

# **Legislation**

# **Attachment 1**



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|---------------------|---------------------------------|
| <b>Bill Number:</b> | <b>SB 294 (Board-Sponsored)</b> |
| <b>Introduced</b>   | 2/15/13                         |
| <b>Last Amend:</b>  |                                 |
| <b>Author:</b>      | Senator Bill Emmerson           |
| <b>Topic:</b>       | Sterile Drug Products           |
| <b>Position:</b>    | SUPPORT (3/25/13)               |

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**Current Bill Status:** 4/2/13 – Passed out of Senate Business, Professions and Economic Development (10-0)

**4/15/13 – Set for Hearing: Senate Appropriations**

**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

**SUMMARY:**

SB 294 contains board-sponsored provisions to strengthen the board's ability to regulate and monitor pharmacies that compound sterile drug products and (for nonresident pharmacies) those that ship those products into California.

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. 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. The bill sets a fee for a nonresident sterile compounding permit, and requires these entities to pay the cost of annual inspection by the board. Failure to pay the fee will result in suspension of the nonresident sterile compounding pharmacy license.

**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. These specialty permits are limited to pharmacies that are licensed as a Pharmacy with the board. This section exempts from the specialty permit requirement those pharmacies that are operated by entities that are licensed by the California Department of Public Health (CDPH) and that have current accreditation, as specified.

**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.

**THIS BILL WILL:**

**Repeal and add Section 4127** to require 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."

**Amend Section 4127.1** to remove references to only 'injectable' sterile drug products; set forth requirements prior to the issuance or renewal of a sterile compounding permit, to

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 24 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 Section 4127.2** to

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

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:**

Staff is currently compiling its estimates for the anticipated staffing resources that will be required to conduct inspections of nonresident sterile compounding pharmacies.

California Pharmacies:

As of April 2012, the board has approximately 6,900 licensed pharmacies, and approximately 263 hold sterile compounding permits. The board estimates there are 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 April 2012, the board issued approximately 500 licenses to nonresident pharmacies, of which approximately 93 hold a nonresident sterile compounding permit.

**Staff Recommendation:** Ratify the board's position taken March 25, 2013



**California State Board of Pharmacy**

1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834  
Phone (916) 574-7900  
Fax (916) 574-8618  
www.pharmacy.ca.gov

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

March 25, 2013

The Honorable Bill Emmerson  
California State Senate  
State Capitol, Room 5082  
Sacramento, CA 95814

RE: Senate Bill 294 – Support

Dear Dr. Emmerson:

The California State Board of Pharmacy thanks you for authoring Senate Bill 294 which will strengthen the Board of Pharmacy's ability to regulate and monitor specialized pharmacies that compound sterile drug products and ship those drugs into California.

In 2001, the California Legislature first enacted specific provisions to strengthen state oversight of sterile drug compounding in pharmacies. The legislation followed 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. The resulting legislation required pharmacies within California to obtain a specialty license if they performed sterile injectable compounding – a license that required annual inspections by board pharmacists before license issuance or renewal. Additional provisions required non-resident pharmacies that shipped sterile injectable drugs into California to also be licensed with this board. However, SB 293 (Torlakson, 2001) carved out an exemption for California and non-resident pharmacies and others to avoid this specialty license if they were accredited or where, in the case of non-resident pharmacies, regulators (other than the Board of Pharmacy) had oversight.

Unfortunately, the tragic incidents that occurred over a decade ago have not ceased. Recently, 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.

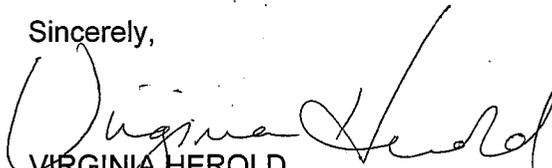
As introduced, SB 294 would

- Require annual inspections by the board of pharmacy of these specialty pharmacies 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.

The Honorable Bill Emmerson  
March 22, 2013  
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Compounding pharmacies are especially important today to produce needed medications that are in short supply. However, it is equally important that California's sterile compounding requirements are met by these specialty pharmacies and that they are monitored for compliance. Once again, it is time to 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.

Sincerely,



VIRGINIA HEROLD  
Executive Officer

**SB 294**  
**(Emmerson)**  
**Sterile Drug Products**

Sponsor: California State Board of Pharmacy

Recent events have highlighted the need to increase oversight of sterile compounding pharmacies to ensure that sterile drug products are safe for consumers. For instance, in June 2012, a sterile injectable pharmacy located in Florida shipped contaminated product into California which resulted in significant patient harm, including blindness in some cases. Then in October 2012, the New England Compounding Center based in Massachusetts shipped contaminated drug products throughout the country, including California, resulting in the death of more than 40 people and 461 patients becoming ill from the tainted steroid injections.

To strengthen consumer protection, SB 294 would require both resident and nonresident pharmacies that compound sterile drug products for injection, administration into the eye, or inhalation for the purpose of dispensing or shipping these medications into the state must apply to the California State Board of Pharmacy for a sterile compounding pharmacy license. The license will be issued after the board has inspected the premises and found the pharmacy to be in compliance with California law. In addition, SB 294 requires the pharmacy to provide to the board a list of all the sterile drug products it compounds. Any disciplinary action taken by another state or suspension of any accreditation held by the pharmacy must also be reported to the board within 10 days. Furthermore, this legislation requires any recall notice issued by the pharmacy for sterile drug products it has compounded to be provided to the board within 24 hours.

Currently, the law requires any pharmacy that furnishes, sells or dispenses dangerous drugs or devices in California, or ships such products into the state, to be licensed by the board. In addition to this license, California law requires either a specialty license issued by the board or specific accreditation for any pharmacy that compounds sterile injectable products within, or ships such products into, California. Because current law allows for accreditation in lieu of licensure, the board lacks the ability to appropriately regulate such entities and in the case of sterile compounding pharmacies, even the ability to inspect such facilities to ensure compliance with pharmacy law. Therefore, SB 294 will require licensure by the board and will expressly authorize the board to conduct inspections of facilities that are licensed to dispense or ship compounded products into California. By doing so, this will ensure consistent oversight of these pharmacies and increase consumer protection.



CALIFORNIA  
**HOSPITAL**  
ASSOCIATION

*Providing Leadership in  
Health Policy and Advocacy*

March 22, 2013

The Honorable Curren Price  
Chair, Senate Business, Professions & Economic Development  
State Capitol, Room 2059  
Sacramento, CA 95814

**SUBJECT: SB 294 (Emmerson) – LETTER OF CONCERN**

Dear Senator Price:

The California Hospital Association (CHA), on behalf of more than 400 hospitals and health systems is writing today with concerns to SB 294 (Emmerson). Due to recent adverse events, CHA is supportive of increased scrutiny of organizations that prepare “compounded sterile preparations” (CSPs). SB 294 would approve the process by which the Board of Pharmacy would conduct in-state and out-of-state inspections of organizations that prepare CSPs. Compliance would be based on present Board of Pharmacy Compounding Regulations and funding through fee assessments.

Currently out-of-state organizations preparing CSPs should comply with industry quality standards and guidelines issued by the United States Pharmacopeial Convention (USP). USP is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, compounded and distributed and consumed worldwide. For organizations preparing CSPs, USP developed internationally recognized standards known as “USP 797.”

The health care industry is experiencing extreme shortages of medications. The reasons for shortages are complex; however, compounding organizations are offering solutions to reduce the incidence of shortages. Therefore, we are concerned with any legislation that may reduce the number of high quality compounding organizations that are already complying with the industry USP 797 standards. Requiring out-of-state compounding organizations to comply with unique California regulations may force some to no longer be interested in the California market. This would further exacerbate the shortage of medications.

CHA will continue to work with the author and sponsor to assure that California patients are receiving high quality CSP’s but does not thwart interest in doing business in the California Market.

Sincerely,

A handwritten signature in cursive script that reads "Connie Delgado".

Connie Delgado  
Deputy Chief Legislative Advocate

CD:dlv

cc: The Honorable Members of Senate Business, Professions & Economic Development  
Sarah Mason, consultant Senate Business, Professions & Economic Development  
Amber Alexander, consultant, Senate Republican Caucus



March 27, 2013

The Honorable Curren Price  
Chair, Senate Business and Professions Committee  
State Capitol, Room 2080  
Sacramento, CA 95814

RE: SB 294 (Emmerson)  
**CSHP Position: *SUPPORT IF AMENDED***

Dear Senator Price:

The California Society of Health-System Pharmacists (CSHP) has respectfully adopted a position of ***Support if Amended*** for **Senate Bill 294 (Emmerson)**.

Like many others, our members were shocked and saddened at the tragedy surrounding the New England Compounding Center (NECC) last year. CSHP represents many pharmacists who services in compounding needed medications for patients is integral for providing the right medications at the right time. The NECC tragedy is not reflective of the pharmacy profession, and CSHP supports efforts by regulators to ensure such a scenario is never repeated.

With that said, our members have several concerns regarding certain elements of SB 294:

- **Clarification Regarding 4127.1(a)(c) – Sterile Compounding List Requirement:** Clarification regarding what components should be included in the list is needed. Current language is very vague – the differences between the Board requiring a daily log vs. simply a list containing the type and quantity of items compounded are huge and have starkly different effects on our workforce.  
Also, CSHP believes that an exception to the list requirement should be made for hospitals compounding products for inpatient use. Problems exemplified by the NECC tragedy involve independent compounding pharmacies shipping products across the country. A hospital pharmacy serving its patients within the confines of the institution should not be lumped in with these independent compounding pharmacies.
- **Amendment to 4052(a)(1) – Compounded Products for a Prescriber for Office Use:** Currently, statute states that a pharmacist may “furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.” This language does not adequately address the many varied sites beyond a “prescriber’s office” which utilize compounded products. CSHP would like to see the language “and to a licensed healthcare facility” added to this section which would effectively modernize the statute.
- **Amendment to 4057 – Add Exemption for Pharmacy Schools to Acquire Products for Use in Teaching Compounding:** Currently, Business and Professions Code Chapter 9, Section 4057 affords Nursing Schools an exemption which allows for the purchase of “dangerous drugs and dangerous devices.” Pharmacy schools have no such exemption. This makes it difficult to



acquire the necessary materials to ensure pharmacy students are effectively taught compounding skills. CSHP would like to add the following language to the statute:

*This chapter does not apply to the furnishing of dangerous drugs and dangerous devices to recognized schools of pharmacy. These dangerous drugs and dangerous devices shall not include controlled substances. The dangerous drugs and dangerous devices shall be used for training purposes only, and not for the cure, mitigation, or treatment of disease in humans. Recognized schools of Pharmacy for purposes of this subdivision are those schools recognized as training facilities by the California Board of Pharmacy.*

We look forward to working with you on this issue. For questions or to discuss further, please contact either Legislative & Regulatory Analyst Jonathan Nelson at 916.447.1033 or [jonathan@cshp.org](mailto:jonathan@cshp.org).

Founded in 1962, CSHP represents over 4,500 pharmacists, student pharmacists, pharmacy technicians and associates who serve patients and the public through the promotion of wellness, patient safety and optimal use of medications. CSHP members practice in a variety of organized healthcare settings – including, but not limited to, hospitals, integrated healthcare systems, medication therapy management clinics, home healthcare and ambulatory care settings.

Sincerely,

Dawn Benton, MBA  
Executive Vice President/CEO

cc: Assemblymember Richard Gordon

Members of the Senate Business, Professions and Economic Development Committee

Kristen Webb, Consultant - Senate Business, Professions and Economic Development Committee



*California*  
LEGISLATIVE INFORMATION

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

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**SENATE BILL**

**No. 294**

**Introduced by Senator Emmerson**

February 15, 2013

**An act to amend Sections 4127.1, 4127.2, and 4400 of, to amend the heading of Article 7.5 (commencing with Section 4127) of Chapter 9 of Division 2 of, and to repeal and add Section 4127 of, the Business and Professions Code, relating to pharmacy.**

LEGISLATIVE COUNSEL'S DIGEST

SB 294, as introduced, Emmerson. Sterile drug products.

The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. Existing law requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy. Existing law requires pharmacies to obtain a license from the board, subject to annual renewal, in order to compound injectable sterile drug products. A similar licensing requirement applies to nonresident pharmacies compounding injectable sterile drug products for shipment into California. A violation of the Pharmacy Law is a crime.

This bill would expand these provisions to prohibit a pharmacy from compounding or dispensing, and a nonresident pharmacy from compounding for shipment into this state, sterile drug products for injection, administration into the eye, or inhalation, unless the pharmacy has obtained a sterile compounding pharmacy license from the board. The bill would specify requirements for the board for issuance or renewal of a license, and requirements for the pharmacy as a licensee. By adding additional requirements to the Pharmacy Law concerning sterile drug products, the violation of which is a crime, the bill would impose a state-mandated local program.

Existing law specifies the fee for issuance or renewal of a nongovernmental license to compound sterile drug products.

This bill would provide that the fee for a nonresident sterile compounding pharmacy license shall also require payment of the travel expenses incurred by the board in inspecting the pharmacy at least once annually.

