

Item B 2a

Active Bills with Positions by the Board

- Bill Analysis
- Bill Language



California State Board of Pharmacy

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

To: Legislation and Regulation Committee

From: Staff

Subject: Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction.

Below is a list of active and inactive bills that the board discussed at the April 2007 Board Meeting. A bill analysis as well as a copy of each active bill is provided. Copies of the inactive bills can be obtained at www.leginfo.ca.gov.

ACTIVE BILLS

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.

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.

AB 501 (Swanson) Pharmaceutical Devices: Hypodermic Needle and Syringe Disposal

This proposal would require every pharmaceutical company whose product requires the use of prefilled syringe, prefilled pen needle or other prefilled injection device to provide a method for California patients to dispose of the device.

AB 543 (Plescia) Ambulatory Surgical Centers: Licensure

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

AB 1025 (Bass) Professions and Vocations: Denial of 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 or for an arrest where a final disposition has not occurred within one year.

AB 1587 (De La Torre) Personal Information: Pharmacy

This proposal would make exemptions to the definition of marketing materials.

SB 472 (Corbett) Prescription Drugs: Labeling Requirements

This proposal is still in the drafting phase, but the intent is to ensure standardization of prescription labels.

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.

SB 963 (Ridley-Thomas) Regulatory Boards: Termination

This proposal would remove the Department of Consumer Affairs as the automatic successor in the event a board is "sunsetting."

SB 966 (Simitian) Pharmaceutical Drug Disposal

This proposal would require pharmacies to accept then dispose of returned unused medications.

INACTIVE BILLS

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 (Calderon) 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.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



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 Fund 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.

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
Lamda 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
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 June 27, 2007

**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:

1. 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 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 Department of Consumer Affairs (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: California Nurses Association
Center for Public Interest Law

Opposition: None on file

HISTORY:

Dates	Actions
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.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 501

VERSION: As introduced February 20, 2007

AUTHOR: Swanson

SPONSOR: Alameda County Board of Supervisors

RECOMMENDED POSITION: Support

SUBJECT: Pharmaceutical devices: hypodermic needle and syringe disposal

EXISTING LAW:

1. Prohibits the disposal of a hypodermic needle or syringe on the grounds of a playground, beach, park, or any public or private elementary school, vocational, junior high or high school.
2. States that a person who knowingly violates this section is guilty of a misdemeanor.
3. Requires that on or after September 1, 2008, no person shall knowingly place home-generated sharps waste in any of the following containers
 - a. Any container used for collection of solid waste, recyclable materials for greenwaste
 - b. Any container used for the commercial collection of solid waste or recyclable materials from a business establishment
 - c. Any roll-off container used for collectables of solid waste, construction, and demolition debris, greenwaste or other recyclable materials
4. Requires that on or after September 1, 2008, home generated sharps waste shall be transported only in a sharps container, or other container approved by the enforcement agency as managed by one of the following:
 - a. A household hazardous waste facility
 - b. A "home generated sharps consolidation point"
 - c. A medical waste generator's facility
 - d. A facility though the use of an approved medical waster mail-back container

THIS BILL WOULD:

1. Make a number of findings and declarations about the medical need and use of self-inject prescription medications.
2. State that the Legislature has found that sharps mail-back programs approved by the US Postal Service offer one of the most convenient means for collecting and destroying home-generated sharps and that cooperative efforts of the pharmaceutical industry is necessary to develop a safe needle disposal system.
3. Require every pharmaceutical company whose product is dispensed through a prefilled syringe, prefilled pen needle or other prefilled injection device shall provide each person in this state with a method to safely dispose of the device.
4. Require that if the person receives the device as part of a starter kit, the pharmaceutical company shall make available to the person, at no additional cost, either a postage pre-paid mail back sharps container or a coupon to obtain such a container or provide the person with a distribution point chosen by the pharmaceutical company.
5. Require the pharmaceutical company to make available, at no additional charge and through an annually renewable program, postage prepaid, mail back sharps containers to any person who uses the pharmaceutical company's product.
6. Define "coupon," "patient starter kit" and "sharps container."

AUTHOR'S INTENT

This bill is intended as a continuation of the legislation regarding the safe needle program - - and to further that purpose. Consumers currently do not have a safe way to dispose of used needles and syringes.

PRIOR HISTORY/RELATED BILLS

SB 1305 (Figueroa) Chapter 64, Statutes of 2006 –Prohibits, as of January 1, 2008, a person from placing home-generated sharps waste in specified commercial and residential solid waste collection containers, including containers used for recyclable materials or greenwaste as well as roll-off containers used for construction and demolition debris. It also requires that home generated-sharps waste be transported in an approved sharps container with an approved facility approved by the Department of Toxics and removes home generated sharps waste as among those items subject to the state's medical waste control laws. The board had no position on this legislation.

FISCAL IMPACT:

The board does not anticipate any substantial fiscal impact on its operations.

HISTORY:

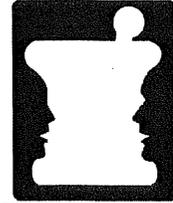
2007

Mar. 22 Referred to Com. on HEALTH.

Feb. 21 From printer. May be heard in committee March 23.

Feb. 20 Read first time. To print..

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 543

VERSION: As Amended April 17, 2007

AUTHOR: Plescia

SPONSOR: CA Ambulatory Surgery Assoc.

BOARD POSITION: Support

SUBJECT: Ambulatory surgical centers: licensure

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 board.
3. Defines the licensing requirements for the board to issue a clinic license to an ambulatory surgery center.

THIS BILL WOULD:

1. Change the name "surgical center" to "ambulatory surgical center."
2. Modify the licensing requirements for a board issued clinic license for an ambulatory surgical center to include:
 - licensure by the DHS under 1204 of the Health and Safety Code
 - accreditation by an approved agency
 - or certification to participate in the Medicare Program.This license would allow the clinic to purchase drugs at wholesale for administration or dispensing as well as commingle medications.
3. Develop standard licensing requirements for the DHS to license ambulatory surgery centers. These requirements are phased in over a period of time.

AUTHOR'S INTENT

The sponsor states that this bill is intended to standardize the licensing requirements for ambulatory surgical clinics. Additional amendments to the existing language will also be made to ensure a consistent and comprehensive set of state-specific licensure requirements for ambulatory surgical centers as required by the DHS.

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 the se 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 0.5 inspector to complete routine inspections and complaint investigations.

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 an ambulatory 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 (AAHC)

- 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 an initial as well as annual inspections of board licensed clinics that are not also licensed by the DHS. 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 proposed amendments will require all board licensed ambulatory surgery centers to complete a self-assessment on an annual basis.

HISTORY:

Dates	Actions
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.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**

BILL NUMBER: AB 1025

VERSION: As amended May 31, 2007

AUTHOR: Bass

SPONSOR:

RECOMMENDED POSITION: None

SUBJECT: Professions and vocations: denial of licensure

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 and there have been no subsequent felony convictions as well as at least three years have passed since the dismissal of the conviction or at least five years have passed since the person completed his sentence.

This shall not apply if the conviction was for any offense that is defined as a violent felony or any offense defined as a serious felony.
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.
3. Permit the board to deny a license on the ground that the applicant knowingly made a false statement of fact to be revealed in the application.
4. 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.
5. 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 board to the applicant. This information must be available upon request by the Department of Justice or the Federal Bureau of Investigation.
6. Prohibit the board from suspending or revoking a license based on any criminal conviction that has been dismissed pursuant to Section 1203.4 or 1203.4a of the Penal Code.
7. 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.

8. 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 the board 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

The board is awaiting a response from the author's office on the amendments.

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. However, the board does not provide a copy of the arrest report or criminal history record, although these documents may be referred to in the legal pleadings used to deny or revoke a license.

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 determine the outcome of any application or disciplinary action to ensure the board's public protection mandate is met.

HISTORY:

Dates Actions

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 June 27, 2007

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1587

VERSION: As Amended May 21, 2007

AUTHOR: De La Torre

SPONSOR: Congress of California Seniors

BOARD POSITION: None

SUBJECT: Personal information: pharmacy.

EXISTING LAW:

1. Defines "marketing" as a communication about a product or service that encourages recipients of the communication to purchase or use the product of service.
2. Details exemptions to the definition to include:
 - Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration
 - Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network.
 - Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about, among other things, treatment options. Such communications may result in direct or indirect remuneration if the individual receiving the communication is notified of such, in a typeface no smaller than 14-point font.

THIS BILL WOULD:

1. Also exempt a written communication or message provided to a pharmacy patient during a face-to-face interaction with a pharmacist or pharmacy personnel, if all of the following apply:
 - The communication does not involve the sale or transfer of individually identifiable patient information
 - The communication assists the pharmacist or pharmacy personnel in the transmittal of use information regarding a prescription drug dispensed to the patient
 - The content of the communication provides information about the dispensed drug, another treatment or therapy for a disease

or health condition for which the drug is dispensed or a drug dispensed within the last three years, general information about a health condition for which the patient's disease may put the patient at risk, or general information about a health condition for which the patient may be at risk given the age or gender of the patient.

- The pharmacist is available upon request of the patient to answer questions regarding the communication
- If the communication is paid for, the communication must also include, among other things, the source of the sponsorship in typeface no smaller than 14-point type.
- The communication contains instruction in typeface no smaller than 14-point font, describing how the patient can opt out of the portion of the communication that is an advertisement paid for.
- The communication does not involve the sale or transfer to medical information by or to the pharmacy by another entity and the communication is based only on medical information that has already been provided to and maintained by the pharmacist.

AUTHOR'S INTENT

This bill is intended to clarify the existing statute and would exempt drug information from the definition of "marketing communications."

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to the board. Any minor impact could most likely be absorbed with existing resources.

SUPPORT and OPPOSITION:

Support

AIDS Emergency Fund
AIDS Legal Referral Panel
American Federation of State, County and Municipal Employees
Bay Positives
Building a Healthy Black Community
Breast Cancer Emergency Fund
California Alliance for Retired Americans
California Retailers Association
Catalina Health Resource
Century Healthcare Institute

Congress of California Seniors (sponsor)
Gray Panthers
Greenling Institute
Latino Coalition for a Healthy California
Magnet
Marin Aids Project
National Association of Chain Drug Stores
National Consumers League
National Council on Patient Information and Education (NCPiE)
Pacific Center for Human Growth
Shanti
Stop Aids Project

Opposition

Pfizer, Inc. (unless amended)

COMMENTS:

The intent of this legislation is to provide additional information to consumers. However the board may want to consider the following if it is appropriate for a pharmacist to provide a patient with drug information on a medication that is not being dispensed by the pharmacist and if this undermines the value of patient consultation. Also, it is unclear who is responsible for the enforcement of these provisions.

HISTORY:

Dates Actions

06/26/07 June 26 From committee: Amend, do pass as amended, and re-refer to Com. on JUD. (Ayes 6. Noes 2.)

06/07/07 June 7 Referred to Coms. on HEALTH and JUD.

05/24/07 May 24 In Senate. Read first time. To Com. on RLS. for assignment.

05/24/07 May 24 Read third time, passed, and to Senate. (Ayes 70. Noes 6. Page 1615.)

05/21/07 May 21 Read third time, amended, and returned to third reading. (Page 1565.)

05/09/07 May 9 Read second time. To third reading.

05/08/07 May 8 Read second time and amended. Ordered returned to second reading.

05/07/07 May 7 From committee: Amend, and do pass as amended. (Ayes 15. Noes 0.) (May 1).

03/29/07 Mar. 29 Referred to Com. on HEALTH.

02/26/07 Feb. 26 Read first time.

02/25/07 Feb. 25 From printer. May be heard in committee March 27.

02/23/07 Feb. 23 Introduced. To print.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



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

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. Makes findings about the cost of health care and prescription drugs
2. Makes findings about the number of medication errors and sites some causes for these errors.
3. States that it is the intent of the Legislature to adopt a standardized prescription drug label that will be designed the California State Board of Pharmacy 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 pints 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:

Given the most recent amendments to the bill, the board does not anticipate any significant fiscal impact to board operations. Minimal fiscal impact can be absorbed within existing resources.

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

COMMENTS:

At the April 2007 Board Meeting, the board voted to take a "Support if Amended" position on this bill. The legislation at that time developed 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.

HISTORY:

2007

- June 20 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on HEALTH.
- June 19 Set, first hearing. Hearing canceled at the request of author.
- June 7 To Coms. on HEALTH and B. & P.
- May 29 In Assembly. Read first time. Held at Desk.
- May 29 Read third time. Passed. (Ayes 27. Noes 10. Page 1097.) To Assembly.
- May 21 Read second time. Amended. To third reading.
- May 17 From committee: Be placed on second reading file pursuant to Senate Rule 28.8 and be amended.
- May 2 Set for hearing May 14.
- Apr. 30 Read second time. Amended. Re-referred to Com. on APPR.
- Apr. 26 From committee: Do pass as amended, but first amend, and re-refer

- to Com. on APPR. (Ayes 7. Noes 1. Page 705.)
- Apr. 16 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on B., P. & E.D.
- 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.
- Feb. 28 To Com. on RLS.
- Feb. 22 From print. May be acted upon on or after March 24.
- Feb. 21 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Revised June 25, 2007

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 606

VERSION: As Amended June 27, 2007

AUTHOR: Scott

**SPONSOR: California Public Interest
Research Group**

BOARD POSITION: Support

SUBJECT: Pharmaceutical information: clinical trial data

EXISTING LAW:

Regulates the packaging, labeling and advertising of food, drugs and cosmetics.

