

ATTACHMENT 1



Bill Number:	SB 294 (Board-Sponsored)
Introduced	2/15/13
Last Amend:	July 3, 2013
Author:	Senator Bill Emmerson
Topic:	Sterile Drug Products
Position:	SUPPORT

Current Bill Status: 8/13/13 – Set for Hearing: Assembly Health

Affected Sections: Amend the heading of Article 7.5 (Commencing with Section 4127) of the Business and Professions Code (BPC)
Repeal and Add Section 4127 BPC
Amend Sections 4127.1, 4127.2 and 4400 BPC

Board Position: Support

Staff Recommendation: No change to position

SUMMARY:

SB 294 contains board-sponsored provisions to strengthen board's ability to regulate and monitor pharmacies that compound sterile drug products and distribute or ship into California sterile products for injection, for administration to the eye, or for inhalation.

Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacies in this state, and requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.

Existing law requires California and nonresident pharmacies to obtain a specialty permit from the board, subject to annual renewal, in order to compound injectable sterile drug products for distribution in California. Current law allows a board-licensed pharmacy to be exempt from the requirement to obtain a specialty permit to compound if they have specified accreditation. Also, the board is currently unable to inspect nonresident pharmacies to ensure compliance with California requirements.

SB 294 will expand the board's provisions to require a pharmacy (resident or nonresident) that compounds sterile drug products for injection, administration to the eye or inhalation to obtain a specialty permit (license) from the board. This specialty permit is in addition to the requisite 'pharmacy' permit such an entity must have to receive a specialty permit. The bill sets a fee for a nonresident sterile compounding permit, and requires these entities to reimburse the board for the actual and necessary costs of conducting an annual inspection. Failure to pay the fee will result in the non-issuance or suspension of the nonresident sterile compounding pharmacy license.

RECENT AMENDMENTS:

The most recent amendments specify a license fee of \$780 for a nonresident compounding permit. This fee is consistent with the fee structure of other pharmacies. In addition, amendments related to fees, require the nonresident sterile compounding pharmacy to reimburse the board of r actual and necessary costs of conducting the inspection. Other amendments include the addition of language that requires the board to adopt emergency regulations for the initial implementation of the bill. Finally, the period of time in which a sterile compounding pharmacy notifies the board of any recall of a compounded drug product dispensed in California was changed from 24 to 12 hours.

The board has requested an additional amendment to remove the reference to the Building Standards Commission within the language that authorizes the board to promulgate emergency regulations. The board does not anticipate the need to implement (on an emergency basis as it relates to initial implementation) additional building standards. At this time, existing board regulations incorporate by reference in its sterile compounding regulations the following building standards:

16 CCR 1751 – With regard to the compounding area for sterile injectable compounding, the board's requirements incorporate by reference the clean room and work station requirements (arrangement of the pharmacy, sinks, surfaces, etc.) found in Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations, as well as the ventilation requirements found in Section 505.5 of Title 24, Chapter 5 CCR.

16 CCR 1751.4 – For pharmacies that prepare parenteral cytotoxic agents, existing regulations require that the preparation of these agents be done in accordance with Sections 505.5 and 505.5.1 of Title 24, Chapter 5, of the CCR which specifies requirements for ventilation and laminar flow biological safety cabinetry.

EXISTING LAW:

Section 4112 BPC prohibits any pharmacy located outside of California from shipping, mailing, or delivering in any manner, controlled substances, dangerous drugs or dangerous devices into California – pursuant to a prescription - without obtaining a license from the board. The section specifies information that shall be disclosed to the board, and sets forth requirements for recordkeeping, patient consultation, and other requirements related to the license.

Section 4120 BPC prohibits a nonresident pharmacy from selling or distributing dangerous drugs or dangerous devices in California through any person or media other than a board-licensed wholesaler.

Section 4127 BPC requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy. Related regulations are at Title 16 Cal.Code Reg Article 4.5 (starting at Section 1735) and Article 7 (starting at Section 1751).

Section 4127.1 BPC restricts the compounding of sterile drug products to pharmacies that have obtained a specialty permit (license) from the board to conduct such compounding. Pharmacies that are licensed by the board or are licensed by the California Department of Public Health AND have specified accreditation are exempt from the requirement to obtain this specialty permit.

Section 4127.2 BPC specifies that a nonresident pharmacy shall not compound injectable sterile drug products without a specialty permit (license) issued by the board. These permits may be issued only to those nonresident pharmacies that are licensed by the board as a

Pharmacy to ship dangerous drugs and devices into California. This section exempts from the requirement to hold a specialty permit those nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have specified accreditation.

Section 4400 BPC sets the fees and penalties as it relates to Pharmacy Law.

AS AMENDED 7/3/13 THIS BILL WILL:

Amend the title of Article 7.5 to be "Sterile Drug Products."

Amend, Repeal and Add Section 4127 to require (after July 1, 2014) any pharmacy that compounds sterile drug products for injection, administration into the eye, or inhalation to possess a sterile compounding pharmacy license pursuant to Article 7.5 "Sterile Drug Products."

Authorize the board to adopt regulations for the implementation of the provisions; first, emergency regulations to initially implement the provisions; and broad/general rulemaking authority thereafter.

Add and Repeal Section 4127.1 to specify requirements (after July 1, 2014) for pharmacies that compound sterile drug products. These provisions require that a pharmacy must first be licensed as a pharmacy with the board in order to seek a specialty permit to compound sterile drug products, and specify that the license is to be renewed annually. These requirements include:

Require the *board* to:

- Perform an onsite inspection of the premises, and any deficiencies noted are corrected
- Review a current copy of the pharmacy's policies and procedures for sterile compounding
- Review the pharmacy's completed self-assessment form required by 16 CCR § 1735.2
- Is provided with copies of all inspection reports conducted of the pharmacy's premises, including those from a private accrediting agency, conducted in the prior 12 month
- Receives a list of all sterile medications compounded by the pharmacy since the last license renewal

Require the pharmacy licensed pursuant to the section to:

- Provide the board with a copy of any disciplinary or other action taken by another state within 10 days of the action
- Notify the board within 10 days of the suspension of any accreditation held by the pharmacy
- Provide the board, within **12 hours**, any recall notice issued by the pharmacy for sterile drug products it has compounded
- Require that adverse effects reported or potentially attributable to a pharmacy's sterile drug product be immediately reported to the Board and to the FDA's MedWatch program

Amend, Repeal and Add Section 4127.2 to specify requirements for nonresident pharmacies that wish to ship sterile drug products into California. These requirements mirror those found in 4127.1, but as they relate to nonresident pharmacies seeking a specialty permit. The requirements include.

- Restrict a nonresident pharmacy from shipping into California any compounded sterile drug product without obtaining a license pursuant to this section.
- Specify that a license issued pursuant to this section can be issued only to a location that is also licensed with the board as a nonresident pharmacy, and specify requirements for the board and pharmacy

- Sets forth requirements of the board and of the nonresident pharmacy (mirrors requirements in 4127.1), including to advise the board of any complaint it receives from a provider, pharmacy, or patient in California

Amend Section 4400 to specify a fee for a nonresident sterile compounding pharmacy license, and require the payment of travel expenses incurred by the board to inspect a nonresident sterile compounding pharmacy at least once annually. Failure to pay the fee within 30 days shall result in suspension of the nonresident sterile compounding pharmacy license.

FISCAL IMPACT ON THE BOARD:

The board anticipates that staffing needed to inspect, administer and enforce the provisions of the bill (4 inspectors, 1 Associate Analyst, 1 Staff Analyst, 1 Office Technician) will be offset by anticipated revenue, at a cost of approximately \$546,000 annual/ongoing; in addition, the board anticipates one-time costs of approximately \$20,000 for system modifications necessary to track and issue licenses. All costs associated with the annual inspections of nonresident sterile compounding pharmacies are expected to be cost-neutral.

California Pharmacies:

As of June 30, 2013, the board had issued licenses to approximately 6,385 California community and outpatient pharmacies; and approximately 286 permits to compound sterile injectable drug products. In April 2012, the board estimated that there were approximately 293 pharmacies that compound sterile drug products that are accredited in lieu of holding a sterile compounding permit with the board.

Nonresident Pharmacies:

As of June 30, 2013, the board issued licenses to approximately 488 Nonresident pharmacies, of which approximately 93 held nonresident sterile compounding permits.

History

Date	Action
07/03/13	Read second time and amended. Re-referred to Com. on HEALTH.
07/02/13	From committee: Do pass as amended and re-refer to Com. on HEALTH. (Ayes 10. Noes 3.) (July 2).
06/24/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/14/13	Referred to Coms. on B.,P. & C.P. and HEALTH.
05/30/13	In Assembly. Read first time. Held at Desk.
05/29/13	Read third time. Passed. (Ayes 39. Noes 0. Page 1165.) Ordered to the Assembly.
05/28/13	Read second time and amended. Ordered to third reading.
05/24/13	From committee: Do pass as amended. (Ayes 7. Noes 0. Page 1010.) (May 23).
05/17/13	Set for hearing May 23.
04/22/13	Placed on APPR. suspense file.
04/12/13	Set for hearing April 22.
04/09/13	Set, first hearing. Hearing canceled at the request of author.
04/05/13	Set for hearing April 15.
04/02/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 10. Noes 0. Page 388.) (April 1). Re-referred to Com. on APPR.
03/19/13	Set for hearing April 1.
02/28/13	Referred to Com. on B., P. & E.D.
02/19/13	From printer. May be acted upon on or after March 21.
02/15/13	Introduced. Read first time. To Com. on RLS. for assignment. To print.



California
LEGISLATIVE INFORMATION

SB-294 Sterile drug products. (2013-2014)

As Amended 7/3/13 - Today's Law As Amended

SECTION 1. *The heading of Article 7.5 (commencing with Section 4127) of Chapter 9 of Division 2 of the Business and Professions Code is amended to read:*

Article 7.5. Sterile Drug Products

SEC. 2. Section 4127 of the Business and Professions Code is amended to read:

4127. (a) The board shall adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.

(b) The board shall adopt emergency regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to initially implement the provisions of this article that become operative on July 1, 2014, including, but not limited to, building standards adopted pursuant to Part 2.5 (commencing with Section 18901) of Division 13 of the Health and Safety Code. The initial adoption, amendment, or repeal of a regulation authorized by this section is deemed to address an emergency for purposes of Sections 11346.1 and 11346.6 of the Government Code, and the board is hereby exempted for that purpose from the requirements of subdivision (b) of Section 11346.1 of the Government Code. After the initial adoption, amendment, or repeal of an emergency regulation pursuant to this section, the board may request approval from the Office of Administrative Law to readopt the regulation as an emergency regulation pursuant to Section 11346.1 of the Government Code.

(c) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 3. Section 4127 is added to the Business and Professions Code, to read:

4127. (a) A pharmacy that compounds sterile drug products for injection, administration into the eye, or inhalation shall possess a sterile compounding pharmacy license as provided in this article.

(b) The board shall adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article, including, but not limited to, building standards adopted pursuant to Part 2.5 (commencing with Section 18901) of Division 13 of the Health and Safety Code.

(c) This section shall become operative on July 1, 2014.

SEC. 4. Section 4127.1 of the Business and Professions Code is amended to read:

4127.1. (a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(d) Pharmacies operated by entities that are licensed by either the board or the State Department of Public Health and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:

(1) The sterile powder was obtained from a manufacturer.

(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

(f) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 5. *Section 4127.1 is added to the Business and Professions Code, to read:*

4127.1. *(a) A pharmacy shall not compound sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board pursuant to this section. The license shall be renewed annually and is not transferable.*

(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a pharmacy and shall be issued only to the owner of the pharmacy licensed at that location.

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:

(1) Reviews a current copy of the pharmacy's policies and procedures for sterile compounding.

(2) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Is provided with copies of all inspection reports conducted of the pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the pharmacy's operations.

(4) Receives a list of all sterile medications compounded by the pharmacy since the last license renewal.

(e) A pharmacy licensed pursuant to this section shall do all of the following:

(1) Provide to the board a copy of any disciplinary or other action taken by another state within 10 days of the action.

(2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.

(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded.

(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be immediately reported to the board and the MedWatch program of the federal Food and Drug Administration.

(g) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following requirements are met:

(1) The sterile powder was obtained from a manufacturer.

(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

(h) This section shall become operative on July 1, 2014.

SEC. 6. Section 4127.2 of the Business and Professions Code is amended to read:

4127.2. (a) A nonresident pharmacy ~~may~~ *shall* not compound injectable sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the nonresident pharmacy license at that location. A license to compound injectable sterile drug products may not be issued or renewed until the board receives the following from the nonresident pharmacy:

(1) A copy of an inspection report issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.

(2) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.

(c) Nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(d) This section shall become ~~effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127; inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.~~

SEC. 7. *Section 4127.2 is added to the Business and Professions Code, to read:*

4127.2. (a) *A nonresident pharmacy shall not compound sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.*

(b) *A license to compound sterile drug products shall be issued only to a location that is licensed as a nonresident pharmacy and shall be issued only to the owner of the nonresident pharmacy licensed at that location.*

(c) *A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident pharmacy shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually pursuant to subdivision (v) of Section 4400.*

(d) *A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:*

(1) *Reviews a current copy of the nonresident pharmacy's policies and procedures for sterile compounding.*

(2) *Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.*

(3) *Is provided with copies of all inspection reports conducted of the nonresident pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the nonresident pharmacy's operations.*

(4) *Receives a list of all sterile drug products compounded by the pharmacy within the prior 12 months.*

(e) *A pharmacy licensed pursuant to this section shall do all of the following:*

(1) *Provide to the board a copy of any disciplinary or other action taken by its state of residence or another state within 10 days of the action.*

(2) *Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.*

(3) *Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.*

(4) *Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.*

(f) Adverse effects reported or potentially attributable to a nonresident pharmacy's sterile compounded drug product shall be immediately reported to the board and the MedWatch program of the federal Food and Drug Administration.

(g) This section shall become operative on July 1, 2014.

SEC. 8. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).

(d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(f) The fee for a nongovernmental wholesaler license and annual renewal shall be six hundred dollars (\$600), and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars (\$125) and may be increased to one hundred sixty-five dollars (\$165).

(h) (1) The fee for application, investigation, and issuance of license as a designated representative pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(j) (1) The application fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(2) For nonresident wholesalers who have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(3) The annual renewal fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(l) The fee for an intern pharmacist license shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars (\$80) and may be increased to one hundred five dollars (\$105). The fee for renewal of a pharmacy technician license shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars (\$405) and may be increased to four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

~~(t) (u) The fee for issuance or renewal of a retired nongovernmental license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) to compound sterile drug products shall be six hundred dollars (\$600) and may be increased to forty-five dollars (\$45); seven hundred eighty dollars (\$780).~~

~~(u) The fee for issuance or renewal of a nongovernmental license to compound sterile drug products shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).~~

The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(v) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 9. *Section 4400 is added to the Business and Professions Code, to read:*

4400. *The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:*

(a) The fee for a nongovernmental pharmacy license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).

(d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(f) The fee for a nongovernmental wholesaler license and annual renewal shall be six hundred dollars (\$600), and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars (\$125) and may be increased to one hundred sixty-five dollars (\$165).

(h) (1) The fee for application, investigation, and issuance of license as a designated representative pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(j) (1) The application fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(2) For nonresident wholesalers who have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(3) The annual renewal fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(l) The fee for an intern pharmacist license shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to

maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars (\$80) and may be increased to one hundred five dollars (\$105). The fee for renewal of a pharmacy technician license shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars (\$405) and may be increased to four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(u) The fee for issuance or renewal of a nongovernmental sterile compounding pharmacy license shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(v) The fee for the issuance or renewal of a nonresident sterile compounding pharmacy license shall be seven hundred eighty dollars (\$780). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) This section shall become operative on July 1, 2014.

SEC. 10. *No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.*



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

June 28, 2013

The Honorable Richard S. Gordon, Chair
and Members
Assembly Committee on Business,
Professions and Consumer Protection
State Capitol, Room 4126
Sacramento, CA 95814

RE: Senate Bill 294 – Support

Dear Assembly Member Gordon and Members:

Senate Bill 294 (Emmerson) will soon be before the Assembly Committee on Business, Professions and Consumer Protection, and the Board of Pharmacy respectfully requests your Aye vote to pass this bill to Appropriations.

The Board of Pharmacy regulates the entities and individuals who distribute dangerous drugs and dangerous devices in this state, and SB 294 is necessary to strengthen the board's ability to regulate specialized pharmacies within and outside California that compound sterile drug products to ensure the safety of Californians.

In 2001, the California Legislature first enacted provisions to strengthen state oversight of sterile drug compounding in pharmacies following the death of three people and multiple hospitalizations due to a pharmacy in California that compounded and distributed a cortisone-based injectable drug that was tainted with meningitis bacteria. That legislation resulted in pharmacies within California being required to obtain a specialty license if they performed sterile injectable compounding. Additional provisions required non-resident pharmacies that shipped sterile injectable drugs into California to also be licensed with this board, but the law carved out an exemption for obtaining the specialty license to compound sterile injectable drug products. Current law allows a California or non-resident pharmacy to avoid this specialty license if they are accredited or where, in the case of non-resident pharmacies, regulators (other than the Board of Pharmacy) have oversight. In light of recent events, this exemption is not protecting the health and lives of Californians.

Unfortunately, the tragic incidents that occurred over a decade ago have not ceased. In June of 2012, a licensed sterile injectable pharmacy located in Florida shipped contaminated products into California and patients here were injured. In September 2012, the New England Compounding Center based in Massachusetts shipped contaminated injectable drugs throughout the country, including California, resulting in the death of more than 50 people and in the illness of more than 700 patients. California was fortunate in that while our patients received products, no deaths or injuries have been reported as a result of these contaminated products. However, in both cases, because the board was unable to inspect these non-resident facilities, the board was not able to ensure that the operations met California's regulatory requirements.

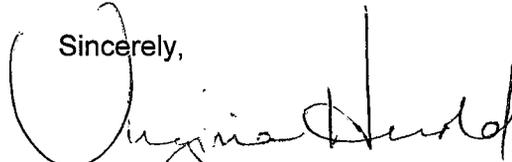
Senate Bill 294 will

- Require annual inspections by the board of pharmacy of specialty pharmacies that want to ship these products into California, to ensure that the operations comply with California's requirements for sterile compounding;
- Expand the types of medications for which a specialty license is required to also include other high-risk types of drugs, such as those administered into the eyes, or inhaled; and
- Ensure California standards are met and enforced for all pharmacies that ship these specialty compounded drug products into California, by requiring board inspections of those who hold a specialty license. In addition to the license fee, the non-resident Pharmacy will also be required to reimburse the board for reasonable / actual costs associated with an out-of-state inspection.

It is time to once again strengthen the state's oversight of pharmacies that compound sterile drug products so that Californians are protected. Senate Bill 294 will provide for such enhanced protection and will ensure that California's standards are enforced and patients are protected.

The Board of Pharmacy respectfully requests your Aye vote to pass SB 294 (Emmerson).

Sincerely,



VIRGINIA HEROLD
Executive Officer

cc: The Honorable Bill Emmerson
Members, Assembly Committee on Business
Professions and Consumer Protection



Bill Number:	SB 821
Introduced	2/22/13
Last Amend:	6/27/13
Author:	Senate Committee on Business, Professions and Economic Development
Topic:	Healing Arts Omnibus Bill
Position:	Support

Current Bill Status: 6/26/13 – Passed ASM Business, Professions & Consumer Protection
Referred to ASM Appropriations

Affected Sections: Add Section 4021.5 to the Business and Professions Code
Amend Section 4053 of the Business and Professions Code
Amend Section 4107 of the Business and Professions Code

Recommendation: Maintain Position of Support

SUMMARY:

SB 821 is a Senate Omnibus measure that contains three board-approved proposals, as summarized below. The bill passed the Senate (on consent) on May 28, 2013, and has passed the Assembly Committee on Business, Professions and Consumer Protection. The board's provisions were amended into SB 821 on June 14.

Due to the length of the bill, only the sections relevant to the board's proposals (SEC. 18 – SEC. 20) are provided in Attachment 1.

THIS BILL WOULD:

Add a Definition of "Correctional Pharmacy" – See SEC. 18 of SB 821

At the April 2013 Board Meeting, the board ratified the language provided to Senate Committee on Business, Professions and Economic Development to specify a definition of "Correctional Pharmacy." The board proposed the definition to be at Section 4066 of the Business and Professions Code. To keep board definitions in alphabetical order, however, Legislative Counsel placed the definition at Section 4021.5. Also, the board suggested that the word "state" be stricken from the definition, so as to broadly apply to any correctional pharmacy. That modification was not accepted as an omnibus provision.

Amendment to Business and Professions Code Section 4053 – Application Requirements for Licensure as a Designated Representative – See SEC. 19 of SB 821

Existing law specifies the requirements that must be satisfied for an applicant who applies for a designated representative license. One of those requirements is to have one year paid work

experience related to the distribution or dispensing of dangerous drugs or dangerous devices, or meet other specified requirements. Pharmacy law does not specify the practice setting or types of facilities in which this one year of paid work experience must be satisfied. The board's proposal specifies that the one year of paid work experience shall be earned in a licensed facility.

Amendment to Business and Professions Code 4107 – One Site License per Premises; Exception – See SEC. 20 of SB 821

Business and Professions Code Section 4107 provides that the board may not issue more than one site license to a single premises, unless there is a specific exemption to do so. Following the passage of AB 377 (Hospital Central Packaging Pharmacy), the board approved language that would provide for a specific exemption to issue the central packaging pharmacy permit to a premise that also holds a hospital permit.

