Federal Bureau of Investigation.

#### **AUTHOR'S INTENT**

According to the author's office, this proposal will restore accountability to the process of criminal background checks, while ensuring that qualified workers are not unfairly denied employment due to an irrelevant or inaccurate criminal record.

#### **FISCAL IMPACT:**

The board does not anticipate any major fiscal impact to the board as criminal history records are already obtained as part of the investigation process. Any additional workload could be absorbed within existing resources.

#### **COMMENTS:**

This bill was initially amended and removed the prohibition of the board to pursue disciplinary action for arrests more than a year old that has no disposition reported. The most recent amendments further define the conditions under which the board can discipline a licensee or deny an application.

Currently, the board initiates disciplinary actions and may revoke, suspend or deny a license based on a conviction that is set aside if the conviction is substantially related to the license currently held, or being sought. Pursuant to the requirements of the Administrative Procedures Act, the board must demonstrate a substantial relation between a criminal conviction and any board action.

The board does not routinely provide a copy of the criminal history record, although these documents may be referred to in the legal pleadings used to deny or revoke a license and would be part of the discovery process.

This proposal would limit the board's ability to pursue administrative action on violations that are substantially related to the practice of pharmacy. As a consumer protection agency, it is necessary for the board to consider all relevant history, including convictions that have been set aside, when determining the outcome of any application or disciplinary action to ensure the board's public protection mandate is met.

#### **SUPPORT and OPPOSITION**

##### Support

National Employment Law Project (sponsor)

Alameda County District Attorney's Office  
California Labor Federation, AFL-CIO  
California Teamsters Public Affairs Council  
Chinese for Affirmative Action  
Drug Policy Alliance Network  
Engineers and Scientists of California  
Friends Committee on Legislation of California  
Georgetown University Public Policy Institute  
Legal Aid Society - Employment Law Center, San Francisco  
Service Employees International Union  
Stanford Community Law Clinic, East Palo Alto  
United Food & Commercial Workers  
Women's Employment Rights Clinic of Golden Gate University School of Law

Oppose

Board for Professional Engineers and Land Surveyors  
Board of Accountancy  
Board of Barbering and Cosmetology  
Board of Behavioral Sciences  
Board of Optometry  
California District Attorneys Association  
Citizens Commission on Human Rights  
Contractors State License Board  
Department of Consumer Affairs  
Structural Pest Control Board

**HISTORY:**

**Dates      Actions**

07/10/07 July 10 From committee: Do pass, and re-refer to Com. on APPR.  
Re-referred. (Ayes 5. Noes 3.) .

07/05/07 July 5 From committee chair, with author's amendments: Amend,  
and re-refer to committee. Read second time, amended, and re-  
referred to Com. on B., P. & E.D.

06/14/07 June 14 Referred to Com. on B., P. & E.D.

06/05/07 June 5 In Senate. Read first time. To Com. on RLS. for assignment.

06/04/07 June 4 Read third time, passed, and to Senate. (Ayes 48. Noes 31.  
Page 1839.)

05/31/07 May 31 Read third time, amended, and returned to third reading.  
(Ayes 43. Noes 27. Page 1707.).

05/14/07 May 14 Read second time. To third reading.

05/10/07 May 10 From committee: Do pass. (Ayes 11. Noes 4.) (May 9).

04/25/07 Apr. 25 From committee: Do pass, and re-refer to Com. on APPR.  
Re-referred. (Ayes 7. Noes 2.) (April 24).

04/17/07 Apr. 17 Re-referred to Com. on B. & P.

- 04/16/07 Apr. 16 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
- 03/12/07 Mar. 12 Referred to Com. on B. & P.
- 02/23/07 Feb. 23 From printer. May be heard in committee March 25.
- 02/22/07 Feb. 22 Read first time. To print.