THIS BILL WOULD:

1. Create the Pharmaceutical Drug Information and Safety Act
2. Define a clinical trial as a clinical investigation as defined by the federal FDA
3. Define pharmaceutical manufacturer as any entity that is
4. Engaged in the production, preparation, propagation, compounding, conversion or processing of pharmaceutical drugs, either directly or indirectly, by means of chemical synthesis or by a combination of extraction and chemical synthesis.
5. Engaged in the packaging, repackaging, labeling, relabeling or distribution of pharmaceutical drugs
6. Does not include a corporation that is in the business of repackaging or compounding prescriptions, if that corporation is not in the business of developing FDA-approved drug products for sale to the general public.
7. Define pharmaceutical drug as any drug which is approved by the federal FDA and commercially available in this state
8. Define a Phase I Trail as the initial studies designed exclusively to determine the metabolic and pharmacologic actions of drugs in humans, and the side effects associated with increasing doses, and to gain early evidence of effectiveness
9. Defines "serious adverse event" as any untoward medical occurrence in a patient or clinical investigation subject who has been administered a pharmaceutical product which does not necessarily have a casual relationship with this treatment
10. Defines "scientific work product" as a writing that reflects a scientist, clinician or researchers impressions, conclusions, opinions, research, statistical calculations or theories.

11. Requires any pharmaceutical company to make publicly available the results of every completed clinical trial, except for a phase I trial, that the company conduct for every drug that the company sells, delivers, offers for sales, or gives away in this state
12. Detail the information required to include:
 - a. The name of the trial
 - b. Commercial and chemical name of all pharmaceutical drugs tested, including comparator drugs
 - c. Dosages tested for each drug, including comparator drugs
 - d. Initiation and completion dates of the trial
 - e. Purposes of the trial, include the medical condition or conditions studied
 - f. Outcomes of the trial including any time points at which outcome data were measured and used to either subsequently for either marketing purposes or other action taken to publicly promote the outcomes of a trial including, but not limited to a news release.
 - g. Trial funding sources
 - h. Number of patients initially enrolled in the trial
 - i. Number of patients completing the trial
 - j. A list of all specific characteristics used to include and exclude people as trial participants, such as gender, race, age, preexisting health conditions, and an explanation of why each characteristic was used to include or exclude patients
 - k. Names and contact information for principal sponsors of the trial to include at least the phone number, mailing address and e-mail address for public inquiries
 - l. Names and contact information for principal researchers of the trial
 - m. Frequency, severity and nature of all adverse events experienced by trial participants, including participants that did not complete the trial for each drug
 - n. All information regarding the relative efficacy of each drug and the relative frequency, severity and nature of all adverse events experienced by trial participants if the study involved a comparison of two or more pharmaceutical drugs
 - o. A complete citation and, if available a hyperlink for any publications of the data from the study
 - p. The name and employer of each author of the study, including the ghostwriters
 - q. Any financial interest the principal researchers of the study have in the drugs tested or compared in the trial and in the principal sponsors of the trial
 - r. A copy of the package insert for the drug that includes any adverse events to the drug
8. Require any pharmaceutical company to make publicly available an explanation of noncompletion for any clinical trial that the pharmaceutical company initiates or sponsors initiate, but does not complete for every pharmaceutical drug that the company sells, delivers,

- offers for sale or gives away. The explanation shall include the reason why the trial was terminated
9. Require that the trial information shall be submitted for inclusion on the Web site administered by the National Institutes of Health or on another publicly accessible Web site directly linked to the pharmaceutical company's primary corporate Web site. A publicly accessible Web site must provide free, nonsubscription access to its contents and clearly indicate the location and instructions for downloading the files or information submitted
 10. Establish timelines for compliance with this section
 11. State that provisions of this chapter shall not be construed to require the public disclosure of a trade secret as defined or scientific work product.
 12. Specifies that only factors, conclusion, results or points of state from a clinical trial that are deemed a trade secret shall be withheld from disclosure.
 13. States that if parts or all of a clinical trial are withheld from disclosure, a pharmaceutical company shall disclose the fact that information was withheld because it constitutes a trade secret.

AUTHOR'S INTENT:

According to the author's office, this bill is to address the concern that consumers do not have enough access to information regarding pharmaceutical drugs and their testing history.

FISCAL IMPACT:

The board is awaiting clarification from the author's office on certain provisions. Until then it is difficult to anticipate any potential fiscal impact on the board.

SUPPORT and OPPOSITION

SUPPORT

California Public Interest Research Group (source)
AIDS Health Care Foundation
California Alliance for Retired Americans
California Association of Family Physicians
California Board of Pharmacy
California Labor Federation (AFL-CIO)
Congress of California Seniors
Consumer Federation of California
Consumers Union
Health Access California

OPPOSITION : (Verified 6/4/07)

Abbott
AstraZeneca
BIOCOM
California Health Care Institute
Civil Justice Association of California
Genentech, Inc.
GlaxoSmithKline
Pfizer
Pharmaceutical Research and Manufacturers of America

HISTORY:

Dates Actions

06/21/07 June 21 To Com. on HEALTH.
06/07/07 June 7 In Assembly. Read first time. Held at Desk.
06/07/07 June 7 Read third time. Passed. (Ayes 25. Noes 15. Page 1330.) To Assembly.
06/05/07 June 5 Read second time. To third reading.
06/04/07 June 4 Read third time. Amended. To second reading. (Corrected June 14.)
(Corrected June 15.)
05/15/07 May 15 Read second time. Amended. To third reading.
05/14/07 May 14 From committee: Do pass as amended. (Ayes 6. Noes 3. Page 932.)
04/17/07 Apr. 17 Set for hearing May 9.
03/08/07 Mar. 8 To Com. on HEALTH.
02/23/07 Feb. 23 From print. May be acted upon on or after March 25.
02/22/07 Feb. 22 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Revised June 29, 2007

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 615

VERSION: As Amended April 16, 2007

AUTHOR: Oropeza

**SPONSOR: The Latino Coalition for a
Health California**

Board Position: Support

**SUBJECT: Pharmacy technicians: scholarship and loan repayment
program.**

EXISTING LAW:

1. Defines the requirements for licensure as a pharmacy technician.

THIS BILL WOULD:

1. Establish a scholarship and loan repayment program for pharmacy technicians.
2. Requires all licensed pharmacy technicians and pharmacies to pay an additional \$10.00 to this account at the time of renewal.

AUTHOR'S INTENT

This bill is intended to provide a financial incentive to recruit more individuals to become pharmacy technicians to assist in medically underserved areas. US Bureau of Labor statistics detail a shortage of technicians from different cultural backgrounds.

FISCAL IMPACT:

The cost associated with the development and implementation of this fund could include modifications to existing cashiering programs, forms and procedures for deposits into separate funds. The estimated costs for these changes at approximately \$24,000.

SUPPORT AND OPPOSITION:

Latino Coalition for a Healthy California (source)

American Federation of State, County and Municipal Employees
Applied Research Center
Association of California Healthcare Districts
California Primary Care Association
California Rural Health Policy Council
California Society of Health-System Pharmacists
California State Rural Health Association
Northern Sierra Rural Health Network
The Greenlining Institute
Welcome Back Initiative

COMMENTS:

As amended this legislation will require all pharmacy technicians and pharmacies to contribute \$10.00 to the Pharmacy Technician Scholarship and Loan Repayment Program Fund at renewal. The language at introduced created the scholarship fund, but did not include a mandatory contribution to the fund, rather made the contribution voluntary.

This proposal is similar to one passed in 2002, which established a scholarship and loan repayment fund for pharmacists. To date, no funds have been distributed from this fund, as the minimum account balance of \$200,000 annually has not yet been obtained. The board was coincidentally doing a newsletter article updating licensees about the status of this law and learned that to date, pharmacies and pharmacists have contributed approximately \$38,000.

Current statutes detail the licensing requirements for technicians to include:

- Completion of a technician training program
- AA degree in pharmacy technology
- Satisfy requirements for RPH exam
- Certification by the Pharmacy Technician Certification Boards.

At the April 2007 Board Meeting, board members were concerned about the number of applicants that would benefit from this scholarship fund and requested information. Information provided by the sponsor detailed that approximately 36 pharmacist technicians could be awarded a scholarship annually. After providing this information to the board, the president changed the board's position to support.

HISTORY:

Dates Actions

06/07/07 June 7 To Com. on B. & P.
05/24/07 May 24 In Assembly. Read first time. Held at Desk.
05/24/07 May 24 Read third time. Passed. (Ayes 22. Noes 13. Page 1057.) To Assembly.
05/10/07 May 10 Read second time. To third reading.
05/09/07 May 9 From committee: Do pass. (Ayes 10. Noes 7. Page 887.)
04/25/07 Apr. 25 Set for hearing May 7.
04/24/07 Apr. 24 From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 6. Noes 2. Page 705.) Re-referred to Com. on APPR.
04/16/07 Apr. 16 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on B., P. & E.D.
04/12/07 Apr. 12 From committee: Do pass, but first be re-referred to Com. on B., P. & E.D. (Ayes 7. Noes 2. Page 542.) Re-referred to Com. on B., P. & E.D.
04/10/07 Apr. 10 Set for hearing April 23.
03/27/07 Mar. 27 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on HEALTH.
03/15/07 Mar. 15 Set for hearing April 11.
03/13/07 Mar. 13 Withdrawn from committee. Re-referred to Coms. on HEALTH and B., P. & E.D.
03/08/07 Mar. 8 To Coms. on B., P. & E.D. and HEALTH.
02/23/07 Feb. 23 From print. May be acted upon on or after March 25.
02/22/07 Feb. 22 Introduced. Read first time. To Com. on RLS. for assignment. To print

Revised June 27, 2007

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 963 **VERSION:** As Amended on June 25, 2007

AUTHOR: Ridley-Thomas **SPONSOR:** BP& ED Committee

RECOMMENDED POSITION: None

SUBJECT: Regulatory boards: termination

EXISTING LAW:

1. States that all existing and proposed consumer-related boards or categories of licensed professionals shall be subject to review every four years to evaluate whether each board has demonstrated a public need for continued existence.
2. Provides that in the event the board becomes inoperative and is repealed, the Department of Consumer Affairs shall succeed the board with all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed.
3. Establishes the appointment of board members.
4. Establishes the authorization to appoint an executive officer.

THIS BILL WOULD:

1. Require the board to post annual on our Web site the number of reports it received that year for criminal convictions, judgments, settlements, or arbitration as well as claims paid by a professional liability insurer caused by a licensee's negligence, error or omission.
2. Provide the board with the authority to adopt regulations that provide an incentive to licensees to provide services within the scope of licensure, on a pro bono basis. The regulations could reduce the amount of renewal fee required for a licensee who demonstrates compliance with the pro bono requirements.
3. Require the board to adopt regulations for the number of staff required to adequately investigate and if necessary bring disciplinary against a licensee and specifies that the staff level shall at minimum be the number of staff per 1,000 persons regulated by the board and shall include the appropriate number of staff to complete all investigatory and disciplinary functions.

4. Require board members to disclose all ex parte communication at the board's next public meeting and that such communication will be recorded in the board's minutes. Defines "ex parte" communication.
5. State that it is the intent of the Legislature to be subject to ongoing and continuous review as well as a periodic thorough review when issues arise requiring that level of review and when such a review is requested by a Member of the Legislature or the Chief of the Office of the Consumer Advocate. The review shall evaluate and determine whether its operations are effectively protecting the public and that protection of the public is the highest priority of the board.
6. Provides that if the board is deemed deficient and its members removed, a successor board shall be appointed that shall succeed to, and be vested with, all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed. Specifies that the number of board members will remain the same and designates the appointing authorities for new members.
7. Requires the board to enter into an agreement with the DCA to provide various administrative functions including personnel, information technology, examination and call centers. States that a board shall not enter into such an agreement if it would reduce the board's ability to comply with its duties prescribed in law.
8. Replaces the duties of the Joint Committee on Boards, Commissions, and Consumer Protection with the Office of Consumer Advocate to determine whether the highest priority of the licensing program is the protection of the public.
9. Makes subject to approval of the DCA director as well as confirmation of the Senate, the appointment of an Executive Officer.
10. Require the board to post on our Web site minutes from public meetings within 10 days of the date of the meeting.
11. Require the board to adopt meaningful, measurable and manageable performance measures to include
 - A comprehensive statement of the board's mission, goals, objectives and legal jurisdiction in protecting the health, safety and welfare of the public.
 - The board's enforcement priorities, complaint and enforcement data, budget expenditures with average and median cost per case, case aging data specific to post and preaccusation cases at the Attorney General's Office
 - The board's fund conditions, sources of revenues and expenditure categories for the last four fiscal years.