FISCAL IMPACT ON THE BOARD:

Staff has not identified any specific fiscal impact on the board or its operations as a result of this measure.

HISTORY:

Date	Action
06/27/13	Read second time and amended. Re-referred to Com. on APPR.
06/26/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (June 25).
06/19/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/14/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/14/13	Referred to Com. on B.,P. & C.P.
05/29/13	In Assembly. Read first time. Held at Desk.
05/28/13	Read third time. Passed. (Ayes 39. Noes 0. Page 1118.) Ordered to the Assembly.
05/22/13	Ordered to special consent calendar.
05/21/13	Read second time. Ordered to third reading.
05/20/13	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
05/10/13	Set for hearing May 20.
05/07/13	Hearing postponed by committee.
05/03/13	Set for hearing May 13.
04/30/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 10. Noes 0. Page 734.) (April 29). Re-referred to Com. on APPR.
04/23/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
04/05/13	Set for hearing April 29.
04/03/13	Referred to Com. on B., P. & E.D.
03/21/13	From printer. May be acted upon on or after April 20.
03/20/13	Introduced. Read first time. To Com. on RLS. for assignment. To print.

Excerpt: Senate Bill No. 821 As Amended June 19, 2013

Sections 18, 19 and 20 related to Pharmacy

(View: Today's Law as Amended)

SEC. 18.

Section 4021.5 is added to the Business and Professions Code, to read:

4021.5.

"Correctional pharmacy" means a pharmacy, licensed by the board, located within a state correctional facility for the purpose of providing pharmaceutical care to inmates of the state correctional facility.

SEC. 19.

Section 4053 of the Business and Professions Code is amended to read:

4053.

(a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.

(b) An individual may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development *certificate* equivalent.

(2) He or she shall have a minimum of one year of paid work ~~experience, in~~ *experience in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, in* the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.

(e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

SEC. 20.

Section 4107 of the Business and Professions Code is amended to read:

4107.

(a) The board may not issue more than one site license to a single premises except as follows:

(1) To issue a veterinary food-animal drug retailer license to a wholesaler pursuant to Section 4196.

(2) To issue a license to compound sterile injectable drugs to a pharmacy pursuant to Section 4127.1.

(3) To issue a centralized hospital packaging license pursuant to Section 4128.

~~The (b) board may not issue more than one site license to a single premises except to issue a veterinary food-animal drug retailer license to a wholesaler or to issue a license to compound sterile injectable drugs to a pharmacy.~~ For the purposes of this subdivision, "premises" means a location with its own address and an independent means of ingress and egress.



Bill Number:	SB 305
Introduced	2/15/13
Last Amend:	6/19/13
Author:	Senator Curren Price
Topic:	Access to Certified Records
Position:	

Current Bill Status: 6/26/13 – Passed ASM Business, Professions & Consumer Protection
Referred to ASM Appropriations

Affected Sections: Add Section 144.5 to the Business and Professions Code

Staff

Recommendation: Support SB 305 as Amended 6/19/13

SUMMARY:

SB 305 contains a version of a board-approved legislative proposal to receive from a local or state agency certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation and further specifies that a local or state agency may provide those records upon request.

It is customary for most boards and bureaus to obtain complete arrest, conviction and other related documentation as part of an applicant's or licensee's disciplinary investigation – and the board must rely on local law enforcement agencies to provide them. In response to some requests for certified documents, jurisdictions refused to provide the certified records, citing the board's lack of authority to request them. This has caused delays in the completion of applicant and licensee investigations.

At the October 2012 Board Meeting, the board approved a proposal to add Section 4008.5 to the B&PC to provide the board with the express authority to receive certified arrest, court and probation records for the purpose of completing applicant and licensee investigations. The board's proposal included a requirement that the jurisdiction provide them upon request, and this mandate was not picked up in the bill due to concern of a state mandate, as well as concerns from local jurisdictions.

THIS BILL WOULD:

Authorize the board to request and receive certified records for the purpose of determining if a crime committee by an applicant or licensee is substantially related to the qualifications, functions or duties for which the license is held or sought.

EXISTING LAW:

Business and Professions Code Section 480 specifies criteria for which a board may deny an application for any crime that is substantially related to the qualifications, functions or duties for which the license is issued.

Business and Professions Code Section 490 permits a board to take action against a licensee on the ground that the licensee has been convicted of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued.

Business and Professions Code Section 493 provides in a proceeding conducted by a board pursuant to law to deny an application for a license or to suspend or revoke a license or otherwise take disciplinary action against a person who holds a license, upon the grounds that the applicant or the licensee has been convicted of a crime substantially related to the qualifications, functions, and duties of the licensee in question, the record of conviction of the crime shall be conclusive evidence of the fact that the conviction occurred, but only of that fact, and that the board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, and duties of the licensee in question.

Business and Professions Code Section 4301 specifies disciplinary proceedings for any holder of license that is guilty of unprofessional conduct or other specified acts.

Business and Professions Code Section 4202(c) requires the board to conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of licensure, as specified.

FISCAL IMPACT ON THE BOARD:

Staff has not identified any specific fiscal impact on the board or its operations as a result of this measure.

HISTORY:

Date	Action
06/25/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (June 25). Re-referred to Com. on APPR.
06/19/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/14/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/14/13	Referred to Com. on B.,P. & C.P.
05/29/13	In Assembly. Read first time. Held at Desk.
05/28/13	Read third time. Passed. (Ayes 37. Noes 0. Page 1100.) Ordered to the Assembly.
05/24/13	Read second time. Ordered to third reading.

Date	Action
05/23/13	From committee: Do pass. (Ayes 7. Noes 0. Page 1011.) (May 23).
05/17/13	Set for hearing May 23.
05/13/13	Placed on APPR. suspense file.
05/03/13	Set for hearing May 13.
04/30/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 10. Noes 0. Page 733.) (April 29). Re-referred to Com. on APPR.
04/25/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
04/15/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
04/05/13	Set for hearing April 29.
02/28/13	Referred to Com. on B., P. & E.D.
02/19/13	From printer. May be acted upon on or after March 21.
02/15/13	Introduced. Read first time. To Com. on RLS. for assignment. To print.



California
LEGISLATIVE INFORMATION

SB-305 Healing arts: boards. (2013-2014)

As Amended 6/19/13 - Today Law As Amended (Only page 1)

SECTION 1. *Section 144.5 is added to the Business and Professions Code, to read:*

144.5. Notwithstanding any other law, a board described in Section 144 may request, and is authorized to receive, from a local or state agency certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation. A local or state agency may provide those records to the board upon request.

SEC. 2. Section 1000 of the Business and Professions Code is amended to read:

1000. (a) The law governing practitioners of chiropractic is found in an initiative act entitled "An act prescribing the terms upon which licenses may be issued to practitioners of chiropractic, creating the State Board of Chiropractic Examiners and declaring its powers and duties, prescribing penalties for violation hereof, and repealing all acts and parts of acts inconsistent herewith," adopted by the electors November 7, 1922.

(b) The State Board of Chiropractic Examiners is within the Department of Consumer Affairs.

(c) Notwithstanding any other law, the powers and duties of the State Board of Chiropractic Examiners, as set forth in this article and under the act creating the board, shall be subject to review by the appropriate policy committees of the Legislature. The review shall be performed as if this chapter were scheduled to be repealed as of January 1, 2018.

SEC. 3. Section 2450 of the Business and Professions Code is amended to read:

2450. There is a Board of Osteopathic Examiners of the State of California, established by the Osteopathic Act, which shall be known as the Osteopathic Medical Board of California which enforces this chapter relating to persons holding or applying for physician's and surgeon's certificates issued by the Osteopathic Medical Board of California under the Osteopathic Act.

Persons who elect to practice using the term of suffix "M.D.," as provided in Section 2275, shall not be subject to this article, and the Medical Board of California shall enforce the provisions of this chapter relating to persons who made the election.

Notwithstanding any other law, the powers and duties of the Osteopathic Medical Board of California, as set forth in this article and under the Osteopathic Act, shall be subject to review by the appropriate policy committees of the Legislature. The review shall be performed as if this chapter were scheduled to be repealed as of January 1, 2018.

SEC. 4. Section 2450.3 of the Business and Professions Code is amended to read:

2450.3. There is within the jurisdiction of the Osteopathic Medical Board of California a Naturopathic Medicine Committee authorized under the Naturopathic Doctors Act (Chapter 8.2 (commencing with Section 3610)). This section shall become inoperative on January 1, ~~2014~~, ~~2018~~, and, as of that date is repealed, unless a later enacted statute that is enacted before January 1, ~~2014~~, ~~2018~~, deletes or extends that date. Notwithstanding any other provision of law, the repeal of this section renders the Naturopathic Medicine Committee subject to review by the appropriate policy committees of the Legislature.

SEC. 5. Section 2530.2 of the Business and Professions Code is amended to read:

2530.2. As used in this chapter, unless the context otherwise requires:

Proposed Legislation for Issuing Licenses with a letter of reprimand
with changes in underline from Legal Counsel

Add Business and Professions Code section 4310.5 as follows:

- (a) Notwithstanding subdivision (c) Section 4300, the board may issue a license to an applicant who has committed minor violations that the board deems, in its discretion, do not merit the denial of a certificate or require probationary status under Section 4300, and may concurrently issue a public letter of reprimand.
- (b) The letter of reprimand shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.
- (c) The letter of reprimand shall inform the licensee that within 30 days of service of the letter of reprimand the licensee may do either of the following:
 - (1) Submit a written request for an office conference to the executive officer of the board to contest the letter of reprimand.
 - (A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.
 - (B) Prior to or at the office conference, the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of reprimand.
 - (C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).
 - (D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of reprimand. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of reprimand.
 - (E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of reprimand.
 - (2) Accept the letter of reprimand. The board shall inform the licensee that the letter of reprimand shall be purged after three years if no letter of admonishment, citation, notice of correction, or disciplinary action is initiated by the board.

- (d) The letter of reprimand shall be served upon the licensee personally or by certified mail at the applicant's address of record with the board. If the applicant is served by certified mail, service shall be effective upon deposit in the United States mail.
- (e) A public letter of reprimand issued concurrently with a board license shall be purged three years from the date of issuance if no letter of admonishment, citation, notice of correction, or disciplinary action is initiated by the board during the three-year period.
- (f) A public letter of reprimand issued pursuant to this section shall be disclosed to an inquiring member of the public and shall be posted on the board's Internet Web site.
- (g) Nothing in this section shall be construed to affect the board's authority to issue an unrestricted license.



Bill Number:	AB 1045 (Quirk-Silva)
Introduced	February 22, 2013
Last Amend:	June 19, 2013
Author:	Assembly Member Sharon Quirk-Silva
Topic:	Nonresident Sterile Compounding Pharmacies; Recall Notices
Position:	Support

Current Bill Status: In Senate Appropriations – as of 7/15/13 no hearing yet set

Affected Sections: Amend Section 4303 of the Business and Professions Code
Add Section 4127.9 to the Business and Professions Code

Board Position: Support (5/10/13)

Recommendation: Ratify the position taken on 5/10/13

SUMMARY:

AB 1045 will strengthen the board's ability to protect Californians in cases where non-resident pharmacies and non-resident sterile compounding pharmacies lose their pharmacy permit in the home state by allowing the board simply to cancel, revoke or suspend the corresponding California non-resident permits. In addition, AB 1045 will require sterile compounding pharmacies to provide notice to a pharmacy, prescriber or patient of a recalled sterile compounded drug that was dispensed, and require the pharmacy to notify the board within 12 hours of a recall notice.

Currently, to revoke a pharmacy permit, the board must take formal disciplinary action to remove the California license where there is no longer regulatory oversight by the home state, unless the non-resident pharmacy requests to cancel its California license. AB 1045 provides for the immediate protection of California's patients by specifying that when the underlying permit in the home state has been canceled, revoked or suspended, the California permit is canceled, revoked or suspended by operation of law.

As of June 30, 2013, the board issued licenses to approximately 488 Nonresident pharmacies, of which approximately 93 held nonresident sterile compounding permits.

EXISTING LAW:

Section 4112 BPC prohibits any pharmacy located outside of California from shipping, mailing, or delivering in any manner, controlled substances, dangerous drugs or dangerous devices into California – pursuant to a prescription - without obtaining a license from the board. The section specifies information that shall be disclosed to the board, and sets forth requirements for recordkeeping, patient consultation, and other requirements related to the license.

Section 4120 BPC prohibits a nonresident pharmacy from selling or distributing dangerous drugs or dangerous devices in California through any person or media other than a board-licensed wholesaler.

Section 4127 BPC requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy. Related regulations are at Title 16 Cal.Code Reg Article 4.5 (starting at Section 1735) and Article 7 (starting at Section 1751).

Section 4127.1 BPC restricts the compounding of sterile drug products to pharmacies that have obtained a specialty permit (license) from the board to conduct such compounding. Pharmacies that are licensed by the board or are licensed by the California Department of Public Health AND have specified accreditation are exempt from the requirement to obtain this specialty permit.

Section 4127.2 BPC specifies that a nonresident pharmacy shall not compound injectable sterile drug products without a specialty permit (license) issued by the board. These permits may be issued only to those nonresident pharmacies that are licensed by the board as a Pharmacy to ship dangerous drugs and devices into California. This section exempts from the requirement to hold a specialty permit those nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have specified accreditation.

Article 19 (Sections 4300-4315) specify disciplinary proceedings that the board may take against a licensee, including grounds for discipline of a nonresident pharmacy (Section 4303).

Article 20 (Sections 4320-4343) specify prohibitions and offenses for which the board is authorized to discipline a license.

Title 16 California Code of Regulations Section 1760 specifies the board's Disciplinary Guidelines.

AS AMENDED 7/3/13 THIS BILL WILL:

Amend Section 4303 to specify that if the home state license of a nonresident pharmacy is canceled, revoked or suspended for any reason, the board shall immediately cancel, revoke or suspend the board-issued license by operation of law.

Add Section 4127.9 to specify that a resident or nonresident pharmacy that holds a sterile compounding permit that issues a recall notice regarding a compounded drug, that the pharmacy shall contact the recipient pharmacy, prescriber or patient of the recalled drug, as well as contact the board within 12 hours, if certain conditions are met, as specified.

FISCAL IMPACT ON THE BOARD:

The board does not anticipate any significant impact should AB 1045 be enacted.

History

Date	Action
07/02/13	Read second time. Ordered to third reading.
07/01/13	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
06/19/13	Read second time and amended. Re-referred to Com. on APPR.
06/18/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 10. Noes 0.) (June 17).
06/06/13	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
06/06/13	Referred to Com. on B., P. & E.D.
05/23/13	In Senate. Read first time. To Com. on RLS. for assignment.
05/23/13	Read third time. Passed. Ordered to the Senate. (Ayes 74. Noes 0. Page 1578.)
05/20/13	Read second time. Ordered to consent calendar.
05/16/13	From committee: Do pass. To consent calendar. (Ayes 17. Noes 0.) (May 15).
04/30/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (April 30). Re-referred to Com. on APPR.
04/25/13	From committee: Be re-referred to Com. on B.,P. & C.P. Re-referred. (Ayes 8. Noes 0.) (April 25). Re-referred to Com. on B.,P. & C.P.
04/25/13	Re-referred to Com. on RLS. pursuant to Assembly Rule 96.
04/23/13	Re-referred to Com. on B.,P. & C.P.
04/22/13	From committee chair, with author's amendments: Amend, and re-refer to Com. on B.,P. & C.P. Read second time and amended.
03/14/13	Referred to Com. on B.,P. & C.P.
02/25/13	Read first time.
02/24/13	From printer. May be heard in committee March 26.
02/22/13	Introduced. To print.



California
LEGISLATIVE INFORMATION

AB-1045 Sterile compounding and nonresident pharmacies. (2013-2014)

As Amended 6/19/13 - Today's Law as Amended

SECTION 1. *Section 4127.9 is added to the Business and Professions Code, to read:*

4127.9. *(a) A pharmacy licensed pursuant to Section 4127.1 or 4127.2, including a pharmacy that is exempt from licensure pursuant to subdivision (d) of Section 4127.1 and subdivision (c) of Section 4127.2, that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:*

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient.

(2) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.

(3) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy, who shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

SEC. 2. Section 4303 of the Business and Professions Code is amended to read:

4303. *(a) The board may report any violation by a nonresident pharmacy of the laws and regulations of this state, any other state, or of the United States, including, but not limited to, any violation of this chapter or of the regulations established by the board, to any appropriate state or federal regulatory or licensing agency, including, but not limited to, the regulatory or licensing agency of the state in which the nonresident pharmacy is a resident or in which the pharmacist is licensed.*

*(b) The board may **cancel**, deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located.*

(c) If the home state pharmacy license of a nonresident pharmacy is canceled, revoked, or suspended for any reason, any license issued pursuant to Section 4112 or 4127.2 shall be immediately canceled, revoked, or suspended by operation of law.

SEC. 3. *No reimbursement is required by this act pursuant to Section 6 of Article XIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIB of the California Constitution.*



Bill Number:	AB 1045 (Quirk-Silva)
Introduced	February 22, 2013
Last Amend:	June 19, 2013
Author:	Assembly Member Sharon Quirk-Silva
Topic:	Nonresident Sterile Compounding Pharmacies; Recall Notices
Position:	Support

Current Bill Status: In Senate Appropriations – as of 7/15/13 no hearing yet set

Affected Sections: Amend Section 4303 of the Business and Professions Code
Add Section 4127.9 to the Business and Professions Code

Board Position: Support (5/10/13)

Recommendation: Ratify the position taken on 5/10/13

SUMMARY:

AB 1045 will strengthen the board's ability to protect Californians in cases where non-resident pharmacies and non-resident sterile compounding pharmacies lose their pharmacy permit in the home state by allowing the board simply to cancel, revoke or suspend the corresponding California non-resident permits. In addition, AB 1045 will require sterile compounding pharmacies to provide notice to a pharmacy, prescriber or patient of a recalled sterile compounded drug that was dispensed, and require the pharmacy to notify the board within 12 hours of a recall notice.

Currently, to revoke a pharmacy permit, the board must take formal disciplinary action to remove the California license where there is no longer regulatory oversight by the home state, unless the non-resident pharmacy requests to cancel its California license. AB 1045 provides for the immediate protection of California's patients by specifying that when the underlying permit in the home state has been canceled, revoked or suspended, the California permit is canceled, revoked or suspended by operation of law.

As of June 30, 2013, the board issued licenses to approximately 488 Nonresident pharmacies, of which approximately 93 held nonresident sterile compounding permits.

EXISTING LAW:

Section 4112 BPC prohibits any pharmacy located outside of California from shipping, mailing, or delivering in any manner, controlled substances, dangerous drugs or dangerous devices into California – pursuant to a prescription - without obtaining a license from the board. The section specifies information that shall be disclosed to the board, and sets forth requirements for recordkeeping, patient consultation, and other requirements related to the license.

Section 4120 BPC prohibits a nonresident pharmacy from selling or distributing dangerous drugs or dangerous devices in California through any person or media other than a board-licensed wholesaler.

Section 4127 BPC requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy. Related regulations are at Title 16 Cal.Code Reg Article 4.5 (starting at Section 1735) and Article 7 (starting at Section 1751).

Section 4127.1 BPC restricts the compounding of sterile drug products to pharmacies that have obtained a specialty permit (license) from the board to conduct such compounding. Pharmacies that are licensed by the board or are licensed by the California Department of Public Health AND have specified accreditation are exempt from the requirement to obtain this specialty permit.

Section 4127.2 BPC specifies that a nonresident pharmacy shall not compound injectable sterile drug products without a specialty permit (license) issued by the board. These permits may be issued only to those nonresident pharmacies that are licensed by the board as a Pharmacy to ship dangerous drugs and devices into California. This section exempts from the requirement to hold a specialty permit those nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have specified accreditation.

Article 19 (Sections 4300-4315) specify disciplinary proceedings that the board may take against a licensee, including grounds for discipline of a nonresident pharmacy (Section 4303).

Article 20 (Sections 4320-4343) specify prohibitions and offenses for which the board is authorized to discipline a license.

Title 16 California Code of Regulations Section 1760 specifies the board's Disciplinary Guidelines.

AS AMENDED 7/3/13 THIS BILL WILL:

Amend Section 4303 to specify that if the home state license of a nonresident pharmacy is canceled, revoked or suspended for any reason, the board shall immediately cancel, revoke or suspend the board-issued license by operation of law.

Add Section 4127.9 to specify that a resident or nonresident pharmacy that holds a sterile compounding permit that issues a recall notice regarding a compounded drug, that the pharmacy shall contact the recipient pharmacy, prescriber or patient of the recalled drug, as well as contact the board within 12 hours, if certain conditions are met, as specified.

FISCAL IMPACT ON THE BOARD:

The board does not anticipate any significant impact should AB 1045 be enacted.

History

Date	Action
07/02/13	Read second time. Ordered to third reading.
07/01/13	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
06/19/13	Read second time and amended. Re-referred to Com. on APPR.
06/18/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 10. Noes 0.) (June 17).
06/06/13	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
06/06/13	Referred to Com. on B., P. & E.D.
05/23/13	In Senate. Read first time. To Com. on RLS. for assignment.
05/23/13	Read third time. Passed. Ordered to the Senate. (Ayes 74. Noes 0. Page 1578.)
05/20/13	Read second time. Ordered to consent calendar.
05/16/13	From committee: Do pass. To consent calendar. (Ayes 17. Noes 0.) (May 15).
04/30/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (April 30). Re-referred to Com. on APPR.
04/25/13	From committee: Be re-referred to Com. on B.,P. & C.P. Re-referred. (Ayes 8. Noes 0.) (April 25). Re-referred to Com. on B.,P. & C.P.
04/25/13	Re-referred to Com. on RLS. pursuant to Assembly Rule 96.
04/23/13	Re-referred to Com. on B.,P. & C.P.
04/22/13	From committee chair, with author's amendments: Amend, and re-refer to Com. on B.,P. & C.P. Read second time and amended.
03/14/13	Referred to Com. on B.,P. & C.P.
02/25/13	Read first time.
02/24/13	From printer. May be heard in committee March 26.
02/22/13	Introduced. To print.