Revised July 13, 2007

AMENDED IN SENATE JULY 5, 2007

AMENDED IN ASSEMBLY MAY 31, 2007

AMENDED IN ASSEMBLY APRIL 16, 2007

CALIFORNIA LEGISLATURE—2007—08 REGULAR SESSION

**ASSEMBLY BILL**

**No. 1025**

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**Introduced by Assembly Member Bass**

February 22, 2007

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An act to amend Sections 480, 485, 490, and 491 of the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 1025, as amended, Bass. Professions and vocations: licensure.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law authorizes a board to deny licensure on certain bases, including an applicant's conviction of a crime regardless of whether the conviction has been dismissed on specified grounds, an applicant's performance of any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself or herself or another or to substantially injure another, or an applicant's performance of any act that would be grounds for suspension or revocation of the license. Existing law requires a board that denies an application for licensure to provide the applicant with notice of the denial, as specified. Existing law authorizes a board to suspend or revoke a license on the basis that a licensee has been convicted of a crime that is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued, regardless of whether the conviction has

been dismissed on specified grounds, and requires the board to provide the ex-licensee with certain information upon doing so.

This bill would provide that a person may not be denied licensure based *solely* on a felony *criminal* conviction ~~that has been dismissed on specified grounds if certain requirements have been met if the person has been rehabilitated, as specified.~~ The bill would *also* provide that a person may not be denied licensure ~~based on a misdemeanor conviction that has been dismissed on specified grounds.~~ The bill would ~~also~~ provide that a person may not *or* have his or her license suspended or revoked *solely* based on a criminal conviction that has been dismissed on specified grounds, *unless the board provides substantial evidence, as specified, justifying the denial suspension, or revocation.* The bill would require the board to provide an applicant or ex-licensee whose application has been denied or whose license has been suspended or revoked based upon a crime with a copy of his or her criminal history record, as specified. The bill would require the board to maintain specified information pertaining to the provision of criminal history records and to make that information available upon request by the Department of Justice or the Federal Bureau of Investigation. *The bill would require the department, to prepare annual reports to the Legislature documenting the board's denial, suspension, or revocation of licenses based on the bill's provisions.*

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

1 SECTION 1. Section 480 of the Business and Professions Code  
2 is amended to read:  
3 480. (a) A board may deny a license regulated by this code  
4 on the grounds that the applicant has done one of the following:  
5 (1) Been convicted of a crime. A conviction within the meaning  
6 of this section means a plea or verdict of guilty or a conviction  
7 following a plea of nolo contendere. Any action which a board is  
8 permitted to take following the establishment of a conviction may  
9 be taken when the time for appeal has elapsed, or the judgment of  
10 conviction has been affirmed on appeal, or when an order granting  
11 probation is made suspending the imposition of sentence.

1 (2) Done any act involving dishonesty, fraud or deceit with the  
2 intent to substantially benefit himself or another, or substantially  
3 injure another; or

4 (3) Done any act which if done by a licentiate of the business  
5 or profession in question, would be grounds for suspension or  
6 revocation of license.

7 The board may deny a license pursuant to this subdivision only  
8 if the crime or act is substantially related to the qualifications,  
9 functions or duties of the business or profession for which  
10 application is made.

11 (b) Notwithstanding any other provision of this ~~code~~ *code*:

12 (1) No person shall be denied a license solely on the basis that  
13 he or she has been convicted of a felony if either of the following  
14 apply:

15 (A) He or she has obtained a certificate of rehabilitation under  
16 Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part  
17 3 of the Penal Code.