- Description of the board's licensing process including the time and cost required to implement and administer the licensing examination, ownership of the license examination, relevancy and validity of the licensing examination and passage rate and areas of examination.
 - Board initiation of legislative efforts, budget change proposals and other initiatives it has taken to improve its legislative mandate.
12. Require the board to report to the director of DCA and the chief of the Office of the Consumer Advocate our performance measures on a quarterly basis as well as to post this information on the board's Web site. In addition require the board to report this information annually to the Department of Finance, the Legislative Analyst's Office and the Legislature.
 13. Require the chief of the Office of the Consumer Advocate in consultation with LAO to annually review the information provided and report to the Legislature if it determines that a board has failed to meet the performance measures established.
 14. Require each board member to provide an annual report to the authority that appointed him or her the extent to which the member has achieved his or her goals and objectives that years as well as to report on goals and objectives for the upcoming year.
 15. Require the board to post these reports on the board's Web site within 30 days of submission.
 16. Require the department to report to the Legislature and the Governor when a board has been unable to schedule or convene a meeting because the board because of a lack of a quorum caused by the absence of its members or by a vacancy in its membership.
 17. Require the director of the DCA work with the State Chief Information Office to replace the department's existing information technology system and allow the director to change each of the board's on a pro rata basis for the costs of replacing the information technology system.
 18. Require the director of DCA to annually report to the chairperson of fiscal committees for each house of the Legislature, as well as the Joint Legislative Budget Committee information specific information about the Office of the Consumer Advocate.
 19. Require the board to submit all notices and final rulemaking records to the chief of the Office of the Consumer Advocate, in addition to the director of the DCA and specifies the timeframes and procedures for review and approval or disapproval.

20. Creates the Office of the Consumer Advocate to promote the efficiency of each board that comprise the department and designates that the office is under the supervision and control of a chief. The chief will be appointed by the Governor and subject to Senate Confirmation and who will serve a four year term.
21. Requires the chief to appointment of chief counsel of the office as well as adequate number of attorneys to carry out the provisions.
22. Specifies the duties of the Office of the Consumer Advocate to serve as an independent monitor and details the powers given to the chief as well as the Office of the Consumer Advocate which includes allowing the office to appear at a board meeting and permitting participation in a disciplinary proceeding by the board whenever the chief determines that the appearance is required to promote and protect the interests of consumers.
23. Allows the office to exercise and perform functions, powers and duties as may be deemed appropriate to protect and promote the interests of consumers as directed by the Governor or the Legislature.
24. Requires the chief to report annually to the Governor and appear annual before committees of the Legislature as specified.
25. Allow the chief to annual charge each board on a pro rata basis an amount sufficient to carry out the provisions.
26. Allow a board member to serve as a public member of more than one board at a time if not prohibited by another law.
27. Authorize a member of the Legislature or the chief to request the appropriate standing policy committee to conduct an analysis to evaluate a state board. This request must describe any perceived deficiencies in the operation of the board and the detailed reasons an analysis of its operations is requested.
28. Require the appropriate standing policy committee to investigate the perceived deficiencies, including holding public meetings. This committee may request the assistance from the Office of the Consumer Advocate.
29. Determination by the committee if based on the information obtained during the course of the investigation if the highest priority of a board's operations is consumer protection.
30. Specifies the types of issues the committee shall review and consider when making their determination.
31. Requires the committee to report to the Join Committee on Rules if a board is deemed deficient at which time each

member of the board will be removed from office without a hearing within 10 business days and a successor board shall be appointed. In addition, the Office of the Consumer Advocate will assume the duties of an independent monitor for the board and shall report to the Legislature within one year making recommendations for required reforms of the board.

AUTHOR'S INTENT

According to the author's office, the intent of this legislation is to develop a more effective method of continuing state licensing and regulation when the Legislature sunsets a licensing board. This bill is intended to perform the ongoing continuation of the licensing and regulation of a profession via a more independent board structure, than by a bureau operated by the Department.

FISCAL IMPACT:

In its amended form, the board will experience fiscal impact to cover the cost of additional staff allowed under this proposal as well as the new computer system and will most likely see a large increase in the amount of pro rata it pays to the department. Unfortunately board staff was unable to obtain information from the department in advance of this meeting to quantify these increases.

COMMENTS:

This legislation was significantly amended on June 25, 2007 to become a new bill. Several of the functions assigned to the Office of the Consumer Advocate are already assigned to the DCA and its director as well as the Bureau of State Audits. It is unclear if the DCA's role will change as an oversight to board or if the board will now be subject to continual review by both the director as well as the chief.

The board currently provides weekly updates to the director's office detailing the board's work for the week as well as any pressing issues. A special report is required monthly. Additionally annual the board completes an Agency Statistical Profile documenting the workload of the board for the previous fiscal year.

Several of the public reporting requirements mandated in this legislation the board already provides on a quarterly basis as part of its inherent committee structure and close adherence to the performance measures established in the board's strategic plan.

The board's record for consumer protection is solid and strong. The board continually demonstrates its commitment to consumer protection and as such further scrutiny by another office would not be problematic for the board except potentially for an increase in reporting requirements and the possible redirection of staff to complete the reports.

Should this proposal become law, the board would need to seek additional staffing to comply with all the requirements and would need to seek a statutory fee increase to cover the increased expenditures for computer systems and pro rate charges.

There are a couple of items of concern:

1. Allowing only 10 days to post public meeting minutes on the board's Web site is not a reasonable time frame given the length of meetings, the complexity of the issues as well as turn around time for board members to vote on minutes. Moreover it eliminates the board's ability to review minutes,
2. The board could lose its ability to hire the executive officer of its choice, and rather this process could become very political in nature. Given the role of the executive officer, the board may want sole discretion in making this hiring decision.

Some benefits of this proposal include

1. A legislative mandate to replace the board's very outdated computer system.
2. A legislative mandate to adopt by regulation the personnel needed to complete all investigatory and disciplinary functions. The ratio included in the legislation is one staff per 1,000 persons regulated.

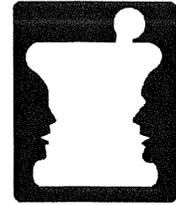
HISTORY:

Date	Action
June 25	From committee with author's amendments. Read second time. Amended. Re-referred to Com. on B. & P.
June 21	To Com. on B. & P.
June 6	In Assembly. Read first time. Held at Desk.
June 6	Read third time. Passed. (Ayes 26. Noes 13. Page 1279.) To Assembly.
May 31	From committee: Do pass. (Ayes 10. Noes 4. Page 1224.) Read second time. To third reading.
May 25	Set for hearing May 31.
May 7	Placed on APPR. suspense file.
Apr. 25	Set for hearing May 7.
Apr. 24	From committee: Do pass, but first be re-referred to Com. on APPR.

(Ayes 6. Noes 2. Page 706.) Re-referred to Com. on APPR.
Apr. 16 From committee with author's amendments. Read second time.
Amended. Re-referred to Com. on B., P. & E.D.
Mar. 29 Set for hearing April 23.
Mar. 15 To Com. on B., P. & E.D.
Feb. 26 Read first time.
Feb. 25 From print. May be acted upon on or after March 27.
Feb. 23 Introduced. To Com. on RLS. for assignment. To print.

Revised June 28, 2007

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 966 **VERSION:** As Amended June 27, 2007

AUTHOR: Simitian and Kuehl **SPONSOR:** Constituent

BOARD POSITION: Oppose

SUBJECT: Pharmaceutical drug disposal

EXISTING LAW:

1. Existing law is silent on how a consumer should dispose of unused medication.

THIS BILL WOULD:

1. Make findings and declarations related to the presence of drugs in streams and the negative effects on fish and other aquatic species.
2. Discuss the potential impact this may have on human health.
3. Establish a program through which the public may return and ensure the safe and environmentally sound disposal of prescription drugs.
4. States that the intent of the Legislature is to
 - Encourage a cooperative relationship between manufacturers, retailers and local, state and federal government agencies to devise a safe, efficient, convenient sustainable and environmentally sound solution.
 - Encourage the use of models used by other jurisdictions
 - Develop a system that recognizes the business practices of retailers and manufactures that is consistent with their drug management programs.
5. Defines consumer as an individual purchaser or owner of a drug.
6. Defines Department as the Department of Toxic Substances Control.
7. Define "drug" as articles recognized in the official United States Pharmacopoeia, the official National Formulary, the office Homeopathic Pharmacopoeia of the United States, or any supplement of the formulary of those pharmacopoeia. "Drug" also includes any articles intended for use in the diagnosis, cure,

- mitigation, treatment or prevention of disease in humans or other animals, or articles, excluding food, intended to affect the structure or any function of the body of humans or other animals
8. Define "retailer" as any entity who makes a retailer sale of a drug to a consumer in this state that is either a supermarket as defined in the Public Resources Code or that has over 10,000 square feet of retail space and that has a pharmacy license issued by the board. Specifies that a retailer does not include a veterinarian.
 9. Define "sale" as transactions conducted through sales outlets, catalogs, or the Internet, or any other similar electronic means, but does not include a sale that is a wholesale transaction with a distributor or retailer.
 10. Allow on or after January 1, 2008, California retailers to conduct projects to collect and properly dispose of drugs rendered by consumers for disposal. States that the purpose of these projects is to develop, test, evaluate and implement program models for the proper collection and disposal of waste drugs.
 11. Require participating programs to:
 - Ensure proper disposal pursuant to all application laws, rules and regulations.
 - Ensure the protection of public health and safety, the environment and the health and safety of retail employees.
 - Provide education materials to consumers informing them of the availability of this program and what constitutes proper and improper disposal of drugs
 - Evaluate the programs efficiency, effectiveness and funding sustainability
 12. Allow pharmacies to partner with local governments to apply for appropriate household hazardous waste grants.
 13. Require the department to coordinate with the applicable state agencies to compile and make available on their Web sites information and resources about models of existing programs and information regarding the proper disposal of drug waste.
 14. Require that after July 1, 2010, the department shall identify the number of collection opportunities that are consistent with the intent of this chapter. Should the department determine that less than 80% of the state's population has access to a collection opportunity that is within one mile of a retailer, the provisions of the bill become mandatory.
 15. Require this system to:
 - Be at no cost to the consumer if it is the type or brand which the retailer sold previously

- Provide a notice to consumers that provides consumers access to obtain more information about opportunities and locations for no-cost drug recycling
 - Provide information about the retailer's drug return opportunities and encouraging consumers to utilize those opportunities. The information may include signage that is prominently displayed and easily visible to the consumer, written materials provided to the consumer at the time of purchase, reference to drug take-back opportunity in retailer advertising or other promotional materials or direct communications with the consumer at the time of purchase.
16. Allows the department to develop regulations that are necessary to implement the provisions in a manner that is enforceable.
 17. Allow the department to adopt regulations to implement these provisions as emergency regulation.
 18. Precludes controlled substances.

AUTHOR'S INTENT

This bill was introduced upon recommendation of a constituent. The intent is to provide a safe and effective method for disposal; prescription drugs may be left indefinitely in medicine cabinets where they pose a threat of potential prescription drug misuse or abuse.

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to the board. Minimal fiscal impact could be absorbed within existing resources of the board.

SUPPORT and OPPOSITION:

SUPPORT

American Federation of State, County and Municipal Employees
Breast Cancer Fund
Californians Against Waste
California Association of Sanitation Agencies
California Nurses Association
California Product Stewardship Council
California Veterinary Medical Association
Central Contra Costa Sanitary District
City of Benicia
City of Elk Grove

City of Livermore (Water Resources Division)
City of Millbrae
City of Palo Alto
City of Petaluma
City of Rohnert Park
City of Roseville
City of Santa Cruz
City and County of San Francisco
City of Sunnyvale
Clean Water Action
County Sanitation Districts of Los Angeles County
East Bay Municipal Utility District
EXP Pharmaceutical Services Corp.
Laguna de Santa Rosa Foundation
League of California Cities
Marin Co. Hazardous & Solid Waste Management Joint Powers Authority
Maine Benzodiazepine Study Group
Mt. View Sanitary District
Orange County Sanitation District
Planning and Conservation League
Regional Council of Rural Counties
Sacramento Regional County Sanitation District
San Francisco Public Utilities Commission
San Luis Obispo County Integrated Waste Management Authority
Sanitation Districts of Los Angeles County
Santa Clara Valley Water District
Save the Bay
Sierra Club California
Solid Waste Association of North America
Sonoma County Water Agency
StopWaste.Org, Alameda County Waste Management Authority
Teleosis Institute
TODOS UNIDOS
Forest Batz, PharmD, Assistant Clinical Professor, School of Pharmacy,
University of California, San Francisco
One individual

OPPOSITION

California Grocers Association
California Manufacturers and Technology Association
California Retailers Association
National Association of Chain Drug Stores
Rite Aid

COMMENTS:

We recognize the need for the intent of this legislation, but are concerned that the appropriate balance is not achievable given the language of the bill as introduced.