California
LEGISLATIVE INFORMATION

AB-1136 Pharmacists: drug disclosures. (2013-2014)

As Amended 4/15/13 - Today's Law As Amended

SECTION 1. Section 4074 of the Business and Professions Code is amended to read:

4074. (a) *A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if both of the following apply:*

~~(a) (1) A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if the drug~~ *The drug* poses substantial risk to the person consuming the drug when taken in combination with alcohol or ~~if~~ the drug may impair a person's ability to drive a motor vehicle, whichever is applicable, ~~and provided the drug is determined by the board pursuant to subdivision (b) to be a drug or drug type for which this warning shall be given.~~ *applicable.*

(2) The drug is determined by the board pursuant to subdivision (c) to be a drug or drug type for which this warning shall be given.

(b) In addition to the requirement described in subdivision (a), on and after July 1, 2014, if a pharmacist exercising his or her professional judgment determines that a drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label required by this subdivision may be printed on an auxiliary label that is affixed to the prescription container.

~~(b) (c)~~ *The board may by regulation require additional information or labeling.*

~~(e) (d)~~ *This section shall not apply to drugs- a drug* furnished to ~~patients-~~ *a patient* in conjunction with treatment or emergency services provided in *a health facilities facility* or, except as provided in subdivision ~~(d)- (e),~~ *to drugs- a drug* furnished to ~~patients-~~ *a patient* pursuant to subdivision (a) of Section 4056.

~~(d) (e)~~ *A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each medication drug given at the time of discharge and each medication drug given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each medication- drug, the precautions and relevant warnings, and the importance of compliance with directions. This information shall be given by a pharmacist or registered nurse, unless already provided by a patient's prescriber, and the written policy shall be developed in collaboration with a physician, a pharmacist, and a registered nurse. The written policy shall be approved by the medical staff. Nothing in this subdivision or any other provision of law shall be construed to require that only a pharmacist provide this consultation.*

SEC. 2. *No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.*



Bill Number:	SB 204
Introduced	2/8/13
Last Amend:	6/27/13
Author:	Senator Ellen Corbet
Topic:	Prescription Drugs: Labeling (Translations)
Position:	<i>(none)</i>

Current Bill Status: 8/13/13 – Hearing in Assembly Health

Affected Sections: Add Section 4076.3 to the Business and Professions Code

THIS BILL WOULD:

Add a new Section 4076.3 to the Business and Professions Code, where the provisions become operative on January 1, 2016 to:

- Require that the translations of the directions for use in non-English languages published on the board’s web site shall be used when labeling a prescription container label.
- Permit English language directions for use to be translated into additional non-English languages so long as a trained and qualified translator or translation service is utilized to complete the translations
- Permit a pharmacy to use its own translations of the directions for use as established by board regulation, if a trained and qualified translator or translation service is utilized.
- Allow a pharmacist to use the English language directions for use if the pharmacist reasonably believes that a translation of the directions for use contains an error due to software or equipment malfunction, as specified
- Provide that a pharmacist has not breached his or her legal duty if the published translations on the board’s website contain an error, where the pharmacist used the translation and did not know, or have reason to know of the error.
- Specify that the English language directions for use be provided in each instance when a non-English translation of the directions for use is used
- Define “translation,” and “trained and qualified translator or translation service.

EXISTING LAW:

Section 4076 of the Business and Professions Code (BPC) specifies requirements for the labeling of a prescription container dispensed to a patient, to include:

- The manufacturer’s trade name of the drug or the generic name and the manufacturer
- ***The directions for use of the drug***
- The name of the patient
- The name of the prescriber
- The date of issue

- The name and address of the pharmacy, and prescription number or other means of identifying the prescription
 - The strength of the drug or drugs dispensed
 - The quantity of the drug or drugs dispensed
 - The expiration date of the effectiveness of the drug dispensed
 - The condition or purpose for which the drug was prescribed, if indicated on the prescription
 - The physical description of the dispensed medication, as specified (exemptions specified)
- Section 4075 further specifies requirements for unit dose medications in specified settings; and other requirements as it relates to the dispensing of a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code.

Section 4076.5 BPC was enacted in 2012 (SB 472, Corbett) to require the board to promulgate regulations to standardize “patient-centered” prescription drug labels, and further specified various factors that the board would consider in developing the regulations. Two of the many factors the board was to consider were improved directions for use, and the needs of patients with limited English proficiency. This resulted in the promulgation of 16 CCR § 1707.5.

Section 11 BPC specifies for purposes of the Code that “writing includes any form of recorded message capable of comprehension by ordinary visual means. Whenever any notice, report, statement, or record is required by this code, it shall be made in writing in the English language unless it is otherwise expressly provided.”

Title 16 CCR 1707.5 specifies requirements for patient-centered labels for prescription drug containers, to include

- Clustering of specified information, printed in at least 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface
- A requirement that the board publish on its website *translations of directions for use* into at least five languages other than English to facilitate the use thereof by California pharmacies
- A requirement that the board collect and publish on its website examples of labels that conform to the stated requirements
- A requirement that pharmacies have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label; and further specifies the minimum content for the policies and procedures
- A requirement that the board re-evaluate the requirements of the regulation by December 2013; and
- Define “appropriate dosage form” for purposes of the section

Background

As reflected in the board’s regulation at 16 CCR § 1707.5, pharmacies are required ensure the labels on drug containers dispensed to Californians conform to the format specified in the regulation. One of the clustered “patient-centered” elements is the directions for use. The regulation specifies multiple standard phrases to use for the “directions for use” if it is applicable to the prescription. For example, a prescriber writes a prescription “Take 1 pill at

bedtime.” The regulation at 1707.5(a)(D)(4)(A) specifies the phrase “Take 1 [insert appropriate dosage form] at bedtime.” Thus the label would include the language as stated in the regulation.

The board maintains on its website ¹translations in five languages of the various “directions for use” as enumerated at 1707.5(a)(D)(4).

STAFF COMMENTS:

The Public Education and Communications Committee began the board’s review of the patient-centered labeling requirements in April 2013, which is to be completed by December 31, 2013.

The board has not taken a position on the bill, as it is in the process of re-evaluating the requirements of the patient centered regulations.

It may be necessary to clarify through regulations what a “trained and qualified translator or translation service” is or would include.

FISCAL IMPACT ON THE BOARD:

The board may need to promulgate regulations, which would be absorbed within existing staff resources.

¹ <http://www.pharmacy.ca.gov/publications/translations.shtml>

Senate Bill 204

Prescription Drug Label Translations Senate Majority Leader Ellen M. Corbett

SUMMARY

Senate Bill 204 requires pharmacists to use the translated standard directions for use currently available on the California Board of Pharmacy (Board) website when providing patients with translated directions in Spanish, Chinese, Vietnamese, Korean, and Russian on their prescription medication labels.

The bill also requires pharmacists to use certified translation services if they choose to provide translations in languages other than the five provided on the website.

BACKGROUND

Title VI of the federal Civil Rights Act of 1964 and The Dymally-Alatorre Bilingual Services Act both require language access and the right to translation services for limited English proficient individuals.

In 2010, as a result of SB 472 (Corbett, 2007,) the Board adopted regulations that require it to publish translations of directions for use on its website and require pharmacies to provide interpretive services to patients, when available. Senator Corbett has actively worked to get more comprehensive assistance for limited English proficient Californians through the regulation process. SB 204 was introduced to ensure that limited English proficient Californians get the same assistance that all other Californians receive.

In October 2012, the U.S. Pharmacopeial Convention (USP) released labeling standards which recommend that pharmacies print the directions for use on a prescription label in the patient's preferred language using a high-quality translation process. This bill adopts the translation standard that the USP recommends.

PROBLEM

The Centers for Disease Control and Prevention recommend that adults follow medication directions to reduce the risk of harm from their medicine.

An estimated 7 million Californians are limited English proficient. It is troubling that studies show only about 2/3 of California pharmacies are providing translated directions, upon request. Patients cannot follow directions

if they cannot read them. This large population of Californians is in danger of accidentally misusing their prescription medications because the directions are provided in a language they cannot read.

With the increased number of limited English proficient Californians who will have access to health coverage and prescription medication through the Affordable Care Act, the state could incur additional costs whenever a person is harmed or hospitalized due to incorrect medication use.

When someone has been harmed by a medicine, they have had an adverse drug event. Preventing this harm saves both lives and money. Adverse drug events cause over 700,000 emergency room (ER) visits around the country every year, and every year almost 120,000 patients are hospitalized after an ER visit for adverse drug events. Depending on the size, hospitals around the country are already spending up to \$5.6 million a year due to adverse drug events. It is safer and more cost-effective to prevent this harm in the first place.

SOLUTION

Many medication disasters can be avoided simply by printing translated directions onto prescription medication labels so limited English proficient patients can read them. This bill corresponds with the standards released by the USP in 2012, and it coincides with the Board's goal of ensuring that pharmacists exhibit greater cultural awareness with respect to primary language in this increasingly diverse state.

SB 204 aims to assist limited English proficient patients in understanding the directions on their prescription labels to reduce the opportunity for errors.

SUPPORT

California Pan-Ethnic Health Network (Sponsor)

STATUS

April 22nd hearing in Senate Business, Professions, and Economic Development Committee.

CONTACT

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California
LEGISLATIVE INFORMATION

SB-204 Prescription drugs: labeling. (2013-2014)

Today's Law As Amended

SECTION 1. *Section 4076.3 is added to the Business and Professions Code, to read:*

4076.3. *(a) Translations of the directions for use in non-English languages published on the board's Internet Web site shall be used, as applicable, when labeling a prescription container pursuant to Section 4076.*

(b) The English language directions for use established by regulation of the board may be translated into additional non-English languages if a trained and qualified translator or translation service is utilized to complete the additional translations.

(c) Notwithstanding subdivision (a), a pharmacy may use its own translations of the directions for use established by regulation of the board in the non-English languages published on the board's Internet Web site when labeling a prescription container pursuant to Section 4076 if a trained and qualified translator or translation service is utilized.

(d) If a pharmacist reasonably believes that a translation of the directions for use contains an error due to software or equipment malfunction, he or she may use the English language directions for use established by regulation of the board when labeling a prescription container pursuant to Section 4076.

(e) A pharmacist that reasonably uses the translations of the directions for use in non-English languages published on the board's Internet Web site has not breached his or her legal duty if the published translations contain an error and the pharmacist did not know, or did not have reason to know, of the error.

(f) The English language directions for use established by regulation of the board shall be provided in each instance in which a non-English translation of the directions for use is used pursuant to this section.

(g) For purposes of this section, "translation" means the conversion of written text to the corresponding written text in a different language.

(h) For purposes of this section, "trained and qualified translator or translation service" means any of the following:

(1) An individual certified by the American Translators Association or any other nationally accredited or state-approved program the board deems satisfactory.

(2) An individual trained in translation who has been assessed as competent by a company specializing in translation that employs, or has a contractual relationship with, the individual.

(3) An individual employed by a pharmacy who meets all of the following requirements:

(A) He or she has written proficiency in both English and a non-English language.

(B) He or she commits to abide by the American Translators Association's Code of Professional Conduct and Business Practices.

(C) He or she exhibits sufficient knowledge and understanding of required health care vocabulary and terminology related to the practice of pharmacy.

A pharmacy shall establish internal policies to determine and document an individual's qualifications pursuant to subparagraphs (A) to (C), inclusive, of this paragraph.

(i) This section shall become operative on January 1, 2016.

SEC. 2. *No reimbursement is required by this act pursuant to Section 6 of Article XIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred*

because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.



Bill Number:	SB 205
Introduced	2/8/13
Last Amend:	July 1, 2013
Author:	Senator Ellen Corbett
Topic:	Prescription Drugs: Labeling (12-pt font)
Position:	(none)

Current Bill Status: 8/13/13 – Hearing in ASM Business, Professions & Consumer Protection

Affected Sections: Amend Section 4076 of the Business and Professions Code

Staff Comment: Should the board take a position on SB 205 before the review of patient-centered label requirements is complete?

SUMMARY

SB 205 would amend Section 4076 to require that any prescription dispensed meets the requirements of state and federal law, and that certain items on the label be printed in at least a 12-point font. Existing regulation at 16 CCR 1707.5 requires that specified “patient-centered” information on a prescription drug label be printed in a minimum 10-point sans serif typeface, but that the pharmacy shall print the drug label in 12-point sans serif typeface if requested by the patient.

At the April 2013 Board Meeting, the board did not take a position on the bill, as it is in the process of re-evaluating the requirements of patient-centered labels, a review that is to be completed by the end of the year.

THIS BILL WOULD:

Amend Section 4076 to

- Add a new subdivision (b) that would specify that the name of the patient, the name and strength of the drug, the directions for use, and the condition or purpose for which the drug is prescribed (if indicated on the Rx) be printed in at least a 12-point typeface; and
- With regard to the dispensing of a dangerous drug or device in a health facility, as defined, the bill removes a reference to a “licensed” facility (pursuant to HSC 1250), and instead references a health facility “defined” in HSC 1250.

EXISTING LAW:

Section 4076 of the Business and Professions Code (BPC) specifies requirements for the labeling of a prescription container dispensed to a patient, to include:

- The manufacturer’s trade name of the drug or the generic name and the manufacturer
- The directions for use of the drug
- The name of the patient
- The name of the prescriber
- The date of issue

- The name and address of the pharmacy, and prescription number or other means of identifying the prescription
 - The strength of the drug or drugs dispensed
 - The quantity of the drug or drugs dispensed
 - The expiration date of the effectiveness of the drug dispensed
 - The condition or purpose for which the drug was prescribed, if indicated on the prescription
 - The physical description of the dispensed medication, as specified (exemptions specified)
- Section 4075 further specifies requirements for unit dose medications in specified settings; and other requirements as it relates to the dispensing of a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code.

Section 4076.5 BPC was enacted in 2012 (SB 472, Corbett) to require the board to promulgate regulations to standardize “patient-centered” prescription drug labels, and further specified various factors that the board would consider in developing the regulations. One of the many factors the board was to consider was improved font types and sizes. This resulted in the promulgation of 16 CCR § 1707.5.

Title 16 CCR 1707.5 specifies requirements for patient-centered labels for prescription drug containers, to include

- Clustering of specified information, printed in at least 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface
- A requirement that the board publish on its website translations of directions for use into at least five languages other than English to facilitate the use thereof by California pharmacies
- A requirement that the board collect and publish on its website examples of labels that conform to the stated requirements
- A requirement that pharmacies have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label; and further specifies the minimum content for the policies and procedures
- A requirement that the board re-evaluate the requirements of the regulation by December 2013; and
- Define “appropriate dosage form” for purposes of the section

Background

As reflected in the board’s regulation at 16 CCR § 1707.5, pharmacies are required to print certain “patient-centered” elements on a prescription drug label in a 12-point sans serif typeface, if requested by the patient. Thus, under the current regulation requirements, pharmacies have the capacity to print the ‘clustered’ elements of the prescription label in 12-point sans serif typeface.

Also, and as specified in the regulation, the board has begun to re-evaluate the requirements of the patient-centered prescription drug labels. This review was initiated through the board’s Communication and Public Education Committee.

STAFF COMMENTS:

Staff is inquiring as to the intent or purpose of removing the reference to a facility “licensed” pursuant to Section 1250 of the Health and Safety Code. Removing the requirement that the facility be “licensed” may cause confusion.

FISCAL IMPACT ON THE BOARD:

If enacted the board would need to update its regulation at 16 CCR § 1707.5 to remove references to the printing in 10-point typeface. Any such update would be absorbed within the board's existing resources.

HISTORY

Date	Action
07/01/13	Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/27/13	From committee: Do pass as amended and re-refer to Com. on B.,P. & C.P. (Ayes 12. Noes 6.) (June 25).
05/28/13	Referred to Coms. on HEALTH and B.,P. & C.P.
05/16/13	In Assembly. Read first time. Held at Desk.
05/16/13	Read third time. Passed. (Ayes 23. Noes 9. Page 944.) Ordered to the Assembly.
05/15/13	Read second time. Ordered to third reading.
05/14/13	From committee: Do pass. (Ayes 5. Noes 0. Page 936.) (May 13).
05/07/13	Set for hearing May 13.
05/06/13	Hearing postponed by committee.
04/26/13	Set for hearing May 6.
04/24/13	Read second time and amended. Re-referred to Com. on APPR.
04/23/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 6. Noes 0. Page 638.) (April 22).
04/05/13	Set for hearing April 22.
02/21/13	Referred to Com. on B., P. & E.D.
02/11/13	From printer. May be acted upon on or after March 13.
02/11/13	Read first time.
02/08/13	Introduced. To Com. on RLS. for assignment. To print.

As of 7/15/13

Senate Bill 205

12 Point Font Prescription Drug Labels Senate Majority Leader Ellen M. Corbett

SUMMARY

Senate Bill 205 requires pharmacists to print all required items on a prescription label in at least 12 point, sans serif typeface to make it easier for patients to read.

BACKGROUND

The California Department on Aging reports that from 1990 to 2020, California's elderly population of the 60 and over age group will increase by 112 percent, over 200 percent in some counties. Even more drastic is the increase in population of the 85 and older age group, which will see an increase of 143 percent from 1990 to 2020. Several counties will even see an increase of 300 to over 400 percent in this age group.

In 2007, SB 472 (Corbett) required the Board of Pharmacy (Board) to standardize the prescription drug label to make it patient-centered. As part of that effort, the Board conducted a survey in 2009 which found that 60% of participants believed that larger or bolder print would make prescription labels easier to read.

Accordingly, 12 point font was proposed to be adopted at the Board's January 20, 2010 meeting. However, due to a last minute appointment to the Board by then-Governor Schwarzenegger, the Board adopted 10 point font as the standard and made 12 point font available only upon request, despite over 1,000 public comment letters opposing the change to a smaller font size.

PROBLEM

The Centers for Disease Control and Prevention recommend that adults read and follow directions to reduce the risk of harm from their medication.

Seniors are having difficulty reading the small print on their prescription labels, and for those who take multiple medications, their inability to read the label puts them in serious danger.

Medications that are taken incorrectly or mixed with other medications can cause dangerous reactions that can lead to injury and death.

SOLUTION

The Board acknowledges that seniors frequently have diminished eyesight and usually take more medication. For prescription labels to meet the needs of California's seniors, the words must be large enough to read.

Patients shouldn't have to struggle to read their prescriptions or worry about harming themselves just by taking their medication. SB 205 aims to make font size larger on prescription labels to make them more patient-centered and to help avoid disasters that occur because of easily preventable medication errors.

SUPPORT

California State Retirees, Chapter 1
California Alliance for Retired Americans (CARA)
California Pan-Ethnic Health Network (CPEHN)

OPPOSITION

California Pharmacists Association
National Association of Chain Drug Stores
California Board of Pharmacy
California Grocers Association

STATUS

April 22nd Hearing in Senate Business, Professions, and Economic Development Committee

CONTACT

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California
LEGISLATIVE INFORMATION

SB-205 Prescription drugs: labeling. (2013-2014)

Today's Law As Amended

SECTION 1. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the

prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) The information required by paragraphs (1), (2), (3), (7), and (10) of subdivision (a) shall be printed in at least a 12-point typeface.

~~(b)~~ (c) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

~~(e)~~ (d) If a pharmacist dispenses a dangerous drug or device in a ~~facility licensed pursuant to~~ health facility, as defined in Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2.

~~(d)~~ (e) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

SEC. 2. *No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.*



Bill Number: SB 306
Introduced
Last Amend: June 20, 2013
Author: Senator Norma Torres
Topic: Automated Drug Delivery Systems
(Sponsor: Molina / InstyMeds)
Position:

Current Bill Status: Hearing: August 13 – ASM Business, Professions and Consumer Protection

Affected Sections: Amend Section 4170 (Article 12. Prescriber Dispensing)
Amend Section 4180 (Article 13. Nonprofit or Free Clinics)
Amend Section 4186 re: Automated Drug Delivery Systems

Staff Recommendation: Oppose Unless Amended

BILL HISTORY:

SB 306 was introduced in the Senate on February 15, 2013, related to the Chiropractic Act. On June 20, 2013 – after passing the policy and fiscal committees of the Senate and passed on to the Assembly – the bill was gutted and provisions related automated drug delivery systems were introduced. The bill has been scheduled for its first policy hearing in the Assembly on August 13.

EXISTING LAW:

Existing Pharmacy Law provides for the licensure of sites and individuals involved in the practice of pharmacy; that is, those settings in which controlled substances, dangerous drugs and dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, and repackaged and from which they are furnished, sold or dispensed; and individuals licensed to practice/work in those settings. These settings include community and retail pharmacies, hospital pharmacies, and nonresident pharmacies. (Article 7 – Pharmacies, commencing with § 4110.)

Existing law specifies entities and individuals to which a pharmacy may furnish dangerous drugs.

Existing law provides for the licensure of wholesalers – to include those who act as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any dangerous drug or dangerous device. Licensed wholesalers must have a designated representative-in-charge, subject to approval by the board, who is responsible for the wholesaler's compliance with state and federal laws related to wholesalers.