18 (B) The felony conviction has been dismissed pursuant to  
19 Section 1203.4 of the Penal Code, ~~there have been no subsequent~~  
20 ~~felony convictions, and either at least three years have passed since~~  
21 ~~the dismissal of the conviction or at least five years have passed~~  
22 ~~since the person completed his or her sentence. This paragraph~~  
23 ~~shall not apply if the conviction was for any offense defined in~~  
24 ~~subdivision (e) of Section 667.5 of the Penal Code as a violent~~  
25 ~~felony or any offense defined in subdivision (e) of Section 1192.7~~  
26 ~~of the Penal Code as a serious felony. *which creates a presumption*~~  
27 ~~*of rehabilitation for purposes of this paragraph, unless the board*~~  
28 ~~*provides substantial evidence to the contrary in writing to the*~~  
29 ~~*person justifying the board's denial of the license based solely on*~~  
30 ~~*his or her dismissed felony conviction that is substantially related*~~  
31 ~~*to the qualifications, functions, or duties of the business or*~~  
32 ~~*profession for which application is made.*~~

33 (2) No person shall be denied a license solely on the basis that  
34 he or she has been convicted of a misdemeanor if either of the  
35 following apply:

36 ~~(A)~~

37 (A) He or she has met all applicable requirements of the criteria  
38 of rehabilitation developed by the board to evaluate the  
39 rehabilitation of a person when considering the denial of a license  
40 under subdivision (a) of Section 482.

1 (B) The misdemeanor conviction has been dismissed pursuant  
2 to either Section 1203.4 or 1203.4a of the Penal Code, *which*  
3 *creates a presumption of rehabilitation for purposes of this*  
4 *paragraph, unless the board provides substantial evidence to the*  
5 *contrary in writing to the person justifying the board's denial of*  
6 *the license based solely on his or her dismissed misdemeanor*  
7 *conviction that is substantially related to the qualifications,*  
8 *functions, or duties of the business or profession for which*  
9 *application is made.*

10 (c) A board may deny a license regulated by this code on the  
11 ground that the applicant knowingly made a false statement of fact  
12 required to be revealed in the application for such license.

13 (d) *The department shall annually prepare a report, to be*  
14 *submitted to the Legislature on October 1, that documents board*  
15 *denials of licenses based solely on dismissed felony or*  
16 *misdemeanor convictions as specified in subdivision (b).*

17 SEC. 2. Section 485 of the Business and Professions Code is  
18 amended to read:

19 485. (a) Upon denial of an application for a license under this  
20 chapter or Section 496, the board shall do either of the following:

21 (1) File and serve a statement of issues in accordance with  
22 Chapter 5 (commencing with Section 11500) of Part 1 of Division  
23 3 of Title 2 of the Government Code.

24 (2) Notify the applicant that the application is denied, stating  
25 (A) the reason for the denial, and (B) that the applicant has the  
26 right to a hearing under Chapter 5 (commencing with Section  
27 11500) of Part 1 of Division 3 of Title 2 of the Government Code  
28 if *a* written request for *a* hearing is made within 60 days after  
29 service of the notice of denial. Unless *a* written request for *a*  
30 hearing is made within the 60-day period, the applicant's right to  
31 a hearing is deemed waived.

32 Service of the notice of denial may be made in the manner  
33 authorized for service of summons in civil actions, or by registered  
34 mail addressed to the applicant at the latest address filed by the  
35 applicant in writing with the board in his or her application or  
36 otherwise. Service by mail is complete on the date of mailing.

37 (b) If the denial of a license is due at least in part to the  
38 applicant's state or federal criminal history record, the board shall  
39 include with the information provided pursuant to paragraph (1)

1 or (2) of subdivision (a) a copy of the applicant's criminal history  
2 record.

3 (1) The state or federal criminal history record shall not be  
4 modified or altered from its form or content as provided by the  
5 Department of Justice.

6 (2) The criminal history record shall be provided in such a  
7 manner as to protect the confidentiality and privacy of the  
8 applicant's criminal history record, and the criminal history record  
9 shall not be made available by the board to any employer.

10 (3) The board shall record and maintain the name of the  
11 applicant, the applicant's address, and the date the criminal history  
12 record was provided by the board to the applicant pursuant to this  
13 section. The board shall make that information available upon  
14 request by the Department of Justice or the Federal Bureau of  
15 Investigation.