The board's Enforcement Committee recently heard concern from a representative of Omnicare who stated that the return of prescription drugs from patients in Long Term Care is problematic as no mechanism is in place to allow for this to occur. Absent any regulation, there is no safeguard to ensure that the returned medications will not be diverted.

At the last board meeting, board members expressed several concerns about the bill. Board staff communicated these concerns both in person and in writing. While the bill has been amended on two occasions, it still does not address some very fundamental concerns.

1. It does not address any security to prevent theft or diversion of returned medication.
2. It allows supermarkets, even those without pharmacies to collect unused medication.
3. Places this program under the authority of the Department of Toxic Substances Control, who then could potentially begin regulating pharmacies for compliance with this section.
4. The board will have no control over the handling of prescription drugs returned to these containers.

Given these concerns and the short time for implementation, the board's President authorized a change in the board's position to oppose.

HISTORY:

Date	Action
June 27	From committee with author's amendments. Read second time. Amended. Re-referred to Com. on HEALTH.
June 27	From committee: Do pass, but first be re-referred to Com. on HEALTH.(Ayes 4. Noes 2.) Re-referred to Com. on HEALTH.
June 26	Hearing postponed by committee.
June 21	Re-referred to Com. on E.S. & T.M. and then be re-referred to Com. on HEALTH
June 11	To Coms. on HEALTH and E.S. & T.M.
May 31	In Assembly. Read first time. Held at Desk.
May 31	Read third time. Passed. (Ayes 21. Noes 13. Page 1125.) To Assembly.
May 17	Motion to reconsider made by Senator Simitian. Reconsideration

granted.

May 17 Read third time. Refused passage. (Ayes 20. Noes 18. Page 1000.)

May 1 Read second time. To third reading.

Apr. 30 Read second time. Amended. Re-referred to Com. on RLS.

Withdrawn from committee. Ordered placed on second reading.

Apr. 26 From committee: Do pass as amended, but first amend, and re-refer to Com. on RLS. (Ayes 5. Noes 3. Page 706.)

Apr. 9 Read second time. Amended. Re-referred to Com. on B., P. & E.D.

Mar. 29 From committee: Do pass as amended, but first amend, and re-refer to Com. on B., P. & E.D. (Ayes 4. Noes 2. Page 385.) Set for hearing April 23.

Mar. 19 Set for hearing March 26.

Mar. 15 To Coms. on E.Q., B., P. & E.D. and RLS.

Feb. 26 Read first time.

Feb. 24 From print. May be acted upon on or after March 26.

Feb. 23 Introduced. To Com. on RLS. for assignment. To print.

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.

Existing law established the Office of AIDS in the State Department of Health Services. That office, among other functions, provides funding for AIDS prevention and education. Commencing July 1, 2007, the office will be transferred to the State Department of Public Health.

This bill would authorize a public entity that receives General Fund money from the State Department of Public Health for HIV prevention and education to use that money to support clean needle and syringe exchange projects authorized by the public entity. The bill would authorize the money to be used for the purchase of sterile hypodermic needles and syringes. The bill would require funds allocated for that purpose to be based upon epidemiological data as reported by the health jurisdiction in its local HIV prevention plan submitted to the Office of AIDS.

(2) Existing law requires the health officer of the participating jurisdiction to annually present a report on the status of clean needle and syringe exchange programs, including relevant statistics on blood-borne infections.

This bill would require the report to also include the use of public funds for these purposes.

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. The Legislature finds and declares all of the
2 following:
3 (a) The continuing spread of the acquired immunodeficiency
4 syndrome (AIDS) epidemic and the spread of blood-borne hepatitis
5 pose two of the gravest public health threats in California.
6 (b) Injection drug users are the second largest group at risk of
7 becoming infected with the human immunodeficiency virus (HIV)
8 and developing AIDS, and they have been the primary source of
9 heterosexual, female, and perinatal transmission in California, the
10 United States, and Europe.
11 (c) According to the Office of AIDS within the State Department
12 of Public Health, injection drug use continues to be one of the most
13 prevalent risk factors for new HIV and AIDS cases in California.
14 Injection drug users continue to be at high risk of HIV/AIDS and
15 hepatitis infection in California. According to an annual report
16 issued by the Office of AIDS, sharing of contaminated syringes

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:

1 CHAPTER 1.5. STATE HIV PREVENTION AND EDUCATION FUNDS

2

3 120780. A public entity that receives General Fund money
4 from the State Department of Public Health for HIV prevention
5 and education may use that money to support clean needle and
6 syringe exchange projects authorized by the public entity pursuant
7 to existing law. The money may be used for, but is not limited to,
8 the purchase of sterile hypodermic needles and syringes. Funds
9 allocated for the purchase of sterile hypodermic needles and
10 syringes shall be based upon epidemiological data as reported by
11 the health jurisdiction in its local HIV prevention plan submitted
12 to the Office of AIDS within the department.

13 SEC. 3. Section 121349.3 of the Health and Safety Code is
14 amended to read:

15 121349.3. The health officer of the participating jurisdiction
16 shall present annually at an open meeting of the board of
17 supervisors or city council a report detailing the status of clean
18 needle and syringe exchange programs including, but not limited
19 to, relevant statistics on blood-borne infections associated with
20 needle sharing activity *and the use of public funds for these*
21 *programs*. Law enforcement, administrators of alcohol and drug
22 treatment programs, other stakeholders, and the public shall be
23 afforded ample opportunity to comment at this annual meeting.
24 The notice to the public shall be sufficient to assure adequate
25 participation in the meeting by the public. This meeting shall be
26 noticed in accordance with all state and local open meeting laws
27 and ordinances, and as local officials deem appropriate.

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.~~

AMENDED IN ASSEMBLY JUNE 21, 2007

AMENDED IN ASSEMBLY APRIL 30, 2007

CALIFORNIA LEGISLATURE—2007—08 REGULAR SESSION

ASSEMBLY BILL

No. 501

Introduced by Assembly Members Swanson and Hancock
(Coauthor: Assembly Member Dymally)

February 20, 2007

An act to add Section 118288 to the Health and Safety Code, relating to pharmaceutical devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 501, as amended, Swanson. Pharmaceutical devices.

The existing Medical Waste Management Act, administered by the State Department of Health Services, regulates the management and handling of medical waste, as defined. Effective July 1, 2007, these duties will be transferred to the State Department of Public Health. Under existing law, certain items, such as home-generated sharps waste, as defined, are specifically excluded from the definition of medical waste. The act also prohibits, on or after September 1, 2008, a person from knowingly placing home-generated sharps waste in certain types of containers, provides that home-generated sharps waste is to be transported only in a sharps container, as defined, or other container approved by the department or local enforcement agency, and requires this waste to only be managed at specified locations consistent with existing law.

This bill would require a pharmaceutical-~~company~~ *manufacturer* whose product is ~~dispensed~~ *administered for home use* through a prefilled syringe, prefilled pen needle, or other prefilled injection device

to provide each person ~~for whom~~ *who uses* the product ~~is prescribed~~ with a ~~specified method~~ *container* for the patient to safely dispose ~~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.*

The bill would require the pharmaceutical manufacturer to keep specified records and make them available to the State Department of Public Health and the California Integrated Waste Management Board.

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. The Legislature finds and declares all of the
2 following:

3 (a) An estimated 1 million Californians must self-inject
4 prescription medications annually to treat a broad range of serious
5 health problems.

6 (b) The use of prefilled syringes, pens, and devices with needles
7 is an effective method of prescription drug delivery and is expected
8 to increase significantly in the future. Prefilled syringes, pens, and
9 devices with needles are clearly identified and linked to specific
10 pharmaceutical manufacturers for the provision of their product
11 to California residents.

12 (c) The increased use of prefilled syringes, pens, and devices
13 with needles will generate millions of home-generated sharps each
14 year. Prefilled pen needles are being used for the treatment of some
15 of the most serious health conditions such as HIV/AIDS, hepatitis
16 C, and many other diseases. If improperly disposed in solid waste
17 and recycling containers these needles will result in significant
18 public health risks.

19 (d) The Legislature has found that sharps mail-back programs
20 utilizing containers and packaging approved by the United States
21 Postal Service offer one of the most convenient means for
22 collecting and destroying home-generated sharps and that the
23 cooperative efforts of the pharmaceutical industry is needed to
24 develop a safe needle disposal system for California.

25 SEC. 2. *Section 118288 is added to the Health and Safety Code,*
26 *to read:*

1 118288. (a) A pharmaceutical manufacturer whose product
2 is administered for home use via a prefilled syringe, prefilled pen
3 needle, or other prefilled injection device shall provide each person
4 who uses the product with a container for the safe disposal of used
5 sharps from the syringe, pen needle, or other injection device. The
6 pharmaceutical manufacturer shall also place on the container a
7 legible sticker that includes, in 12 point font both of the following:

8 (1) A toll-free telephone number for patients to receive
9 instructions for safe disposal methods of the container.

10 (2) The following warning note: "As of September 2008, you
11 are prohibited from disposing of used sharps in city or county
12 waste or recyclable containers or receptacles."

13 (b) The toll-free number shall identify for a person who has a
14 container for the safe disposal of used sharps safe disposal methods
15 of the container. These disposal methods shall include a mail-back
16 option, whereby, upon request of the person with the container,
17 the pharmaceutical manufacturer shall provide this person with
18 the means to mail the container to an approved medical waste
19 treatment facility for treatment and disposal in a container
20 approved by the United States Postal Service and the State
21 Department of Public Health for this purpose.

22 (c) The pharmaceutical manufacturer shall keep verifiable
23 records as to the number of prefilled syringes, prefilled pens
24 needles, or other prefilled injection devices that are dispensed
25 with its products and the disposition of those units. These records
26 shall be made available to the State Department of Public Health
27 and the California Integrated Waste Management Board, upon
28 request by either governmental entity, to ensure that these prefilled
29 syringes, prefilled pen needles, and prefilled injection devices are
30 being disposed of properly and are diverted from the solid waste
31 stream.

32 (d) This section shall not apply to drugs compounded or
33 dispensed for use within a hospital.

34 ~~SEC. 2. Section 118288 is added to the Health and Safety Code,~~
35 ~~to read:~~

36 ~~118288. (a) Effective January 1, 2008, pharmaceutical~~
37 ~~manufacturers whose product is dispensed via a prefilled syringe,~~
38 ~~prefilled pen needle, or other prefilled injection device shall provide~~
39 ~~each new patient for whom the product is dispensed in this state~~
40 ~~with a method described in this section to safely dispose of the~~

1 prefilled syringe, prefilled pen needle, or other prefilled injection
2 device after it is used. If the new patient receives this prefilled
3 syringe, prefilled pen needle, or other prefilled injection device as
4 part of the patient's treatment, the pharmaceutical manufacturer
5 shall make available to the new patient, at no additional charge, a
6 postage prepaid, mail-back sharps container, or an alternative safe
7 needle disposal method. The safe needle disposal method shall be
8 accountable and substantiated by documented evidence that these
9 prefilled syringes, prefilled pen needles, and prefilled devices are
10 being disposed of properly and are diverted from the solid waste
11 stream. If using a mail-back container as a safe needle disposal
12 method of choice, the container shall be approved by the United
13 States Postal Service and State Department of Public Health.

14 (b) The pharmaceutical manufacturer shall also make available,
15 at no additional charge, an annually renewable program which
16 provides postage prepaid mail-back sharps containers or an
17 alternative disposal method to any person who continues to use
18 the pharmaceutical manufacturer's product.

19 (c) This section shall not apply to drugs compounded or
20 dispensed for use within a hospital.

21 (d) For purposes of this section, the following definitions shall
22 apply:

23 (1) "Coupon" means any written material that allows a person
24 who uses a pharmaceutical company's product pursuant to a
25 prescription to receive a postage prepaid, mail-back sharps
26 container from a distribution point chosen by the pharmaceutical
27 company.

28 (2) "New patient" means a new start or treatment-naive patient
29 who is initiating self-injected drug therapy.

30 (3) "Patient starter kit" means a package of educational, training,
31 or otherwise instructional materials prepared by, or on behalf of,
32 the pharmaceutical company to educate a person on how to safely
33 use the pharmaceutical company's self-injectable pharmaceutical
34 product.

35 (4) "Sharps container" has the same meaning as in Section
36 117750.

AMENDED IN ASSEMBLY APRIL 17, 2007

AMENDED IN ASSEMBLY MARCH 28, 2007

CALIFORNIA LEGISLATURE—2007—08 REGULAR SESSION

ASSEMBLY BILL

No. 543

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

February 21, 2007

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.