Existing law (§ 4170) authorizes a prescriber to dispense dangerous drugs and devices in his or her office, so long as specified conditions are met

Existing law provides for board licensure of various ¹clinics, including

- Nonprofit or free clinics
- Surgical clinics
- Primary care clinics owned by a county
- Clinics operated by a federally recognized Indian tribe or tribal organization
- Student health center clinics operated by public institutions of higher education, and others

Existing law (§ 1204 of the Health and Safety Code) provides for the licensure of clinics by the California Department of Public Health. This section provides for the licensing of clinics operated by a tax-exempt, nonprofit corporation, as well as specialty clinics, as specified.

Eligible clinics may purchase drugs for wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic, as specified. Further, the dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs.

Existing law specifies requirements for ⁱⁱⁱautomated delivery device systems, which may be located in any Nonprofit or Free clinic that is licensed by the board.

Only upon authorization by a pharmacist may drugs be removed from an automated drug delivery system, and they shall be provide to the patient by a health professional licensed pursuant to Division 2 of the Business and Professions Code. Only a pharmacist shall restock an automated delivery device system.

Existing law defines a ²dangerous drug or dangerous device to be one that can be dispensed only upon a valid prescription.

Section 4037 defines a “pharmacy” as any area, place, or premise licensed by the board in which the profession of pharmacy is practiced to include any area, place, or premise where controlled substances, dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold or dispensed at retail.

Section 4040 defines a “prescription” as that which is given individually for a person or persons for whom it is ordered (i.e., patient-specific), and that is issued by a prescriber, as specified. That section further specifies additional requirements for the content of a valid prescription.

Section 4076 specifies requirements for labeling of a prescription, and 16 CCR § 1707.6 specify additional patient-centered labeling requirements.

Section 4111 places restrictions on physician ownership of a pharmacy.

Existing law at Health and Safety Code § 1206 specifies those entities that are **exempt from licensure** as a clinic by the California Department of Public Health. These exempt clinics include, but are not limited to

- “Free clinics” that are owned or leased and operated as a clinic or office by one or more licensed health care practitioners and used as an office for the practice of their profession.

¹ See Article 13 - Nonprofit or Free Clinics, commencing with § 4180, and Article 14 – Clinics, commencing with § 4190.

² Business and Professions Code § 4022.

- Community clinics, Tribal clinics, and clinics conducted, operated, or maintained as outpatient departments of hospitals.
- Clinics operated by a nonprofit corporation exempt from federal income taxation, as specified.
- A clinic that provides health care services to patients covered under Medicare, or through physicians and surgeons who, in the aggregate, devote no more than 30 percent of their professional time to direct patient care activities for which charges for professional services are paid.
- A freestanding clinic, as specified

Existing law at Health and Safety Code § 1375.4 specifies requirements for contracts between a health care service plan and a ^{iv}risk-bearing organization, and defines a “risk-bearing organization.”

THIS BILL WOULD:

Amend Section 4170 (Prescriber Dispensing) to

- Remove the restriction that specifies that a nurse or physician attendant do not furnish the physician’s drugs or devices to a patient, and instead allow health care professional or a physician’s designee to physically furnish the drug or device to the patient. (“Designees” are not defined, and there is no criterion for which the individual must abide.) This section specifically states that an automated drug delivery system may be utilized.
- Removes the restriction that a prescriber not use an automated dispensing device unless he or she personally owns the device, and the drugs that are within the device.
- Specify that the prescriber identified by the manufacturer or wholesaler on invoices, bills of lading, etc., is the recipient of and responsible for the safe and secure storage of drugs and devices. (There is no requirement that the responsible prescriber be located at the location in which an automated drug dispensing system is housed.)
- Add a requirement that when a physician dispenses a dangerous drug or device, that the physician provide the patient with an oral consultation regarding *issues that the physician deems necessary* and other items required by board regulation, to ensure the safe and effective use of the drug or device.
- Specifies conditions under which a physician group practice can own an inventory of dangerous drugs and devices, and dispense from those drugs and devices, to include
 - Each prescriber dispenses drugs or devices only to patients seen or treated at the group practice, and that all drugs or devices packaged, labeled, and that all recordkeeping requirements of pharmacy law are met.
 - The group identifies a “responsible provider” within the group that shall be named by the drug manufacturer or wholesaler as the recipient of drugs and devices, and who shall be responsible for the record-keeping and storage of the drug inventory.
 - Requires that records be maintained by each provider to identify the patient, and the name, strength, quantity and directions for use for each drug dispensed.
 - Require that a daily log or some other paper or electronic record is created each day to document the daily inventory of all drugs that are jointly owned by the group, and the name, strength and quantity of all drugs dispensed by each prescriber.
- Authorizes a prescriber that is employed by the group, or under contract to the group, to dispense drugs out of the group practice drug inventory.
- Specifies that dangerous drugs are ‘owned’ if they are ‘delivered’ to the possession of the prescriber, clinic, or group practice. Subdivision (f) further specifies that each prescriber, clinic or group practice has the responsibility for the security and recordkeeping associated with the possession of the dangerous drugs, regardless of the person or entity responsible for payment of the drug inventory.
- Defines “group practice” to be more than one prescriber practicing under a single professional corporation or license, including a medical group or risk-bearing organization as defined in the Knox-Keene Health Care Service Plan Act of 1975.

Amend Section 4180 (Clinics that can purchase drugs at wholesale) to

- Allow a group practice, licensed by Section 4170, to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, or other prescriber when permitted by law, to patients registered for care at a clinic.
- Make conforming changes to provisions that currently require clinics to notify the board of address changes, and the requirement to maintain records of drug inventory for three years.

Amend Section 4186 (Automated Drug Delivery systems) to

- Allow a clinic or group practice (specified in Section 4180) to have an automated drug delivery system.
- Require a physician group practice that utilizes an automated drug delivery system to develop and implement written policies and procedures. This provision specifies that all prescribers who dispense drugs from the system, and *all health care professionals and delegated personnel* authorized to stock, refill or retrieve the drugs from the system have to comply with the written policies and procedures.
- Strikes the requirement that only a pharmacist stock an automated drug delivery system and, in a physician group practice, allow a prescriber *or designee of a prescriber* to stock an automated drug delivery system.
- Amend provisions that require an automated drug delivery system to maintain 2-way audio and video, to allow for only two-way audio where a consultation is provided by the prescriber in a physician group practice.
- Amends provisions that require a pharmacist that operates an automated drug delivery system to be located in California; rather, that they be licensed in California.
- Amends the definition of an automated drug delivery system to specify that if it is used to facilitate prescriber dispensing, that the system
 - Be located within a clinic or office of the group practice, and the contents be secure from access or removal from unauthorized individuals.
 - That a policy and procedure manual be developed and maintained, and shall include information related to the system and provisions related to security, drug stocking, etc.
 - Requirements to ensure the security of the system to prevent unauthorized access to the drugs within the system.
 - Specify requirements for the stocking or filling of the system by a pharmacist, prescriber, or other person designated by the pharmacist or prescriber, and that certain requirements be met.
 - Maintain electronic or hard copy records of medications in the system.
 - Maintain readily retrievable electronic records to identify all persons involved in the dispensing of a drug.
 - Be able to comply with product recalls.
 - Specify records of transactions be available to board inspectors.
 - Provide patients with telephonic access to consultation by a California-licensed pharmacist, unless the prescriber provides a consultation.
 - Specify that a prescriber or designee reconstitute any medication that requires reconstitution.
- Authorizes the board to adopt regulations authorizing the use of an automated drug delivery system that delivers dispensed medications directly to a patient, and that any such regulations be based, in part, on the board's assessment of the safety of the systems.

Discussion

Staff has met with the sponsors of the bill on a couple of occasions and as a starting point for discussion, in June provided draft language that would reflect a licensing structure similar to that which was crafted for the licensure of surgical clinics (i.e., those authorized by SB 1095 (Rubio), 2012). A copy of the draft language offered is provided in Attachment 1. This licensing structure allows clinics, with a consulting pharmacist, to purchase drugs at wholesale, where a comingled drug supply is utilized by physicians at the surgical clinic for administration to patients at the clinic.

Staff is concerned where a Pharmacist is taken out of the picture where inventories of dangerous drugs and dangerous devices, including controlled substances, are maintained and where multiple prescribers dispense from this drug stock.

Staff is concerned about provisions that remove the requirement for a pharmacist, located in California, to maintain an automated drug delivery system. Staff is also concerned where those other than pharmacists or physicians and surgeons have full access to a comingled drug stock and where "designees" can stock, re-stock and retrieve dangerous drugs and dangerous devices from an automated drug delivery system.

The provisions of SB 306 may conflict with Business and Professions Code Section 4111, which place restrictions on prescriber ownership of a pharmacy.

Related to automated drug delivery systems,

- Should automated drug delivery systems be authorized outside of a pharmacy or clinic?
- Should only a pharmacist be authorized to stock and re-stock the device? Should a physician, a "designee" of the physician, and/or a wholesaler be authorized to stock and restock an automated drug delivery system?
- Should a pharmacist that operates an automated drug delivery system be "located in" California (current law), or just licensed to practice in California?
- Would the provisions of the bill that specify the drugs are "owned" upon delivery, regardless of who pays for them, comply with e-Pedigree requirements?
- Is it necessary to retain existing provisions that provide for 2-way telephonic and video at an automated drug delivery system, even if the physician provides a consultation to a patient?
- Should each automated drug delivery system be separately registered, and tied back to a board licensee?

FISCAL IMPACT ON THE BOARD:

A physician group practice would require the board to develop a new license category, applications, etc. for the processing of these entities.

The board may experience challenges in establishing a new "license type" in the existing licensing tracking system.

The board may experience a one-time cost of up to \$20,000 to develop a new licensing category in the BreEZe system.

SUPPORT:

Molina Healthcare of California (Sponsor)

OPPOSITION:

California Pharmacists Association (copy of letter provided)

HISTORY:

Date	Action
06/20/13	From committee with author's amendments . Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/14/13	Referred to Com. on B.,P. & C.P.
05/29/13	In Assembly. Read first time. Held at Desk.
05/28/13	Read third time. Passed. (Ayes 38. Noes 0. Page 1100.) Ordered to the Assembly.
05/24/13	Read second time. Ordered to third reading.
05/23/13	From committee: Do pass. (Ayes 7. Noes 0. Page 1011.) (May 23).
05/21/13	Set for hearing May 23.
05/20/13	Placed on APPR. suspense file.
05/10/13	Set for hearing May 20.
05/07/13	Read second time and amended. Re-referred to Com. on APPR.
05/06/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 10. Noes 0. Page 733.) (April 29).
04/18/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
04/05/13	Set for hearing April 29.
02/28/13	Referred to Com. on B., P. & E.D.
02/19/13	From printer. May be acted upon on or after March 21.
02/15/13	Introduced. Read first time. To Com. on RLS. for assignment. To print.

ⁱ Wholesalers. See Article 11, commencing with § 4160. A wholesaler permit is required before any firm or organization that sells for resale or negotiates for distribution, may distribute, broker or transact the sale or return of dangerous drugs or dangerous devices in California. Wholesalers sell and distribute dangerous drugs and dangerous devices (also called "legend" items or prescription-required drugs and devices) to other business entities that are authorized by law to purchase the items or sell to licensed health care providers who are authorized by law to possess the dangerous drugs and dangerous devices. Wholesalers are not authorized to sell or distribute these items directly to patients unless the wholesaler is delivering dialysis drugs and devices to home dialysis patients in case(s) or full shelf package lots (see section 4054 of the California Business & Professions Code).

ⁱⁱ Prescribers are defined at B&PC Section 4170(c) as a person who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice naturopathic medicine, a license to practice dentistry, a license to practice veterinary medicine, or a certificate to practice podiatry, as specified. Article 12 prohibits a prescriber from keeping a pharmacy, open shop, or drug store for the retailing of dangerous drugs, dangerous devices, or poisons. Prescribers are authorized to distribute dangerous drugs or dangerous devices to their own patients; these drugs or devices are not to be furnished by a nurse or physician attendant. There is no restriction on a prescriber dispensing to his or her patient a controlled substance. A prescriber must ensure that dangerous drugs dispensed by the prescriber meet specified conditions:

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- The drugs and devices are dispensed to the prescriber's own patient, and they are not furnished by a nurse or physician attendant.
 - The drugs and devices are necessary in the treatment of the condition for which the prescriber is attending the patient.
 - The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.
 - The prescriber fulfills all of the label requirements imposed upon pharmacists, as specified.
 - The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and that any drugs dispensed therefrom are packaged and labeled in accordance with pharmacy laws.
 - The prescriber offers a written prescription to the patient, so that the patient may elect to have the prescription filled at a pharmacy.
 - The prescriber provides the patient with a written disclosure that the patient has the choice of obtaining the prescription from the dispensing prescriber, or from a pharmacy of the patient's choice.
 - Those authorized to hand a prescription to the patient include: certified nurse-midwife, nurse practitioner, physician assistant, or a naturopathic doctor

ⁱⁱⁱ Automated Drug delivery systems are defined at § 4186(h) as a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing or distribution of pre-packaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

^{iv} H&SC § 1375.4 (g) (1) For purposes of this section, a "risk-bearing organization" means a professional medical corporation, other form of corporation controlled by physicians and surgeons, a medical partnership, a medical foundation exempt from licensure pursuant to subdivision (l) of Section 1206, or another lawfully organized group of physicians that delivers, furnishes, or otherwise arranges for or provides health care services, but does not include an individual or a health care service plan, and that does all of the following:

(A) Contracts directly with a health care service plan or arranges for health care services for the health care service plan's enrollees.

(B) Receives compensation for those services on any capitated or fixed periodic payment basis.

(C) Is responsible for the processing and payment of claims made by providers for services rendered by those providers on behalf of a health care service plan that are covered under the capitation or fixed periodic payment made by the plan to the risk-bearing organization. Nothing in this subparagraph in any way limits, alters, or abrogates any responsibility of a health care service plan under existing law.

(2) Notwithstanding paragraph (1), risk-bearing organizations shall not be deemed to include a provider organization that meets either of the following requirements:

(A) The health care service plan files with the department consolidated financial statements that include the provider organization.

(B) The health care service plan is the only health care service plan with which the provider organization contracts for arranging or providing health care services and, during the previous and current fiscal years, the provider organization's maximum potential expenses for providing or arranging for health care services did not exceed 115 percent of its maximum potential revenue for providing or arranging for those services.

Increasing Patient Access to Vital Medication



PURPOSE

This measure would expand access to prescription medication for patients and improve medication compliance, potentially saving the health care system millions of dollars. The bill would allow physicians in a group practice to jointly own and dispense from a single inventory of drugs and authorize the use of automated dispensing machines, under rigorous controls, so that California patients can receive prescription medications for acute conditions at their doctor's offices.

PROBLEM

More than 30 percent of all prescriptions written never get filled. This statistic has been documented in studies as well as in clinical experience. The failure to fill these prescriptions increases health care costs because patients often wind up in emergency rooms and hospitals as a result. Some reports estimate that 10 percent of patients will subsequently require hospital care due to noncompliance with medication therapy and that medication noncompliance leads to 125,000 premature deaths. The costs of medication non-compliance are estimated at more than \$4 billion for California's health care system annually.

The lack of point-of-care access to prescription medication is the primary reason prescriptions go unfilled. Getting to an offsite pharmacy is particularly difficult for the poor, the elderly, the disabled, caregivers with sick children, patients with limited transportation options or ill patients who cannot drive.

Existing California law, however, makes it difficult for physicians to dispense medications in their offices. Physicians, physician assistants and nurse

practitioners are permitted to dispense prescription medication to their patients. However, current statute requires these medical practitioners to personally own the medication and the dispensing equipment. The tracking, storage, inventory control and payment processing requirements, coupled with the need for safe and appropriate dispensing and labeling, make physician ownership and dispensing of drugs at the point of care difficult. In addition, current law prohibits health care providers in a group practice from jointly owning and dispensing medication from a single inventory.

Moreover, California law does not permit a physician group practice to jointly own an inventory of drugs, so that the group practice could take advantage of the efficiencies management of an inventory by the practice as a whole. Though advanced technologies exist to solve this problem through automated dispensing machines that handle tracking, labeling, dispensing, and inventory control, California law does not clearly permit the use of these machines by group practices.

SOLUTION

This measure would amend existing law pertaining to the ownership and dispensing of prescription medications that hinder the use of automated dispensing machines in group practices. The proposed legislation would amend existing law to permit group practices to own the medication and equipment, provided they are licensed by the Board of Pharmacy and comply with rigorous requirements for safety and security pertaining to use of automated dispensing machines. This legislation will expand access to prescription medication for millions of Californians who currently don't fill prescriptions and the millions who will soon receive services under the ACA.

It has been proven that providing prescription medication at the point-of-care increases the rates of prescription filling from 70 percent to 95 percent because patients can quickly and conveniently get their medication without having to go to another facility. These dramatic increases in fill rates reduce the chance of noncompliance with medication therapy and the associated costs of additional treatment.

As a result of implementation of the ACA, about 4.7 million more Californians will be eligible for health insurance starting in 2014. Many newly insured Californians will have a pent-up demand for services and will create even more pressure on the already stressed health care system, particularly in medically underserved areas. In these areas, it's not uncommon for patients to wait 8 hours or more to fill a prescription. Higher patient demand will increase wait times resulting in greater medication noncompliance.

BACKGROUND ON AUTOMATED PRESCRIPTION DISPENSING

Automated prescription medication dispensing at the point-of-care has been available for over 10 years and has safely and accurately dispensed more than 2 million prescriptions in 28 states. The dispensing system consists of an ATM-style, secure machine and HIPAA compliant software to write medication orders, control dispensing, adjudicate costs, receive payment, and track and report on all transactions.

After the patient sees the physician, physician assistant or nurse practitioner, a medication order form is issued and printed with patient drug education material. The practitioner consults with the patient about the medication therapy and answers any questions. The health care professional or his or her designee then takes the order form to the dispenser, which is located in the provider's office, and uses the touch-screen to enter in the order's one-time, unique

access code along with the patient's birthday. If the patient has insurance, the claim will be processed and the cost or insurance co-pay is calculated. The dispenser accepts a variety of forms of payment. Public insurance plans are also accepted, including Medicare, Medicaid and other government programs. If desired, the health care facility can elect to provide the medications at no cost to the patient.

After payment is processed, precision robotics locate the proper medication in the dispenser using a triple barcode check system to ensure accuracy while eliminating handwriting errors. A label with all required information is printed and affixed to the container, and the medication is dispensed directly to the patient. A telephone located on the dispenser with direct dialing to a call center, including a licensed pharmacist, may be used if questions arise. The patient takes the medication and receipt, and is on his or her way in minutes.

CONCLUSION

Other states have recognized these advances in dispensing technology and taken advantage of them implementing regulations that ensure safety and appropriate prescribing. This legislative proposal will allow Californians to improve their health and reduce health care costs by providing medication at the point of care. Californians deserve this expanded access to prescription medication offered by safe, efficient advanced dispensing technology.

SPONSOR

Molina Healthcare of California



California
LEGISLATIVE INFORMATION

SB-306 Pharmacy: dangerous drugs and dangerous devices: automated drug delivery systems.

(2013-2014)

As Amended June 20, 2013 - Today's Law As Amended

SECTION 1. *Section 4170 of the Business and Professions Code is amended to read:*

4170. (a) No prescriber shall dispense *dangerous* drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own ~~patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.~~ *patient. A health care professional who is licensed as described in this section, or his or her designee, shall physically furnish the dangerous drug or device to the patient.*

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) ~~The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).~~ *Unless the prescriber is employed by or under contract to a clinic or group practice that is licensed by the board pursuant to Section 4180, the prescriber is identified by the drug manufacturer or wholesaler supplying the drugs as the recipient of the drugs and identified by name and registration number as the recipient in all invoices, bills of lading, state or federal order forms, and other documentation. As the recipient of the drugs, the prescriber is responsible for ensuring that the drugs are securely and safely stored prior to dispensing and is responsible for maintaining all required records regarding the receipt, storage, and dispensing or other disposition of all drugs and devices.*

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

(8) The prescriber provides the patient with an oral consultation regarding issues that the prescriber, in his or her professional judgment, deems necessary to ensure the safe and effective use of the prescribed drug or device. The oral consultation shall include all subjects that pharmacists are required to discuss pursuant to regulations adopted by the board pursuant to Section 4005.

~~(8)~~ *(9) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to Section 3502.1, a registered nurse who functions pursuant to Section 2725.1, or a naturopathic doctor who functions pursuant to Section 3640.5, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist. Nothing in this section shall preclude the use of an automated drug delivery system described in Section 4186.*

(b) The Medical Board of California, the State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) "Prescriber," as used in this section, means a ~~person, who~~ *person who is licensed to prescribe and dispense dangerous drugs and devices, including, but not limited to, a person who* holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice naturopathic medicine, a license to practice dentistry, a license to practice veterinary medicine, or a certificate to practice podiatry, and who is duly registered by the Medical Board of California, the State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Veterinary Medical Board, or the Board of Osteopathic Examiners of this state.

(d) This section shall not prevent a group practice, licensed pursuant to Section 4180, from owning an inventory of dangerous drugs and devices and dispensing the drugs and devices from the inventory owned by the group practice provided that the following conditions are met:

(1) Each prescriber dispenses dangerous drugs or devices only to the patients seen or treated by that prescriber, and not to the patient of any other prescriber in the group practice, and the drugs or devices are packaged, labeled, and recorded in accordance with paragraph (4) of subdivision (a).