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

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

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**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. ~~Injectable~~-Sterile Drug Products**

**SEC. 2.** Section 4127 of the Business and Professions Code is repealed.

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

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

**4127.** 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 before dispensing the compounded medication.

**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 *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 ~~injectable~~ sterile drug products ~~may only shall~~ be issued ~~for only to~~ a location that is licensed as a pharmacy. Furthermore, the license to compound ~~injectable~~ sterile drug products ~~may only shall~~ be issued *only* to the owner of the pharmacy ~~license licensed~~ at that location. A license to compound ~~injectable~~ sterile drug products ~~may shall~~ 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 shall~~ not be *issued or* 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:~~ *board does all of the following:*

~~(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.~~

*(1) Performs an onsite inspection of the premises, and any deficiencies noted are corrected.*

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

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

*(4) 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.*

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

*(d) 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 24 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded.*

*(e) 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.*

~~(e)~~

(f) 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.

**SEC. 5.** 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~~ *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 ~~injectable~~ sterile drug products ~~may only~~ *shall* be issued ~~for only to~~ a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound ~~injectable~~ sterile drug products ~~may only~~ *shall* be issued *only* to the owner of the nonresident pharmacy ~~license licensed~~ at that location. A license to compound ~~injectable~~ sterile drug products ~~may~~ *shall* not be issued ~~or renewed until the board receives the following from the nonresident pharmacy:~~ *until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board.*

~~(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.~~

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

*(1) Performs an onsite inspection of the premises, and any deficiencies noted are corrected. The nonresident pharmacy shall be responsible for payment of reasonable travel expenses incurred by the board in connection with inspecting the pharmacy at least once annually pursuant to subdivision (v) of Section 4400.*

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

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

*(4) 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.*

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

*(d) 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 24 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.*

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

**SEC. 6.** 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).

(u) The fee for issuance or renewal of a nongovernmental *sterile compounding pharmacy* 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).

*(v) The fee for a nonresident sterile compounding pharmacy license shall also require payment of the travel expenses incurred by the board in inspecting the pharmacy at least once annually. Failure to pay this fee within 30 days shall result in the suspension of the nonresident sterile compounding pharmacy license.*

**SEC. 7.** 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.

Oral Testimony of Sarah Sellers, PharmD MPH, speaking on her own behalf, before the  
Joint Committee on Public Health March 2, 2013

Mr. Chairmen and members of the committee, thank you for the opportunity to speak with you today regarding pending state legislation for the oversight of pharmacy compounding.

I'd like to open my testimony with a quote that I have made reference to in many if not all of the exhaustive discussions I have had on the matter before us today. The following words refer to the role of the federal Food Drug and Cosmetic Act, and are written by Supreme Court Justice Stephen Breyer, in the dissenting opinion in the Western States pharmacy compounding case.

*The objective of this elaborate and time consuming regulatory regime is to identify those health risks, both large and small, that a doctor or pharmacist might not otherwise notice...That objective, as the Court concedes, is to confine the sale of untested, compounded drugs to where they are medically necessary.*

Justice Breyer goes on further to state that policy must:

*...distinguish (1) sales of compounded drugs to those who clearly need them from (2) sales of compounded drugs to those for whom a specially tailored but untested drug is a convenience but not a medical necessity.*

In testimony on the Implications of the 2012 Meningitis Outbreak to the U.S. Senate Health, Education, Labor and Pensions Committee, Commissioner of the Tennessee Department of Health Dr. John J. Dreyzehner raised important business ethics concerns:

*This does not appear merely to have been an unfortunate lapse or error in pharmacy judgment or practice. It appears to have been a cascade of increasingly serious and obvious omissions and commissions that were persistently not addressed for reasons currently unknown. The people who compounded these medications knew they were being relied upon to be sterile by patients and clinicians—real people who trusted them.*

Dr. Dreyzehner went on further, stating that:

*This was a blatant disregard for health and safety by pharmacists who should understand the potential consequences of the final catastrophic failure that ultimately occurred. This was, at root, a fundamental breach of an ethical duty and sacred obligation by the New England Compounding Center to first, do no harm.*

At the time of the U.S. Senate Hearing in November of last year, we had information on inspection findings for the NECC and Ameridose pharmacies alone. Until recently, we believed NECC to be an outlier both in magnitude and in practices that could result in contamination and patient harm. As a result of current and on-going state and federal inspections and investigations, and the vigilance of front-line healthcare professionals, we are beginning to expose a larger and more complex public health concern—a “wicked problem,” described as difficult to identify, characterize and solve because of incomplete, contradictory, and changing requirements that are often resistant to resolution.

Historically, pharmacies have not intended to meet federal standards for the compounded products they produce. Yet, prescribers, health systems and patients may be relying on compounded products as if they were FDA-approved: expecting the same level of assurance of sterility, safety and effectiveness, manufacturing quality and liability protection. Lack of transparency to the differences between federal and practical pharmacy standards and the implications for patient safety and medical liability has created a dangerous and deceptive environment where substandard products can be easily comingled and exchanged in the marketplace as equals to FDA-approved drugs. And, as we have seen in other areas of the healthcare marketplace, where there exists such an imbalance of information between sellers and purchasers, demand can be artificially induced as intended consequence of sophisticated marketing or even the as a consequence of individual patient deference to a medical authority figure. Today, health systems, physicians and patients may be lured into purchasing a compounded drug marketed for convenience or for cost, where buyers do not have access to clear information regarding a compounded drug’s assurances of safety, efficacy and manufacturing quality.

Despite this complicated marketplace, professional responsibility and accountability can, and must be, immediately and clearly established. Given the current magnitude of demand and potential populations at risk for substandard drug exposures:

- Current prescribing and use of non-FDA approved compounded drug products should be reviewed in scope and magnitude and accounted for by state medical boards
- Current non-FDA approved, compounded drug purchasing practices of hospitals and clinics should be reviewed in scope and magnitude and accounted for by individual hospitals
- Insurance policies should undergo formal review/updates/modernization to adequately cover current purchasing, prescribing and pharmacy compounding behaviors
- Current pharmacy and medical compounding practices from chemical and product formula outsourcing to marketing and use should be formally investigated with results brought before an advisory committee with appropriate training and experience to make recommendations on risk-based approaches to regulation and oversight
- Entities responsible for making benefit-risk assessments for population or individual use of non-FDA approved, compounded products can and should be immediately and clearly identified
- Frameworks for individual and population benefit-risk assessments can and should be developed for the purchase and use of non-FDA approved, compounded products for populations and individuals

In the aftermath of the NECC fungal meningitis outbreak, the state of Massachusetts rapidly initiated and continues to conduct a regulatory risk assessment of in-state pharmacies, which will provide critical information for the development and refinement of state legislation to enhance the oversight of pharmacy compounding. Other states are acting based on the NECC outbreak alone, without further investigation of pharmacy and medical practices that fall within the scope of their oversight responsibilities. In general, state legislation should seek to:

I. Reduce induced and potentially artificial demand for non-FDA approved products  
 State legislation should seek to correct current professional pharmacy and medical practices that have resulted in the artificial demand for non-FDA approved products. Without adjustment, regulatory resources required for effective oversight may outreach both state and federal capabilities and resources.

- Provide high levels of transparency to close current information gaps between chemical suppliers, pharmacies, health systems, prescribers, insurers and patients that may create vulnerabilities for inducing artificial demand for compounded drugs

- Ensure appropriate levels of insurance for current medical, hospital and pharmacy business practices that result in the prescribing, compounding and use of non-FDA approved products
- Ensure public and private payer policies do not incentivize the substitution of compounded drugs for cost or convenience

II. Preserve FDA-approved generic and branded drugs as the expected standard of pharmaceutical care for U.S. populations and individuals

Policies and regulation at the state and federal level should not intentionally or unintentionally, through commission or omission, allow for the circumvention of FDA-approval or federal manufacturing oversight.

III. Support and resource state regulatory and public health authorities as first responders

States should rely on and facilitate the enforcement of the U.S. Federal Food Drug and Cosmetic Act where the risk to products and patients are expected to outweigh deference or discretion for the practice of medicine and pharmacy for individual patients.

IV. Include a broad range of disciplines in the oversight of pharmacy compounding, including pharmacy, medical, epidemiology, regulatory and drug safety scientists.

Thank you for the opportunity to provide high-level comments.

Sarah Sellers is a pharmacoepidemiologist with primary focus on drug, biologic and vaccine benefit-risk assessment throughout product lifecycles. During her career tenure, Sellers has designed and conducted epidemiologic analyses and benefit-risk assessments to support the global development and marketing of complex therapies including critical need antibiotics, stem cell therapies and pandemic vaccines. She has developed global safety surveillance, signal detection and risk management programs for large 400(+) product companies and small, single-product companies utilizing quality systems management principles. Sellers has organized and led internal, external and multi-company working groups on high profile population level, and individual patient level, benefit-risk assessments involving manufacturing quality. She has served as an advisor and consultant on policy matters to FDA, States, U.S. Congress, pharmacies, professional medical and patient organizations and international human rights organizations on safety concerns related to manufacturing under the guise of pharmacy compounding. She has served as a research fellow in FDA's Office of Compliance and as a safety reviewer in FDA's Office of Safety and Epidemiology. Sarah holds a clinical research-based Doctorate of Pharmacy from the University of Florida and a Masters in Public Health in Epidemiology and Public Policy from Johns Hopkins University. In her early career, Sellers practiced pharmacy in both teaching hospital and infusion pharmacy settings.

## Board-Approved Proposals for 2013-2014

**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~~ ~~or~~ ~~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.

(b) For the purposes of this subdivision, "premises" means a location with its own address and an independent means of ingress and egress.

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To address the board's proposal to add Section 4008.5.

Section 144.5. is added to the Business and Professions Code:

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

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### **4053. Designated Representative to Supervise Wholesaler or Veterinary Food-Animal Drug Retailer**

(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 a licensed pharmacy, 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.

## Board-Approved Proposals for 2013-2014

(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).

# **Legislation**

## **Attachment 2**



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|                     |                              |
|---------------------|------------------------------|
| <b>Bill Number:</b> | <b>AB 670</b>                |
| <b>Introduced</b>   | 2/21/13                      |
| <b>Last Amend:</b>  | <b>4/2/2013</b>              |
| <b>Author:</b>      | Assemblymember Toni Atkins   |
| <b>Topic:</b>       | Pharmacy: Incentive Payments |
| <b>Position:</b>    |                              |

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**Current Bill Status:** In ASM Committee on Business, Professions & Consumer Protection

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

**EXISTING 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.”

**16 CCR § 1716** precludes a pharmacist from deviating from the requirements of a prescription except upon the prior consent of the prescriber, or to select a drug product in accordance with Section 4073.

Staff is unaware of a law that makes the use of drug substitutions that are therapeutic and cheaper for the insured illegal (i.e., provide a substitution based on PPO or drug formulary coverage).

**THIS BILL WOULD:**

Add Section 4073.5 to the B&PC to specify that a pharmacist or pharmacy employer shall not receive any payment or other compensation as an inducement to specifically recommend or replace an originally prescribed drug product that does not have the same active ingredient as the originally prescribed drug product.

The section further states that nothing shall be construed to prohibit contracts that contain incentive plans that involve general payments for consultation services that are not directly tied to payments for recommending or replacing a specific drug product.

**STAFF COMMENTS:**

According to the author, AB 670 would reassure patients that any change made by a pharmacy to their prescription medication is based on medical necessity and professional judgment, and not because such a change is rewarded with a financial incentive. Thus, AB 670 would eliminate any specific financial inducements that would encourage a pharmacist to change one drug product for another that does not have the same active ingredient.

The author states “Over the past several years, physicians have seen an increase in the number of requests from pharmacists to authorize a therapeutic switch. Prescribers have no way of knowing if the pharmacist is recommending the switch because it is best for the patient, or because the pharmacist is being financially induced.” The author’s office states that the priority of the decision should be based on science and the medical needs of the patient, and not because a healthcare professional receives a financial benefit.

Further, subdivision (b) addresses consultation services and that the section not be construed to prohibit contracts that contain incentive plans that involve general payments for consultation services that are not directly tied to payments for recommending or replacing a specific drug product. It is unclear what “consultation services” are intended to be exempted.

Health insurers argue that formularies help control drug costs for the health plan and its members. The Knox-Keene Health Care Service Plan Act of 1975 (Health & Safety Code sections 1340 et seq.) expressly permits the use of drug formularies provided certain conditions, including notice to the consumer and providing a process for authorization of a medically necessary non-formulary drug, are met.

The way AB 670 is currently drafted, it is not clear if the proposal would conflict with current laws that allow formularies.

**FISCAL IMPACT ON THE BOARD:**

Staff has not identified any fiscal impact on the board as a result of AB 670 as amended.

*As of 4/5/2013*

**SUPPORT:****OPPOSITION:**



## IN BRIEF -

AB 670 reassures patients that any change made by a pharmacy to their prescription medication is based on medical necessity and professional judgment; and not because such a change is rewarded with a financial incentive.

This bill does not restrict the pharmacist's ability to perform therapeutic substitution nor does it restrict their ability to be reimbursed for performing medication therapy management counseling. Rather, AB 670 eliminates the specific financial inducements that encourage pharmacists to change one drug product for another drug that does not have the same active ingredients.