LEGISLATIVE COUNSEL'S DIGEST

AB 543, as amended, Plescia. Ambulatory surgical centers: 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. 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, 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 within 45 calendar days of the date of an application, 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 to prepare a comprehensive report on the training program, as provided. By imposing new licensure requirements on ambulatory surgical centers, a violation of which would be a crime, the 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. Section 2472 of the Business and Professions
2 Code is amended to read:
3 2472. (a) The certificate to practice podiatric medicine
4 authorizes the holder to practice podiatric medicine.
5 (b) As used in this chapter, "podiatric medicine" means the
6 diagnosis, medical, surgical, mechanical, manipulative, and
7 electrical treatment of the human foot, including the ankle and
8 tendons that insert into the foot and the nonsurgical treatment of
9 the muscles and tendons of the leg governing the functions of the
10 foot.
11 (c) A doctor of podiatric medicine may not administer an
12 anesthetic other than local. If an anesthetic other than local is

1 required for any procedure, the anesthetic shall be administered
2 by another licensed health care practitioner who is authorized to
3 administer the required anesthetic within the scope of his or her
4 practice.

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

7 (A) Perform surgical treatment of the ankle and tendons at the
8 level of the ankle pursuant to subdivision (e).

9 (B) Perform services under the direct supervision of a physician
10 and surgeon, as an assistant at surgery, in surgical procedures that
11 are otherwise beyond the scope of practice of a doctor of podiatric
12 medicine.

13 (C) Perform a partial amputation of the foot no further proximal
14 than the Chopart's joint.

15 (2) Nothing in this subdivision shall be construed to permit a
16 doctor of podiatric medicine to function as a primary surgeon for
17 any procedure beyond his or her scope of practice.

18 (e) A doctor of podiatric medicine may perform surgical
19 treatment of the ankle and tendons at the level of the ankle only
20 in the following locations:

21 (1) A licensed general acute care hospital, as defined in Section
22 1250 of the Health and Safety Code.

23 (2) A licensed ambulatory surgical center, as defined in Section
24 1204 of the Health and Safety Code, if the doctor of podiatric
25 medicine has surgical privileges, including the privilege to perform
26 surgery on the ankle, in a general acute care hospital described in
27 paragraph (1) and meets all the protocols of the ambulatory surgical
28 center.

29 (3) An ambulatory surgical center that is certified to participate
30 in the Medicare Program under Title XVIII (42 U.S.C. Sec. 1395
31 et seq.) of the federal Social Security Act, if the doctor of podiatric
32 medicine has surgical privileges, including the privilege to perform
33 surgery on the ankle, in a general acute care hospital described in
34 paragraph (1) and meets all the protocols of the ambulatory surgical
35 center.

36 (4) A freestanding physical plant housing outpatient services
37 of a licensed general acute care hospital, as defined in Section
38 1250 of the Health and Safety Code, if the doctor of podiatric
39 medicine has surgical privileges, including the privilege to perform
40 surgery on the ankle, in a general acute care hospital described in

1 paragraph (1). For purposes of this section, a “freestanding physical
2 plant” means any building that is not physically attached to a
3 building where inpatient services are provided.

4 (5) An outpatient setting accredited pursuant to subdivision (g)
5 of Section 1248.1 of the Health and Safety Code.

6 (f) A doctor of podiatric medicine shall not perform an admitting
7 history and physical examination of a patient in an acute care
8 hospital where doing so would violate the regulations governing
9 the Medicare Program.

10 (g) A doctor of podiatric medicine licensed under this chapter
11 is a licentiate for purposes of paragraph (2) of subdivision (a) of
12 Section 805, and thus is a health care practitioner subject to the
13 provisions of Section 2290.5 pursuant to subdivision (b) of that
14 section.

15 SEC. 2. Section 4190 of the Business and Professions Code is
16 amended to read:

17 4190. (a) Notwithstanding any provision of this chapter, an
18 ambulatory surgical center, licensed pursuant to Section 1212.5
19 of the Health and Safety Code, accredited by an accreditation
20 agency as defined in Section 1248 of the Health and Safety Code,
21 or certified to participate in the Medicare Program under Title
22 XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security
23 Act, may purchase drugs at wholesale for administration or
24 dispensing, under the direction of a physician, to patients registered
25 for care at the center, as provided in subdivision (b). The center
26 shall keep records of the kind and amounts of drugs purchased,
27 administered, and dispensed, and the records shall be available
28 and maintained for a minimum of three years for inspection by all
29 properly authorized personnel.

30 (b) The drug distribution service of an ambulatory surgical
31 center shall be limited to the use of drugs for administration to the
32 patients of the ambulatory surgical center and to the dispensing of
33 drugs for the control of pain and nausea for patients of the center.
34 Drugs shall not be dispensed in an amount greater than that
35 required to meet the patient’s needs for 72 hours. Drugs for
36 administration shall be those drugs directly applied, whether by
37 injection, inhalation, ingestion, or any other means, to the body of
38 a patient for his or her immediate needs.

39 (c) No ambulatory surgical center shall operate without a license
40 issued by the board nor shall it be entitled to the benefits of this

1 section until it has obtained a license from the board. A separate
2 license shall be required for each center location. A center shall
3 notify the board of any change in the center's address on a form
4 furnished by the board.

5 (d) Any proposed change in ownership or beneficial interest in
6 the licensee shall be reported to the board, on a form to be furnished
7 by the board, at least 30 days prior to the execution of any
8 agreement to purchase, sell, exchange, gift, or otherwise transfer
9 any ownership or beneficial interest or prior to any transfer of
10 ownership or beneficial interest, whichever occurs earlier.

11 SEC. 3. Section 1204 of the Health and Safety Code is amended
12 to read:

13 1204. Clinics eligible for licensure pursuant to this chapter are
14 primary care clinics and specialty clinics.

15 (a) (1) Only the following defined classes of primary care
16 clinics shall be eligible for licensure:

17 (A) A "community clinic" means a clinic operated by a
18 tax-exempt nonprofit corporation that is supported and maintained
19 in whole or in part by donations, bequests, gifts, grants, government
20 funds or contributions, that may be in the form of money, goods,
21 or services. In a community clinic, any charges to the patient shall
22 be based on the patient's ability to pay, utilizing a sliding fee scale.
23 No corporation other than a nonprofit corporation, exempt from
24 federal income taxation under paragraph (3) of subsection (c) of
25 Section 501 of the Internal Revenue Code of 1954 as amended, or
26 a statutory successor thereof, shall operate a community clinic;
27 provided, that the licensee of any community clinic so licensed on
28 the effective date of this section shall not be required to obtain
29 tax-exempt status under either federal or state law in order to be
30 eligible for, or as a condition of, renewal of its license. No natural
31 person or persons shall operate a community clinic.

32 (B) A "free clinic" means a clinic operated by a tax-exempt,
33 nonprofit corporation supported in whole or in part by voluntary
34 donations, bequests, gifts, grants, government funds or
35 contributions, that may be in the form of money, goods, or services.
36 In a free clinic there shall be no charges directly to the patient for
37 services rendered or for drugs, medicines, appliances, or
38 apparatuses furnished. No corporation other than a nonprofit
39 corporation exempt from federal income taxation under paragraph
40 (3) of subsection (c) of Section 501 of the Internal Revenue Code

1 of 1954 as amended, or a statutory successor thereof, shall operate
2 a free clinic; provided, that the licensee of any free clinic so
3 licensed on the effective date of this section shall not be required
4 to obtain tax-exempt status under either federal or state law in
5 order to be eligible for, or as a condition of, renewal of its license.
6 No natural person or persons shall operate a free clinic.

7 (2) Nothing in this subdivision shall prohibit a community clinic
8 or a free clinic from providing services to patients whose services
9 are reimbursed by third-party payers, or from entering into
10 managed care contracts for services provided to private or public
11 health plan subscribers, as long as the clinic meets the requirements
12 identified in subparagraphs (A) and (B). For purposes of this
13 subdivision, any payments made to a community clinic by a
14 third-party payer, including, but not limited to, a health care service
15 plan, shall not constitute a charge to the patient. This paragraph is
16 a clarification of existing law.

17 (b) The following types of specialty clinics shall be eligible for
18 licensure as specialty clinics pursuant to this chapter:

19 (1) An “ambulatory surgical center” means a clinic that is not
20 part of a hospital and that provides ambulatory surgical care for
21 patients who remain less than 24 hours. An ambulatory surgical
22 center does not include any place or establishment owned or leased
23 and operated as a clinic or office by one or more physicians or
24 dentists in individual or group practice, regardless of the name
25 used publicly to identify the place or establishment, provided,
26 however, that physicians or dentists may, at their option, apply for
27 licensure.

28 (2) A “chronic dialysis clinic” means a clinic that provides less
29 than 24-hour care for the treatment of patients with end-stage renal
30 disease, including renal dialysis services.

31 (3) A “rehabilitation clinic” means a clinic that, in addition to
32 providing medical services directly, also provides physical
33 rehabilitation services for patients who remain less than 24 hours.
34 Rehabilitation clinics shall provide at least two of the following
35 rehabilitation services: physical therapy, occupational therapy,
36 social, speech pathology, and audiology services. A rehabilitation
37 clinic does not include the offices of a private physician in
38 individual or group practice.

39 (4) An “alternative birth center” means a clinic that is not part
40 of a hospital and that provides comprehensive perinatal services

1 and delivery care to pregnant women who remain less than 24
2 hours at the facility.

3 SEC. 4. Section 1206 of the Health and Safety Code is amended
4 to read:

5 1206. This chapter does not apply to the following:

6 (a) Except with respect to the option provided with regard to
7 ambulatory surgical centers described in paragraph (1) of
8 subdivision (b) of Section 1204 and further, with respect to chronic
9 dialysis clinics described in paragraph (2) of subdivision (b) of
10 Section 1204, any place or establishment owned or leased and
11 operated as a clinic or office by one or more licensed health care
12 practitioners and used as an office for the practice of their
13 profession, within the scope of their license, regardless of the name
14 used publicly to identify the place or establishment.

15 (b) Any clinic directly conducted, maintained, or operated by
16 the United States or by any of its departments, officers, or agencies,
17 and any primary care clinic specified in subdivision (a) of Section
18 1204 that is directly conducted, maintained, or operated by this
19 state or by any of its political subdivisions or districts, or by any
20 city. Nothing in this subdivision precludes the department from
21 adopting regulations that utilize clinic licensing standards as
22 eligibility criteria for participation in programs funded wholly or
23 partially under Title XVIII or XIX of the federal Social Security
24 Act.

25 (c) Any clinic conducted, maintained, or operated by a federally
26 recognized Indian tribe or tribal organization, as defined in Section
27 450b or 1603 of Title 25 of the United States Code, that is located
28 on land recognized as tribal land by the federal government.

29 (d) Clinics conducted, operated, or maintained as outpatient
30 departments of hospitals.

31 (e) Any facility licensed as a health facility under Chapter 2
32 (commencing with Section 1250).

33 (f) Any freestanding clinical or pathological laboratory licensed
34 under Chapter 3 (commencing with Section 1200) of Division 2
35 of the Business and Professions Code.

36 (g) A clinic operated by, or affiliated with, any institution of
37 learning that teaches a recognized healing art and is approved by
38 the state board or commission vested with responsibility for
39 regulation of the practice of that healing art.

1 (h) A clinic that is operated by a primary care community or
2 free clinic and that is operated on separate premises from the
3 licensed clinic and is only open for limited services of no more
4 than 20 hours a week. An intermittent clinic as described in this
5 subdivision shall, however, meet all other requirements of law,
6 including administrative regulations and requirements, pertaining
7 to fire and life safety.

8 (i) The offices of physicians in group practice who provide a
9 preponderance of their services to members of a comprehensive
10 group practice prepayment health care service plan subject to
11 Chapter 2.2 (commencing with Section 1340).

12 (j) Student health centers operated by public institutions of
13 higher education.

14 (k) Nonprofit speech and hearing centers, as defined in Section
15 1201.5. Any nonprofit speech and hearing clinic desiring an
16 exemption under this subdivision shall make application therefor
17 to the director, who shall grant the exemption to any facility
18 meeting the criteria of Section 1201.5. Notwithstanding the
19 licensure exemption contained in this subdivision, a nonprofit
20 speech and hearing center shall be deemed to be an organized
21 outpatient clinic for purposes of qualifying for reimbursement as
22 a rehabilitation center under the Medi-Cal Act (Chapter 7
23 (commencing with Section 14000) of Part 3 of Division 9 of the
24 Welfare and Institutions Code).

25 (l) A clinic operated by a nonprofit corporation exempt from
26 federal income taxation under paragraph (3) of subsection (c) of
27 Section 501 of the Internal Revenue Code of 1954, as amended,
28 or a statutory successor thereof, that conducts medical research
29 and health education and provides health care to its patients through
30 a group of 40 or more physicians and surgeons, who are
31 independent contractors representing not less than 10
32 board-certified specialties, and not less than two-thirds of whom
33 practice on a full-time basis at the clinic.