(2) The group practice identifies a responsible prescriber within the group practice who shall be named by the drug manufacturer or wholesaler supplying the drugs as the recipient of the drugs on all invoices, bills of lading, state or federal order forms, and other documentation, and who shall be responsible for the record-keeping and storage of the drug inventory.

(3) Records are maintained by each prescriber to identify the identity of the patient and the name, strength, quantity, and directions for use for each dangerous drug dispensed by the prescriber to his or her patient.

(4) A daily dispensing log or some other paper or electronic record is created each day, and maintained by the group practice, to identify both of the following:

(A) A daily starting inventory of all dangerous drugs that are jointly owned by the prescribers who comprise the group practice.

(B) The name, strength, and quantity of all dangerous drugs dispensed by each prescriber.

(e) A prescriber employed by, or under contract to, a clinic or group practice licensed under Section 4180 may dispense drugs that are owned by the clinic or group practice.

(f) (1) For purposes of this section, a dangerous drug is owned if it is delivered to the possession of a prescriber, clinic, or group practice, and each prescriber, clinic, or group practice has responsibility for the security and recordkeeping associated with possession of the dangerous drugs, regardless of the person or entity responsible for payment for the dangerous drug inventory.

(2) For the purposes of this section, "group practice" means more than one prescriber practicing under a single professional corporation or license, including a medical group or risk-bearing organization as defined in the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

SEC. 2. *Section 4180 of the Business and Professions Code is amended to read:*

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following *clinics entities* may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, *or other prescriber when permitted by law*, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraph (1) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

(G) A group practice, as defined in Section 4170, that uses an automated drug delivery system, as described in Section 4186.

(2) The clinic *or group practice* shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(b) No clinic *or group practice* shall be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic *or group practice* shall notify the board of any change in the ~~clinic's address~~ *address of the clinic or group practice* on a form furnished by the board.

SEC. 3. *Section 4186 of the Business and Professions Code is amended to read:*

4186. *(a) An automated drug delivery system, as defined in subdivision (i), may be located in any clinic or group practice licensed by the board as described in Section 4180.*

~~(a) (b) Automated (1) drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180.~~ If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

(2) If an automated drug delivery system is located in a group practice, the group practice shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All prescribers who will be dispensing drugs from the automated drug delivery system and all health care professionals and delegated personnel authorized to stock, refill, or retrieve the drugs inventory from the automated drug delivery system shall be required to comply with the policies and procedures developed by the group practice. All policies and procedures shall be maintained at the location where the automated drug system is being used.

~~(b) (c)~~ Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist *or prescriber* after the pharmacist *or prescriber* has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this ~~division~~ *division or an individual operating under the supervision of the prescriber*.

~~(c) (d)~~ The stocking of an automated drug delivery system shall be performed by a ~~pharmacist~~ *pharmacist or, in a clinic or group practice, by a prescriber or a designee of the prescriber*.

~~(d) (e)~~ Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the ~~clinic~~ *clinic in a clinic setting or by the responsible prescriber in a group practice*. The review shall be conducted on a monthly basis by a pharmacist *or responsible prescriber* and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

~~(e) (f)~~ The automated drug delivery system used at the clinic *or group practice* shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and ~~video~~ *video, unless a consultation is provided by the prescriber pursuant to paragraph (8) of subdivision (a) of Section 4170*.

~~(f) (g)~~ ~~The A~~ pharmacist operating the automated drug delivery system shall be ~~located~~ *licensed* in

California.

~~(g)~~ *(h)* Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.

~~(h)~~ *(i)* For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a ~~pharmacist~~ *pharmacist, or, if used to facilitate prescriber dispensing by a prescriber*, that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and ~~accountability~~. *accountability and shall meet all of the following requirements:*

(1) The system shall be located within the clinic or office of the group practice, and its contents shall be secure from access or removal by unauthorized individuals.

(2) A policy and procedure manual shall be developed and maintained and shall include the type or name of the system including a serial number or other identifying nomenclature and a description of the security provisions, stocking processes, and other documentation practices of the clinic or group practice.

(3) The system shall have a method to ensure security of the system to prevent unauthorized access to dangerous drugs or devices contained within the system. The method may include the use of electronic passwords, biometric identification, including optic scanning or fingerprint, or other coded identification.

(4) The clinic or group practice shall employ a process of filling and stocking the system with drugs. The stocking or restocking of a drug shall only be completed by a pharmacist, prescriber, or personnel designated by the pharmacist or prescriber and all of the following shall apply:

(A) The cartridges or containers to be stocked or restocked shall be provided by a licensed wholesale drug distributor or repackaged by the pharmacy or prescriber in compliance with state and federal law. The licensed wholesale drug distributor shall have a method of receiving and disposing of rejected, expired, or unused medications consistent with state or federal law.

(B) The individual cartridge or container shall be transported to the dispensing site in a secure, tamper-evident package.

(C) The system shall use a bar code verification, electronic verification, weight verification, radio frequency identification, or similar process to ensure that the cartridge or container is accurately stocked or restocked into the automated system. The system shall provide for alerts to the responsible pharmacist or prescriber if a cartridge or container is not recorded in the automated system.

(D) The pharmacist or prescriber responsible for the dispensed drug shall be responsible if the cartridge or container is stocked or restocked incorrectly by the personnel designated to load the cartridges or containers.

(5) The system shall maintain an electronic or hard copy record of medication filled into the system, including the product identification, lot number, and expiration date.

(6) The system shall maintain a readily retrievable electronic record to identify all pharmacists, registered pharmacy technicians, prescribers, and all other personnel involved in the dispensing of a drug.

(7) The system shall be able to comply with product recalls generated by any manufacturer or distributor and shall have a process in place to isolate affected lot numbers.

(8) The record of transactions conducted through the automated drug delivery system shall be available to authorized agents of the board. The record of transactions shall, only to the extent authorized or permitted by state or federal law, include the following:

(A) Name of the patient.

(B) Name, strength, and dosage form of the drug product dispensed.

(C) Quantity of drug dispensed.

(D) Date and time of dispensing.

(E) Prescription number or other unique serial number assigned to the transaction.

(F) Name of prescriber.

(G) Identity of the pharmacist who approved the prescription, or of the prescriber.

(H) Identity of the person to whom the drug was released.

(9) Unless the prescriber provides consultation pursuant to regulations adopted by the board pursuant to Section 4005, the system shall provide patients with telephonic access to consultation by a California-licensed pharmacist.

(10) In the case of dangerous drugs that require reconstitution, the prescriber or his or her designee shall reconstitute the medication for the patient.

(j) The board is authorized to adopt regulations authorizing the use of an automated drug delivery system that delivers dispensed medications directly to a patient. The regulations shall be based, in part, upon the board's assessment of the safety of the systems.

SEC. 4. *No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.*

Article 14.5 Medical Professional Corporations Licensed as Clinics

4197

- (a) A professional corporation comprised of physicians may apply for a clinic permit under this article provided at least 75 percent of the patients served by the corporation are provided medical services funded through a MediCal Managed Care Program.
- (b) No entity shall be entitled to the benefits of this article until it has obtained a license from the board.
- (c) A separate license shall be required for each clinic location. No clinic may be located in a home. A clinic shall notify the board of any change in the clinic's address on a form furnished by the board at least 30 days in advance of a move.
- (d) The license shall be renewed annually.
- (e) If a clinic is licensed by the board, any proposed change in ownership or beneficial interest in the licensed premises shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.
- (f) If at any time during the year the percentage of MediCal patients being served by the corporation decreases below 75 percent of all patients served, the corporation shall notify the board and shall have 90 days to resume serving MediCal Managed Care patients in a proportion that is at least 75 percent of all patients served. If the percentage of MediCal Managed Care patients stays below 75 percent for more than three consecutive months, the medical professional corporation is no longer eligible for a clinic permit under this section, and the permit may be cancelled by the board.

4197.1

A clinic licensed under this article may purchase prescription drugs and devices at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic.

- (a) Prior to the issuance of a clinic license authorized under Section 4197, the clinic shall comply with all applicable laws and regulations of the board relating to the drug distribution service to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the

- promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.
- (b) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.
 - (c) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel, including the board.
 - (d) Each clinic that makes an application for a license under Section 4197 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this article shall prohibit the consulting pharmacist from visiting more frequently than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.
 - (e) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate.
 - (f) For the purposes of this article, "professional director" means a physician and surgeon acting in his or her capacity as medical director.
 - (g) Clinics licensed under this article shall notify the board within 30 days of any change in professional director on a form furnished by the board.
 - (h) The board shall have the authority to inspect a clinic that is licensed pursuant to this article at any time in order to determine whether the clinic is, or is not, operating in compliance with this article and all other provisions of the law

4197.2 No clinic dispensing drugs pursuant to this article shall be eligible for any professional dispensing fee that may be authorized under the Medi-Cal

Program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

- 4197.3 No Schedule II controlled substance shall be dispensed by the clinic. The board shall have the authority to inspect a clinic at any time in order to determine whether a clinic is, or is not, operating in compliance with this article.
- 4197.4 (a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4197. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.
- (b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided only to a patient and only by a health professional licensed pursuant to this division.
- (c) The stocking of an automated drug delivery system shall be performed by a pharmacist.
- (d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
- (e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.
- (f) The pharmacist operating the automated drug delivery system shall be located in California.
- (g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Sections 4076 and 4076.5.
- (h) For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all

transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

4197.5 The drug distribution service of a clinic shall be limited to the use of drugs for administration to the patients of the clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

No clinic holding a license pursuant to this article shall offer drugs for sale or shall charge or bill for professional services for the dispensing or administering of drugs.

No Schedule II controlled substance shall be dispensed in the clinic. This limitation does not prohibit a physician from dispensing a Schedule II drug to the extent permitted by subdivision (b) of Section 11158 of the Health and Safety Code and all other provisions of law, nor does it prevent the lawful administration of Schedule II drugs on the premises of the clinic.



June 27, 2013

The Honorable Norma Torres
California State Senate
State Capitol, Room 3056
Sacramento, CA 95814

Re: **SB 306 – OPPOSE**

Dear Senator Torres:

The California Pharmacists Association (CPhA) must respectfully **oppose your bill, SB 306**. This bill would make a number of changes to the Pharmacy Law to allow physician group practices to purchase prescription drugs as a group and dispense those drugs through automated dispensing machines without important oversight and safeguards.

Pharmacists share your interest in improving medication adherence among patients and we appreciate your intent in this regard. However, as currently structured, this bill takes an inappropriate path to achieving that goal. The scheme proposed by this bill completely cuts pharmacists out of the equation, effectively exempts physician group practices from numerous safeguards with which pharmacies and clinics that dispense drugs must currently comply, and increases the risk of diversion of controlled substances by allowing unlicensed staff to handle medications and allowing all schedules of controlled substances to be dispensed.

This bill significantly expands the existing authority for prescriber dispensing in multiple ways. The proposal allows prescribers operating in group practice to commingle drugs and essentially operate as a pharmacy under the prescriber dispensing authority without the appropriate Board of Pharmacy oversight. Under existing law, prescriber dispensing authority has numerous limitations and requirements—including that the prescriber not be operating a pharmacy. When significant amounts of drugs are dispensed (for example, in a clinic or outpatient surgical center), it is considered to be operating as a pharmacy and the facility must be licensed by the Board of Pharmacy. However, SB 306 would allow group practices to dispense drugs, as if they are a pharmacy, under the prescriber dispensing authority.

This bill also seeks to simultaneously expand the use of and relax the regulation of automated dispensing machines. Dispensing machines are currently allowed to be used by nonprofit clinics. However, each individual site is licensed by both the Department of Public Health and the Board of Pharmacy, all prescriptions must be reviewed by a pharmacist prior to being dispensed to ensure the safety of the prescribed drug, and numerous other safeguards must be in place to ensure the safety and security of the drugs. By contrast, this bill does not require review by a pharmacist, does not require each site to be licensed, does not provide clear

inspection authority by the Board of Pharmacy, and allows unlicensed personnel to operate the dispensing machine and handle drugs.

In general, existing practice and California law require prescription drugs to be prescribed by a licensed healthcare provider with prescriptive authority and then be dispensed by a licensed pharmacist working in a pharmacy, hospital pharmacy, or clinic pharmacy. The pharmacist is responsible for reviewing the prescription for contraindications and for the appropriateness of the therapy. In outpatient settings, nearly half of preventable adverse drug events occur because of prescription errors. The secondary review by a pharmacist helps catch many medication errors before they happen. By cutting pharmacists completely out of the equation, this bill eliminates this important step to protect patients' health and safety.

Again, we share your concerns regarding the number of patients who do not take their medications as prescribed. There are a number of factors leading to medication non-adherence and we would be pleased to work with you on comprehensive solutions to this problem. If you have any questions, please do not hesitate to contact me at (916) 779-4517.

Sincerely,



Brian Warren
Director, Government and Professional Affairs

cc: Members, Assembly Business, Professions, and Consumer Protection Committee
Sarah Huchel, Consultant, Assembly BPCP Committee
Ted Blanchard, Assembly Republican Caucus



Bill Number:	SB 598
Introduced	2/22/13
Last Amend:	June 20, 2013
Author:	Senator Jerry Hill
Topic:	Biosimilars
Position:	Oppose (4/24/13)

Current Bill Status: Referred to ASM Appropriations
7/2/13 - Passed out of ASM Health

Affected Sections: Add Section 4073.5 to the Business and Professions Code

SUMMARY:

SB 598 would add Section 4073.5 to specify conditions under which a pharmacist can exercise professional discretion to substitute a biosimilar where a biologic has been prescribed. For prescriptions filled prior to January 1, 2017, SB 598 requires the pharmacy to notify the prescriber of any substitution made within five business days of the selection.

The board opposed SB 598 at the April 2013 Board Meeting stating the board's concerns that the bill may be premature, the burden placed on the pharmacy to provide follow-up notification to a prescriber, as well as the role a pharmacist plays in substitutions. The board noted that once deemed "biosimilar" the board would support an approach similar to the authority that allows the substitution of generics. The board also has conveyed to the author that where there is an adverse event attributed to the use of a biosimilar that such an event be required to be reported to the FDA's "Medwatch."

During a recent policy hearing (ASM Health), the committee made comments in support of pharmacist notification to physicians each time a substitution would be made.

EXISTING LAW:

U.S. Food and Drug Administration

The Patient Protection and Affordable Care Act (Affordable Care Act) amends the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. This pathway is provided in the part of the law known as the *Biologics Price Competition and Innovation Act* (BPCI Act). Under the BPCI Act, a biological product may be demonstrated to be "biosimilar" if data show that, among other things, the product is "highly similar" to an already-approved biological product.

(<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm>)

According to the Biosimilar User Fee Act (BsUFA)

A “¹biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

Some products that meet the drug definition or both the drug and device definitions, and that also meet the definition of biological product, might be classified as biological products, rather than as devices or drugs, and be subject to licensure under the PHS Act². The FDA’s Office of Combination Products provides guidance as to whether a product meets the definition of biological product.

Pharmacy Law***Article 4 – Requirements for Prescriptions***

Section 4073 of the B&PC authorizes pharmacists filling prescription orders for drug products prescribed by their trade or brand names to substitute generic drugs for orders if the generic contains the same active chemical ingredients of equivalent strength and duration of therapy, subject to a patient notification and bottle labeling requirement, unless the prescriber specifies that a pharmacist may not substitute another drug product by either indicating on the form submitted for the filling of the prescription drug orders “Do not substitute” or words of similar meaning or selecting a box on the form marked “Do not substitute.”

Article 3 – Scope of Practice and Exemptions

Section 4052.5 of the B&PC authorizes pharmacists filling prescription orders for drug products prescribed by their trade or brand names to substitute a drug product with a different form of medication with the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product when the change will improve the ability of the patient to comply with the prescribed drug therapy, subject to a patient notification and bottle labeling requirement, unless the prescriber specifies that a pharmacist may not substitute another drug product by either indicating on the form submitted for the filling of the prescription drug orders “Do not substitute” or words of similar meaning or selecting a box on the form marked “Do not substitute.”

Section 4059 of the B&PC specifies requirements regarding the dispensing and furnishing of dangerous drugs and devices

¹ Section 351(i) (as amended by the Biologics Price Competition and Innovation Act of 2009, title VII of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7002 (2010))

² http://www.fda.gov/RegulatoryInformation/Guidances/ucm258946.htm#_ftn4

THIS BILL WOULD:***In Article 4 “Requirements for Prescriptions”***

Add Section 4073.5 to the Business and Professions Code to specify conditions under which a pharmacist may exercise professional discretion to substitute a ***biosimilar*** for a prescribed ***biological*** product, if:

- The biosimilar is approved by the FDA, as specified, and has been determined to be interchangeable with the prescribed biological product;
- The prescriber does not indicate “Do not substitute”;
- The pharmacist notifies the prescriber or enters appropriate information in a patient record system shared by the prescriber within five days of the selection (the method of notification is not specified);
- The pharmacy retains a written record of the biosimilar selection, as specified.
- The pharmacist shall communicate to the patient the substitution;
- Require the board to maintain on its website a link to a current list, if available, of biosimilar products determined by the FDA to be interchangeable;
- Define terminology, including “biological product,” “biosimilar,” “Interchangeable,” “prescription” and “351(k) pathway.”

FISCAL IMPACT ON THE BOARD:

As introduced, SB 598 will have an unknown fiscal impact on the board to

- Create and maintain on its website a link to an FDA approved list of interchangeable biosimilars. As of 4/5/13, staff has been unable to allocate such a link.
- Update its self-assessment forms for pharmacies.

.As of 7/15/2013

The 6/28/13 analysis by the Assembly Committee on Health lists wide support, and many in opposition to the measure.

HISTORY:

Date	Action
06/25/13	From committee: Do pass and re-refer to Com. on HEALTH. (Ayes 12. Noes 0.) (June 25). Re-referred to Com. on HEALTH.
06/20/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/17/13	Referred to Coms. on B.,P. & C.P. and HEALTH.
05/24/13	In Assembly. Read first time. Held at Desk.
05/24/13	Read third time. Passed. (Ayes 29. Noes 4. Page 1044.) Ordered to the Assembly.
05/21/13	Read second time. Ordered to third reading.
05/20/13	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
05/10/13	Set for hearing May 20.
05/07/13	Hearing postponed by committee.
05/03/13	Set for hearing May 13.
05/02/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 6. Noes 1. Page 791.) (May 1). Re-referred to Com. on APPR.
04/23/13	Set for hearing May 1.
04/16/13	Read second time and amended. Re-referred to Com. on HEALTH.

Date	Action
04/15/13	From committee: Do pass as amended and re-refer to Com. on HEALTH. (Ayes 10. Noes 0. Page 464.) (April 8).
03/21/13	Set for hearing April 8.
03/11/13	Referred to Coms. on B., P. & E.D. and HEALTH.
02/25/13	Read first time.
02/23/13	From printer. May be acted upon on or after March 25.
02/22/13	Introduced. To Com. on RLS. for assignment. To print.



California

LEGISLATIVE INFORMATION

SB-598 Biosimilars. (2013-2014)

As Amended 6/20/13 - Today's Law As Amended

SECTION 1. *Section 4052.55 is added to the Business and Professions Code, to read:*

4052.55. *(a) In addition to the authority allowed under Section 4073.5, a pharmacist filling a prescription order for a prescribed biological product may select a biosimilar only if all of the following conditions are met:*

(1) The product selected as a biosimilar has been approved by the federal Food and Drug Administration (FDA) under the 351(k) pathway of the federal Public Health Service Act (42 U.S.C. Sec. 262(k)) and has been determined to be interchangeable with the prescribed biological product.

(2) The prescriber does not personally indicate, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning, pursuant to subdivision (b).

(3) For prescriptions filled prior to January 1, 2017, the pharmacy notifies the prescriber or enters the appropriate information in a patient record system shared by the prescriber within five business days of the selection.

(4) For prescriptions filled prior to January 1, 2017, the pharmacy retains a written record of the biosimilar selection for a period of at least three years.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute" if the prescriber personally initials the box or checkmark.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The pharmacist who selects the biosimilar to be dispensed pursuant to this section shall assume the same responsibility for substituting the dispensed biosimilar as would be incurred in filling a prescription for a biosimilar using the prescribed form of medication. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the Medi-Cal Act set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a selection is made pursuant to this section, the substitution of a biosimilar shall be communicated to the patient.

(f) The board shall maintain on its public Internet Web site a link to the current list, if available, of biosimilar products determined by the FDA to be interchangeable, as provided in paragraph (1) of subdivision (a).

(g) For purposes of this section, the following terms shall have the following meanings:

(1) "Biological product," "biosimilar," and "interchangeable" have the same meanings that apply to those terms under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262).

(2) "Prescription," with respect to a biological product, means a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)).

(3) "351(k) pathway" refers to the licensure of a biological product as a biosimilar or an interchangeable biosimilar by the FDA pursuant to Section 351(k) of the federal Public Health Service Act (42 U.S.C. Sec. 262(k)).

(h) Nothing in this section prohibits the administration of immunizations, as permitted in Section 4052.

SEC. 2. *Section 4073.5 is added to the Business and Professions Code, to read:*

4073.5. *(a) A pharmacist filling a prescription order for a prescribed biological product may select a biosimilar only if all of the following conditions are met:*

(1) The product selected as a biosimilar has been approved by the federal Food and Drug Administration (FDA) under the 351(k) pathway of the federal Public Health Service Act (42 U.S.C. Sec. 262(k)) and has been determined to be interchangeable with the prescribed biological product.

(2) The prescriber does not personally indicate, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning in the manner provided in subdivision (b).