16 SEC. 3. Section 490 of the Business and Professions Code is  
17 amended to read:

18 490. (a) A board may suspend or revoke a license on the  
19 ground that the licensee has been convicted of a crime, if the crime  
20 is substantially related to the qualifications, functions, or duties of  
21 the business or profession for which the license was issued. A  
22 conviction within the meaning of this section means a plea or  
23 verdict of guilty or a conviction following a plea of nolo  
24 contendere. Any action which a board is permitted to take  
25 following the establishment of a conviction may be taken when  
26 the time for appeal has elapsed, or the judgment of conviction has  
27 been affirmed on appeal, or when an order granting probation is  
28 made suspending the imposition of sentence. ~~No~~

29 (b) *No license shall be suspended or revoked based solely on  
30 any criminal conviction that has been dismissed pursuant to Section  
31 1203.4 or 1203.4a of the Penal Code, since that dismissal creates  
32 a presumption of rehabilitation for purposes of this section, unless  
33 the board provides substantial evidence to the contrary in writing  
34 to the person justifying the board's suspension or revocation of  
35 the license based solely on his or her dismissed conviction that is  
36 substantially related to the qualifications, functions, or duties of  
37 the business or profession for which the license was made.*

38 (c) *The department shall annually prepare a report, to be  
39 submitted to the Legislature on October 1, that documents board*

1 *suspensions or revocations of licenses based solely on dismissed*  
2 *criminal convictions as specified in subdivision (b).*

3 SEC. 4. Section 491 of the Business and Professions Code is  
4 amended to read:

5 491. (a) Upon suspension or revocation of a license by a board  
6 on one or more of the grounds specified in Section 490, the board  
7 shall do both of the following:

8 (1) Send a copy of the provisions of Section 11522 of the  
9 Government Code to the ex-licensee.

10 (2) Send a copy of the criteria relating to rehabilitation  
11 formulated under Section 482 to the ex-licensee.

12 (b) If the suspension or revocation of a license is due at least in  
13 part to the ex-licensee's state or federal criminal history record,  
14 the board shall include with the information provided pursuant to  
15 subdivision (a) a copy of the ex-licensee's criminal history record.

16 (1) The state or federal criminal history record shall not be  
17 modified or altered from its form or content as provided by the  
18 Department of Justice.

19 (2) The criminal history record shall be provided in such a  
20 manner as to protect the confidentiality and privacy of the  
21 ex-licensee's criminal history record, and the criminal history  
22 record shall not be made available by the board to any employer.

23 (3) The board shall record and maintain the name of the  
24 ex-licensee, the ex-licensee's address, and the date the criminal  
25 history record was provided by the board to an ex-licensee pursuant  
26 to this section. The board shall make that information available  
27 upon request by the Department of Justice or the Federal Bureau  
28 of Investigation.



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

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

June 15, 2007

The Honorable Karen Bass  
California State Assembly  
State Capitol, Room 319  
Sacramento, CA 95814

AB 1025 Oppose

Dear Assembly Member Bass:

The Board of Pharmacy regrets to advise you that it opposes your Assembly Bill 1025. This bill would prohibit the board from denying, revoking or suspending a license based on a criminal conviction that had been dismissed pursuant to Section 1203.4 or 1203.4(a) of the Penal Code.

The board's mandate is consumer protection. When evaluating an applicant for licensure the board requires a state and federal criminal background check. Our licensees have access to and the ability to purchase prescription drugs including controlled substances. They also have access to sensitive patient medical information as well as credit card information.

The board appreciates your concern behind AB 1025 and recognizes the need not to bar individuals from a profession; however the board must balance that need with its mandate to protect California consumers. To that end, the board's Disciplinary Guidelines require board members to consider rehabilitation efforts by an applicant or licensee as one of the factors when rendering a decision to issue or deny a license or discipline a licensee. The board is required to comply with the Administrative Procedures Act when pursuing administrative action. The APA also dictates the policies the board must take to prohibit the board from denying an individual due process.