34 (m) Any clinic, limited to in vivo diagnostic services by
35 magnetic resonance imaging functions or radiological services
36 under the direct and immediate supervision of a physician and
37 surgeon who is licensed to practice in California. This shall not
38 be construed to permit cardiac catheterization or any treatment
39 modality in these clinics.

1 (n) A clinic operated by an employer or jointly by two or more
2 employers for their employees only, or by a group of employees,
3 or jointly by employees and employers, without profit to the
4 operators thereof or to any other person, for the prevention and
5 treatment of accidental injuries to, and the care of the health of,
6 the employees comprising the group.

7 (o) A community mental health center, as defined in Section
8 5667 of the Welfare and Institutions Code.

9 (p) (1) A clinic operated by a nonprofit corporation exempt
10 from federal income taxation under paragraph (3) of subsection
11 (c) of Section 501 of the Internal Revenue Code of 1954, as
12 amended, or a statutory successor thereof, as an entity organized
13 and operated exclusively for scientific and charitable purposes and
14 that satisfied all of the following requirements on or before January
15 1, 2005:

16 (A) Commenced conducting medical research on or before
17 January 1, 1982, and continues to conduct medical research.

18 (B) Conducted research in, among other areas, prostatic cancer,
19 cardiovascular disease, electronic neural prosthetic devices,
20 biological effects and medical uses of lasers, and human magnetic
21 resonance imaging and spectroscopy.

22 (C) Sponsored publication of at least 200 medical research
23 articles in peer-reviewed publications.

24 (D) Received grants and contracts from the National Institutes
25 of Health.

26 (E) Held and licensed patents on medical technology.

27 (F) Received charitable contributions and bequests totaling at
28 least five million dollars (\$5,000,000).

29 (G) Provides health care services to patients only:

30 (i) In conjunction with research being conducted on procedures
31 or applications not approved or only partially approved for payment
32 (I) under the Medicare Program pursuant to Section 1395y(a)(1)(A)
33 of Title 42 of the United States Code, or (II) by a health care service
34 plan registered under Chapter 2.2 (commencing with Section 1340),
35 or a disability insurer regulated under Chapter 1 (commencing
36 with Section 10110) of Part 2 of Division 2 of the Insurance Code;
37 provided that services may be provided by the clinic for an
38 additional period of up to three years following the approvals, but
39 only to the extent necessary to maintain clinical expertise in the
40 procedure or application for purposes of actively providing training

1 in the procedure or application for physicians and surgeons
2 unrelated to the clinic.

3 (ii) Through physicians and surgeons who, in the aggregate,
4 devote no more than 30 percent of their professional time for the
5 entity operating the clinic, on an annual basis, to direct patient care
6 activities for which charges for professional services are paid.

7 (H) Makes available to the public the general results of its
8 research activities on at least an annual basis, subject to good faith
9 protection of proprietary rights in its intellectual property.

10 (I) Is a freestanding clinic, whose operations under this
11 subdivision are not conducted in conjunction with any affiliated
12 or associated health clinic or facility defined under this division,
13 except a clinic exempt from licensure under subdivision (m). For
14 purposes of this subparagraph, a freestanding clinic is defined as
15 “affiliated” only if it directly, or indirectly through one or more
16 intermediaries, controls, or is controlled by, or is under common
17 control with, a clinic or health facility defined under this division,
18 except a clinic exempt from licensure under subdivision (m). For
19 purposes of this subparagraph, a freestanding clinic is defined as
20 “associated” only if more than 20 percent of the directors or trustees
21 of the clinic are also the directors or trustees of any individual
22 clinic or health facility defined under this division, except a clinic
23 exempt from licensure under subdivision (m). Any activity by a
24 clinic under this subdivision in connection with an affiliated or
25 associated entity shall fully comply with the requirements of this
26 subdivision. This subparagraph shall not apply to agreements
27 between a clinic and any entity for purposes of coordinating
28 medical research.

29 (2) By January 1, 2007, and every five years thereafter, the
30 Legislature shall receive a report from each clinic meeting the
31 criteria of this subdivision and any other interested party
32 concerning the operation of the clinic’s activities. The report shall
33 include, but not be limited to, an evaluation of how the clinic
34 impacted competition in the relevant health care market, and a
35 detailed description of the clinic’s research results and the level
36 of acceptance by the payer community of the procedures performed
37 at the clinic. The report shall also include a description of
38 procedures performed both in clinics governed by this subdivision
39 and those performed in other settings. The cost of preparing the

1 reports shall be borne by the clinics that are required to submit
2 them to the Legislature pursuant to this paragraph.

3 SEC. 5. Section 1212.5 is added to the Health and Safety Code,
4 to read:

5 1212.5. (a) On or after January 1, 2008, in addition to other
6 licensing requirements of this chapter, any person, firm,
7 association, partnership, or corporation desiring a license for an
8 ambulatory surgical center shall meet the following standards:

9 (1) Comply with the Medicare conditions of coverage for
10 ambulatory surgical centers, as set forth in Subpart C of Part 416
11 of Title 42 of the Code of Federal Regulations, as those regulations
12 existed on January 1, 2007.

13 (2) Limit surgical procedures to those that:

14 (A) Do not generally exceed an average of four hours of total
15 operating time.

16 (B) Do not result in extensive blood loss.

17 (C) Do not require major or prolonged invasion of body cavities.

18 (D) Do not directly involve major blood vessels.

19 ~~(E)~~

20 (E) Are not emergency or life threatening in nature.

21 (3) Establish and implement policies and procedures consistent
22 with the Medicare conditions of coverage set forth in Subpart C
23 of Part 416 of Title 42 of the Code of Federal Regulations, as those
24 regulations existed on January 1, 2007, including, but not limited
25 to:

26 (A) Physician services policies and procedures, including
27 surgical and anesthesia services.

28 (B) Nursing services policies and procedures.

29 (C) Infection control policies and procedures.

30 (D) Pharmaceutical services policies and procedures.

31 (E) Housekeeping services policies and procedures which
32 include provisions for maintenance of a safe and clean
33 environment.

34 (F) Laboratory and radiology services.

35 (G) Patient health records policies and procedures, which shall
36 be developed with the assistance of a person skilled in record
37 maintenance and preservations.

38 (H) Personnel policies and procedures.

39 (b) ~~The~~ *Notwithstanding subdivision (c) of Section 1228, the*
40 department shall perform initial inspections of an ambulatory

1 surgical center within 45 calendar days of the date of an
2 application, and periodic inspections shall occur at least once every
3 three years thereafter.

4 ~~(e) The department may contract for outside personnel to~~
5 ~~perform inspections of ambulatory surgical centers for compliance~~
6 ~~with state licensing standards, as necessary, in a manner consistent~~
7 ~~with the inspections conducted by the department pursuant to~~
8 ~~Section 1228.~~

9 ~~(d)~~

10 (c) Surgical clinic licenses issued by the department pursuant
11 to paragraph (1) of subdivision (b) of Section 1204 prior to January
12 1, 2008, shall on or after January 1, 2008, not be subject to the
13 requirements set forth in paragraph (1) of subdivision (a) until
14 January 1, 2013, and an applicant to which this subdivision applies
15 shall be issued an ambulatory surgical center license upon
16 ~~submission of documentation to a determination by the department~~
17 ~~that the applicant has met the requirements set for in paragraph~~
18 ~~(1) of forth in~~ subdivision (a) and surrenders the license issued by
19 the department as a surgical clinic.

20 ~~(e)~~

21 (d) On or after January 1, 2008, the department shall not issue
22 any new surgical clinic licenses.

23 ~~(f)~~

24 (e) Contingent upon an appropriation in the annual Budget Act,
25 the department shall until January 1, 2015, establish a program for
26 training of ambulatory surgical center inspection personnel. The
27 goal of this program shall be to provide a sufficient number of
28 qualified persons to facilitate the timely performance of the
29 department's duties and responsibilities relating to initial and
30 periodic licensing inspections of ambulatory surgical centers, in
31 order to ensure compliance with this chapter.

32 ~~(g)~~

33 (f) (1) The department shall prepare a comprehensive report
34 on the training program setting forth its goals, objectives, and
35 structure. The report shall assess processing time for initial and
36 periodic licensing inspections of ambulatory surgical centers and
37 include information on all of the following:

38 (A) The number of ambulatory surgical center inspection
39 personnel to be trained annually.

40 (B) A timeline for completion of training.

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

3 (D) A mechanism to annually assess the need for the training
4 program to continue.

5 (2) The report required by paragraph (1) shall be submitted to
6 the Joint Legislative Budget Committee no later than February 1,
7 2008, and no later than February 1 of each year thereafter, through
8 February 1, 2014.

9 (g) *For purposes of this section, a surgical clinic means a health*
10 *clinic that is not part of a hospital and that provides ambulatory*
11 *surgical care for patients who remain less than 24 hours. A*
12 *surgical clinic does not include any place or establishment owned*
13 *or leased and operated as a clinic or office by one or more*
14 *physicians and surgeons or dentists in individual or group practice,*
15 *regardless of the name used publicly to identify the place or*
16 *establishment. However, these physicians and surgeons or dentists*
17 *may apply for licensure as an ambulatory surgical center.*

18 SEC. 6. Section 1214.1 of the Health and Safety Code is
19 amended to read:

20 1214.1. Notwithstanding the provisions of Section 1214, each
21 application for an ambulatory surgical center or a chronic dialysis
22 clinic under this chapter for an initial license, renewal license,
23 license upon change of ownership, or special permit shall be
24 accompanied by an annual Licensing and Certification Program
25 fee set in accordance with Section 1266.

26 SEC. 7. Section 1226 of the Health and Safety Code is amended
27 to read:

28 1226. (a) The regulations shall prescribe the kinds of services
29 which may be provided by clinics in each category of licensure
30 and shall prescribe minimum standards of adequacy, safety, and
31 sanitation of the physical plant and equipment, minimum standards
32 for staffing with duly qualified personnel, and minimum standards
33 for providing the services offered. These minimum standards shall
34 be based on the type of facility, the needs of the patients served,
35 and the types and levels of services provided.

36 (b) The Office of Statewide Health Planning and Development,
37 in consultation with the Community Clinics Advisory Committee,
38 shall prescribe minimum construction standards of adequacy and
39 safety for the physical plant of clinics as found in the California
40 Building Standards Code.

1 (c) A city or county, as applicable, shall have plan review and
2 building inspection responsibilities for the construction or alteration
3 of buildings described in paragraph (1) and paragraph (2) of
4 subdivision (b) of Section 1204 and shall apply the provisions of
5 the latest edition of the California Building Standards Code in
6 conducting these plan review responsibilities. For these buildings,
7 construction and alteration shall include conversion of a building
8 to a purpose specified in paragraphs (1) and (2) of subdivision (b)
9 of Section 1204.

10 Upon the initial submittal to a city or county by the governing
11 authority or owner of these clinics for plan review and building
12 inspection services, the city or county shall reply in writing to the
13 clinic whether or not the plan review by the city or county will
14 include a certification as to whether or not the clinic project
15 submitted for plan review meets the standards as propounded by
16 the office in the California Building Standards Code.

17 If the city or county indicates that its review will include this
18 certification it shall do all of the following:

19 (1) Apply the applicable clinic provisions of the latest edition
20 of the California Building Standards Code.

21 (2) Certify in writing, to the applicant within 30 days of
22 completion of construction whether or not these standards have
23 been met.

24 (d) If upon initial submittal, the city or county indicates that its
25 plan review will not include this certification, the governing
26 authority or owner of the clinic shall submit the plans to the Office
27 of Statewide Health Planning and Development which shall review
28 the plans for certification whether or not the clinic project meets
29 the standards, as propounded by the office in *the* California
30 Building Standards Code.

31 (e) When the office performs review for certification, the office
32 shall charge a fee in an amount that does not exceed its actual
33 costs.

34 (f) The office of the State Fire Marshal shall prescribe minimum
35 safety standards for fire and life safety in ambulatory surgical
36 centers.

37 (g) Notwithstanding subdivision (c), the governing authority or
38 owner of a clinic may request the office to perform plan review
39 services for buildings described in subdivision (c). If the office
40 agrees to perform these services, after consultation with the local

1 building official, the office shall charge an amount not to exceed
2 its actual costs. The construction or alteration of these buildings
3 shall conform to the applicable provisions of the latest edition of
4 the California Building Standards Code for purposes of the plan
5 review by the office pursuant to this subdivision.

6 (h) Regulations adopted pursuant to this chapter establishing
7 standards for laboratory services shall not be applicable to any
8 clinic that operates a clinical laboratory licensed pursuant to
9 Section 1265 of the Business and Professions Code.

10 SEC. 8. Section 1226.5 of the Health and Safety Code is
11 amended to read:

12 1226.5. (a) It is the intent of the Legislature to establish seismic
13 safety standards for facilities licensed as ambulatory surgical
14 centers pursuant to this chapter, and for facilities certified for
15 participation in the federal Medicare Program as ambulatory
16 surgical centers, which accommodate surgical patients under
17 general anesthesia, but are not required to remain open and usable
18 after an earthquake to accommodate emergency patients.