(3) For prescriptions filled prior to January 1, 2017, the pharmacy notifies the prescriber or enters the appropriate information in a patient record system shared by the prescriber within five business days of the selection.

(4) For prescriptions filled prior to January 1, 2017, the pharmacy retains a written record of the biosimilar selection for a period of at least three years.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute," provided that the prescriber personally initials the box or checkmark. To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on selection be manually initialed by the prescriber.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The pharmacist who selects the biosimilar to be dispensed pursuant to this section shall assume the same responsibility for substituting the dispensed biological product as would be incurred in filling a prescription for a biosimilar using the prescribed form of medication. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a biological product pursuant to this section. In no case shall the pharmacist substitute a biological product pursuant to this section unless the biological product selected costs the patient less than the prescribed biological product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the Medi-Cal Act set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a selection is made pursuant to this section, the substitution of a biosimilar shall be communicated to the patient.

(f) The board shall maintain on its public Internet Web site a link to the current list, if available, of biosimilar products determined by the FDA to be interchangeable, as provided in paragraph (1) of subdivision (a).

(g) For purposes of this section, the following terms shall have the following meanings:

(1) "Biological product," "biosimilar," and "interchangeable" have the same meanings that apply to those terms under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262).

(2) "Prescription," with respect to a biological product, means a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)).

(3) "351(k) pathway" refers to the licensure of a biological product as a biosimilar or an interchangeable biosimilar by the FDA pursuant to Section 351(k) of the federal Public Health Service Act.

(h) Nothing in this section prohibits the administration of immunizations, as permitted in Section 4052.

SEC. 3. *No reimbursement is required by this act pursuant to Section 6 of Article XIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred*

because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

May 10, 2013

The Honorable Jerry Hill
Member, California State Senate
State Capitol, Room 5064
Sacramento, CA 95816

RE: SB 598 - Oppose

Dear Senator Hill:

I regret to advise you that the Board of Pharmacy has taken an oppose position on your SB 598. This proposal would specify conditions under which a pharmacist may substitute a biosimilar where a biological product has been initially prescribed.

The board believes that SB 598 is premature in that no biosimilar products have yet been approved by the U.S. Food and Drug Administration (FDA). Nevertheless, the board applauds your effort to provide a pathway for biosimilar substitution. We share your belief that one day such substitution will be important to patient health care. However, we see no need to rush to secure statutory authorization before such determinations have been made.

The board suggests that once the FDA approves the lawful substitution of a biosimilar product would be the appropriate time to make such changes to California law. We also note that once deemed "biosimilar," we would support an approach like that which currently exists for substituting generic drugs, whereby the pharmacist can substitute a biosimilar without prescriber approval, unless the prescriber indicates 'do not substitute.'

Please do not hesitate to contact me at (916) 574-7913 if you have any questions. You may also contact the board's Executive Officer Virginia (Giny) Herold at (916) 574-7911.

Sincerely,

A handwritten signature in cursive script that reads "Carolyn Klein".

CAROLYN KLEIN, Manager
Legislation and Regulations



July 9, 2013

The Honorable Jerry Hill
California State Senate
State Capitol, Room 5064
Sacramento, CA 95814

Re: SB 598 (Hill) – Oppose

Dear Senator Hill:

The California Pharmacists Association (CPhA) must respectfully **oppose your bill, SB 598**. This bill would authorize a pharmacist to substitute a biologic drug product with an interchangeable biosimilar drug product, provided certain procedures are followed. The substitution process established by this bill closely mirrors that for substituting name brand drugs with generic drugs, except this bill requires the pharmacist to send notification to the prescriber upon dispensing either the prescribed biologic or an interchangeable biosimilar.

As the medication experts, pharmacists strongly support efforts to improve access and adherence to life saving medications. One of the most frequently cited reasons for patients not taking their medications is the high cost of drugs. To that end, pharmacists support the use of less expensive generic medications when available and medically appropriate. With the increasing use of biologics in the treatment of diseases, we look forward to the approval and availability of interchangeable biosimilars as a means of increasing patient access and affordability while reducing the overall cost of delivering healthcare.

CPhA supports appropriate communication and sharing of information between providers; this is why we had previously been neutral on SB 598. However, we strongly believe that pharmacists and other healthcare providers must be allowed to work together, using their professional judgment to ensure optimal medication therapy for their patients, unhindered by burdensome or unnecessary statutory frameworks. Amendments to SB 598 taken in the Assembly Committee on Health establish new and unnecessary notification requirements that will place a burden on pharmacists without any obvious benefit to providers or patients. For this reason, we must respectfully oppose SB 598.

If you have any questions, please do not hesitate to contact me at (916) 779-4517.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Brian Warren'.

Brian Warren
Director, Government and Professional Affairs



Bill Number:	SB 669
Introduced	2/22/13
Last Amend:	July 3, 2013
Author:	Senate Republican Leader Bob Huff
Topic:	Emergency Medical Care: Epinephrine Auto-Injectors
Position:	Support If Amended

Current Bill Status: 8/13/13 – Set for Hearing in ASM Judiciary

Affected Sections: Add Section 4119.3 to the Business and Professions Code
Add Section 1714.23 to the Civil Code
Add Section 1797.197(a) to the Health and Safety Code

SUMMARY:

SB 669 would create a training program and standards for the safe and proper use of epinephrine auto-injectors, make them available to trained individuals (as specified) and allow those individuals, in good faith and not for compensation, to administer an epinephrine auto-injector without facing civil liability, in an emergency situation to a person suffering from a potentially fatal anaphylactic allergic reaction.

The board established a position of Support if Amended at the April 2013 Board Meeting, with the suggested amendment to also authorize a pharmacist to approve the requisite training certification and issue the prescription for an epinephrine auto-injector, as specified in the bill.

To that end, staff recently met with the author's staff and sponsor and conveyed the board's request to amend the bill, as noted.

EXISTING LAW:

Section 4022 of the Business and Professions Code defines a Dangerous Drug or Dangerous Device (i.e., Rx, and one that can be dispensed only upon a valid prescription).

Section 4040 of the Business and Professions Code defines a "prescription" as that which is given individually for a person or persons for whom it is ordered (i.e., patient-specific), and that is issued by a prescriber, as specified. That section further specifies additional requirements for the content of a valid prescription.

Section 4076 of the Business and Professions Code specifies requirements for labeling of a prescription, and 16 CCR § 1707.6 specifies additional patient-centered labeling requirements.

Title 16 CCR § 1761 limits the dispensing of an erroneous or uncertain prescription.

THIS BILL WOULD:

Add Section 4119.3 to Pharmacy Law to authorize a pharmacy to dispense epinephrine auto-injectors to specified persons, in accordance with Section 1797.197a of the Health and Safety Code, provided specified requirements are met, including

- The prescription shall specify that the dispensed auto-injector is for “EMS Purposes Only” and that the named recipient is a “Section 1797.197a Responder.”
- Require a new prescription for additional epinephrine auto-injectors required.
- Require specified labeling of a prescription dispensed pursuant to this section.

Add Section 1714.23 to the Civil Code to

- Define “anaphylaxis” and “epinephrine auto-injector”;
- Grant immunity to an individual who administers epinephrine to another in good faith, at the scene of an emergency situation, in accordance with the provisions of the bill; and
- Provide immunity from alleged civil damages those organizations or others who provide or develop standards for training programs or standards.

Add Section 1797.197 to the Health and Safety to

- Establish definitions, to also include “anaphylaxis” and “epinephrine auto-injector” and others;
- Authorize a health care provider to issue a prescription for an epinephrine auto-injector to a person, as defined, upon presentation of current certification demonstrating that the person is trained and qualified to administer the auto-injector;
- Authorize specified (defined) persons to render emergency care to another person, so long as specified requirements are met; and
- Specify minimum training requirements for the use of epinephrine auto-injectors by the California Emergency Medical Services (EMS) Authority

STAFF COMMENTS

According to the author, SB 669 would create a training program and standards for the safe and proper use of epinephrine auto-injectors, make them available to trained individuals (as specified) and allow those individuals to administer the auto-injectors without facing civil liability, in an emergency situation to a person suffering from a potentially fatal anaphylactic allergic reaction.

Staff is continuing to discuss the board’s request for amendment with the author’s staff in advance of the August hearing in Assembly Judiciary.

FISCAL IMPACT ON THE BOARD:

Staff has not identified any specific fiscal impact on the board or its operations.

According to the 6/28/13 Analysis of the ASM Committee on Business, Professions and Consumer Protection, the following are in Support of the bill:

SUPPORT:

Conference of California Bar Associations (sponsor)
 California Association of Joint Powers Authorities
 California Hospital Association
 California Medical Association
 Civil Justice Association of California
 Food Allergy Research and Education

Hospital Corporation of America

Opposition
None on file.



California
LEGISLATIVE INFORMATION

SB-669 Emergency medical care: epinephrine auto-injectors. (2013-2014)

As Amended 7/3/13 - Today's Law As Amended

SECTION 1. *Section 4119.3 is added to the Business and Professions Code, to read:*

4119.3. *(a) Notwithstanding any other law, a pharmacy may dispense epinephrine auto-injectors to a prehospital emergency medical care person, first responder, or lay rescuer for the purpose of rendering emergency care in accordance with Section 1797.197a of the Health and Safety Code, if both of the following requirements are met:*

(1) A physician and surgeon provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed to a person described in subdivision (b) of Section 1797.197a of the Health and Safety Code. The physician and surgeon may issue the prescription only upon presentation of a current certificate demonstrating that the person is trained and qualified under Section 1797.197a of the Health and Safety Code to administer an epinephrine auto-injector to another person in an emergency situation. The prescription shall specify that the dispensed epinephrine auto-injector is for "EMS Purposes Only" and that the named recipient is a "Section 1797.197a Responder." A new prescription shall be written for any additional epinephrine auto-injectors required.

(2) (A) The pharmacy shall label each epinephrine auto-injector dispensed with all of the following:

(i) The name of the person to whom the prescription was issued.

(ii) The designations "Section 1797.197a Responder" and "EMS Purposes Only."

(iii) The dosage, use, and expiration date.

(B) Each dispensed prescription shall include the manufacturer's product information sheet for the epinephrine auto-injector.

(b) The person described in subdivision (b) of Section 1797.197a of the Health and Safety Code receiving epinephrine auto-injectors pursuant to this section shall make and maintain a record for five years reflecting dates of receipt, use, and destruction of each auto-injector dispensed, the name of any person to whom epinephrine was administered using an auto-injector, and the circumstances and manner of destruction of any auto-injectors.

(c) The epinephrine auto-injectors dispensed pursuant to this section may be used only for the purpose, and under the circumstances, described in Section 1797.197a of the Health and Safety Code.

SEC. 2. *Section 1714.23 is added to the Civil Code, to read:*

1714.23. *(a) For purposes of this section, the following definitions shall apply:*

(1) "Anaphylaxis" means a potentially life-threatening hypersensitivity or allergic reaction to a substance.

(A) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.

(B) Causes of anaphylaxis may include, but are not limited to, insect stings or bites, foods, drugs, and other allergens, as well as idiopathic or exercise-induced anaphylaxis.

(2) "Epinephrine auto-injector" means a disposable drug delivery system with a spring-activated concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis.

(b) Any person described in subdivision (b) of Section 1797.197a of the Health and Safety Code who

administers an epinephrine auto-injector, in good faith and not for compensation, to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with the requirements and standards of Section 1797.197a of the Health and Safety Code.

(c) The protection specified in subdivision (b) shall not apply in a case of personal injury or wrongful death that results from the gross negligence or willful or wanton misconduct of the person who renders emergency care treatment by the use of an epinephrine auto-injector.

(d) (1) In order to encourage training of persons described in subdivision (b) of Section 1797.197a of the Health and Safety Code in the emergency administration of epinephrine auto-injectors, and to encourage that emergency care, a local agency, entity of state or local government, or other public or private organization that sponsors, authorizes, supports, finances, or supervises the training of those persons, or develops standards in accordance with Section 1797.197a of the Health and Safety Code, including, but not limited to, the California Emergency Medical Services (EMS) Authority, the local emergency medical system agency, the county department of health, the State Department of Public Health, the American Academy of Allergy, Asthma & Immunology, the American Academy of Pediatrics, the American Heart Association, the American Red Cross, and the California Medical Association, shall not be liable for civil damages alleged to result from those training programs or standards.

(2) The protection specified in paragraph (1) shall not apply when it is alleged that the personal injury or wrongful death was proximately caused by an authorized training provider's failure to meet the minimal statutory training requirements and standards established pursuant to subdivision (c) of Section 1797.197a of the Health and Safety Code, or it is alleged that the authorized training provider otherwise demonstrated gross negligence in the training or certification of an individual whose subsequent actions caused personal injury or wrongful death in the rendering of emergency care treatment by the use of an epinephrine auto-injector.

(e) Nothing in this section relieves a manufacturer, designer, developer, distributor, or supplier of an epinephrine auto-injector of liability under any other applicable law.

SEC. 3. *Section 1797.197a is added to the Health and Safety Code, to read:*

1797.197a. *(a) For purposes of this section, the following definitions shall apply:*

(1) "Anaphylaxis" means a potentially life-threatening hypersensitivity or allergic reaction to a substance.

(A) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.

(B) Causes of anaphylaxis may include, but are not limited to, insect stings or bites, foods, drugs, and other allergens, as well as idiopathic or exercise-induced anaphylaxis.

(2) "Epinephrine auto-injector" means a disposable drug delivery system with a spring-activated concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis.

(3) "First responder" means a police officer, firefighter, rescue worker, or any other person who provides emergency response, first aid care, or other medically related assistance either in the course of the person's occupational duties or as a volunteer.

(4) "Lay rescuer" means any person who has met the training standards and other requirements of this section but who is not otherwise licensed or certified to use an epinephrine auto-injector on another person.

(5) "Prehospital emergency medical care person" has the same meaning as defined in paragraph (2) of subdivision (a) of Section 1797.189.

(b) A prehospital emergency medical care person, first responder, or a lay rescuer may use an epinephrine auto-injector to render emergency care to another person if all of the following requirements are met:

(1) The epinephrine auto-injector is legally obtained by prescription from an authorized health care provider. An authorized health care provider may issue a prescription for an epinephrine auto-injector to a person described in this subdivision for the purpose of rendering emergency care to another person, upon

presentation of current certification demonstrating that person is trained and qualified pursuant to this section to administer an epinephrine auto-injector as a prehospital emergency medical care person, first responder, or lay rescuer.

(2) The epinephrine auto-injector is used on another, with the expressed or implied consent of that person, to address the conditions described in subparagraph (A) of paragraph (1) of subdivision (a).

(3) The epinephrine auto-injector is stored and maintained as directed by the manufacturer's instructions for that product.

(4) The person using the epinephrine auto-injector has successfully completed a course of training with an authorized training provider, as described in subdivision (c), and has current certification of training issued by the provider.

(c) (1) The authorized training providers shall be approved, and the minimum standards for training and the use and administration of epinephrine auto-injectors pursuant to this section shall be established and approved, by the California Emergency Medical Services (EMS) Authority. The authority may designate existing training standards for the use and administration of epinephrine auto-injectors by first responders and prehospital emergency medical care personnel to satisfy the requirements of this section.

(2) The minimum training and requirements shall include all of the following components:

(A) Techniques for recognizing circumstances, signs, and symptoms of anaphylaxis.

(B) Standards and procedures for proper storage and emergency use of epinephrine auto-injectors.

(C) Emergency followup procedures, including activation of the Emergency Medical System, by calling the emergency 911 telephone number or otherwise alerting and summoning more advanced medical personnel and services.

(D) Compliance with all regulations governing the training, indications, use, and precautions concerning epinephrine auto-injectors.

(E) Written material covering the information required under this provision, including the manufacturer product information sheets on commonly available models of epinephrine auto-injectors.

(F) Completion of a training course in cardiopulmonary resuscitation and the use of an automatic external defibrillator (AED) for infants, children, and adults that complies with regulations adopted by the EMS Authority and the standards of the American Heart Association or the American Red Cross, and a current certification for that training.

(3) Training certification shall be valid for no more than two years, after which recertification with an authorized training provider is required.

(d) This section shall not apply to a school district or county office of education, or its personnel, that provides and utilizes epinephrine auto-injectors to provide emergency medical aid pursuant to Section 49414 of the Education Code.

(e) This section shall not be construed to limit or restrict the ability of prehospital emergency medical care personnel, under any other statute or regulation, to administer epinephrine, including the use of epinephrine auto-injectors, or to require additional training or certification beyond what is already required under the other statute or regulation.

SEC. 4. *No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.*



Bill Number:	SB 809
Introduced	2/22/13
Last Amend:	June 26, 2013
Author:	Senator Mark DeSaulnier
Topic:	CURES Funding (Sponsor: Attorney General)
Position:	Support

Current Bill Status: 8/13/13 – Set for Hearing in ASM Business, Professions and Consumer Protection

Affected Sections: Add Sections 805.8 and 2196.7 to the Business and Professions Code
Amend Sections 11164.1, 11165 and 11165.1 of the Health and Safety Code
Add Section 11165.4 to the Health and Safety Code

EXISTING LAW:

Health and Safety Code Sections 11165 – 11165.3 establishes and defines the parameters and use of the CURES Program within the California Department of Justice. Under current law, prescribers and pharmacies are required to report each week to DOJ every Schedule II, III and IV prescription dispensed.

Following substantial funding reductions that were part of the 2011-2012 Governor's Budget, the Department of Justice has been maintaining the program with limited resources. In 2009 DOJ launched an automated Prescription Drug Monitoring Program (PDMP) within CURES. This program allows authorized users, including pharmacists, prescribers, and others, to access at the point of care patient controlled substance prescription information. This information allows prescribers and pharmacists to make informed decisions about patient care and to detect patients who may be abusing controlled substances by obtaining multiple prescriptions from various practitioners.

THIS BILL WOULD:

- Establish the CURES Fund
- Modernize the existing CURES Program within the California Department of Justice, and specify dedicated funding mechanisms
- Require specified health care practitioner fees to be increased by up to 1.16 percent to provide dedicated funds to sustain CURES, and
- Require the Board of Pharmacy to increase fees charge to wholesalers, nonresident wholesalers, and veterinary food-animal drug retailers by up to 1.16 percent to be deposited into the CURES Fund for sustaining the CURES Program

FISCAL IMPACT ON THE BOARD:

Currently, the board through an interagency agreement with the Department of Justice provides CURES with \$92,000 a year (FY 11/12 – FY 13/14), for a total deposit of \$276,000 for the three years. The board does not receive any itemization or other detailed accounting from the DOJ related to actual maintenance costs for the CURES system. The DOJ contracts with Atlantic Associates (believed to be approximately \$1,000,000 year) who collects and cleans the data in the system.

As proposed, SB 809 would increase application and renewal fees of specified by licensees by up to 1.16 percent. Preliminary estimates indicate this 1.16% increase may result in approximately \$60,000 per year deposited into the CURES Fund from the following licensing categories, based on a 3-year average of the following licensee populations at the current statutory maximum fee:

	Current Statutory Max (Fee)
Pharmacist Applicants/Exam (4400d)	260.00
Pharmacist License (4400e)	195.00
Pharmacist Renewals (4400e)	195.00
Wholesalers (4400f)	780.00
Nonresident Wholesalers (4400j)	780.00
Veterinary Food-Animal Drug Retailers (4400s)	425.00
Vet Food-Animal Drug Retailer Renewal (4400s)	325.00

HISTORY:

Date	Action
06/26/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/26/13	From committee: Do pass and re-refer to Com. on B.,P. & C.P. (Ayes 7. Noes 0.) (June 25). Re-referred to Com. on B.,P. & C.P.
06/17/13	Referred to Com. on PUB. S.
05/30/13	In Assembly. Read first time. Held at Desk.
05/30/13	Read third time. Urgency clause adopted. Passed. (Ayes 39. Noes 0. Page 1201.) Ordered to the Assembly.
05/29/13	Read second time. Ordered to third reading.
05/28/13	Ordered to second reading.
05/28/13	Read third time and amended.
05/28/13	Reconsideration granted. (Ayes 39. Noes 0. Page 1115.)
05/28/13	Motion to reconsider made by Senator DeSaulnier.
05/28/13	Read third time. Urgency clause refused adoption. (Ayes 23. Noes 14. Page 1115.)
05/24/13	Read second time and amended. Ordered to third reading.
05/23/13	From committee: Do pass as amended. (Ayes 5. Noes 1. Page 1020.) (May 23).
05/21/13	Set for hearing May 23.
05/20/13	Placed on APPR. suspense file.
05/16/13	Set for hearing May 20.
05/14/13	Read second time and amended. Re-referred to Com. on APPR.
05/13/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 5. Noes 2. Page 882.) (May

Date	Action
8).	
05/01/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on GOV. & F.
04/24/13	Set for hearing May 8.
04/16/13	From committee: Do pass and re-refer to Com. on GOV. & F. (Ayes 7. Noes 2. Page 564.) (April 15). Re-referred to Com. on GOV. & F.
03/28/13	Set for hearing April 15.
03/11/13	Referred to Coms. on B., P. & E.D. and GOV. & F.
02/25/13	Read first time.
02/24/13	From printer. May be acted upon on or after March 26.
02/22/13	Introduced. To Com. on RLS. for assignment. To print.