## THE ISSUE

Pharmacists are highly regarded and valuable healthcare providers. As part of their responsibilities, pharmacists provide patients with valuable consultation services to promote medication adherence and help avoid drug contraindications. Medicare and other entities pay pharmacists for their consulting services. During these consultations, pharmacists are allowed to suggest or make, with prescriber approval, therapeutic substitutions where they switch the prescribed drug for another drug that is therapeutically similar but chemically different. Prescribing physicians routinely take alternative medication therapy advice from pharmacists, often without question, for a number of reasons, i.e. the pharmacist identified a patient's possible interactions with other medications, or plan doesn't cover the medicine.

Unfortunately, while such substitutions are intended to be in the best interest of the patient, the motivation of this practice is compromised by the existence of financial incentives, which are carved out fees specifically directed to reward pharmacists for making therapeutic switches. Over the past several years, physicians have seen an increase in the number of requests from pharmacists to authorize a therapeutic switch. Prescribers truly have no way of knowing if the pharmacist is recommending the switch because it is best for the patient, or because the pharmacist is being financially induced.

How much are these fees? Some "targeted intervention programs" can earn a pharmacy anywhere from \$20 or more for each drug switch that is made at the retail pharmacy counter. Not only may patients not fully understand that the medication they receive is not exactly the same as the one they were prescribed, they rarely know of this financial arrangement between the pharmacy and the insurance company.

Patients need to be concerned about the growing tendency of pharmacies to switch a prescription to a drug with a different chemical composition. The FDA is particularly concerned about potentially "biased" promotion of drug-switching by drug manufacturers with alliances to companies that manage the prescription-drug benefits of health-care plans. The Office of the Inspector General has stated that "quality of patient care can be compromised" if drug formulary programs become "primarily marketing efforts conducted by Pharmacy Benefit Managers (PBM's) on behalf of their [drug company] partners, rather than sound practices guided by predetermined protocols that promote quality drug use."<sup>1</sup>

As is current practice, physicians should not automatically reject a particular formulary or a recommendation to prescribe an alternate medication. They should work to prescribe the least expensive medication that is also most medically appropriate. Drug prices are soaring, and there is no reason to prescribe an expensive drug if a lower cost medication is just as safe and effective. However, the priority of the decision should be based on science and the medical needs of the patient, and not because a healthcare professional receives a financial benefit.

## BACKGROUND

Current law allows pharmacists to replace a brand-name drug with a generic formulation of the exact medication. The law also allows, with physician permission, for pharmacists to recommend and/or make therapeutic substitutions, which means the

<sup>1</sup> OIG Report, 15 *supra*. *Uses and Abuses of Prescription Drug Information in Pharmacy Benefits Management Programs*, Journal of the American Medical Association (2000) Vol. 283, No. 6, pp. 801-806

patient could receive a different drug that is in the same class as the prescribed drug and treats the same condition, but it is not the same medication.

If done incorrectly and without proper analysis, therapeutic substitutions can be life threatening. For example, one report identified a woman diagnosed with epilepsy who had a finely tuned cocktail of medications that would prohibit her from having seizures. When her condition was finally under control, she filled a prescription for one of two drugs and shortly after, she had a seizure during a bike ride. While being treated for her injuries, the physicians noticed the blood level of her medication decline. She later learned that her pharmacist changed her drug for another drug that worked differently. She was fortunate, but this incident could easily have been worse. Examples such as this prove why drug switching, particularly therapeutic substitutions, should not be taken lightly.

## **THE SOLUTION**

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AB 670 would prevent pharmacists and pharmacist employers from being financially induced to specifically recommend or substitute a therapeutically similar, but chemically different, drug product for the drug product referred to on the patient's prescription.

## **FOR MORE INFORMATION**

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Ryan Spencer, Office of Asm. Toni Atkins  
916 319 2078 | [ryan.spencer@asm.ca.gov](mailto:ryan.spencer@asm.ca.gov)

Juan Thomas, California Medical Association  
916 444 5532 | [jthomas@cmanet.org](mailto:jthomas@cmanet.org)



California  
LEGISLATIVE INFORMATION

AB-670 Pharmacy Law: incentive payments. (2013-2014)

AMENDED IN ASSEMBLY APRIL 02, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**ASSEMBLY BILL**

**No. 670**

**Introduced by Assembly Member Atkins**

February 21, 2013

**An act to ~~amend Section 500 of~~ add Section 4073.5 to the Business and Professions Code, relating to healing arts.**

LEGISLATIVE COUNSEL'S DIGEST

AB 670, as amended, Atkins. ~~Healing arts: reproduction of board records.~~ Pharmacy Law: incentive payments.

*The Pharmacy Law governs the practice of pharmacy in this state, including the permissible duties of licensed pharmacists. Among other permitted acts, a pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined, as specified, of those drug products having the same active chemical ingredients. A person who violates the Pharmacy Law is guilty of a crime, as specified.*

*This bill would prohibit a pharmacist or pharmacy employer from receiving any payment or other compensation, in the form of money or otherwise, that is used as an inducement to specifically recommend or replace an originally prescribed drug product with a drug product that does not have the same active ingredient as the originally prescribed drug product. By creating a new crime, the bill would impose a state-mandated local program.*

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

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

~~Existing law establishes the Medical Board of California, the Dental Board of California, and the California State Board of Pharmacy to regulate the practice of medicine, dentistry, and pharmacy, respectively, including licensing professionals in those fields. Existing law provides that whenever the register or book of registration of one of those entities is destroyed by fire or other public calamity, the board, whose duty it is to keep the register or book, may reproduce it so that there may be shown as nearly as possible the record existing in the original at the time of destruction.~~

~~This bill would provide that acceptable forms for the reproduction include the portable document format (PDF) or other secure electronic format. The bill would also make technical, nonsubstantive changes.~~

Vote: majority Appropriation: no Fiscal Committee: ~~no~~yes Local Program: ~~no~~yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** *Section 4073.5 is added to the Business and Professions Code, to read:*

**4073.5.** (a) A pharmacist or pharmacy employer shall not receive any payment or other compensation, in the form of money or otherwise, that is used as an inducement to specifically recommend or replace an originally prescribed drug product with a drug product that does not have the same active ingredient as the originally prescribed drug product.

(b) Nothing in this section shall be construed to prohibit contracts that contain incentive plans that involve general payments for consultation services that are not directly tied to payments for recommending or replacing a specific drug product.

**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.*

~~SECTION 1. Section 500 of the Business and Professions Code is amended to read: 500.~~

~~Whenever the register or book of registration of the Medical Board of California, the Dental Board of California, or the California State Board of Pharmacy is destroyed by fire or other public calamity, the board, whose duty it is to keep the register or book, may reproduce it so that there may be shown as nearly as possible the record existing in the original at the time of destruction. Acceptable forms for the reproduction include the portable document format (PDF) or other secure electronic format.~~



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|                     |  |
|---------------------|--|
| <b>Bill Number:</b> | <b>AB 1136</b>   |
| <b>Introduced</b>   | 2/22/13  |
| <b>Last Amend:</b>  | <b>3/20/13</b>   |
| <b>Author:</b>      | Assembly Member Levine                                 |
| <b>Topic:</b>       | Pharmacists: Drug Disclosures<br>(Drug Warning Labels) |
| <b>Position:</b>    |  |

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**Current Bill Status:** 4/2/13 Passed out of ASM Health as amended (11-1). Re-referred to Assembly Business, Professions and Consumer Protection  
4/24/13 - Possible hearing date in ASM BP&CP

**Affected Sections:** Amend Section 4074 of the Business and Professions Code

**EXISTING LAW:**

Section 4074 of the Business and Professions Code requires a pharmacist to inform a patient orally or in writing of the harmful effects of a dangerous drug if the drug poses substantial risk to the person when the drug is taken in combination with alcohol or if the drug may impair a person's ability to drive a motor vehicle, 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. (Pursuant to this section, the board promulgated a regulation at 16 CCR 1744.)

Section 4076 of the Business and Professions Code specifies that a pharmacist shall not dispense any prescription except in a container that meets requirements of state and federal law, and specifies elements that shall be on the label. Additional statute (§ 4076.5) and related regulations (16 CCR § 1707.6) further specify the font size, format and other requirements for information on a dispensed prescription label.

Related Regulation

Title 16 CCR § 1707.2 (Duty to Consult) provides that when a consultation is provided, it shall include precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

Title 16 CCR § 1744 (Drug Warnings) specifies seven classes of drugs that may impair a person's ability to drive a motor vehicle or operate machinery when taken alone or in combination with alcohol. That section further defines examples of drugs that may have harmful effects when taken in combination with alcohol, but that may or may not affect a person's ability to operate a motor vehicle.

**COMMON PRACTICE**

The California Legislature has declared that the practice of pharmacy is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health. It is common practice, and within the appropriate scope of a pharmacist's duty, that a dispensed prescription be labeled with appropriate information.

**THIS BILL WOULD:**

Amend Section 4074 to require that a pharmacist label a prescription container with a drug warning if the drug would impair a person's ability to operate a vehicle or vessel.

**STAFF COMMENTS:**

The last time substantive changes were made to the board's regulation at 16 CCR 1744 was in 1983. At that time, the board determined that it was necessary that a pharmacist be required to inform a patient when a dispensed drug may impair the person's ability to drive a motor vehicle or operate machinery when taken alone or in combination with alcohol. In practice, pharmacists include this warning in an oral consultation, and also affix a drug warning label to the container, though the label is not specifically required in the regulation.

At a hearing of the Assembly Health Committee on April 2, 2013, staff answered the committee's questions related to the current labeling requirements in Pharmacy Law. At that time, others conveyed to the committee the desire to preserve a pharmacist's professional judgment in determining what drug warning labels should accompany a dispensed prescription.

**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.

Should the board choose to review and amend its current regulation to also include a requirement that a drug warning label be affixed to a prescription container, the board would absorb this workload with its existing staff resources.

**Staff Recommendation:**

*According to the Author, as of 4/5/2013*

**SUPPORT:**

California Senior Legislature  
California Narcotic Officers Association  
California State Sheriffs Association  
California Police Chiefs Association (expected)

**OPPOSITION:**

None known



## OFFICE OF ASSEMBLYMEMBER

**Marc Levine**

TENTH ASSEMBLY DISTRICT

### **AB 1136: Prescription Drug Labeling Requirements**

#### **SUMMARY**

AB 1136 requires pharmacists to place a warning label on prescription medication that can impair a person's ability to drive.

#### **EXISTING LAW/BACKGROUND**

Drugged driving is a growing problem in California and the United States.

The National Highway Traffic Safety Administration reports that drugged driving is at an all-time high with 1/3<sup>rd</sup> of fatally injured drivers testing positive for drugs. Comparatively, fatally injured drivers testing positive for alcohol decreased from more than 20,000 in 1982, to 10,228 in 2010.

The National Transportation Safety Board (NTSB) recommends requiring a prominently displayed warning label on all prescription medication that can impair a person's ability to drive. NTSB subsequently reiterated a White House recommendation that drugged driving be made a national priority on par with drunk driving.

In California, there is no requirement to include a warning label or sticker on prescription medication which the Board of Pharmacy identifies as capable of impairing a person's ability to drive. Current law only requires that a pharmacist inform a patient orally or in writing

Medical research in the last decade has concurrently emphasized the value of container labels, while questioning the effectiveness of oral and written consultations.

A report Commissioned by the American College of Physicians Foundation (ACPF)

concluded that prescription medication labeling is the 'last line' of informational support.

The Same ACPF report stated that pharmacists often fail to orally communicate detailed information to patients, and that the last opportunity to counsel patients is the container label and accompanying inserts.

The Journal for Patient and Education Counseling found that the typical prescription medication guide insert or leaflet averages more than 2200 words, is read by less than a quarter of patients, and is not written at the reading level recommended by the FDA. In a separate study more than twice as many patients reported seeing container warning labels, with 78% indicating that they followed the instructions.

Despite the stated medical value of warning stickers, an American Medical Association Report found great variance in the use of labels, with between 8% and 25% of pharmacies not using any warning label for prescribed drugs with potentially harmful side-effects.

In 2011, The International Commission on Narcotic Drugs adopted a resolution, at the urging of President Obama's Office of National Drug Control Policy, recognizing prescription drug use as a key contributor to the emerging problem of drugged driving.

#### **THIS BILL**

AB 1136 combats the growing epidemic of drugged driving by mandating best practices among California pharmacies to ensure that warning labels are included on dangerous drugs.

#### **SUPPORT**

California Senior Legislature



California  
LEGISLATIVE INFORMATION

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

AMENDED IN ASSEMBLY MARCH 20, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**ASSEMBLY BILL**

**No. 1136**

**Introduced by Assembly Member Levine**

**February 22, 2013**

**An act to amend Section 4074 of the Business and Professions Code, relating to pharmacy.**

LEGISLATIVE COUNSEL'S DIGEST

AB 1136, as amended, Levine. Pharmacists: drug disclosures.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Under existing law, in certain instances, if a prescription drug poses a 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, a pharmacist is required to inform the patient orally or in writing of those harmful effects when the drug is dispensed. A violation of the Pharmacy Law is a crime.