19 (b) A facility described in subdivision (a) which, after January
20 1, 1991, anchors fixed medical equipment to the floor or roof of
21 the facility with a gross operating weight of more than 400 pounds
22 or anchors fixed medical equipment to the walls or ceiling with a
23 gross operating weight of more than 20 pounds shall retain the
24 services of an architect licensed in California, a structural engineer
25 licensed in California, or a civil engineer registered in California
26 to assure that the equipment is anchored in such a manner to meet
27 the requirements of an occupancy importance factor of 1.00, as
28 set forth in Title 24 of the California Code of Regulations.

29 (c) A facility described in subdivision (a) which retains the
30 services of an architect or engineer for the anchorage of fixed
31 medical equipment shall keep available for inspection by the
32 department for a period of five years following the installation, a
33 current written certification from the architect or engineer that the
34 equipment is mounted in accordance with the applicable
35 requirements.

36 SEC. 9. Section 1233 of the Health and Safety Code is amended
37 to read:

38 1233. An ambulatory surgical center may restrict use of its
39 facilities to members of the medical staff of the ambulatory surgical

1 center and other physicians and surgeons approved by the medical
2 staff to practice at the center.

3 SEC. 10. Section 1242 of the Health and Safety Code is
4 amended to read:

5 1242. The director may temporarily suspend any license issued
6 to a specialty clinic or special permit prior to any hearing, when
7 in his or her opinion this action is necessary to protect the public
8 welfare. The director shall notify the licensee or holder of a special
9 permit of the temporary suspension and the effective date thereof,
10 and at the same time shall serve such provider with an accusation.
11 Upon receipt of a notice of defense by the licensee or holder of a
12 special permit, the director shall set the matter for hearing within
13 30 days after receipt of such notice. The temporary suspension
14 shall remain in effect until the time when the hearing is completed
15 and the director has made a final determination on the merits;
16 provided, however, that the temporary suspension shall be deemed
17 vacated if the director fails to make a final determination on the
18 merits within 60 days after the original hearing has been completed.

19 If the provisions of this chapter or the rules or regulations
20 promulgated by the director are violated by a licensed ambulatory
21 surgical center or chronic dialysis clinic or holder of a special
22 permit which is a group, corporation, or other association, the
23 director may suspend the license or special permit of the
24 organization or may suspend the license or special permit as to
25 any individual person within the organization who is responsible
26 for the violation.

27 SEC. 11. Section 1248.1 of the Health and Safety Code is
28 amended to read:

29 1248.1. No association, corporation, firm, partnership, or person
30 shall operate, manage, conduct, or maintain an outpatient setting
31 in this state, unless the setting is one of the following:

32 (a) An ambulatory surgical center that is certified to participate
33 in the Medicare Program under Title XVIII (42 U.S.C. Sec. 1395
34 et seq.) of the federal Social Security Act.

35 (b) Any clinic conducted, maintained, or operated by a federally
36 recognized Indian tribe or tribal organization, as defined in Section
37 450 or 1601 of Title 25 of the United States Code, and located on
38 land recognized as tribal land by the federal government.

39 (c) Any clinic directly conducted, maintained, or operated by
40 the United States or by any of its departments, officers, or agencies.

1 (d) Any primary care clinic licensed under subdivision (a) of
2 Section 1204 or any ambulatory surgical center licensed under
3 subdivision (b) of Section 1204.

4 (e) Any health facility licensed as a general acute care hospital
5 under Chapter 2 (commencing with Section 1250).

6 (f) Any outpatient setting to the extent that it is used by a dentist
7 or physician and surgeon in compliance with Article 2.7
8 (commencing with Section 1646) or Article 2.8 (commencing with
9 Section 1647) of Chapter 4 of Division 2 of the Business and
10 Professions Code.

11 (g) An outpatient setting accredited by an accreditation agency
12 approved by the division pursuant to this chapter.

13 (h) A setting, including, but not limited to, a mobile van, in
14 which equipment is used to treat patients admitted to a facility
15 described in subdivision (a), (d), or (e), and in which the procedures
16 performed are staffed by the medical staff of, or other health care
17 practitioners with clinical privileges at, the facility and are subject
18 to the peer review process of the facility but which setting is not
19 a part of a facility described in subdivision (a), (d), or (e).

20 Nothing in this section shall relieve an association, corporation,
21 firm, partnership, or person from complying with all other
22 provisions of law that are otherwise applicable.

23 SEC. 12. Section 139.3 of the Labor Code is amended to read:

24 139.3. (a) Notwithstanding any other provision of law, to the
25 extent those services are paid pursuant to Division 4 (commencing
26 with Section 3200), it is unlawful for a physician to refer a person
27 for clinical laboratory, diagnostic nuclear medicine, radiation
28 oncology, physical therapy, physical rehabilitation, psychometric
29 testing, home infusion therapy, outpatient surgery, or diagnostic
30 imaging goods or services, whether for treatment or medical-legal
31 purposes, if the physician, or his or her immediate family, has a
32 financial interest with the person or in the entity that receives the
33 referral.

34 (b) For purposes of this section and Section 139.31, the
35 following shall apply:

36 (1) "Diagnostic imaging" includes, but is not limited to, all
37 X-ray, computed axial tomography, magnetic resonance imaging,
38 nuclear medicine, positron emission tomography, mammography,
39 and ultrasound goods and services.

1 (2) “Immediate family” includes the spouse and children of the
2 physician, the parents of the physician, and the spouses of the
3 children of the physician.

4 (3) “Physician” means a physician as defined in Section 3209.3.

5 (4) A “financial interest” includes, but is not limited to, any
6 type of ownership, interest, debt, loan, lease, compensation,
7 remuneration, discount, rebate, refund, dividend, distribution,
8 subsidy, or other form of direct or indirect payment, whether in
9 money or otherwise, between a licensee and a person or entity to
10 whom the physician refers a person for a good or service specified
11 in subdivision (a). A financial interest also exists if there is an
12 indirect relationship between a physician and the referral recipient,
13 including, but not limited to, an arrangement whereby a physician
14 has an ownership interest in any entity that leases property to the
15 referral recipient. Any financial interest transferred by a physician
16 to, or otherwise established in, any person or entity for the purpose
17 of avoiding the prohibition of this section shall be deemed a
18 financial interest of the physician.

19 (5) A “physician’s office” is either of the following:

20 (A) An office of a physician in solo practice.

21 (B) An office in which the services or goods are personally
22 provided by the physician or by employees in that office, or
23 personally by independent contractors in that office, in accordance
24 with other provisions of law. Employees and independent
25 contractors shall be licensed or certified when that licensure or
26 certification is required by law.

27 (6) The “office of a group practice” is an office or offices in
28 which two or more physicians are legally organized as a
29 partnership, professional corporation, or not-for-profit corporation
30 licensed according to subdivision (a) of Section 1204 of the Health
31 and Safety Code for which all of the following are applicable:

32 (A) Each physician who is a member of the group provides
33 substantially the full range of services that the physician routinely
34 provides, including medical care, consultation, diagnosis, or
35 treatment, through the joint use of shared office space, facilities,
36 equipment, and personnel.

37 (B) Substantially all of the services of the physicians who are
38 members of the group are provided through the group and are
39 billed in the name of the group and amounts so received are treated
40 as receipts of the group, and except that in the case of

1 multispecialty clinics, as defined in subdivision (l) of Section 1206
2 of the Health and Safety Code, physician services are billed in the
3 name of the multispecialty clinic and amounts so received are
4 treated as receipts of the multispecialty clinic.

5 (C) The overhead expenses of, and the income from, the practice
6 are distributed in accordance with methods previously determined
7 by members of the group.

8 (7) Outpatient surgery includes both of the following:

9 (A) Any procedure performed on an outpatient basis in the
10 operating rooms, ambulatory surgery rooms, endoscopy units,
11 cardiac catheterization laboratories, or other sections of a
12 freestanding ambulatory surgical center, whether or not licensed
13 under paragraph (1) of subdivision (b) of Section 1204 of the
14 Health and Safety Code.

15 (B) The ambulatory surgery itself.

16 (c) (1) It is unlawful for a licensee to enter into an arrangement
17 or scheme, such as a cross-referral arrangement, that the licensee
18 knows, or should know, has a principal purpose of ensuring
19 referrals by the licensee to a particular entity that, if the licensee
20 directly made referrals to that entity, would be in violation of this
21 section.

22 (2) It shall be unlawful for a physician to offer, deliver, receive,
23 or accept any rebate, refund, commission, preference, patronage
24 dividend, discount, or other consideration, whether in the form of
25 money or otherwise, as compensation or inducement for a referred
26 evaluation or consultation.

27 (d) No claim for payment shall be presented by an entity to any
28 individual, third-party payer, or other entity for any goods or
29 services furnished pursuant to a referral prohibited under this
30 section.

31 (e) A physician who refers to or seeks consultation from an
32 organization in which the physician has a financial interest shall
33 disclose this interest to the patient or if the patient is a minor, to
34 the patient's parents or legal guardian in writing at the time of the
35 referral.

36 (f) No insurer, self-insurer, or other payer shall pay a charge or
37 lien for any goods or services resulting from a referral in violation
38 of this section.

39 (g) A violation of subdivision (a) shall be a misdemeanor. The
40 appropriate licensing board shall review the facts and circumstances

1 of any conviction pursuant to subdivision (a) and take appropriate
2 disciplinary action if the licensee has committed unprofessional
3 conduct. Violations of this section may also be subject to civil
4 penalties of up to five thousand dollars (\$5,000) for each offense,
5 which may be enforced by the Insurance Commissioner, Attorney
6 General, or a district attorney. A violation of subdivision (c), (d),
7 (e), or (f) is a public offense and is punishable upon conviction by
8 a fine not exceeding fifteen thousand dollars (\$15,000) for each
9 violation and appropriate disciplinary action, including revocation
10 of professional licensure, by the Medical Board of California or
11 other appropriate governmental agency.

12 SEC. 13. No reimbursement is required by this act pursuant to
13 Section 6 of Article XIII B of the California Constitution because
14 the only costs that may be incurred by a local agency or school
15 district will be incurred because this act creates a new crime or
16 infraction, eliminates a crime or infraction, or changes the penalty
17 for a crime or infraction, within the meaning of Section 17556 of
18 the Government Code, or changes the definition of a crime within
19 the meaning of Section 6 of Article XIII B of the California
20 Constitution.

AMENDED IN ASSEMBLY MAY 31, 2007

AMENDED IN ASSEMBLY APRIL 16, 2007

CALIFORNIA LEGISLATURE—2007—08 REGULAR SESSION

ASSEMBLY BILL

No. 1025

Introduced by Assembly Member Bass

February 22, 2007

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 ~~or have his or her license suspended or revoked~~ based on a ~~criminal felony~~ conviction that has been dismissed on specified grounds *if certain requirements have been met.* ~~This~~ *The bill would 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 have his or her license suspended or revoked based on a criminal conviction that has been dismissed on specified grounds. 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.*

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.
12 (2) Done any act involving dishonesty, fraud or deceit with the
13 intent to substantially benefit himself or another, or substantially
14 injure another; or
15 (3) Done any act which if done by a licentiate of the business
16 or profession in question, would be grounds for suspension or
17 revocation of license.
18 The board may deny a license pursuant to this subdivision only
19 if the crime or act is substantially related to the qualifications,

1 functions or duties of the business or profession for which
2 application is made.

3 (b) Notwithstanding any other provision of this ~~code, no code.~~

4 (1) No person shall be denied a license solely on the basis that
5 he or she has been convicted of a felony if ~~he~~ *either of the following*
6 *apply:*

7 (A) He or she has obtained a certificate of rehabilitation under
8 ~~Section 4852.01 and following Chapter 3.5 (commencing with~~
9 ~~Section 4852.01) of Title 6 of Part 3 of the Penal Code or Code.~~

10 (B) *The felony conviction has been dismissed pursuant to Section*
11 *1203.4 of the Penal Code, there have been no subsequent felony*
12 *convictions, and either at least three years have passed since the*
13 *dismissal of the conviction or at least five years have passed since*
14 *the person completed his or her sentence. This paragraph shall*
15 *not apply if the conviction was for any offense defined in*
16 *subdivision (c) of Section 667.5 of the Penal Code as a violent*
17 *felony or any offense defined in subdivision (c) of Section 1192.7*
18 *of the Penal Code as a serious felony.*

19 (2) No person shall be denied a license solely on the basis that
20 he or she has been convicted of a misdemeanor if ~~he~~ *either of the*
21 *following apply:*

22 (A) He or she has met all applicable requirements of the criteria
23 of rehabilitation developed by the board to evaluate the
24 rehabilitation of a person when considering the denial of a license
25 under subdivision (a) of Section 482. ~~In addition, no person shall~~
26 ~~be denied a license based on any criminal conviction that~~

27 (B) *The misdemeanor conviction has been dismissed pursuant*
28 *to either Section 1203.4 or 1203.4a of the Penal Code.*

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

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

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

36 (1) File and serve a statement of issues in accordance with
37 Chapter 5 (commencing with Section 11500) of Part 1 of Division
38 3 of Title 2 of the Government Code.