California

LEGISLATIVE INFORMATION

SB-809 Controlled substances: reporting. (2013-2014)

As Amended 6/26/13 - Today's Law As Amended

SECTION 1. *The Legislature finds and declares all of the following:*

(a) The Controlled Substance Utilization Review and Evaluation System (CURES) is a valuable preventive, investigative, and educational tool for health care providers, regulatory boards, educational researchers, and law enforcement. Recent budget cuts to the Attorney General's Division of Law Enforcement have resulted in insufficient funding to support the CURES Prescription Drug Monitoring Program (PDMP). The PDMP is necessary to ensure health care professionals have the necessary data to make informed treatment decisions and to allow law enforcement to investigate diversion of prescription drugs. Without a dedicated funding source, the CURES PDMP is not sustainable.

(b) Each year CURES responds to more than 800,000 requests from practitioners and pharmacists regarding all of the following:

(1) Helping identify and deter drug abuse and diversion of prescription drugs through accurate and rapid tracking of Schedule II, Schedule III, and Schedule IV controlled substances.

(2) Helping practitioners make better prescribing decisions.

(3) Helping reduce misuse, abuse, and trafficking of those drugs.

(c) Schedule II, Schedule III, and Schedule IV controlled substances have had deleterious effects on private and public interests, including the misuse, abuse, and trafficking in dangerous prescription medications resulting in injury and death. It is the intent of the Legislature to work with stakeholders to fully fund the operation of CURES which seeks to mitigate those deleterious effects and serve as a tool for ensuring safe patient care, and which has proven to be a cost-effective tool to help reduce the misuse, abuse, and trafficking of those drugs.

(d) The following goals are critical to increase the effectiveness and functionality of CURES:

(1) Upgrading the PDMP so that it is capable of accepting real-time updates and is accessible in real-time, 24 hours a day, seven days a week.

(2) Upgrading all prescription drug monitoring programs in California so that they are capable of operating in conjunction with all national prescription drug monitoring programs.

(3) Providing subscribers to prescription drug monitoring programs access to information relating to controlled substances dispensed in California, including those dispensed through the United States Department of Veterans Affairs, the Indian Health Service, the Department of Defense, and any other entity with authority to dispense controlled substances in California.

(4) Upgrading the PDMP so that it is capable of accepting electronic prescriptions, thereby enabling more reliable, complete, and timely prescription monitoring.

SEC. 2. *Section 805.8 is added to the Business and Professions Code, to read:*

805.8. *(a) (1) In addition to the fees charged for licensure, certification, and renewal, at the time those fees are charged, the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the Naturopathic Medicine Committee of the Osteopathic Medical Board of California, the State Board of Optometry, and the California Board of Podiatric Medicine shall charge each licensee authorized pursuant to Section 11150 of the Health and Safety Code to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV*

controlled substances a fee of up to 1.16 percent of the renewal fee that the licensee was subject to as of July 1, 2013, to be assessed annually. This fee shall be due and payable at the time the licensee renews his or her license and shall be submitted with the licensee's renewal fee. In no case shall this fee exceed the reasonable costs associated with operating and maintaining CURES for the purpose of regulating prescribers and dispensers of controlled substances licensed or certificated by these boards.

(2) In addition to the fees charged for licensure, certification, and renewal, at the time those fees are charged, the California State Board of Pharmacy shall charge wholesalers and nonresident wholesalers of dangerous drugs, licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9, a fee of up to 1.16 percent of the renewal fee that the wholesaler or nonresident wholesaler was subject to as of July 1, 2013, to be assessed annually. This fee shall be due and payable at the time the wholesaler or nonresident wholesaler renews its license and shall be submitted with the wholesaler's or nonresident wholesaler's renewal fee. In no case shall this fee exceed the reasonable costs associated with operating and maintaining CURES for the purpose of regulating wholesalers and nonresident wholesalers of dangerous drugs licensed or certificated by that board.

(3) In addition to the fees charged for licensure, certification, and renewal, at the time those fees are charged, the California State Board of Pharmacy shall charge veterinary food-animal drug retailers, licensed pursuant to Article 15 (commencing with Section 4196) of Chapter 9, a fee of up to 1.16 percent of the renewal fee that the drug retailer was subject to as of July 1, 2013, to be assessed annually. This fee shall be due and payable at the time the drug retailer renews its license and shall be submitted with the drug retailers' renewal fee. In no case shall this fee exceed the reasonable costs associated with operating and maintaining CURES for the purpose of regulating veterinary food-animal drug retailers licensed or certificated by that board.

(b) The funds collected pursuant to subdivision (a) shall be deposited in the CURES accounts, which are hereby created, within the Contingent Fund of the Medical Board of California, the State Dentistry Fund, the Pharmacy Board Contingent Fund, the Veterinary Medical Board Contingent Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, the Osteopathic Medical Board of California Contingent Fund, the Optometry Fund, and the Board of Podiatric Medicine Fund. Moneys in the CURES accounts of each of those funds shall, upon appropriation by the Legislature, be available to the Department of Justice solely for operating and maintaining CURES for the purposes of regulating prescribers and dispensers of controlled substances. All moneys received by the Department of Justice pursuant to this section shall be deposited in the CURES Fund described in Section 11165 of the Health and Safety Code.

SEC. 3. Section 2196.8 is added to the Business and Professions Code, to read:

2196.8. The board shall periodically develop and disseminate information and educational material regarding assessing a patient's risk of abusing or diverting controlled substances and information relating to the Controlled Substance Utilization Review and Evaluation System (CURES), described in Section 11165 of the Health and Safety Code, to each licensed physician and surgeon and to each general acute care hospital in this state. The board shall consult with the State Department of Health Care Services and the Department of Justice in developing the materials to be distributed pursuant to this section.

SEC. 4. Section 11164.1 of the Health and Safety Code is amended to read:

11164.1. (a) (1) Notwithstanding any other provision of law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) All prescriptions for Schedule II and Schedule III controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision ~~(e)~~ (e) of Section 11165.

(b) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

(c) This section shall become operative on January 1, 2005.

SEC. 5. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist *health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances*, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds ~~from the~~ *in the CURES accounts within the* Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, ~~and the~~ *the Naturopathic Doctor's Fund, the* Osteopathic Medical Board of California Contingent Fund, *the Veterinary Medical Board Contingent Fund, the Optometry Fund, the Board of Podiatric Medicine Fund, and the CURES Fund*, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to ~~prescribe~~ *prescribe, order, administer, furnish*, or dispense these controlled substances.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds for the Department of Justice for the purpose of funding CURES.

~~(b) (c) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The department~~ *Department of Justice* may seek and use grant funds to pay the costs incurred ~~from the reporting of controlled substance prescriptions to CURES. Funds~~ *by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES. Grant funds* shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, ~~or~~ *the* Osteopathic Medical Board of California Contingent ~~Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to~~ *Fund, the Veterinary Medical Board Contingent Fund, the Optometry Fund, or the Board of Podiatric Medicine Fund, for the purpose of funding* CURES.

(d) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

~~(e) (2)~~ CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal ~~persons or~~ public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party. *The Department of Justice may establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, and security of the information within CURES, consistent with this subdivision.*

~~(d) (e)~~ For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing ~~pharmacy or clinic shall provide~~ *pharmacy, clinic, or other dispenser shall report* the following information to the Department of Justice ~~on a weekly basis~~ *as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, unless monthly reporting is permitted pursuant to subdivision (f) of Section 11190*, and in a format specified by the Department of Justice:

(1) Full name, address, and ~~the~~ telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure and license ~~number;~~ *number, the* federal controlled substance registration ~~number;~~ *number*, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

- (4) ~~NDC (National Drug Code)~~ *National Drug Code (NDC)* number of the controlled substance dispensed.
- (5) Quantity of the controlled substance dispensed.
- (6) ~~ICD-9 (diagnosis code)~~, *International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code*, if available.
- (7) Number of refills ordered.
- (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
- (9) Date of origin of the prescription.
- (10) Date of dispensing of the prescription.

~~(e) (f) This section shall become operative on January 1, 2005. The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber invitees shall be licensed by one of the boards or committees identified in subdivision (a) of Section 805.8 of the Business and Professions Code, in active practice in California, and a regular user of CURES.~~

(g) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (a) of Section 805.8 of the Business and Professions Code, one or more of the regulatory boards or committees identified in subdivision (a) of Section 805.8 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program.

(h) The Department of Justice may establish a process to educate authorized subscribers of CURES on how to access and use CURES.

(i) The CURES Fund is hereby established within the State Treasury. The CURES Fund shall consist of all funds made available to the Department of Justice for the purpose of funding CURES. Money in the CURES Fund shall, upon appropriation by the Legislature, be available for allocation to the Department of Justice for the purpose of funding CURES.

SEC. 6. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist ~~may provide a notarized~~ *shall submit an* application developed by the Department of Justice to obtain approval to access information ~~stored on the Internet~~ *online* regarding the controlled substance history of a patient *that is stored on the Internet and* maintained within the Department of Justice, ~~and~~ *and, upon approval,* the department ~~may shall~~ release to that practitioner or ~~pharmacist,~~ *pharmacist* the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(A) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

- (i) Materially falsifying an application for a subscriber.
- (ii) Failure to maintain effective controls for access to the patient activity report.
- (iii) Suspended or revoked federal Drug Enforcement Administration (DEA) registration.
- (iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.
- (v) Any subscriber accessing information for any other reason than caring for his or her patients.

(B) Any authorized subscriber shall notify the Department of Justice within ~~10~~ *30* days of any changes to the subscriber account.

(2) To allow sufficient time for licensed health care practitioners eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances and a pharmacist to apply and receive access to PDMP, a written request may be made, until July 1, 2012, and the Department of Justice may release to that practitioner or pharmacist the history of controlled substances dispensed to an individual under his or her care based on data

contained in CURES.

(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(c) ~~It~~ (1) *Until the Department of Justice has issued the notification described in paragraph (3), in* order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(2) Upon the Department of Justice issuing the notification described in paragraph (3), licensed health care practitioners eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances and pharmacists shall be strongly encouraged to access and consult the electronic history of controlled substances dispensed to an individual under his or her care prior to prescribing or dispensing a Schedule II, Schedule III, or Schedule IV controlled substance.

(3) The Department of Justice shall notify licensed health care practitioners and pharmacists who have submitted the application required pursuant to subdivision (a) when the department determines that CURES is capable of accommodating all users, but not before June 1, 2015. The department shall provide a copy of the notification to the Secretary of State, the Secretary of the Senate, the Chief Clerk of the Assembly, and the Legislative Counsel, and shall post the notification on the department's Internet Web site.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

SEC. 7. *Section 11165.4 is added to the Health and Safety Code, to read:*

11165.4. *(a) The Department of Justice may seek private funds from insurers, health care service plans, and qualified manufacturers for the purpose of supporting CURES. Insurers, health care service plans, and qualified manufacturers may contribute by submitting their payment to the Controller for deposit into the CURES Fund established pursuant to subdivision (e) of Section 11165. The department shall make information about the amount and the source of all private funds it receives for support of CURES available to the public. Contributions to the CURES Fund pursuant to this subdivision shall be nondeductible for state tax purposes.*

(b) For purposes of this section, the following definitions apply:

(1) "Controlled substance" means a drug, substance, or immediate precursor listed in any schedule in Section 11055, 11056, or 11057 of the Health and Safety Code.

(2) "Health care service plan" means an entity licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(3) "Insurer" means an admitted insurer writing health insurance, as defined in Section 106 of the Insurance Code, and an admitted insurer writing workers' compensation insurance, as defined in Section 109 of the Insurance Code.

(4) "Qualified manufacturer" means a manufacturer of a controlled substance, but does not mean a wholesaler or nonresident wholesaler of dangerous drugs, regulated pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code, a veterinary food-animal drug retailer, regulated pursuant to Article 15 (commencing with Section 4196) of Chapter 9 of Division 2 of the Business and Professions Code, or an individual regulated by the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, or the California Board of Podiatric Medicine.

SEC. 8. *This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts*

constituting the necessity are:

In order to protect the public from the continuing threat of prescription drug abuse at the earliest possible time, it is necessary that this act take effect immediately.



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

May 10, 2013

The Honorable Mark DeSaulnier
Member, California State Senate
State Capitol, Room 5035
Sacramento, CA 95816

RE: SB 809 - Support

Dear Senator DeSaulnier:

The Board of Pharmacy supports SB 809 which would provide for dedicated funding for the Controlled Substances Utilization Review and Evaluation System (CURES) and to ensure point-of-care system access to the Prescription Drug Monitoring Program (PDMP) for pharmacists and prescribers. The Board of Pharmacy has long worked with the Department of Justice to support and ensure the operation of CURES. Moreover, as the regulator of the state's 6,900 pharmacies, we regularly utilize CURES data to identify potential drug diversion and violations of Pharmacy Law.

The board very much appreciates your long-term efforts to secure permanent funding for CURES and to establish a PDMP system that can be accessed by prescribers and pharmacists at the time they provide care to patients.

Please don't hesitate to contact me at (916) 574-7913 or the board's Executive Officer Virginia (Giny) Herold at (916) 574-7911 if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Carolyn Klein".

CAROLYN KLEIN, Manager
Legislation and Regulations



Bill Number:	SB 62
Introduced	1/8/13
Last Amend:	June 27, 2013
Author:	Senator Curren Price, Jr.
Topic:	Coroners: reporting requirements: prescription drug use
Position:	Support (2/13/13)

Current Bill Status: In Assembly Appropriations (As of 7/15/13 no hearing date set)

Affected Sections: Amend Section 802.5 Business and Professions Code (BPC)

SUMMARY

Under existing law, Section 802.5 of the Business and Professions Code, when a coroner receives information that a death may be the result of gross negligence or incompetence, as specified, the coroner shall file a report with the Medical Board of California and other entities. The introduced version of the bill would have added the California State Board of Pharmacy to those entities to which these reports shall be transmitted, and the Board established a position of Support at the February 2013 Board Meeting.

The April 9, 2013, amendment struck from the list of entities that would receive the reports from the coroner's offices. Since that time, staff has requested amendments to authorize the board's specified in subdivision (a) of the bill to share those coroners reports and other information received with the Board of Pharmacy.

EXISTING LAW

Section 802.5 BPC requires that when a coroner receives information that is based on findings where a death may be the result of a physician and surgeon's, podiatrist's, or physician assistant's gross negligence or incompetence, a report containing specified information shall be filed with specified healing arts boards. The section requires that the initial report be followed, within 90 days, by copies of the coroner's report, autopsy protocol, and all other relevant information. The information reported pursuant to this section is deemed confidential, and provides civil immunity from those required to file such a report.

THIS BILL WOULD:

As amended, where a coroner receives information based on findings that a death may be the result of prescription drug use, a report containing specified information shall be filed with specified entities. The section specifies information that is to be contained in the report, and

requires that within 90 days of the initial report, copies of the coroner's report, autopsy protocol, and all other relevant information be provided.

FISCAL IMPACT ON THE BOARD:

Depending on the number of reports the board receives, the board may require additional staff resources (four inspectors) to conduct inspections and compliance investigations associated with these reports.

HISTORY

Date	Action
06/27/13	Read second time and amended. Re-referred to Com. on APPR.
06/26/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 9. Noes 4.) (June 25).
06/14/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/10/13	Referred to Com. on B.,P. & C.P.
05/29/13	In Assembly. Read first time. Held at Desk.
05/28/13	Read third time. Passed. (Ayes 39. Noes 0. Page 1096.) Ordered to the Assembly.
05/24/13	Read second time. Ordered to third reading.
05/23/13	From committee: Do pass. (Ayes 7. Noes 0. Page 1006.) (May 23).
05/17/13	Set for hearing May 23.
04/29/13	Placed on APPR. suspense file.
04/23/13	Set for hearing April 29.
04/22/13	Read second time and amended. Re-referred to Com. on APPR.
04/18/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 10. Noes 0. Page 563.) (April 15).
04/09/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
03/28/13	Set for hearing April 15.
01/17/13	Referred to Com. on B., P. & E.D.
01/09/13	From printer. May be acted upon on or after February 8.
01/08/13	Introduced. Read first time. To Com. on RLS. for assignment. To print.



California

LEGISLATIVE INFORMATION

SB-62 Coroners: reporting requirements: prescription drug use. (2013-2014)

As Amended 6/27/13 - Today's Law As Amended

SECTION 1. Section 802.5 of the Business and Professions Code is amended to read:

802.5. (a) When a coroner receives information that is based on findings that were reached by, or documented and approved ~~by a board-certified or board-eligible~~ by, a pathologist indicating that a death may be the result of a physician and surgeon's, podiatrist's, or physician assistant's gross negligence or incompetence, a report shall be filed with the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, or the Physician Assistant Board. The initial report shall include the name of the decedent, date and place of death, attending ~~physicians or podiatrists,~~ *physicians, podiatrists, or physician assistants*, and all other relevant information available. The initial report shall be followed, within 90 ~~days,~~ *days or as soon as possible once the coroner's final report of investigation is complete*, by copies of the coroner's report, autopsy protocol, and all other relevant information.

(b) ~~The A~~ report required by ~~this section subdivision (a)~~ shall be confidential. No coroner, physician and surgeon, or medical examiner, nor any authorized agent, shall be liable for damages in any civil action as a result of his or her acting in compliance with this section. No ~~board-certified or board-eligible~~ pathologist, nor any authorized agent, shall be liable for damages in any civil action as a result of his or her providing information under subdivision (a).

(c) When a coroner receives information that is based on findings that were reached by, or documented and approved by, a pathologist indicating that the cause of death is due to a Schedule II, III, or IV drug, a report shall be filed with the Medical Board of California. The initial report shall include, when known, the name of the decedent, date and place of death, attending physicians, podiatrists, or physician assistants, and all other relevant information, including, but not limited to, any information available to identify the prescription drugs, prescribing physicians, and dispensing pharmacy. The initial report shall be followed, within 90 days or as soon as possible once the coroner's final report of investigation is complete, by copies of the coroner's report, autopsy protocol, and all other relevant information.

SEC. 2. *If the Commission on State Mandates determines that this act contains costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.*



Bill Number:	AB 258
Introduced	2/7/13
Amendment Date:	April 23, 2013
Author:	Assembly Member Colonel Rocky J. Chavez
Topic:	State Agencies: Veterans
Position:	(none)

Affected Sections: Add Section 11019.11 to the Government Code (GC)

Status: As of 7/2/13, on the Senate Third Reading File

EXISTING LAW:

Article 1 [of Chapter 1 of Part 1 of Division 3 of Title 2] of the Government Code (Sections 11000.-11019.10) specifies general requirements for state departments and agencies.

THIS BILL WOULD:

Add Section 11019.11 to the Government Code to specify that on or after July 1, 2014, every agency that requests on any written form or written publication, or through its Internet Web site, whether a person is a veteran, that the information be requested in the following format:

“Have you ever served in the United States military?”

ACCORDING TO THE AUTHOR:

SB 258 would standardize the way any state government organization would ask an individual as to their veteran status. The author states that individuals who may not identify themselves as a veteran because the way a question is asked may lose out on many Federal benefits to which they are entitled.

STAFF COMMENTS:

The board does not currently query as to a person’s veteran status on individual applications for Pharmacist, Pharmacist Intern, or Pharmacy Technician. This is one of many bills the Department of Consumer Affairs is tracking, and staff continue to monitor this measure.

RELATED LEGISLATION:

AB 1057 would add Section 114.5 to the Business and Professions Code to require every board to inquire on every application for licensure, if the individual applying is serving in, or has previously served in, the military.

FISCAL IMPACT ON THE BOARD:

If enacted, and if AB 1057 is also enacted, the board would need to update its application forms, which would be absorbed with existing staff resources.

HISTORY

7/2/13 – Read second time. Ordered to third reading.

7/1/13 – Passed Senate Appropriations

6/11/13 – Passed out of Senate Com. on Veterans Affairs

4/25/13 – Approved by the Assembly

4/11/13 – Passed from ASM Appropriations

4/4/13 – Passed out of Assembly Comm. on Veterans Affairs



California
LEGISLATIVE INFORMATION

AB-258 State agencies: veterans. (2013-2014)

As Amended 4/23/13 - Today's Law As Amended

SECTION 1. *Section 11019.11 is added to the Government Code, to read:*

11019.11. *(a) Every state agency that requests on any written form or written publication, or through its Internet Web site, whether a person is a veteran, shall request that information only in the following format: "Have you ever served in the United States military?"*

(b) This section shall apply only to a written form or written publication that is newly printed on or after July 1, 2014.



Bill Number:	AB 512
Introduced	2/20/13
Amendment Date:	
Author:	Assembly Member Rendon
Topic:	Healing Arts: Licensure Exemption
Position:	Support (4/24/13)

Affected Sections: Amend Section 901 of the Business and Professions Code (BPC)

Status: As of 7/8/13, Passed to the Senate

EXISTING LAW:

Section 901 BPC provides that until 1/1/14, an individual may be exempt from the licensure and regulation requirements for defined health care practitioners, to offer or provide health care services for which he or she is licensed or certified, through a sponsored event, as defined. This section also requires an exempt health care practitioner to obtain prior authorization to provide these services from the applicable licensing board, as defined, and to satisfy other requirements, including the payment of a fee as determined by a board.

THIS BILL:

Currently, until January 1, 2014, an individual can be exempt from licensure and regulation requirements to provide health care services through sponsored events. AB 512 extends these provisions to 2018.

The board established a Support position for AB 512 and stated its support of free and sponsored health care events. The board noted it is in the board's best interest to ensure that matters related to the practice of pharmacy at these events were adequately enforced and monitored.

ACCORDING TO THE AUTHOR:

The author states that the Medical Board of California promulgated regulations in August 2012, but they were not done in time to allow out-of-state practitioners to volunteer at an LA event; The author states that the program needs additional time to demonstrate its success.