This bill would ~~delete the requirement that the disclosure of harmful effects be performed orally or in writing. The bill would, in addition to that disclosure,~~ require the pharmacist to include a written label on the drug container indicating ~~the substantial risk to the person consuming the drug~~ *that the drug may impair a person's ability to operate a vehicle or vessel*. Because a violation of this requirement would be a crime, the bill would impose a state-mandated local program.

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

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

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes



California  
LEGISLATIVE INFORMATION

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

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

**4074.** (a) (1) 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) (A) 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.

(B) 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.

(2) 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.

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

(c) 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), to ~~drugs-~~ a drug furnished to ~~patients-~~ a patient pursuant to subdivision (a) of Section 4056.

(d) 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.



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**Bill Number:** AB 1139  
**Introduced** 2/22/13  
**Last Amend:**  
**Author:** Assemblymember Bonnie Lowenthal  
**Topic:** Prescriptions: Biosimilar Products  
**Position:**

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**Current Bill Status:** In ASM Committee on Business, Professions & Consumer Protection

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

**EXISTING 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.”

**16 CCR § 1716** precludes a pharmacist from deviating from the requirements of a prescription except upon the prior consent of the prescriber, or to select a drug product in accordance with Section 4073.

**THIS BILL WOULD:**

**Amend Section 4073** to specify that a pharmacist filling a prescription order for a biological product, as specified, may select a biosimilar product, provided that the substituted biosimilar product is deemed by the FDA to be interchangeable with the prescribed product.

**STAFF COMMENTS:**

According to the author, AB 1139 would authorize a pharmacist to dispense a lower cost, equivalent biosimilar drug product for a brand name biological product, consistent with the procedures in place for generic drug substitution, so long as the substituted biosimilar product has been deemed by the FDA to be interchangeable with the prescribed product.

**FISCAL IMPACT ON THE BOARD:**

Staff has not identified any fiscal impact on the board as a result of AB 670 as amended.

**SUPPORT:**

Generic Pharmaceutical Manufacturers  
Association  
Hospira  
Walgreens  
Mylan, Inc.

California Retailers Association  
Teva Pharmaceutical Industries, Ltd.

**OPPOSITION:** None known

## AB 1139 (B. Lowenthal) Prescriptions: Biosimilar Products

### SUMMARY

AB 1139 authorizes pharmacists to dispense a lower cost, equivalent biosimilar drug product for a brand name biological product, consistent with the procedures in place for generic drug product substitution.

### BACKGROUND

Biologic medicines are manufactured from living organisms, such as live proteins or bacterias through a complex manufacturing process conducted in a highly controlled environment. In contrast to other medicines, biologics are manufactured using biology, rather than chemistry.

Biosimilars or “follow on biologics” are manufactured through similar processes with the goal of reproducing the composition of the innovator biologic therapeutic. *A biosimilar is essentially a “generic” biologic medication.*

The Biologics Price Competition and Innovation Act (BPCI Act) was passed as part of the Affordable Care Act and signed into law by President Obama on March 23, 2010. The BPCI Act creates a process for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference product as referenced by section 351(k) of the Public Health Service Act. The Federal Food and Drug Administration (the “FDA”) is currently developing guidance regarding the regulatory process for approval of biosimilar and interchangeable biologic products.

The FDA is in the process of establishing scientifically strong standards for the approval of biosimilars, including standards for interchangeability (equivalent to current law permitting pharmacists to dispense a generic equivalent). The federal framework is intended to be more rigorous than the approval process for generic drug products. As with generics, a biosimilar is a biological product that is highly similar to a U.S.-licensed reference biological product notwithstanding minor differences in clinically inactive compounds.

In the coming years, when the FDA has determined that safety and efficacy standards have been met, these less-costly biosimilars will become available to patients.

Biosimilar leaders in the generic industry have been successfully producing safe and effective biosimilars for sale in Europe since the early 2000s. In the US, the approval process developed by the FDA for biosimilars

will be more rigorous than the approval process used in the European Union. In contrast to the existing approval process for generic medications which only requires the manufacturer to demonstrate that the generic drug has the same molecular make-up as the name brand medication, the process for approving a biosimilar will require additional testing to ensure that biosimilar has the same effect as the biologic. As with all other medicines, all biologics and biosimilars are permanently monitored to help ensure ongoing safety.

In addition to demonstrating the same outcomes as the name brand biologics, biosimilars offer considerable cost savings and increased availability for consumers. While a biologic can cost up to \$15,000 a month, a biosimilar can cost 30% less. For groups and health plans grappling with the retirement of the baby boomer generation and the higher cost of providing health care coverage, the variance in cost can make a significant difference in the plan’s ability to cover treatment at an affordable rate.

### AB 1139

AB 1139 allows pharmacists to select and dispense at a lower cost, equivalent biosimilar drug products, **once they are approved for use by the FDA.**

Physicians will use the same process for prescribing biosimilars as they do for other drugs, including the option to prohibit the substitution the prescribed drug, by simply checking the “dispense as written” box on the prescription itself, the same specification that’s allowed for the prescribing of name brand or generic medication.

### SUPPORT

- Generic Pharmaceutical Manufacturers Association
- Hospira
- Walgreens
- Mylan, Inc.
- California Retailers Association
- Teva Pharmaceutical Industries, Ltd.

### STAFF CONTACT

Allison Ruff, Chief of Staff  
Assemblymember Bonnie Lowenthal  
(916) 319-2070  
[allison.ruff@asm.ca.gov](mailto:allison.ruff@asm.ca.gov)



California  
LEGISLATIVE INFORMATION

AB-1139 Prescriptions: biosimilar products. (2013-2014)

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**ASSEMBLY BILL**

**No. 1139**

**Introduced by Assembly Member Lowenthal  
(Principal Coauthor(s): Senator DeSaulnier)**

February 22, 2013

**An act to amend Section 4073 of the Business and Professions Code, relating to  
pharmacy.**

LEGISLATIVE COUNSEL'S DIGEST

AB 1139, as introduced, Lowenthal. Prescriptions: biosimilar products.

The Pharmacy Law governs the practice of pharmacy in this state, including the permissible duties of licensed pharmacists. Among other permitted acts, a pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by a specified federal entity, of those drug products having the same active chemical ingredients. A person who knowingly violates the Pharmacy Law is guilty of a misdemeanor, as specified.

This bill would authorize a pharmacist filling a prescription order for a biological product subject to the Federal Food, Drug, and Cosmetic Act, as specified, to select a biosimilar product, as defined by federal statute, provided that product is deemed by the federal Food and Drug Administration (FDA) to be interchangeable with the prescribed product.

Vote: majority Appropriation: no Fiscal Committee: no Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** Section 4073 of the Business and Professions Code is amended to read:

**4073.** (a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

*(b) A pharmacist filling a prescription order for a biological product subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)), may select a biosimilar product, as defined by Section*

*351 of the federal Public Health Service Act (42 U.S.C. Sec. 262), provided that product is deemed by the FDA to be interchangeable with the prescribed product.*

~~(b)~~

(c) 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 substitution be manually initialed by the prescriber.

~~(e)~~

(d) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision ~~(b)~~ (c). The person who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. 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. In no case shall the pharmacist select a drug product pursuant to this section unless the drug product selected costs the patient less than the prescribed drug product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

~~(e)~~

(e) 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 California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

~~(e)~~

(f) When a substitution is made pursuant to this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label, except where the prescriber orders otherwise.



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| <b>Bill Number:</b> | <b>SB 204</b>                               |
| <b>Introduced</b>   | 2/8/13                                      |
| <b>Last Amend:</b>  |   |
| <b>Author:</b>      | Senator Ellen Corbett                       |
| <b>Topic:</b>       | Prescription Drugs: Labeling (Translations) |
| <b>Position:</b>    |   |

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**Current Bill Status:** 4/22/13 – Hearing in Senate Business, Professions & Economic Development

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

**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 <sup>1</sup>translations in five languages of the various “directions for use” as enumerated at 1707.5(a)(D)(4).

### **THIS BILL WOULD:**

Add Section 4076.5 BPC to require a pharmacist to use the translations for the “directions for use” on the board’s website, as applicable, when labeling a prescription.

The section authorizes a pharmacist to translate the directions for use into additional non-English languages if certified translation services are utilized to complete the translations.

### **STAFF COMMENTS:**

Staff has requested a Fact Sheet from the author’s office, and has reached out to seek clarification on the following:

- Is the intent of the bill to require that translated “directions for use” be *in addition to* the English printed “directions for use” or *in lieu of* English?
- What are “certified” translation services?

### **FISCAL IMPACT ON THE BOARD:**

If enacted as introduced, the board may need to update its regulation at 16 CCR § 1707.5 and may need to further clarify what “certified” translation services are. Regulation updates would be absorbed within the board’s existing staff resources.

### **Staff Recommendation:**

**Support / Opposition:** None known as of 4/5/13

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



California  
LEGISLATIVE INFORMATION

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

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**SENATE BILL**

**No. 204**

**Introduced by Senator Corbett**

February 08, 2013

**An act to add Section 4076.3 to the Business and Professions Code, relating to pharmacy.**

LEGISLATIVE COUNSEL'S DIGEST

SB 204, as introduced, Corbett. Prescription drugs: labeling.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law prohibits a pharmacist from dispensing any prescription unless it is in a specified container that is correctly labeled to include, among other information, the directions for the use of the drug. A violation of the Pharmacy Law is a crime.

This bill would require a pharmacist to use translations of the directions for use in non-English languages published on the board's Internet Web site, as applicable, when labeling a prescription container. The bill would authorize a pharmacist to translate the directions for use into additional non-English languages if certified translation services are utilized to complete the additional translations. Because a violation of this requirement would be a crime, the bill would impose a state-mandated local program.

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

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

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

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

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

(b) A pharmacist may translate the directions for use into additional non-English languages if certified translation services are utilized to complete the additional translations.

**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.



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| <b>Bill Number:</b> | <b>SB 205</b>                             |
| <b>Introduced</b>   | 2/8/13                                    |
| <b>Last Amend:</b>  |   |
| <b>Author:</b>      | Senator Ellen Corbett                     |
| <b>Topic:</b>       | Prescription Drugs: Labeling (12-pt font) |
| <b>Position:</b>    |   |

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**Current Bill Status:** 4/22/13 – Hearing in Senate Business, Professions & Economic Development

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

**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.

### **THIS BILL WOULD:**

Amend Section 4076 BPC to

- Require that any prescription dispensed meet requirements of state and federal law, and is correctly labeled in at least a **12-point** sans serif typeface, as specified.
- 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.

### **STAFF COMMENTS:**

Staff has requested a Fact Sheet from the author’s office, and has reached out to ask why the “licensed” provision has been removed from subdivision (c) of the section.

Removing the reference to a “licensed” facility makes the language in subdivision (c) inconsistent with subdivision (d) of that section and may cause confusion.

### **FISCAL IMPACT ON THE BOARD:**

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

### **Staff Recommendation:**

*As of 4/5/2013*

**SUPPORT:**

**OPPOSITION:**



California  
LEGISLATIVE INFORMATION

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

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**SENATE BILL**

**No. 205**

**Introduced by Senator Corbett**

**February 08, 2013**

**An act to amend Section 4076 of the Business and Professions Code, relating to pharmacy.**

LEGISLATIVE COUNSEL'S DIGEST

SB 205, as introduced, Corbett. Prescription drugs: labeling.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law requires every prescription, as defined, to include a legible, clear notice of the condition or purpose for which the drug is prescribed, if requested by the patient. Existing law prohibits a pharmacist from dispensing any prescription unless it is in a specified container that is correctly labeled to include, among other information, the condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription. A violation of the Pharmacy Law is a crime.

This bill would require the information on the prescription label to be printed in at least a 12-point sans serif typeface. Because a violation of this requirement would be a crime, the bill would impose a state-mandated local program.

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

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

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**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, *in at least a 12-point sans serif typeface*, 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) 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.

(c) 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) 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.



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**Bill Number:** SB 506  
**Introduced** 2/21/13  
**Last Amend:**  
**Author:** Senator Jerry Hill  
**Topic:** Ephedrine: Retail Sale  
**Position:**

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**Current Bill Status:** 4/9/13 – Set for Hearing in Senate Public Safety

**Affected Sections:** Amend, repeal and Add Section 11100 Health & Safety Code (HSC)  
**Add, repeal Section 11100.02 HSC**

**EXISTING LAW:**

**The Uniform Controlled Substances Act** (Section 11000 et seq) (Act) of the Health and Safety Code sets for general provision, definitions, standards and (five) schedules for controlled substances, and other information and requirements related to controlled substances. Existing law does not classify ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine within any of the five schedules (i.e., ephedrine products).

**Section 11100 HSC** requires any manufacturer, wholesaler, retailer or other person or entity that sells, transfers, or otherwise furnishes specified substances (including ephedrine products) to any person or entity to report those transactions to the California Department of Justice. However, a pharmacist may sell or furnish these substances pursuant to a valid prescription. The section specifies additional requirements, exclusions and penalties for violation of the section.

Without a prescription, Section 11100(g)(3) prohibits the sale of more than 3 packages or 9 grams of nonprescription product containing ephedrine, as specified.