It is essential that the board retain its ability to pursue disciplinary action of a licensee or applicant for all arrests and convictions, even those that could be set aside.

You are welcome to contact me at (916) 574-7911 if you would like to discuss this further or have questions about the board's comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Virginia Herold".

Virginia Herold  
Executive Officer

**CALIFORNIA STATE BOARD OF PHARMACY  
BILL ANALYSIS**



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**BILL NUMBER: SB 472**

**VERSION: As amended June 20, 2007**

**AUTHOR: Corbett**

**SPONSOR: Latino Coalition for a Healthy  
California, Gray Panthers California & Senior  
Action Network**

**BOARD POSITION: SUPPORT**

**SUBJECT: Pharmacies: prescription labels**

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**EXISTING LAW:**

1. Details the labeling requirements for a prescription container.
2. Prohibits a pharmacist from dispensing a prescription that does not meet the labeling requirements

**THIS BILL WOULD:**

1. Make findings about the cost of health care and prescription drugs
2. Make findings about the number of medication errors and site some causes for these errors
3. State that it is the intent of the Legislature to adopt a standardized prescription drug label that will be designed by the California State Board of Pharmacy (board) for use on any prescription drug dispensed to a patient in California.
4. Require the board to promulgate regulations that require on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to California patients
5. Require the board to hold public meetings statewide that are separate from the normally scheduled board meetings to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties
6. Require the board to consider all of the following factors when developing the requirements for the prescription label:
  - Medical literacy research that points to increased understandability of labels
  - Improved directions for use
  - Improved font types and sizes
  - Placement of information that is patient-centered
  - The needs of those patients with limited English proficiency

- The needs of seniors
  - Technology requirements necessary to implement the standards
7. Require the board to report to the legislature on or before January 1, 2010, on the progress under this section as of the time of the report
  8. Require the board to report to the legislature on or before January 1, 2013, on the status of the implementation of the standardized prescription label requirements

**AUTHOR'S INTENT:**

To create a standardized prescription label.

**FISCAL IMPACT:**

The board anticipates a fiscal impact of approximately \$40,000.

**COMMENTS:**

At the April 2007 Board Meeting, the board voted to take a "Support if Amended" position on this bill. The legislation proposed at that time suggested development of a panel of individuals representing consumers, seniors as well as the pharmaceutical industry. This panel was charged with developing the requirements for a standardized prescription label and making such recommendations to the board who would be required to promulgate regulations based upon the recommendations of the panel. Board discussion included an agreement with the basic intent of the proposal, but concern about the process to achieve the intent.

As a result, board staff and the board's President began working with the bill's sponsors to address concerns with the legislative proposal. After several meetings with stakeholders, the author's office and/or the bill's sponsors, the bill was amended to charge the board with the responsibility to develop the requirements for the standardized prescription label through a series of public, statewide meetings.

After the bill was amended to address our concerns, the board's President changed the board's position to support.

Board staff mailed a letter expressing the board's support for the June 20, 2007 version of the bill.

**SUPPORT and OPPOSITION:**

Support  
Latino Coalition for a Healthy California (sponsor)

Gray Panthers California (sponsor)  
Senior Action Network (sponsor)  
California State Board of Pharmacy  
AIDS Healthcare Foundation  
American Federation of State, County and Municipal Employees  
Applied Research Center  
Asian Pacific American Legal Center of Southern California  
California Alliance for Retired Americans  
California Association of Public Authorities for In- Supportive Services  
California Medical Association  
Latino Health Alliance  
Mexican American Legal Defense and Education Fund  
Pharmacist's Planning Service, Inc.  
Southern California HIV Advocacy Coalition

#### Opposition

California Alliance for Consumer Protection

#### **HISTORY:**

##### **Dates Actions**

07/05/07 July 5 From committee: Do pass, but first be re-referred to Com. on APPR.  
(Ayes 10. Noes 0.) Re-referred to Com. on APPR.