39 (2) Notify the applicant that the application is denied, stating

40 (A) the reason for the denial, and (B) that the applicant has the

1 right to a hearing under Chapter 5 (commencing with Section
2 11500) of Part 1 of Division 3 of Title 2 of the Government Code
3 if written request for hearing is made within 60 days after service
4 of the notice of denial. Unless written request for hearing is made
5 within the 60-day period, the applicant's right to a hearing is
6 deemed waived.

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

12 (b) If the denial of a license is due at least in part to the
13 applicant's state or federal criminal history record, the board shall
14 include with the information provided pursuant to paragraph (1)
15 or (2) of subdivision (a) a copy of the applicant's criminal history
16 record.

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

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

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

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

32 490. A board may suspend or revoke a license on the ground
33 that the licensee has been convicted of a crime, if the crime is
34 substantially related to the qualifications, functions, or duties of
35 the business or profession for which the license was issued. A
36 conviction within the meaning of this section means a plea or
37 verdict of guilty or a conviction following a plea of nolo
38 contendere. Any action which a board is permitted to take
39 following the establishment of a conviction may be taken when
40 the time for appeal has elapsed, or the judgment of conviction has

1 been affirmed on appeal, or when an order granting probation is
2 made suspending the imposition of sentence. No license shall be
3 suspended or revoked based on any criminal conviction that has
4 been dismissed pursuant to Section 1203.4 or 1203.4a of the Penal
5 Code.

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

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

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

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

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

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

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

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

AMENDED IN SENATE JUNE 27, 2007
AMENDED IN ASSEMBLY MAY 21, 2007
AMENDED IN ASSEMBLY MAY 8, 2007

CALIFORNIA LEGISLATURE—2007—08 REGULAR SESSION

ASSEMBLY BILL

No. 1587

Introduced by Assembly Member De La Torre

February 23, 2007

An act to amend Section 56.05 of the Civil Code, relating to personal information.

LEGISLATIVE COUNSEL'S DIGEST

AB 1587, as amended, De La Torre. Personal information: pharmacy. The Confidentiality of Medical Information Act prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, using for marketing, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, unless a specified exception applies. That law excludes from the definition of marketing communications that are for a specified descriptive purpose, that are tailored to the circumstances of a particular individual, or for which the communicator does not receive remuneration from a 3rd party, as specified.

This bill would additionally exclude from the definition of marketing a written communication or written message provided to a pharmacy patient by a pharmacist or pharmacy personnel that meets specified conditions.

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

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

1 SECTION 1. Section 56.05 of the Civil Code is amended to
2 read:

3 56.05. For purposes of this part:

4 (a) "Authorization" means permission granted in accordance
5 with Section 56.11 or 56.21 for the disclosure of medical
6 information.

7 (b) "Authorized recipient" means any person who is authorized
8 to receive medical information pursuant to Section 56.10 or 56.20.

9 (c) "Contractor" means any person or entity that is a medical
10 group, independent practice association, pharmaceutical benefits
11 manager, or a medical service organization and is not a health care
12 service plan or provider of health care. "Contractor" does not
13 include insurance institutions as defined in subdivision (k) of
14 Section 791.02 of the Insurance Code or pharmaceutical benefits
15 managers licensed pursuant to the Knox-Keene Health Care Service
16 Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340)
17 of Division 2 of the Health and Safety Code).

18 (d) "Health care service plan" means any entity regulated
19 pursuant to the Knox-Keene Health Care Service Plan Act of 1975
20 (Chapter 2.2 (commencing with Section 1340) of Division 2 of
21 the Health and Safety Code).

22 (e) "Licensed health care professional" means any person
23 licensed or certified pursuant to Division 2 (commencing with
24 Section 500) of the Business and Professions Code, the Osteopathic
25 Initiative Act or the Chiropractic Initiative Act, or Division 2.5
26 (commencing with Section 1797) of the Health and Safety Code.

27 (f) "Marketing" means to make a communication about a
28 product or service that encourages recipients of the communication
29 to purchase or use the product or service.

30 "Marketing" does not include any of the following:

31 (1) Communications made orally or in writing for which the
32 communicator does not receive direct or indirect remuneration,
33 including, but not limited to, gifts, fees, payments, subsidies, or
34 other economic benefits, from a third party for making the
35 communication.

36 (2) Communications made to current enrollees solely for the
37 purpose of describing a provider's participation in an existing
38 health care provider network or health plan network of a

1 Knox-Keene licensed health plan to which the enrollees already
2 subscribe; communications made to current enrollees solely for
3 the purpose of describing if, and the extent to which, a product or
4 service, or payment for a product or service, is provided by a
5 provider, contractor, or plan or included in a plan of benefits of a
6 Knox-Keene licensed health plan to which the enrollees already
7 subscribe; or communications made to plan enrollees describing
8 the availability of more cost-effective pharmaceuticals.

9 (3) Communications that are tailored to the circumstances of a
10 particular individual to educate or advise the individual about
11 treatment options, and otherwise maintain the individual's
12 adherence to a prescribed course of medical treatment, as provided
13 in Section 1399.901 of the Health and Safety Code, for a chronic
14 and seriously debilitating or life-threatening condition as defined
15 in subdivisions (d) and (e) of Section 1367.21 of the Health and
16 Safety Code, if the health care provider, contractor, or health plan
17 receives direct or indirect remuneration, including, but not limited
18 to, gifts, fees, payments, subsidies, or other economic benefits,
19 from a third party for making the communication, if all of the
20 following apply:

21 (A) The individual receiving the communication is notified in
22 the communication in typeface no smaller than 14-point type of
23 the fact that the provider, contractor, or health plan has been
24 remunerated and the source of the remuneration.

25 (B) The individual is provided the opportunity to opt out of
26 receiving future remunerated communications.

27 (C) The communication contains instructions in typeface no
28 smaller than 14-point type describing how the individual can opt
29 out of receiving further communications by calling a toll-free
30 number of the health care provider, contractor, or health plan
31 making the remunerated communications. No further
32 communication may be made to an individual who has opted out
33 after 30 calendar days from the date the individual makes the opt
34 out request.

35 (4) A written communication or written message provided to a
36 pharmacy patient during a face-to-face interaction with a
37 pharmacist or pharmacy personnel, in conjunction with dispensing
38 a prescription drug, if all of the following apply:

39 (A) The communication does not involve the sale or transfer of
40 medical information by the pharmacy to any other entity, or to the

1 pharmacy from another entity. Additionally, the communication
2 is based only on medical information that has already been
3 provided to, and maintained by, the pharmacist as necessary to the
4 performance of the pharmacist's duties to fill prescriptions.

5 (B) The communication, either in whole or in part, assists the
6 pharmacist or pharmacy personnel in meeting the goals of Section
7 601 of Public Law 104-180 with respect to the transmittal of useful
8 information regarding a prescription drug dispensed to the patient.

9 (C) The content of the communication provides information
10 regarding any of the following:

11 (i) The dispensed drug or a disease or health condition for which
12 the dispensed drug is indicated.

13 (ii) Another treatment or therapy for a disease or health condition
14 for which the dispensed drug is indicated if the content of the
15 communication does not include any mention of, or negative
16 statements regarding, the dispensed drug by proprietary or brand
17 name and the treatment or therapy satisfies one or more of the
18 following conditions:

19 (I) Is an adjunctive treatment or therapy that augments or assists
20 the dispensed drug or therapy.

21 (II) Is ~~less expensive in the dispensing pharmacy than a generic~~
22 *alternative for the dispensed drug.*

23 (III) Has demonstrable benefits for the patient as compared to
24 the dispensed drug based upon the prescribing information
25 approved by the federal Food and Drug Administration (FDA), a
26 finding or conclusion contained in the FDA approval package, or
27 ~~a publicly available clinical trial requirements or policies of the~~
28 *FDA. Any such claim may not be inconsistent with applicable*
29 *requirements or policies of the FDA.* These demonstrable benefits
30 may include being more effective, having fewer or less serious
31 side effects, or offering more convenient dosing.

32 (iii) A drug dispensed to the patient during the preceding year
33 or a disease or health condition for which that drug is indicated.

34 (iv) General information about a health condition for which the
35 patient's disease or health condition puts the patient at risk and
36 that, if left untreated, may result in worsening of the health,
37 symptoms, or daily functioning of the patient.

38 (v) General information about a health condition for which the
39 patient may be at risk given the age or gender of the patient and

1 that, if left untreated, may result in worsening of the health,
2 symptoms, or daily functioning of the patient.

3 (vi) The information described in clauses (iii) to (v), inclusive,
4 shall not include any mention, by the proprietary name, brand
5 name, or generic name, of a specific drug or other product,
6 treatment, therapy, or service, other than the dispensed drug or a
7 drug dispensed to the patient during the preceding year.

8 (D) The pharmacist is available upon request of the patient to
9 answer questions regarding the communication and the
10 communication notifies the patient that he or she should consult
11 a health care provider.

12 (E) If the communication is paid for, in whole or in part, by a
13 manufacturer, distributor, or provider of a health care product or
14 service, other than the pharmacy or a business associate of the
15 pharmacy, the communication shall comply with all of the
16 following:

17 (i) The communication shall, in a clear written statement placed
18 in a clear and conspicuous location, disclose the source of the
19 sponsorship in a typeface no smaller than 14-point type.

20 (ii) If the communication is related to information referenced
21 in clause (i), (ii), or (iii) of subparagraph (C) and mentions a
22 prescription drug or other product, treatment, therapy, or service,
23 other than the dispensed prescription drug, by its proprietary name,
24 brand name, or generic name, the communication shall also contain
25 the words "paid advertisement" in a typeface no smaller than
26 14-point type at the top of each sponsored message.

27 (iii) If a sponsored message is printed on more than one page
28 of a communication, the statement required by clause (ii) shall
29 appear on each page on which the sponsored message appears.

30 (iv) If a sponsored message is printed on more than one panel
31 of the same page of a communication, the statement required by
32 clause (ii) shall appear on each panel on which the sponsored
33 message appears.

34 (v) *If the communication is related to information referenced*
35 *in clause (i), (ii), or (iii) of subparagraph (C) and mentions a*
36 *prescription or other product, treatment, therapy, or service, other*
37 *than the dispensed prescription drug, by its proprietary name,*
38 *brand name, or generic name, the communication shall also*
39 *contain the words "results may vary—consult your doctor."*

1 (F) The communication contains instructions in a typeface no
2 smaller than 14-point type describing how the patient can opt out
3 of the portion of a pharmacy's communication that is paid for by
4 a manufacturer, distributor, or provider of a health care product
5 or service by calling a toll-free number. No further sponsored
6 message from the pharmacy may be made to an individual who
7 has opted out after 30 calendar days from the date the individual
8 makes the opt out request.

9 (G) A majority of the printed space of the entire communication
10 delivered to the patient in the pharmacy is used for purposes other
11 than a sponsored message that is subject to clause (ii) of
12 subparagraph (E).

13 (H) *Compliance with any provision in this paragraph shall not*
14 *necessarily render any communication as truthful, not misleading,*
15 *fairly balanced, or adequately substantiated, within the meaning*
16 *of any applicable federal or state law, if that communication is*
17 *otherwise false, misleading, lacking in fair balance, or not*
18 *adequately substantiated.*

19 (g) "Medical information" means any individually identifiable
20 information, in electronic or physical form, in possession of or
21 derived from a provider of health care, health care service plan,
22 pharmaceutical company, or contractor regarding a patient's
23 medical history, mental or physical condition, or treatment.
24 "Individually identifiable" means that the medical information
25 includes or contains any element of personal identifying
26 information sufficient to allow identification of the individual,
27 such as the patient's name, address, electronic mail address,
28 telephone number, or social security number, or other information
29 that, alone or in combination with other publicly available
30 information, reveals the individual's identity.

31 (h) "Patient" means any natural person, whether or not still
32 living, who received health care services from a provider of health
33 care and to whom medical information pertains.

34 (i) "Pharmaceutical company" means any company or business,
35 or an agent or representative thereof, that manufactures, sells, or
36 distributes pharmaceuticals, medications, or prescription drugs.
37 "Pharmaceutical company" does not include a pharmaceutical
38 benefits manager, as included in subdivision (c), or a provider of
39 health care.

1 (j) "Provider of health care" means any person licensed or
2 certified pursuant to Division 2 (commencing with Section 500)
3 of the Business and Professions Code; any person licensed pursuant
4 to the Osteopathic Initiative Act or the Chiropractic Initiative Act;
5 any person certified pursuant to Division 2.5 (commencing with
6 Section 1797) of the Health and Safety Code; any clinic, health
7 dispensary, or health facility licensed pursuant to Division 2
8 (commencing with Section 1200) of the Health and Safety Code.
9 "Provider of health care" does not include insurance institutions
10 as defined in subdivision (k) of Section 791.02 of the Insurance
11 Code.

O