**THIS BILL WOULD:**

Until January 1, 2019, and related to the furnishing of ephedrine products *without* a valid prescription, SB 506 would eliminate the current reporting of specified ephedrine products to the Ca. DOJ and, instead, provide for the collection and reporting into a single web-based database operated by the National Precursor Log Exchange (NPLEx) specified proposed transactions of those products, as specified (see new Section 11100.02). This web-based single database would be available to a retailer at no charge and would provide a retailer with an immediate, real-time alert at the point of sale where a transaction violates the provisions of the section, and where the transaction should not be completed.

The section provides that pursuant to a MOU between Ca. DOJ and NADDI, the collected data shall be transmitted to the C. DOJ weekly and provide DOJ with real-time access to the system, as specified.

To comply with the provisions of SB 506, a pharmacy would be required to have access to the Internet in order to access the web-based database.

**AUTHOR'S INTENT:**

According to the author, SB 506 will require California retailers selling over-the-counter (OTC) products containing pseudoephedrine (PSE) to submit data required to be collected under federal law to a unified electronic logbook through a web-based interface prior to completing the sale. These retailers would be alerted immediately when a consumer is about to exceed the purchase limits, and required to stop the transaction.

**FISCAL IMPACT ON THE BOARD:**

Staff has not identified any fiscal impact to the board as a result of the provisions of SB 506. The board's self-assessment forms provide references related to the current recordkeeping requirements of Section 11100 et seq. HSC, and may need to be updated. Any such update would be absorbed with the board's existing staff resources.

**STAFF COMMENTS:**

In new Section 11100.02, subdivision (c)(6) specifies that if a retail distributor experiences mechanical or electronic failure of the system and cannot comply with the stated requirements, the retailer shall maintain a written or alternate electronic log of specified information, but the paragraph does not specify whether or not the retailer would be authorized to complete a transaction under those circumstances.

**Support / Opposition:** See attached Fact Sheet for SB 506 (3/6/2013)



## IN BRIEF

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SB 506 requires California retailers selling over-the-counter (OTC) products containing pseudoephedrine (PSE) to submit data required to be collected under federal law to a unified electronic logbook prior to completing the sale. Current law limits sales of PSE, but does not provide retailers with a mechanism to ensure that a sale is legal prior to completing it. The electronic logbook required by this bill fills that gap. Retailers would be alerted immediately when a consumer is about to exceed the purchase limits, and required to stop the sale.

## THE ISSUE

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Since 2006, federal law has required that all OTC PSE products be stored behind the counter, requires purchasers to provide identification and sign a paper logbook, and limits the quantities which may be purchased to 3.6 grams per day and 9 grams per month. This is to prevent criminals from accumulating large quantities of PSE and using it in the illegal production of methamphetamine. California currently has no mechanism to prevent criminals who are involved in illegal trafficking of PSE from visiting multiple stores and buying as many packages of PSE-containing products as they want, because retailers' logbooks are not connected.

## BACKGROUND

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Twenty-six states already mandate the use of real-time electronic logbooks for PSE sales: Alabama, Arizona, Arkansas, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Michigan, Missouri, Nebraska, North Carolina, North Dakota, Ohio, Oklahoma, South Carolina, Tennessee, Texas, Virginia, Washington, and West Virginia.

Some propose to limit consumer access to these U.S. Food and Drug Administration (FDA) approved OTC cold and allergy medications by making them available by prescription only. They assert that this is the only way to prevent clandestine methamphetamine production.

While the goal of preventing diversion of the consumer products is laudable, this prescription-only approach will only serve to cut off access for millions of California allergy sufferers, and millions of uninsured Californians. It will cost the state lost sales tax revenues to the general fund because OTCs are taxed and prescription medicines are not. Furthermore, it is not the most efficient way to

prevent criminal activity. The most efficient mechanism is a uniform, centralized system of electronic reporting and monitoring of sales.

## THE SOLUTION

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Once required by SB 506, access to the electronic tracking system will be provided at no cost to retailer. The bill directs retailers to use the National Precursor Log Exchange (NPLEx) administered by the National Association of Drug Diversion Investigators (NADDI). NPLEx is paid for by manufacturers of PSE products to provide real-time information exchange between all retailers and ensure that the products are only sold within legal limits.

When a consumer seeks to purchase any OTC PSE-containing product from a retailer, the retailer will be required to input the federally-mandated consumer information into the electronic logbook. Retailers can access the system through a web-based interface, where the only requirement is a computer with internet access. The system will have an electronic mechanism for alerting the retailer at the point of sale if the consumer is ineligible to make the purchase because s/he is about to purchase amounts in excess of the amounts authorized by law. If an alert is received by the retailer, the sale cannot be made.

Once in effect, any retailer making a sale without entering the information into the central database through this system, or making a sale notwithstanding an alert, will be subject to prosecution for a misdemeanor. A second conviction is punishable by up to one year in county jail and a \$10,000 fine.

The bill provides that the transaction information **shall not be used** by retailers other than for complying with state and federal law, that purchasers shall be notified that the information is being collected pursuant to law, and establishes strict privacy standards for the security of the information.

## FOR MORE INFORMATION

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Meegen Murray  
916-651-4013  
[Meegen.Murray@sen.ca.gov](mailto:Meegen.Murray@sen.ca.gov)

[Support on backside](#)

## **SUPPORT**

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BayBio  
BIOCOM  
California District Attorneys Association  
California Healthcare Institute  
California Manufactures and Technology Association  
California Retailers Association  
California Pharmacists Association  
California State Sheriffs' Association  
CalChamber  
Consumer Healthcare Products Association  
Johnson & Johnson  
National Association of Chain Drug Stores  
Peace Officers Research Association of California  
Reckitt Benckiser  
Rite Aid  
Shasta County Sheriff  
Valley Industry & Commerce Association



*California*  
LEGISLATIVE INFORMATION

SB-506 Ephedrine: retail sale. (2013-2014)

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**SENATE BILL**

**No. 506**

**Introduced by Senator Hill**

**February 21, 2013**

**An act to amend, repeal, and add Section 11100 of, and to add and repeal Section 11100.02 of, the Health and Safety Code, relating to controlled substances.**

LEGISLATIVE COUNSEL'S DIGEST

SB 506, as introduced, Hill. Ephedrine: retail sale.

(1) Existing law classifies controlled substances into 5 schedules, with the most restrictive limitations placed on controlled substances classified in Schedule I, and the least restrictive limitations placed on controlled substances classified in Schedule V. A controlled substance in any of the schedules may be possessed or dispensed only upon a lawful prescription, as specified. Existing law does not classify ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine within any of these 5 schedules, but provides that it is a crime, punishable as specified, for a person in this state who engages in specified transactions involving those drugs to fail to submit a report to the Department of Justice of all of those transactions, or to fail to submit an application to, and obtain a permit for the conduct of that business from, the Department of Justice, as specified. Existing law prohibits the sale of more than 3 packages or 9 grams of a nonprescription product containing ephedrine or the other drugs, as specified.

This bill would instead provide that it is a misdemeanor, punishable as specified, for a retail distributor, except pursuant to a valid prescription from a licensed practitioner with prescriptive authority, to sell or distribute to a person specified amounts of nonprescription products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine within specified time limits, to sell or distribute any of those substances to a person whose information has generated an alert, or, except under specified conditions, to sell or distribute to a purchaser a nonprescription product containing any amount of those substances. The bill would contain provisions requiring the secure storage and monitoring of products containing any amount of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, as specified.

The bill would require retail distributors to transmit, on and after July 1, 2014, sale information to the National Precursor Log Exchange (NPLEx) for purposes of determining whether the sale would violate these provisions. The bill would require the Department of Justice to enter into a memorandum of understanding with the National Association of Drug Diversion Investigators regarding the transaction records in NPLEx, as specified. The bill would provide that the information in the system may not be used for any purpose other than to meet the requirements of, or comply with, this act or a certain federal act, as specified. The bill would require that the system be available to the department and state law enforcement at no charge and would prohibit the

Department of Justice or any other state agency from bearing any cost for the development, installation, or maintenance of the system. The bill would specify legislative findings and intent. The bill's provisions would remain in effect only until January 1, 2019. By creating a new crime, this bill would impose a state-mandated local program.

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

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

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

## THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** Section 11100 of the Health and Safety Code is amended to read:

**11100.** (a) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes any of the following substances to any person or entity in this state or any other state shall submit a report to the Department of Justice of all of those transactions:

- (1) Phenyl-2-propanone.
- (2) Methylamine.
- (3) Ethylamine.
- (4) D-lysergic acid.
- (5) Ergotamine tartrate.
- (6) Diethyl malonate.
- (7) Malonic acid.
- (8) Ethyl malonate.
- (9) Barbituric acid.
- (10) Piperidine.
- (11) N-acetylanthranilic acid.
- (12) Pyrrolidine.
- (13) Phenylacetic acid.
- (14) Anthranilic acid.
- (15) Morpholine.
- (16) Ephedrine.
- (17) Pseudoephedrine.
- (18) Norpseudoephedrine.
- (19) Phenylpropanolamine.
- (20) Propionic anhydride.
- (21) Isosafrole.
- (22) Safrole.
- (23) Piperonal.
- (24) Thionyl chloride.
- (25) Benzyl cyanide.

(26) Ergonovine maleate.

(27) N-methylephedrine.

(28) N-ethylephedrine.

(29) N-methylpseudoephedrine.

(30) N-ethylpseudoephedrine.

(31) Chloroephedrine.

(32) Chloropseudoephedrine.

(33) Hydriodic acid.

(34) Gamma-butyrolactone, including butyrolactone; butyrolactone gamma; 4-butyrolactone; 2(3H)-furanone dihydro; dihydro-2(3H)-furanone; tetrahydro-2-furanone; 1,2-butanolide; 1,4-butanolide; 4-butanolide; gamma-hydroxybutyric acid lactone; 3-hydroxybutyric acid lactone and 4-hydroxybutanoic acid lactone with Chemical Abstract Service number (96-48-0).

(35) 1,4-butanediol, including butanediol; butane-1,4-diol; 1,4-butylene glycol; butylene glycol; 1,4-dihydroxybutane; 1,4-tetramethylene glycol; tetramethylene glycol; tetramethylene 1,4-diol with Chemical Abstract Service number (110-63-4).

(36) Red phosphorus, including white phosphorus, hypophosphorous acid and its salts, ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, sodium hypophosphite, and phosphorous acid and its salts.

(37) Iodine or tincture of iodine.

(38) Any of the substances listed by the Department of Justice in regulations promulgated pursuant to subdivision (b).

(b) The Department of Justice may adopt rules and regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that add substances to subdivision (a) if the substance is a precursor to a controlled substance and delete substances from subdivision (a). However, no regulation adding or deleting a substance shall have any effect beyond March 1 of the year following the calendar year during which the regulation was adopted.

(c) (1) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state, prior to selling, transferring, or otherwise furnishing any substance specified in subdivision (a) to any person or business entity in this state or any other state, shall require (i) a letter of authorization from that person or business entity that includes the currently valid business license number or federal Drug Enforcement Administration (DEA) registration number, the address of the business, and a full description of how the substance is to be used, and (ii) proper identification from the purchaser. The manufacturer, wholesaler, retailer, or other person or entity in this state shall retain this information in a readily available manner for three years. The requirement for a full description of how the substance is to be used does not require the person or business entity to reveal their chemical processes that are typically considered trade secrets and proprietary information.

(B) For the purposes of this paragraph, "proper identification" for in-state or out-of-state purchasers includes two or more of the following: federal tax identification number; seller's permit identification number; city or county business license number; license issued by the State Department of Public Health; registration number issued by the federal Drug Enforcement Administration; precursor business permit number issued by the Department of Justice; driver's license; or other identification issued by a state.

(2) (A) ~~Any~~ *A* manufacturer, wholesaler, retailer, or other person or entity in this state that exports a substance specified in subdivision (a) to ~~any~~ *a* person or business entity located in a foreign country shall, on or before the date of exportation, submit to the Department of Justice a notification of that ~~transaction, which~~ *transaction*. *The* notification shall include the name and quantity of the substance to be exported and the name, address, and, if assigned by the foreign country or subdivision thereof, business identification number of the person or business entity located in a foreign country importing the substance.

(B) The department may authorize the submission of the notification on a monthly basis with respect to repeated, regular transactions between an exporter and an importer involving a substance specified in subdivision (a), if the department determines that a pattern of regular supply of the substance exists between

the exporter and importer and that the importer has established a record of utilization of the substance for lawful purposes.

(d) (1) ~~Any-A~~ manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes a substance specified in subdivision (a) to a person or business entity in this state or any other state shall, not less than 21 days prior to delivery of the substance, submit a report of the transaction, which includes the identification information specified in subdivision (c), to the Department of Justice. The Department of Justice may authorize the submission of the reports on a monthly basis with respect to repeated, regular transactions between the furnisher and the recipient involving the substance or substances if the Department of Justice determines that a pattern of regular supply of the substance or substances exists between the manufacturer, wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes the substance or substances and the recipient of the substance or substances, and the recipient has established a record of utilization of the substance or substances for lawful purposes.