06/27/07 June 27 From committee: Do pass, but first be re-referred to Com. on B. & P.  
(Ayes 14. Noes 1.) Re-referred to Com. on B. & P.

06/20/07 June 20 From committee with author's amendments. Read second time.  
Amended. Re-referred to Com. on HEALTH.

06/19/07 June 19 Set, first hearing. Hearing canceled at the request of author.

06/07/07 June 7 To Coms. on HEALTH and B. & P.

05/29/07 May 29 In Assembly. Read first time. Held at Desk.

05/29/07 May 29 Read third time. Passed. (Ayes 27. Noes 10. Page 1097.) To Assembly.

05/21/07 May 21 Read second time. Amended. To third reading.

05/17/07 May 17 From committee: Be placed on second reading file pursuant to Senate  
Rule 28.8 and be amended.

05/02/07 May 2 Set for hearing May 14.

04/30/07 Apr. 30 Read second time. Amended. Re-referred to Com. on APPR.

04/26/07 Apr. 26 From committee: Do pass as amended, but first amend, and re-refer to  
Com. on APPR. (Ayes 7. Noes 1. Page 705.)

04/16/07 Apr. 16 From committee with author's amendments. Read second time.  
Amended. Re-referred to Com. on B., P. & E.D.

04/09/07 Apr. 9 From committee with author's amendments. Read second time.  
Amended. Re-referred to Com. on RLS. Re-referred to Com. on B., P. & E.D.  
Set for hearing April 23.

02/28/07 Feb. 28 To Com. on RLS.

02/22/07 Feb. 22 From print. May be acted upon on or after March 24.

02/21/07 Feb. 21 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Revised July 13, 2007

AMENDED IN ASSEMBLY JUNE 20, 2007

AMENDED IN SENATE MAY 21, 2007

AMENDED IN SENATE APRIL 30, 2007

AMENDED IN SENATE APRIL 16, 2007

AMENDED IN SENATE APRIL 9, 2007

**SENATE BILL**

**No. 472**

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**Introduced by Senator Corbett**

February 21, 2007

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An act to add Section 4076.5 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 472, as amended, Corbett. Prescription drugs: labeling requirements and panel. *requirements.*

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy in the Department of Consumer Affairs. Existing law prohibits a pharmacist from dispensing a prescription, except in a container that meets certain labeling requirements.

This bill would require the board to convene a prescription drug label panel, with specified membership, for purposes of reviewing and making recommendations on a standard format for the labeling of prescription drug containers dispensed in the state that is affordable for pharmacies. The bill would require the panel to make a recommendation for a standardized prescription drug container label to the board on or before October 31, 2008, would require the board to promulgate regulations establishing requirements for a mandatory standardized label for

~~prescription drug containers within 90 days of receiving the panel's recommendation, and would require specified pharmacies in the state to begin using the standardized labels within 90 days of the effective date of the regulations. The bill would require that pharmacy consultations by a telephonic translation service be available to patients with limited English language proficiency, and that pharmacies be authorized to issue translated prescription drug labels, as specified~~  
*promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. The bill would require the board to hold special public meetings statewide in order to seek information from certain groups, and would require the board to consider specified factors in developing the label requirements. The bill would require the board to report to the Legislature on or before January 1, 2010, on its progress at the time of the report, and to report to the Legislature on or before January 1, 2013, on the status of implementation of the requirements.*

Because a knowing violation of the Pharmacy Law constitutes a crime, and because the above-described provisions would impose additional duties under that law, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
 State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. This act shall be known and may be cited as the  
 2 California Patient Medication Safety Act.

3 SEC. 2. The Legislature hereby finds and declares all of the  
 4 following:

5 (a) Health care costs and spending in California are rising  
 6 dramatically and are expected to continue to increase.