STAFF COMMENTS:

The board does not have regulations to specify requirements for pharmacists from other states to serve at sponsored healthcare events, as allowed by Section 901 BPC.

FISCAL IMPACT ON THE BOARD:

None identified

HISTORY

Date	Action
07/08/13	Read third time. Passed. Ordered to the Assembly.
06/25/13	Read second time. Ordered to third reading.
06/24/13	From committee: Do pass. (Ayes 7. Noes 0.) (June 24).
06/10/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 10. Noes 0.) (June 10). Re-referred to Com. on APPR.
05/09/13	Referred to Com. on B., P. & E.D.
04/25/13	In Senate. Read first time. To Com. on RLS. for assignment.
04/25/13	Read third time. Passed. Ordered to the Senate. (Ayes 74. Noes 0. Page 1111.)
04/18/13	Read second time. Ordered to third reading.
04/17/13	From committee: Do pass. (Ayes 16. Noes 0.) (April 17).
04/09/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (April 9). Re-referred to Com. on APPR.
03/04/13	Referred to Com. on B.,P. & C.P.
02/21/13	From printer. May be heard in committee March 23.
02/20/13	Read first time. To print.



California
LEGISLATIVE INFORMATION

AB-512 Healing arts: licensure exemption. (2013-2014)

As Introduced 2/20/13

SECTION 1. Section 901 of the Business and Professions Code is amended to read:

901. (a) For purposes of this section, the following provisions apply:

(1) "Board" means the applicable healing arts board, under this division or an initiative act referred to in this division, responsible for the licensure or regulation in this state of the respective health care practitioners.

(2) "Health care practitioner" means any person who engages in acts that are subject to licensure or regulation under this division or under any initiative act referred to in this division.

(3) "Sponsored event" means an event, not to exceed 10 calendar days, administered by either a sponsoring entity or a local government, or both, through which health care is provided to the public without compensation to the health care practitioner.

(4) "Sponsoring entity" means a nonprofit organization organized pursuant to Section 501(c)(3) of the Internal Revenue Code or a community-based organization.

(5) "Uninsured or underinsured person" means a person who does not have health care coverage, including private coverage or coverage through a program funded in whole or in part by a governmental entity, or a person who has health care coverage, but the coverage is not adequate to obtain those health care services offered by the health care practitioner under this section.

(b) A health care practitioner licensed or certified in good standing in another state, district, or territory of the United States who offers or provides health care services for which he or she is licensed or certified is exempt from the requirement for licensure if all of the following requirements are met:

(1) Prior to providing those services, he or she does all of the following:

(A) Obtains authorization from the board to participate in the sponsored event after submitting to the board a copy of his or her valid license or certificate from each state in which he or she holds licensure or certification and a photographic identification issued by one of the states in which he or she holds licensure or certification. The board shall notify the sponsoring entity, within 20 calendar days of receiving a request for authorization, whether that request is approved or denied, provided that, if the board receives a request for authorization less than 20 days prior to the date of the sponsored event, the board shall make reasonable efforts to notify the sponsoring entity whether that request is approved or denied prior to the date of that sponsored event.

(B) Satisfies the following requirements:

(i) The health care practitioner has not committed any act or been convicted of a crime constituting grounds for denial of licensure or registration under Section 480 and is in good standing in each state in which he or she holds licensure or certification.

(ii) The health care practitioner has the appropriate education and experience to participate in a sponsored event, as determined by the board.

(iii) The health care practitioner shall agree to comply with all applicable practice requirements set forth in this division and the regulations adopted pursuant to this division.

(C) Submits to the board, on a form prescribed by the board, a request for authorization to practice without a license, and pays a fee, in an amount determined by the board by regulation, which shall be available, upon appropriation, to cover the cost of developing the authorization process and processing the request.

(2) The services are provided under all of the following circumstances:

- (A) To uninsured or underinsured persons.
 - (B) On a short-term voluntary basis, not to exceed a 10-calendar-day period per sponsored event.
 - (C) In association with a sponsoring entity that complies with subdivision (d).
 - (D) Without charge to the recipient or to a third party on behalf of the recipient.
- (c) The board may deny a health care practitioner authorization to practice without a license if the health care practitioner fails to comply with this section or for any act that would be grounds for denial of an application for licensure.
- (d) A sponsoring entity seeking to provide, or arrange for the provision of, health care services under this section shall do both of the following:
- (1) Register with each applicable board under this division for which an out-of-state health care practitioner is participating in the sponsored event by completing a registration form that shall include all of the following:
 - (A) The name of the sponsoring entity.
 - (B) The name of the principal individual or individuals who are the officers or organizational officials responsible for the operation of the sponsoring entity.
 - (C) The address, including street, city, ZIP Code, and county, of the sponsoring entity's principal office and each individual listed pursuant to subparagraph (B).
 - (D) The telephone number for the principal office of the sponsoring entity and each individual listed pursuant to subparagraph (B).
 - (E) Any additional information required by the board.
 - (2) Provide the information listed in paragraph (1) to the county health department of the county in which the health care services will be provided, along with any additional information that may be required by that department.
- (e) The sponsoring entity shall notify the board and the county health department described in paragraph (2) of subdivision (d) in writing of any change to the information required under subdivision (d) within 30 calendar days of the change.
- (f) Within 15 calendar days of the provision of health care services pursuant to this section, the sponsoring entity shall file a report with the board and the county health department of the county in which the health care services were provided. This report shall contain the date, place, type, and general description of the care provided, along with a listing of the health care practitioners who participated in providing that care.
- (g) The sponsoring entity shall maintain a list of health care practitioners associated with the provision of health care services under this section. The sponsoring entity shall maintain a copy of each health care practitioner's current license or certification and shall require each health care practitioner to attest in writing that his or her license or certificate is not suspended or revoked pursuant to disciplinary proceedings in any jurisdiction. The sponsoring entity shall maintain these records for a period of at least five years following the provision of health care services under this section and shall, upon request, furnish those records to the board or any county health department.
- (h) A contract of liability insurance issued, amended, or renewed in this state on or after January 1, 2011, shall not exclude coverage of a health care practitioner or a sponsoring entity that provides, or arranges for the provision of, health care services under this section, provided that the practitioner or entity complies with this section.
- (i) Subdivision (b) shall not be construed to authorize a health care practitioner to render care outside the scope of practice authorized by his or her license or certificate or this division.
- (j) ~~(1) The~~ (1) *The* board may terminate authorization for a health care practitioner to provide health care services pursuant to this section for failure to comply with this section, any applicable practice requirement set forth in this division, any regulations adopted pursuant to this division, or for any act that would be grounds for discipline if done by a licensee of that board.
- (2) The board shall provide both the sponsoring entity and the health care practitioner with a written notice of

termination including the basis for that termination. The health care practitioner may, within 30 days after the date of the receipt of notice of termination, file a written appeal to the board. The appeal shall include any documentation the health care practitioner wishes to present to the board.

(3) A health care practitioner whose authorization to provide health care services pursuant to this section has been terminated shall not provide health care services pursuant to this section unless and until a subsequent request for authorization has been approved by the board. A health care practitioner who provides health care services in violation of this paragraph shall be deemed to be practicing health care in violation of the applicable provisions of this division, and be subject to any applicable administrative, civil, or criminal fines, penalties, and other sanctions provided in this division.

(k) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(l) This section shall remain in effect only until January 1, ~~2014~~, ~~2018~~, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2014~~, ~~2018~~, deletes or extends that date.



Bill Number:	AB 1057
Introduced	2/22/13
Amendment Date:	June 3, 2013
Author:	Assembly Member Medina
Topic:	Professions and Vocation: Licenses: Military Service
Position:	None

Affected Sections: Add Section 114.5 to the Business and Professions Code (BPC)

Status: As of 6/25/13 – on the Senate Third Reading File

Position: The board does not have a position on this bill.

EXISTING LAW:

The Business and Professions Code provides for the licensure and regulation of various professions and vocations by DCA board, and provides that a licensee or registrant whose license expired while the licensee or registrant was on military active duty, upon application, may reinstate his or her license without penalty and without examination, if certain requirements are met.

THIS BILL WOULD:

Add Section 114.5 to the Business and Professions Code to require every board on or after January 1, 2015, to inquire on every application for licensure if the applicant is serving in, or has previously served in, the military.

RELATED LEGISLATION:

AB 258 would add Section 11019.11 to the Government Code to specify that on or after July 1, 2014, every agency that requests on any written form or written publication, or through its Internet Web site, whether a person is a veteran, that the information be requested in the following format: *“Have you ever served in the United States military?”*

FISCAL IMPACT ON THE BOARD:

This bill may have a fiscal impact on the DCA/board, in that the existing applicant tracking system does not track accommodate the tracking of the information required by this section. Further, and with the department’s migration to a new licensing system (BreZE), the board is unable to modify its existing licensing requirements. Staff will continue to work with DCA on how the department may plan to implement the provisions of the bill for all boards.

To comply with the requirement to inquire as to a person’s military service, the board would be required to update its applications, which would be absorbed with existing staff resources.



California
LEGISLATIVE INFORMATION

AB-1057 Professions and vocations: licenses: military service. (2013-2014)

As Amended 6/3/13 - Today's Law As Amended

SECTION 1. *Section 114.5 is added to the Business and Professions Code, to read:*

114.5. *Commencing January 1, 2015, each board shall inquire in every application for licensure if the individual applying for licensure is serving in, or has previously served in, the military.*



Bill Number:	SB 146
Introduced	1/31/13
Amended:	6/13/13
Author:	Senator Lara
Topic:	Workers' Compensation: medical treatment: billing
Position:	(None)

Current Bill Status: **Urgency Clause Adopted
Ordered to Engrossing and Enrolling (7/3/13)**

Affected Sections: Amend Section 4603.2 of the Labor Code related to Workers' Compensation

EXISTING LAW:

Section 4603.2 of the Labor code provides that any provider of services, as defined, shall submit with a request for payment an itemization of services to include a copy of the prescription.

AS AMENDED, THIS BILL WOULD:

Specify that a copy of a prescription shall not be required with a request for payment for pharmacy services, unless the provider of services has entered into a written agreement that requires a copy of a prescription for a pharmacy service.

The bill specifies that any request for payment as established by the Division of Workers' Compensation that was denied for not providing a copy of the prescription, may resubmit the bill for payment, until March 31, 2014.

SB 146 also provides that nothing shall preclude an employer, insurer, pharmacy benefits manager, or third-party claims administrator from requesting a copy of the prescription during a review of any records of prescription drugs that were dispensed by a pharmacy.

STAFF COMMENTS:

This measure was of interest because, as introduced, SB 146 would have allowed for the billing and payment of pharmacy services without having to provide a copy of the (currently required) prescription; thus, only the electronic record would indicate that such a prescription was filled.

The author states this measure was a result of changes made in the prior session (SB 863) related to the workers' compensation system and that, as enacted, pharmacies and pharmacy billers were not able to comply with requirements of the electronic billing standard – because the system did not allow a copy of a prescription to be attached to an electronic claim.

The amended version does allow specified entities to request a copy of the prescription during a review of records of prescription drugs dispensed by a pharmacy.

FISCAL IMPACT ON THE BOARD:

None identified.

SUPPORT:

CompPharma (sponsor)

OPPOSITION: None known



California
LEGISLATIVE INFORMATION

SB-146 Workers' compensation: medical treatment: billing. (2013-2014)

As Amended 6/13/13 - Today's Law As Amended

SECTION 1. Section 4603.2 of the Labor Code is amended to read:

4603.2. (a) (1) Upon selecting a physician pursuant to Section 4600, the employee or physician shall notify the employer of the name and address, including the name of the medical group, if applicable, of the physician. The physician shall submit a report to the employer within five working days from the date of the initial examination, as required by Section 6409, and shall submit periodic reports at intervals that may be prescribed by rules and regulations adopted by the administrative director.

(2) If the employer objects to the employee's selection of the physician on the grounds that the physician is not within the medical provider network used by the employer, and there is a final determination that the employee was entitled to select the physician pursuant to Section 4600, the employee shall be entitled to continue treatment with that physician at the employer's expense in accordance with this division, notwithstanding Section 4616.2. The employer shall be required to pay from the date of the initial examination if the physician's report was submitted within five working days of the initial examination. If the physician's report was submitted more than five working days after the initial examination, the employer and the employee shall not be required to pay for any services prior to the date the physician's report was submitted.

(3) If the employer objects to the employee's selection of the physician on the grounds that the physician is not within the medical provider network used by the employer, and there is a final determination that the employee was not entitled to select a physician outside of the medical provider network, the employer shall have no liability for treatment provided by or at the direction of that physician or for any consequences of the treatment obtained outside the network.

(b) (1) Any provider of services provided pursuant to Section 4600, including, but not limited to, physicians, hospitals, pharmacies, interpreters, copy services, transportation services, and home health care services, shall submit its request for payment with an itemization of services provided and the charge for each service, a copy of all reports showing the services performed, the prescription or referral from the primary treating physician if the services were performed by a person other than the primary treating physician, and any evidence of authorization for the services that may have been received. Nothing in this section shall prohibit an employer, insurer, or third-party claims administrator from establishing, through written agreement, an alternative manual or electronic request for payment with providers for services provided pursuant to Section 4600.

(A) Notwithstanding the requirements of this paragraph, a copy of the prescription shall not be required with a request for payment for pharmacy services, unless the provider of services has entered into a written agreement, as provided in this paragraph, that requires a copy of a prescription for a pharmacy service.

(B) Notwithstanding timely billing and payment rules established by the Division of Workers' Compensation, any entity submitting a pharmacy bill for payment, on or after January 1, 2013, and denied payment for not including a copy of the prescription from the treating physician, may resubmit those bills for payment until March 31, 2014.

(C) Nothing in this section shall preclude an employer, insurer, pharmacy benefits manager, or third-party claims administrator from requesting a copy of the prescription during a review of any records of prescription drugs that were dispensed by a pharmacy.

(2) Except as provided in subdivision (d) of Section 4603.4, or under contracts authorized under Section 5307.11, payment for medical treatment provided or prescribed by the treating physician selected by the employee or designated by the employer shall be made at reasonable maximum amounts in the official medical fee schedule, pursuant to Section 5307.1, in effect on the date of service. Payments shall be made by

the employer with an explanation of review pursuant to Section 4603.3 within 45 days after receipt of each separate, itemization of medical services provided, together with any required reports and any written authorization for services that may have been received by the physician. If the itemization or a portion thereof is contested, denied, or considered incomplete, the physician shall be notified, in the explanation of review, that the itemization is contested, denied, or considered incomplete, within 30 days after receipt of the itemization by the employer. An explanation of review that states an itemization is incomplete shall also state all additional information required to make a decision. Any properly documented list of services provided and not paid at the rates then in effect under Section 5307.1 within the 45-day period shall be paid at the rates then in effect and increased by 15 percent, together with interest at the same rate as judgments in civil actions retroactive to the date of receipt of the itemization, unless the employer does both of the following:

(A) Pays the provider at the rates in effect within the 45-day period.

(B) Advises, in an explanation of review pursuant to Section 4603.3, the physician, or another provider of the items being contested, the reasons for contesting these items, and the remedies available to the physician or the other provider if he or she disagrees. In the case of an itemization that includes services provided by a hospital, outpatient surgery center, or independent diagnostic facility, advice that a request has been made for an audit of the itemization shall satisfy the requirements of this paragraph.

An employer's liability to a physician or another provider under this section for delayed payments shall not affect its liability to an employee under Section 5814 or any other provision of this division.

(3) Notwithstanding paragraph (1), if the employer is a governmental entity, payment for medical treatment provided or prescribed by the treating physician selected by the employee or designated by the employer shall be made within 60 days after receipt of each separate itemization, together with any required reports and any written authorization for services that may have been received by the physician.

(4) Duplicate submissions of medical services itemizations, for which an explanation of review was previously provided, shall require no further or additional notification or objection by the employer to the medical provider and shall not subject the employer to any additional penalties or interest pursuant to this section for failing to respond to the duplicate submission. This paragraph shall apply only to duplicate submissions and does not apply to any other penalties or interest that may be applicable to the original submission.

(c) Any interest or increase in compensation paid by an insurer pursuant to this section shall be treated in the same manner as an increase in compensation under subdivision (d) of Section 4650 for the purposes of any classification of risks and premium rates, and any system of merit rating approved or issued pursuant to Article 2 (commencing with Section 11730) of Chapter 3 of Part 3 of Division 2 of the Insurance Code.

(d) (1) Whenever an employer or insurer employs an individual or contracts with an entity to conduct a review of an itemization submitted by a physician or medical provider, the employer or insurer shall make available to that individual or entity all documentation submitted together with that itemization by the physician or medical provider. When an individual or entity conducting a *an* itemization review determines that additional information or documentation is necessary to review the itemization, the individual or entity shall contact the claims administrator or insurer to obtain the necessary information or documentation that was submitted by the physician or medical provider pursuant to subdivision (b).

(2) An individual or entity reviewing an itemization of service submitted by a physician or medical provider shall not alter the procedure codes listed or recommend reduction of the amount of the payment unless the documentation submitted by the physician or medical provider with the itemization of service has been reviewed by that individual or entity. If the reviewer does not recommend payment for services as itemized by the physician or medical provider, the explanation of review shall provide the physician or medical provider with a specific explanation as to why the reviewer altered the procedure code or changed other parts of the itemization and the specific deficiency in the itemization or documentation that caused the reviewer to conclude that the altered procedure code or amount recommended for payment more accurately represents the service performed.

(e) (1) If the provider disputes the amount paid, the provider may request a second review within 90 days of service of the explanation of review or an order of the appeals board resolving the threshold issue as stated in the explanation of review pursuant to paragraph (5) of subdivision (a) of Section 4603.3. The request for a second review shall be submitted to the employer on a form prescribed by the administrative director and shall include all of the following:

(A) The date of the explanation of review and the claim number or other unique identifying number provided

on the explanation of review.

(B) The item and amount in dispute.

(C) The additional payment requested and the reason therefor.

(D) The additional information provided in response to a request in the first explanation of review or any other additional information provided in support of the additional payment requested.

(2) If the only dispute is the amount of payment and the provider does not request a second review within 90 days, the bill shall be deemed satisfied and neither the employer nor the employee shall be liable for any further payment.

(3) Within 14 days of a request for second review, the employer shall respond with a final written determination on each of the items or amounts in dispute. Payment of any balance not in dispute shall be made within 21 days of receipt of the request for second review. This time limit may be extended by mutual written agreement.

(4) If the provider contests the amount paid, after receipt of the second review, the provider shall request an independent bill review as provided for in Section 4603.6.

(f) Except as provided in paragraph (4) of subdivision (e), the appeals board shall have jurisdiction over disputes arising out of this subdivision pursuant to Section 5304.

SEC. 2. *This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:*

In order to avoid jeopardizing injured workers' access to medically necessary medications, it is necessary that this bill take effect immediately.



Bill Number:	SB 445
Introduced	2/21/13
Amendment Date:	
Author:	Senator Current Price, Jr.
Topic:	Controlled Substances Advertising
Position:	(None)

Affected Sections: Amend Section 4121 of the Business and Professions Code (BPC)

Status: In the Assembly. Referred to Assembly Committee on Business, Professions and Consumer Protection

EXISTING LAW:

Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacies.

Notwithstanding Section 651, **Section 4121 BPC** requires that an advertisement of the retail price of a drug shall be limited to quantities of the drug that are consistent with good medical practice, and specifies information required for such an advertisement. There is no section that restricts the advertising of controlled substances.

Section 4122 BPC requires every pharmacy to post a notice concerning the availability of prescription price information; the notice may be provided to consumers via a written receipt with the required information, and allows an individual to receive price information, as specified.

THIS BILL WOULD:

Amend Section 4121 to specify that under no circumstances may an advertisement from a pharmacy specifically promote the sale or dispensing of controlled substances.

ACCORDING TO THE AUTHOR:

In an effort to combat the rising tide of prescription drug abuse and seeking behavior by organized crime and attics, SB 445 seeks to limit drug seeking behavior at pharmacies by prohibiting pharmacies from advertising the sale of controlled substances.

FISCAL IMPACT ON THE BOARD:

None identified.

HISTORY:

Date	Action
05/20/13	Referred to Com. on B.,P. & C.P.
05/06/13	In Assembly. Read first time. Held at Desk.
05/06/13	Read third time. Passed. (Ayes 25. Noes 9. Page 805.) Ordered to the Assembly.
04/30/13	Read second time. Ordered to third reading.
04/29/13	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
04/19/13	Set for hearing April 29.
04/16/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 9. Noes 1. Page 564.) (April 15). Re-referred to Com. on APPR.
03/28/13	Set for hearing April 15.
03/11/13	Referred to Com. on B., P. & E.D.
02/22/13	From printer. May be acted upon on or after March 24.
02/21/13	Introduced. Read first time. To Com. on RLS. for assignment. To print.



California
LEGISLATIVE INFORMATION

SB-445 Pharmacies: advertising: controlled substances. (2013-2014)

As Introduced 2/21/13 - Today's Law As Amended

SECTION 1. Section 4121 of the Business and Professions Code is amended to read:

4121. (a) (1) Notwithstanding Section 651, an advertisement of the retail price for a drug that requires a prescription shall be limited to quantities of the drug that are consistent with good medical practice and shall include the strength, dosage form, and the exact dates during which the advertised price will be in effect.

~~(b)~~ (2) This ~~section~~ *subdivision* shall not apply to a pharmacy that is located in a licensed hospital and that is accessible only to hospital medical staff and personnel.

(b) Under no circumstances may an advertisement specifically promote the sale or dispensing of any controlled substances.

SEC. 2. *No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.*