(2) The person selling, transferring, or otherwise furnishing ~~any a~~ substance specified in subdivision (a) shall affix his or her signature or otherwise identify himself or herself as a witness to the identification of the purchaser or purchasing individual, and shall, if a common carrier is used, maintain a manifest of the delivery to the purchaser for three years.

(e) This section shall not apply to any of the following:

(1) ~~Any-A~~ pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian.

(2) ~~Any-A~~ physician, dentist, podiatrist, or veterinarian who administers or furnishes a substance to his or her patients.

(3) ~~Any-A~~ manufacturer or wholesaler licensed by the California State Board of Pharmacy that sells, transfers, or otherwise furnishes a substance to a licensed pharmacy, physician, dentist, podiatrist, or veterinarian, or a retail distributor ~~as defined in subdivision (h)~~, provided that the manufacturer or wholesaler submits records of any suspicious sales or transfers as determined by the Department of Justice.

(4) ~~Any-An~~ analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice.

(5) A state-licensed health care facility that administers or furnishes a substance to its patients.

(6) (A) ~~Any-The~~ sale, transfer, furnishing, or receipt of ~~any a~~ product that contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and ~~which that~~ is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the ~~federal~~ *Federal* Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder. However, this section shall apply to preparations in solid or liquid dosage form, except pediatric liquid forms, as defined, containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine where the individual transaction involves more than three packages or nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

(B) Any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine product subsequently removed from exemption pursuant to Section 814 of Title 21 of the United States Code shall similarly no longer be exempt from any state reporting or permitting requirement, unless otherwise reinstated pursuant to ~~subdivision (d) or (e) of Section 814~~ *814(d)* of Title 21 of the United States Code as an exempt product.

(7) The sale, transfer, furnishing, or receipt of ~~any a~~ betadine or povidone solution with an iodine content not exceeding 1 percent in containers of eight ounces or less, or ~~any a~~ tincture of iodine not exceeding 2 percent in containers of one ounce or less, that is sold over the counter.

(8) ~~Any-The~~ transfer of a substance specified in subdivision (a) for purposes of lawful disposal as waste.

(f) (1) ~~Any-A~~ person specified in subdivision (a) or (d) who does not submit a report as required by that subdivision or who knowingly submits a report with false or fictitious information shall be punished by imprisonment in a county jail not exceeding six months, by a fine not exceeding five thousand dollars (\$5,000), or by both the fine and imprisonment.

(2) Any person specified in subdivision (a) or (d) who has previously been convicted of a violation of paragraph (1) shall, upon a subsequent conviction thereof, be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars (\$100,000), or by both the fine and imprisonment.

(g) (1) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for ~~any~~ a manufacturer, wholesaler, retailer, or other person to sell, transfer, or otherwise furnish a substance specified in subdivision (a) to a person under 18 years of age.

(2) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for any person under 18 years of age to possess a substance specified in subdivision (a).

~~(3) Notwithstanding any other law, it is unlawful for any retail distributor to (i) sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or (ii) knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids as defined. Except as otherwise provided in this section, the three package per transaction limitation or nine gram per transaction limitation imposed by this paragraph shall apply to any product that is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), or regulations adopted thereunder, unless exempted from the requirements of the federal Controlled Substances Act by the federal Drug Enforcement Administration pursuant to Section 814 of Title 21 of the United States Code.~~

~~(4)~~

(3) (A) A first violation of this subdivision is a misdemeanor.

(B) ~~Any~~ A person who has previously been convicted of a violation of this subdivision shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars (\$10,000), or by both the fine and imprisonment.

~~(h) For the purposes of this article, the following terms have the following meanings:~~

~~(1) "Drug store" is any entity described in Code 5912 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.~~

~~(2) "General merchandise store" is any entity described in Codes 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.~~

~~(3) "Grocery store" is any entity described in Code 5411 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.~~

~~(4) "Pediatric liquid" means a nonencapsulated liquid whose unit measure according to product labeling is stated in milligrams, ounces, or other similar measure. In no instance shall the dosage units exceed 15 milligrams of phenylpropanolamine or pseudoephedrine per five milliliters of liquid product, except for liquid products primarily intended for administration to children under two years of age for which the recommended dosage unit does not exceed two milliliters and the total package content does not exceed one fluid ounce.~~

~~(5) "Retail distributor" means a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as a distributor of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products, are limited exclusively to the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products for personal use both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. "Retail distributor" includes an entity that makes a direct sale, but does not include the parent company of that entity if the company is not involved in direct sales regulated by this article.~~

~~(6) "Sale for personal use" means the sale in a single transaction to an individual customer for a legitimate medical use of a product containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in dosages at or below that specified in paragraph (3) of subdivision (g). "Sale for personal use" also includes the sale of those products to employers to be dispensed to employees from first-aid kits or medicine chests.~~

~~(i) It is the intent of the Legislature that this section shall preempt all local ordinances or regulations governing the sale by a retail distributor of over-the-counter products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.~~

~~(h) This section shall remain in effect only until January 1, 2019, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2019, deletes or extends that date.~~

**SEC. 2.** Section 11100 is added to the Health and Safety Code, to read:

**11100.** (a) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes any of the following substances to any person or entity in this state or any other state shall submit a report to the Department of Justice of all of those transactions:

- (1) Phenyl-2-propanone.
- (2) Methylamine.
- (3) Ethylamine.
- (4) D-lysergic acid.
- (5) Ergotamine tartrate.
- (6) Diethyl malonate.
- (7) Malonic acid.
- (8) Ethyl malonate.
- (9) Barbituric acid.
- (10) Piperidine.
- (11) N-acetylanthranilic acid.
- (12) Pyrrolidine.
- (13) Phenylacetic acid.
- (14) Anthranilic acid.
- (15) Morpholine.
- (16) Ephedrine.
- (17) Pseudoephedrine.
- (18) Norpseudoephedrine.
- (19) Phenylpropanolamine.
- (20) Propionic anhydride.
- (21) Isosafrole.
- (22) Safrole.
- (23) Piperonal.
- (24) Thionyl chloride.
- (25) Benzyl cyanide.
- (26) Ergonovine maleate.
- (27) N-methylephedrine.
- (28) N-ethylephedrine.
- (29) N-methylpseudoephedrine.
- (30) N-ethylpseudoephedrine.
- (31) Chloroephedrine.
- (32) Chloropseudoephedrine.
- (33) Hydriodic acid.

(34) Gamma-butyrolactone, including butyrolactone; butyrolactone gamma; 4-butyrolactone; 2(3H)-furanone dihydro; dihydro-2(3H)-furanone; tetrahydro-2-furanone; 1,2-butanolide; 1,4-butanolide; 4-butanolide; gamma-hydroxybutyric acid lactone; 3-hydroxybutyric acid lactone and 4-hydroxybutanoic acid lactone with Chemical Abstract Service number (96-48-0).

(35) 1,4-butanediol, including butanediol; butane-1,4-diol; 1,4-butylene glycol; butylene glycol; 1,4-dihydroxybutane; 1,4-tetramethylene glycol; tetramethylene glycol; tetramethylene 1,4-diol with Chemical Abstract Service number (110-63-4).

(36) Red phosphorus, including white phosphorus, hypophosphorous acid and its salts, ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, sodium hypophosphite, and phosphorous acid and its salts.

(37) Iodine or tincture of iodine.

(38) Any of the substances listed by the Department of Justice in regulations promulgated pursuant to subdivision (b).

(b) The Department of Justice may adopt rules and regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that add substances to subdivision (a) if the substance is a precursor to a controlled substance and delete substances from subdivision (a). However, no regulation adding or deleting a substance shall have any effect beyond March 1 of the year following the calendar year during which the regulation was adopted.

(c) (1) (A) A manufacturer, wholesaler, retailer, or other person or entity in this state, prior to selling, transferring, or otherwise furnishing a substance specified in subdivision (a) to a person or business entity in this state or any other state, shall require (i) a letter of authorization from that person or business entity that includes the currently valid business license number or federal Drug Enforcement Administration (DEA) registration number, the address of the business, and a full description of how the substance is to be used, and (ii) proper identification from the purchaser. The manufacturer, wholesaler, retailer, or other person or entity in this state shall retain this information in a readily available manner for three years. The requirement for a full description of how the substance is to be used does not require the person or business entity to reveal chemical processes that are typically considered trade secrets and proprietary information.

(B) For the purposes of this paragraph, "proper identification" for in-state or out-of-state purchasers includes two or more of the following: federal tax identification number; seller's permit identification number; city or county business license number; license issued by the State Department of Public Health; registration number issued by the federal Drug Enforcement Administration; precursor business permit number issued by the Bureau of Narcotic Enforcement of the Department of Justice; driver's license; or other identification issued by a state.

(2) (A) A manufacturer, wholesaler, retailer, or other person or entity in this state that exports a substance specified in subdivision (a) to a person or business entity located in a foreign country shall, on or before the date of exportation, submit to the Department of Justice a notification of that transaction. The notification shall include the name and quantity of the substance to be exported and the name, address, and, if assigned by the foreign country or subdivision thereof, business identification number of the person or business entity located in a foreign country importing the substance.

(B) The department may authorize the submission of the notification on a monthly basis with respect to repeated, regular transactions between an exporter and an importer involving a substance specified in subdivision (a), if the department determines that a pattern of regular supply of the substance exists between the exporter and importer and that the importer has established a record of utilization of the substance for lawful purposes.

(d) (1) A manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes a substance specified in subdivision (a) to a person or business entity in this state or any other state shall, not less than 21 days prior to delivery of the substance, submit a report of the transaction, which includes the identification information specified in subdivision (c), to the Department of Justice. The Department of Justice may authorize the submission of the reports on a monthly basis with respect to repeated, regular transactions between the furnisher and the recipient involving the substance or substances if the Department of Justice determines that a pattern of regular supply of the substance or substances exists between the manufacturer, wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes the substance or substances and the recipient of the substance or substances, and the recipient has established a record of utilization of the substance or substances for lawful purposes.

(2) The person selling, transferring, or otherwise furnishing a substance specified in subdivision (a) shall affix his or her signature or otherwise identify himself or herself as a witness to the identification of the purchaser or purchasing individual, and shall, if a common carrier is used, maintain a manifest of the delivery to the purchaser for three years.

(e) This section shall not apply to any of the following:

(1) A pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian.

(2) A physician, dentist, podiatrist, or veterinarian who administers or furnishes a substance to his or her patients.

(3) A manufacturer or wholesaler licensed by the California State Board of Pharmacy that sells, transfers, or otherwise furnishes a substance to a licensed pharmacy, physician, dentist, podiatrist, or veterinarian, or a retail distributor, provided that the manufacturer or wholesaler submits records of any suspicious sales or transfers as determined by the Department of Justice.

(4) An analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice.

(5) A state-licensed health care facility that administers or furnishes a substance to its patients.

(6) (A) The sale, transfer, furnishing, or receipt of a product that contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and that is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder. However, this section shall apply to preparations in solid or liquid dosage form, except pediatric liquid forms, as defined, containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine where the individual transaction involves more than three packages or nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

(B) An ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine product subsequently removed from exemption pursuant to Section 814 of Title 21 of the United States Code shall similarly no longer be exempt from state reporting or permitting requirements, unless otherwise reinstated pursuant to Section 814(d) of Title 21 of the United States Code as an exempt product.

(7) The sale, transfer, furnishing, or receipt of a betadine or povidone solution with an iodine content not exceeding 1 percent in containers of eight ounces or less, or a tincture of iodine not exceeding 2 percent in containers of one ounce or less, that is sold over the counter.

(8) Transfer of a substance specified in subdivision (a) for purposes of lawful disposal as waste.

(f) (1) A person specified in subdivision (a) or (d) who does not submit a report as required by that subdivision or who knowingly submits a report with false or fictitious information shall be punished by imprisonment in a county jail not exceeding six months, by a fine not exceeding five thousand dollars (\$5,000), or by both the fine and imprisonment.

(2) A person specified in subdivision (a) or (d) who has previously been convicted of a violation of paragraph (1) shall, upon a subsequent conviction thereof, be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars (\$100,000), or by both the fine and imprisonment.

(g) (1) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for a manufacturer, wholesaler, retailer, or other person to sell, transfer, or otherwise furnish a substance specified in subdivision (a) to a person under 18 years of age.

(2) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for a person under 18 years of age to possess a substance specified in subdivision (a).

(3) Notwithstanding any other law, it is unlawful for a retail distributor to (A) sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or (B) knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids as defined. Except as otherwise provided in this section, the three package per transaction limitation or nine gram per transaction limitation imposed by this paragraph shall apply to any product that is lawfully sold, transferred, or furnished

over the counter without a prescription pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), or regulations adopted thereunder, unless exempted from the requirements of the federal Controlled Substances Act (21 U.S.C. Sec. 801 et seq.) by the federal Drug Enforcement Administration pursuant to Section 814 of Title 21 of the United States Code.

(4) (A) A first violation of this subdivision is a misdemeanor.

(B) A person who has previously been convicted of a violation of this subdivision shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars (\$10,000), or by both the fine and imprisonment.