7 (b) In California, prescription drug spending totaled over \$188  
 8 billion in 2004, a \$14 billion dollar per year spending increase  
 9 from 1984.

1 (c) Prescription drug cost continues to be among the most  
2 significant cost factors in California’s overall spending on health  
3 care.

4 (d) According to the Institution of Medicine of the National  
5 Academies, medication errors are among the most common medical  
6 errors, harming at least 1.5 million people every year.

7 (e) Up to one-half of all medications are taken incorrectly or  
8 mixed with other medications that cause dangerous reactions that  
9 can lead to injury and death.

10 (f) Approximately 46 percent of American adults cannot  
11 understand the label on their prescription medications.

12 (g) Ninety percent of Medicare patients take medications for  
13 chronic conditions and nearly one-half of them take five or more  
14 different medications.

15 (h) Nearly six out of 10 adults in the United States have taken  
16 prescription medications incorrectly.

17 (i) The people of California recognize the importance of  
18 reducing medication-related errors and increasing health care  
19 literacy regarding prescription drugs and prescription container  
20 labeling, which can increase consumer protection and improve the  
21 health, safety, and well-being of consumers.

22 (j) The Legislature affirms the importance of identifying  
23 deficiencies in, and opportunities for improving, patient medication  
24 safety systems in order to identify and encourage the adoption of  
25 structural safeguards related to prescription drug container labels.

26 (k) It is the intent of the Legislature to adopt a standardized  
27 prescription drug label that will be designed by ~~a panel appointed~~  
28 ~~to work with the California State Board of Pharmacy and that will~~  
29 ~~be implemented in all California outpatient community and mail~~  
30 ~~service pharmacies providing prescriptions to patients. *the*~~  
31 *California State Board of Pharmacy for use on any prescription*  
32 *drug dispensed to a patient in California.*

33 SEC. 3. Section 4076.5 is added to the Business and Professions  
34 Code, to read:

35 ~~4076.5.—(a) The board, in consultation with professionals in~~  
36 ~~the field, shall convene a prescription drug label panel to review~~  
37 ~~and make recommendations regarding the standardization of~~  
38 ~~prescription drug labels. The panel shall work with the board.~~

39 ~~(b) The board shall delegate board members to work with the~~  
40 ~~panel as it sees fit, and shall staff the panel. Members of the panel~~

1 shall include equal membership among groups representing  
2 consumers, such as seniors, and groups representing those with  
3 special issues regarding language and cultural competency in the  
4 use of prescription drugs, as well as pharmacy and medical  
5 professionals. The panel may include, but is not limited to,  
6 representatives of all of the following:

- 7 (1) Health plans or their representative association.
- 8 (2) Pharmacy representatives.
- 9 (3) Health care providers or their representative association.
- 10 (4) Faculty representatives from a school of pharmacy.
- 11 (5) Associations related to research, manufacturers, or  
12 distributors of pharmaceutical drugs.
- 13 (6) Medical associations.
- 14 (7) Consumer groups, such as senior citizens groups.
- 15 (8) Health advocacy groups.
- 16 (9) The board.
- 17 (10) Language accessibility experts.

18 (c) The panel may secure private contributions to fund its  
19 responsibilities pursuant to this section.

20 (d) The panel's review shall include a study and  
21 recommendations of best practices for prescription drug labels,  
22 including all of the following topics:

- 23 (1) Medical literacy research that points to increased  
24 understandability of labels.
- 25 (2) Improved directions for use.
- 26 (3) Improved font types and sizes.
- 27 (4) Placement of information that is patient centered.
- 28 (5) Standards for implementation by pharmacies, including both  
29 of the following:

- 30 (A) Technology requirements to implement the standards.
- 31 (B) Affordability to pharmacies of implementing the standards.

32 The panel shall ensure that its recommendation for implementation  
33 of a standardized label is affordable for pharmacies.