(h) For the purposes of this article, the following terms have the following meanings:

(1) "Drug store" is an entity described in Code 5912 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(2) "General merchandise store" is an entity described in Codes 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(3) "Grocery store" is an entity described in Code 5411 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(4) "Pediatric liquid" means a nonencapsulated liquid whose unit measure according to product labeling is stated in milligrams, ounces, or other similar measure. In no instance shall the dosage units exceed 15 milligrams of phenylpropanolamine or pseudoephedrine per five milliliters of liquid product, except for liquid products primarily intended for administration to children under two years of age for which the recommended dosage unit does not exceed two milliliters and the total package content does not exceed one fluid ounce.

(5) "Retail distributor" means a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as a distributor of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products, are limited exclusively to the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products for personal use both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. "Retail distributor" includes an entity that makes a direct sale, but does not include the parent company of that entity if the company is not involved in direct sales regulated by this article.

(6) "Sale for personal use" means the sale, in a single transaction, to an individual customer for a legitimate medical use of a product containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in dosages at or below that specified in paragraph (3) of subdivision (g). "Sale for personal use" also includes the sale of those products to employers to be dispensed to employees from first aid kits or medicine chests.

(i) It is the intent of the Legislature that this section shall preempt all local ordinances or regulations governing the sale by a retail distributor of over-the-counter products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

(j) This section shall become operative on January 1, 2019.

**SEC. 3.** Section 11100.02 is added to the Health and Safety Code, to read:

**11100.02.** (a) Notwithstanding any other law, it is unlawful for a retail distributor to knowingly do any of the following, except pursuant to a valid prescription from a licensed practitioner with prescriptive authority:

(1) To sell or distribute to the same purchaser within a 30-day period more than 9 grams, or within a day more than 3.6 grams, of ephedrine base, pseudoephedrine base, norpseudoephedrine base, or phenylpropanolamine base contained in a product that is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), or regulations adopted thereunder, unless exempted from the requirements of the federal Controlled Substances Act (21 U.S.C. Sec. 801 et seq.) by the federal Drug Enforcement Administration pursuant to Section 814 of Title 21 of the United States Code.

(2) To sell or distribute ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine to a person whose information has generated an alert as described in paragraph (3) of subdivision (d) regarding that sale.

(3) To sell or distribute to a purchaser a nonprescription product containing any amount of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, except under the following conditions:

(A) The purchaser shall produce valid government-issued photo identification.

(B) The purchaser shall sign a written or electronic log showing all of the following:

(i) The date and time of the transaction.

(ii) The identification number presented.

(iii) The agency issuing the identification and the type of identification issued.

(iv) The name, date of birth, and address of the purchaser.

(v) The amount of ephedrine base, pseudoephedrine base, norpseudoephedrine base, or phenylpropanolamine base contained in the material, compound, mixture, or preparation sold.

(b) The retail distributor shall store any product containing any amount of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine either behind the counter or in a locked cabinet so that the customer does not have access to the product.

(c) (1) To facilitate the monitoring of the sales of nonprescription products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, the retail distributor shall record all of the following information at the point of sale regarding the proposed transaction for the purpose of complying with this section or the federal Combat Methamphetamine Epidemic Act of 2005, or any regulation adopted pursuant to this section or that act, and for no other purpose:

(A) The date and time of the transaction.

(B) The identification number of the purchaser, issuing agency of the identification, and the type of identification used.

(C) The name, date of birth, and address of the purchaser verified through a photo identification of the purchaser.

(D) The name, quantity of packages, and total gram weight of ephedrine base, pseudoephedrine base, norpseudoephedrine base, or phenylpropanolamine base contained in a product or products purchased, received, or otherwise acquired.

(E) The name or initials of the person making the sale.

(2) On and after July 1, 2014, the retail distributor shall transmit the information immediately to the National Precursor Log Exchange (NPLeX) administered by the National Association of Drug Diversion Investigators (NADDI) for purposes of determining whether the proposed sale would violate this section and therefore may not proceed, provided that the NPLeX system is available to retailers in the state without a charge for accessing the system. The transaction information shall not be accessed, stored, or used by the retail distributor or law enforcement for any purpose other than to meet the requirements set forth in this section or to comply with the provisions of the federal Combat Methamphetamine Epidemic Act of 2005, or any regulation adopted pursuant to this section or that act. The retail distributor shall not maintain a separate copy of the transaction information and shall not have direct access to individual information or sales records entered into the NPLeX system, except as required by the federal Combat Methamphetamine Epidemic Act of 2005.

(3) (A) A retail distributor shall provide notice electronically, in writing, or by signage to purchasers at the time of purchase that the information collected pursuant to the federal Combat Methamphetamine Epidemic Act of 2005 and this section shall be entered into a single database as specified in paragraph (2) and provided to law enforcement for purposes of determining the legality of a proposed sale.

(B) The Legislature finds that it is necessary for probable cause to be demonstrated to trigger an investigation in connection with an individual whose requested purchase is denied by the system a single time.

(C) Access by law enforcement to the data contained in the system from a location other than the retailer shall be limited to the records of an individual whose attempted purchase has been denied by the system.

(4) This subdivision shall not be construed to require a retail distributor to maintain state-required records relating to the sale of products containing ephedrine, pseudoephedrine, norpseudoephedrine, or

phenylpropanolamine in a separate location or log from records required by federal law to be kept with respect to those products.

(5) The recording requirements specified in this subdivision shall not apply to the sale of a single package containing not more than 60 milligrams of pseudoephedrine, consistent with the federal Combat Methamphetamine Epidemic Act of 2005.

(6) If a retail distributor experiences mechanical or electronic failure of the system and is unable to comply with the recording requirements of this subdivision, the retail distributor shall maintain the required records in a written log or an alternative electronic recordkeeping mechanism until the retail distributor is able to comply with the recording requirements of this subdivision. Written logs shall be maintained only for the purpose of compliance with this subdivision.

(d) (1) Provided that the department executes a memorandum of understanding (MOU) with NADDI governing access, pursuant to this subdivision, NADDI shall forward California transaction records in NPLeX to the Department of Justice weekly and provide real-time access to NPLeX information through the NPLeX online portal to law enforcement in the state as authorized by the department. The MOU shall constitute an enforceable contract.

(2) Access to the system shall be available at no charge to the department and law enforcement in this state as authorized pursuant to paragraph (1).

(3) The system shall allow retail distributors of products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine to enter into the database the information specified in subdivision (c) regarding the proposed sale of those products.

(4) The system shall be capable of providing the retail distributor with an immediate real-time alert any time a provision of this section is being violated by a proposed sale.

(5) Neither the department nor any state agency shall bear any cost for the development, installation, or maintenance of the system.

(6) The MOU shall state that no party to the MOU nor any entity under contract to provide the electronic authorization and monitoring system shall be authorized to use the information contained in the system for any purpose other than those set forth in this section, the federal Combat Methamphetamine Epidemic Act of 2005, or any regulation adopted pursuant to this section or that act. However, the system operator shall be authorized to analyze the information for the sole purpose of assessing and improving the performance and efficacy of the system. In addition, the MOU shall require that a retail distributor's access to the electronic authorization and monitoring system's database is limited solely to records of sales transactions made by that retail distributor, which access shall be solely for purposes of complying with the federal Combat Methamphetamine Epidemic Act of 2005 or this section, or to respond to a duly authorized law enforcement request or court order for information collected under that act or this section.

(7) The system's security program shall comply with the security standards for the Criminal Justice Information System of the Federal Bureau of Investigation and may be audited once a year by the department.

(8) The use of the system by a retail distributor or vendor of the NPLeX system shall be subject to Section 56.101 of the Civil Code. A retail distributor or a vendor of the NPLeX system holding the NPLeX data shall not maintain any records collected under this system for longer than two years, or as otherwise required by the federal Combat Methamphetamine Epidemic Act of 2005 and shall be destroyed pursuant to Section 1798.81 of the Civil Code.

(9) Law enforcement access to the system shall be recorded by means of a unique access code for each individual accessing the system. Each user's history shall be maintained and may be audited by the department.

(10) The department may submit recommendations to NADDI regarding system changes to assist in identifying false identification cards.

(11) Disputes relating to compliance with this section arising against a vendor of the NPLeX system shall be subject to a court of competent jurisdiction in California and shall be governed by California law.

(e) The State Board of Equalization shall notify all retailers about the requirement to submit transactions to NPLeX no later than April 1, 2014.

(f) This section shall not apply to a health care practitioner with prescriptive authority who is currently licensed in this state.

(g) (1) A first violation of this section is a misdemeanor.

(2) A person who has previously been convicted of a violation of this section shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars (\$10,000), or by both the fine and imprisonment.

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

(1) "Department" means the Department of Justice.

(2) "Drug store" is an entity described in Code 5912 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(3) "General merchandise store" is an entity described in Codes 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(4) "Grocery store" is an entity described in Code 5411 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(5) "Retail distributor" means a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as a distributor of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products, are limited exclusively to the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products for personal use both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. "Retail distributor" includes an entity that makes a direct sale, but does not include the parent company of that entity if the company is not involved in direct sales regulated by this article.

(6) "Sale for personal use" means the sale in a single transaction to an individual customer for a legitimate medical use of a product containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in amounts at or below that specified in subdivision (a). "Sale for personal use" also includes the sale of those products to employers to be dispensed to employees from first aid kits or medicine chests.

(i) It is the intent of the Legislature that this section shall preempt all local ordinances or regulations governing the sale by a retail distributor of over-the-counter products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

(j) This section shall remain in effect only until January 1, 2019, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2019, deletes or extends that date.

**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.



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|---------------------|--------------------|
| <b>Bill Number:</b> | <b>SB 598</b>      |
| <b>Introduced</b>   | 2/22/13            |
| <b>Last Amend:</b>  |                    |
| <b>Author:</b>      | Senator Jerry Hill |
| <b>Topic:</b>       | Biosimilars        |
| <b>Position:</b>    |                    |

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**Current Bill Status:** 4/8/13 - Hearing in SEN Business, Professions & Economic Development

**Affected Sections:** Add Sections 4052.55 and 4073.5 to the Business and Professions Code

**EXISTING:**

***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 “<sup>1</sup>biological 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 Act<sup>2</sup>. The FDA’s Office of Combination Products provides guidance as to whether a product meets the definition of biological product.

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<sup>1</sup> 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))

<sup>2</sup> [http://www.fda.gov/RegulatoryInformation/Guidances/ucm258946.htm#\\_ftn4](http://www.fda.gov/RegulatoryInformation/Guidances/ucm258946.htm#_ftn4)

## 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

## THIS BILL WOULD:

### **Article 3 – Scope of Practice and Exemptions**

Add Section 4052.55 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.”

### **In Article 4 “Requirements for Prescriptions”**

Add Section 4073.5 to the Business and Professions Code to repeat the provisions added in Section 4052.55 (above).

**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.

Staff has requested a Fact Sheet from the author's office.

*As of 4/5/2013*

**SUPPORT:**

**OPPOSITION:**



*California*  
LEGISLATIVE INFORMATION

SB-598 Biosimilars. (2013-2014)

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**SENATE BILL**

**No. 598**

**Introduced by Senator Hill**

**February 22, 2013**

**An act to add Sections 4052.55 and 4073.5 to the Business and Professions Code, relating to pharmacy.**

LEGISLATIVE COUNSEL'S DIGEST

SB 598, as introduced, Hill. Biosimilars.

The Pharmacy Law governs the practice of pharmacy in this state, including the permissible duties of licensed pharmacists. Among other permitted acts, a pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined, as specified, of those drug products having the same active chemical ingredients. A person who knowingly violates the Pharmacy Law is guilty of a misdemeanor, as specified.

This bill would authorize a pharmacist, in his or her discretion, except as specified, to select a biosimilar, as defined, when filling a prescription order for a prescribed biological product only if certain conditions are met. The bill would prohibit a pharmacist from substituting a biological product pursuant to these provisions unless the biological product selected costs the patient less than the prescribed biological product. The bill would also require that the substitution of a biosimilar be communicated to the patient and that the full name and manufacturer of the biosimilar be indicated on the prescription label. Because a knowing violation of these requirements would be a misdemeanor, the bill would create new crimes, thereby imposing a state-mandated local program.

The bill would also require the California State Board of Pharmacy to maintain on its public Internet Web site a link to the current list, if available, of biosimilar products determined by the federal Food and Drug Administration to be interchangeable, as specified.

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

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

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

## THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**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) The pharmacist 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) 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 and the full name and manufacturer of the dispensed biosimilar shall be indicated on the prescription label, unless where the prescriber orders otherwise.

(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) The pharmacist 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) 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 and the full name and manufacturer of the dispensed biosimilar shall be indicated on the prescription label, unless where the prescriber orders otherwise.

(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 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.



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|                     |   |
|---------------------|---|
| <b>Bill Number:</b> | <b>SB 669</b>   |
| <b>Introduced</b>   | 2/22/13   |
| <b>Last Amend:</b>  |   |
| <b>Author:</b>      | Senate Republican Leader Bob Huff                     |
| <b>Topic:</b>       | Emergency Medical Care: Epinephrine<br>Auto-Injectors |
| <b>Position:</b>    |   |

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**Current Bill Status:** Set for Hearing: April 17 in SEN Health Committee

**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

**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 (EpiPens), make them available to trained individuals (as specified) and allow those individuals to administer an EpiPen, without facing civil liability, in an emergency situation to a person suffering from a potentially fatal anaphylactic allergic reaction.