34 (e) On the recommendation of the panel, the board shall, by  
35 regulation, adopt a standardized label for prescription drug  
36 containers. The label shall be developed so that it meets all of the  
37 following requirements:

- 38 (1) It is understandable for prescription drug users.
- 39 (2) It describes the contents of the container so that prescription  
40 drug users with low medical literacy levels can understand it.

1 ~~(3) It displays necessary information about properly taking the~~  
2 ~~container's contents so that prescription drug users with low~~  
3 ~~medical literacy levels can understand it.~~

4 ~~(4) It displays mandated warnings about the container's contents~~  
5 ~~so that prescription drug users with low medical literacy levels~~  
6 ~~can understand it.~~

7 ~~(5) Implementation of the standardized label is affordable for~~  
8 ~~pharmacies.~~

9 ~~(f) Pharmacy consultations by a telephonic translation service~~  
10 ~~shall be available to patients with limited English language~~  
11 ~~proficiency. A pharmacy shall be permitted to issue translated~~  
12 ~~labels for prescriptions, provided that those labels are found to be~~  
13 ~~safe and reliable.~~

14 ~~(g) (1) The panel shall be established and begin meeting as~~  
15 ~~soon as possible after January 1, 2008.~~

16 ~~(2) The panel shall make a recommendation for a standardized~~  
17 ~~label to the board on or before October 31, 2008.~~

18 ~~(3) Within 90 days of receiving the panel's recommendation,~~  
19 ~~the board shall promulgate regulations to establish requirements~~  
20 ~~for a standardized label for prescription drug containers, pursuant~~  
21 ~~to subdivision (e), which shall be required to be used by all~~  
22 ~~California outpatient community and mail service pharmacies~~  
23 ~~providing prescriptions to patients.~~

24 ~~(4) Within 90 days of the effective date of the adopted~~  
25 ~~regulations, each pharmacy described in paragraph (3) shall begin~~  
26 ~~using the standardized labels for prescription drug containers.~~

27 *4076.5. (a) The board shall promulgate regulations that*  
28 *require, on or before January 1, 2011, a standardized,*  
29 *patient-centered, prescription drug label on all prescription*  
30 *medicine dispensed to patients in California.*

31 *(b) To ensure maximum public comment, the board shall hold*  
32 *public meetings statewide that are separate from its normally*  
33 *scheduled hearings in order to seek information from groups*  
34 *representing consumers, seniors, pharmacists or the practice of*  
35 *pharmacy, other health care professionals, and other interested*  
36 *parties.*

37 *(c) When developing the requirements for prescription drug*  
38 *labels, the board shall consider all of the following factors:*

39 *(1) Medical literacy research that points to increased*  
40 *understandability of labels.*

- 1     (2) *Improved directions for use.*  
2     (3) *Improved font types and sizes.*  
3     (4) *Placement of information that is patient-centered.*  
4     (5) *The needs of those patients with limited English proficiency.*  
5     (6) *The needs of seniors.*  
6     (7) *Technology requirements necessary to implement the*  
7     *standards.*  
8     (d) (1) *On or before January 1, 2010, the board shall report*  
9     *to the Legislature on its progress under this section as of the time*  
10    *of the report.*  
11    (2) *On or before January 1, 2013, the board shall report to the*  
12    *Legislature the status of implementation of the prescription drug*  
13    *label requirements adopted pursuant to this section.*  
14    SEC. 4. No reimbursement is required by this act pursuant to  
15    Section 6 of Article XIII B of the California Constitution because  
16    the only costs that may be incurred by a local agency or school  
17    district will be incurred because this act creates a new crime or  
18    infraction, eliminates a crime or infraction, or changes the penalty  
19    for a crime or infraction, within the meaning of Section 17556 of  
20    the Government Code, or changes the definition of a crime within  
21    the meaning of Section 6 of Article XIII B of the California  
22    Constitution.