Staff has sought clarification from the author on the following:

- Are the labeling requirements of proposed Section 4119.3 intended to be in addition to the labeling requirements of Section 4076 or *in lieu* of the requirements of 4076;
- The prescription for the EpiPens is to specify a named recipient as “Section 1797.197a Responder.” It is unclear if this is in addition to the name of the person to whom such a prescription is given, or if the prescription is to be written to “Section 1797.197a Responder” (which may constitute an erroneous prescription)
- Should the definition of an epinephrine auto-injector also include its designation as a “dangerous drug” (i.e., Rx required)?

### **FISCAL IMPACT ON THE BOARD:**

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

*As of 4/1/2013*

### **SUPPORT:**

Conference of California Bar Association / Larry Doyle (Sponsor)

### **OPPOSITION:**

None known

# California State Senate

SENATOR  
BOB HUFF

SENATE REPUBLICAN LEADER  
TWENTY-NINTH SENATE DISTRICT



## Senate Bill 669 EpiPens: Training and Authorization for Emergency Use

### Summary

SB 669 would create a training program and standards for the safe and proper use of epinephrine auto-injectors (EpiPens), make them available to trained first responders and group leaders and allow them to use it on a person suffering from a potentially fatal anaphylaxis allergic reaction, without facing civil liability for trying to save a life.

### Background

Despite all improvements in the law expanding Good Samaritan protection fostering trained first responders and group supervisors to provide emergency care (first aid, cardiopulmonary resuscitation and automatic external defibrillation) for someone with a life-threatening allergic reaction, there is effectively nothing anyone can do to prevent cardio-pulmonary shutdown unless the anaphylaxis victim has an EpiPen and is able to self-administer epinephrine before losing consciousness.

Unless specifically used by and for the person for whom it was prescribed, an EpiPen may not be administered by non-physicians – even if an auto-injector is on the scene. Until recent enabling legislation, this was even a problem for school nurses, who could do nothing for students suffocating in anaphylactic shock because the student had not been prescribed an EpiPen. Yet, death from anaphylaxis remains a real and pervasive problem outside of school, in the wilderness and even in the community, where group leaders overseeing the welfare of others, and even trained first responders at the scene of an emergency, cannot obtain or administer this miraculous life-saving device, which even little children are trained to safely use.

EpiPens require a prescription and can only be used by that person on him or herself. If given by anyone else, outside of a physician's direction, it is illegal and subjects the rescuer to major liability exposure.

Anaphylaxis is a pervasive lethal threat, both to those with known allergies and those who suddenly become sensitized to a substance – be it a simple bee sting, ingestion of shellfish or coming in contact with peanuts.

### This Bill

- Augments and facilitates the present statutory scheme for first aid, CPR and AED emergency services with Good Samaritan immunity.
- Broadens the provision concerning epinephrine auto-injectors in a school setting (Education Code, § 49414) and the enabling provision calling for guidelines by the EMS Authority (Health & Safety Code, §1797.197).

### Sponsor

Conference of California Bar Associations | Larry Doyle | (916) 761-8959 | [Larry@LarryDoyleLaw.com](mailto:Larry@LarryDoyleLaw.com)

### Staff Contact

Office of Senator Bob Huff | Kelly Garman | (916) 651-4029 | [kelly.garman@sen.ca.gov](mailto:kelly.garman@sen.ca.gov)



*California*  
LEGISLATIVE INFORMATION

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

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**SENATE BILL**

**No. 669**

**Introduced by Senator Huff**

February 22, 2013

**An act to add Section 4119.3 to the Business and Professions Code, to add Section 1714.23 to the Civil Code, and to add Section 1797.197a to the Health and Safety Code, relating to emergency medical care.**

LEGISLATIVE COUNSEL'S DIGEST

SB 669, as introduced, Huff. Emergency medical care: epinephrine auto-injectors.

(1) Existing law authorizes a school district or county office of education to provide emergency epinephrine auto-injectors to trained personnel, and authorizes that trained personnel to utilize those epinephrine auto-injectors to provide emergency medical aid to persons suffering from an anaphylactic reaction. The Pharmacy Law authorizes a pharmacy to furnish epinephrine auto-injectors to a school district or county office of education if certain conditions are met. A violation of the Pharmacy Law is a crime.

Existing law requires the Emergency Medical Services Authority to establish training and standards for all prehospital emergency care personnel regarding the characteristics and method of assessment and treatment of anaphylactic reactions and the use of epinephrine, and to promulgate regulations therefor.

This bill would authorize a prehospital emergency medical care person, first responder, or lay rescuer to use an epinephrine auto-injector to render emergency care to another person, as specified. The bill would require the California Emergency Medical Services (EMS) Authority to establish or approve authorized training providers and minimum standards for training and the use and administration of epinephrine auto-injectors, in consultation with the local emergency medical system agency, the county health department, the manufacturer, the State Department of Health Care Services, and other private organizations. The bill would specify components to be included in the minimum training and requirements. The bill would provide that these minimum standards apply to a school district or county office of education for the emergency administration of epinephrine auto-injectors, but would permit the adoption of more stringent standards.

The bill would authorize a pharmacy to 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 these provisions. Because a violation of this requirement would be a crime, the bill would impose a state-mandated local program.

(2) Under existing law, everyone is generally responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person, except so far as the latter has, willfully or by want of ordinary care, brought the injury upon himself or herself.

This bill would provide that a prehospital emergency care person, first responder, or lay rescuer who administers an epinephrine auto-injector to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation, in good faith and not for compensation, 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 specified certification and training requirements and standards. The bill also would provide immunity to 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, for civil damages alleged to result from those training programs or standards.

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

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

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

## THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**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 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. 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 to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation, in good faith and not for compensation, 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) This section does not grant immunity from civil damages to any person whose conduct in rendering emergency care constitutes gross negligence.

(d) 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 Health Care Services, 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.

(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 not otherwise licensed or certified to use an epinephrine auto-injector on another who has met the training standards and other requirements of this section.

(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, for the indicated purpose described in paragraphs (1) and (2) 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 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 and 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 in consultation with the local emergency medical system agency, the county health department, manufacturers, the State Department of Health Care Services, 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.

(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 follow-up 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.

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

(3) The minimum standards established and approved pursuant to this subdivision apply to a school district or county office of education, which may adopt more stringent standards for training and the use and emergency administration of epinephrine auto-injectors pursuant to Section 49414 of the Education Code.

**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.



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| <b>Bill Number:</b> | <b>SB 809</b>                             |
| <b>Introduced</b>   | 2/22/13                                   |
| <b>Last Amend:</b>  |   |
| <b>Author:</b>      | Senator Mark DeSaulnier                   |
| <b>Topic:</b>       | CURES Funding (Sponsor: Attorney General) |
| <b>Position:</b>    |   |

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**Current Bill Status:** Set for Hearing: April 15 in SEN Business, Professions and Economic Development

**Affected Sections:** Add Section 805.8 to the Business and Professions Code  
Amend Sections 11165 and 11165.1 of the Health and Safety Code  
Add Part 21 Division 2 to the Revenue and Taxation 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                      |

**Staff Recommendation:**

*As of 4/1/2013*

**SUPPORT:**

Attorney General Kamala Harris (Sponsor)

Troy and Alana Pack Foundation

**OPPOSITION:**

None known

**SB 809 (DeSaulnier)  
As Introduced – February 22, 2013**

**CONTROLLED SUBSTANCE UTILIZATION REVIEW AND EVALUATION SYSTEM  
Fact Sheet**

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**SUMMARY**

SB 809 provides dedicated funds to assist healthcare providers, law enforcement, and regulatory agencies in their efforts to control the diversion and abuse of prescription drugs. The funding will support the Controlled Substances Utilization Review and Evaluation System (CURES) program administered by the California Department of Justice (DOJ).

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**BACKGROUND**

Due to the rise in prescription drug abuse, in 2009, the DOJ launched its automated Prescription Drug Monitoring Program (PDMP) within the CURES program. The program allows licensed health care practitioners eligible to prescribe schedule II, III, and IV controlled substances access to patient controlled substance prescription information in real-time, 24 hours a day, at the point of care. Prescribers and pharmacists use the PDMP to make informed decisions about patient care and detect patients who may be abusing controlled substances by obtaining multiple prescriptions from various practitioners. Under current law, California doctors and pharmacies are required to report to the DOJ, on a weekly basis, every schedule II, III, and IV prescription filled.

While the automated PDMP is a valuable investigative, preventative, and educational tool for healthcare providers, law enforcement, and regulatory boards, recent funding reductions have resulted in insufficient funds to support the CURES program. Without dedicated resources, the CURES program will be suspended on July 1, 2013.

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**PREVIOUS LEGISLATION**

SB 734 (Torlakson) Chapter 487, Statutes of 2005 AB 2548 (Block) of 2010 - Held Asm Appropriation SB 1071 (DeSaulnier) of 2010 – Held Senate Health SB 360 (DeSaulnier) of 2011 - Signed by Governor SB 616 (DeSaulnier) of 2012 – Failed passage Asm. Business & Professions

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**THIS BILL**

SB 809 establishes the CURES Fund to provide sufficient revenue to upgrade and fully modernize the CURES program, maintain program operations, establish enforcement capability, and improve utilization by requiring all practitioners and pharmacists to enroll and consult the CURES PDMP once the program is capable of accommodating all users.

To provide dedicated funds, SB 809 increases fees, by 1.16 percent, per licensee, that is authorized to prescribe or dispense controlled substances; levies a onetime tax assessment on health insurance plans and workers compensation insurers to fund the CURES modernization upgrade; and imposes annual taxes on drug manufacturers of schedule II, III, and IV controlled substances doing business in California to establish and support enforcement capability necessary to prevent diversion and the abuse of prescription narcotics.

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**STATUS**

March 11, 2013 – Referred to Coms. on B., P. & E.D. and GOV. & F.

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**SUPPORT**

- Attorney General Kamala Harris (Sponsor)
- Troy and Alana Pack Foundation

**OPPOSITION**

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None Received

**FOR MORE INFORMATION**

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Indira McDonald  
Office of Senator Mark DeSaulnier  
(916) 651-4007

Ken Pogue  
Deputy Attorney General Legislative Advocate  
Office of the Attorney General  
(916) 445-4864



*California*  
LEGISLATIVE INFORMATION

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

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**SENATE BILL**

**No. 809**

**Introduced by Senator DeSaulnier, Steinberg  
(Coauthor(s): Senator Hancock, Lieu, Pavley, Price)  
(Coauthor(s): Assembly Member Blumenfield)**

February 22, 2013

**An act to add Section 805.8 to the Business and Professions Code, to amend Sections 11165 and 11165.1 of the Health and Safety Code, and to add Part 21 (commencing with Section 42001) to Division 2 of the Revenue and Taxation Code, relating to controlled substances, and declaring the urgency thereof, to take effect immediately.**

LEGISLATIVE COUNSEL'S DIGEST

SB 809, as introduced, DeSaulnier. Controlled substances: reporting.

(1) Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

Existing law requires dispensing pharmacies and clinics to report, on a weekly basis, specified information for each prescription of Schedule II, Schedule III, or Schedule IV controlled substances, to the department, as specified.

This bill would establish the CURES Fund within the State Treasury to receive funds to be allocated, upon appropriation by the Legislature, to the Department of Justice for the purposes of funding CURES, and would make related findings and declarations.

This bill would require 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, and the California Board of Podiatric Medicine to increase the licensure, certification, and renewal fees charged to practitioners under their supervision who are authorized to prescribe or dispense controlled substances, by up to 1.16%, the proceeds of which would be deposited into the CURES Fund for support of CURES, as specified. This bill would also require the California State Board of Pharmacy to increase the licensure, certification, and renewal fees charged to wholesalers, nonresident wholesalers, and veterinary food-animal

drug retailers under their supervision by up to 1.16%, the proceeds of which would be deposited into the CURES Fund for support of CURES, as specified.

(2) Existing law permits a licensed health care practitioner, as specified, or a pharmacist to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under his or her care. Existing law also authorizes the Department of Justice to provide the history of controlled substances dispensed to an individual to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

This bill would require licensed health care practitioners, as specified, and pharmacists to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under his or her care, and, upon the happening of specified events, to access and consult that information prior to prescribing or dispensing Schedule II, Schedule III, or Schedule IV controlled substances.

(3) Existing law imposes various taxes, including taxes on the privilege of engaging in certain activities. The Fee Collection Procedures Law, the violation of which is a crime, provides procedures for the collection of certain fees and surcharges.

This bill would impose a tax upon qualified manufacturers, as defined, for the privilege of doing business in this state, as specified. This bill would also impose a tax upon specified insurers, as defined, for the privilege of doing business in this state, as specified. The tax would be administered by the State Board of Equalization and would be collected pursuant to the procedures set forth in the Fee Collection Procedures Law. The bill would require the board to deposit all taxes, penalties, and interest collected pursuant to these provisions in the CURES Fund, as provided. Because this bill would expand application of the Fee Collection Procedures Law, the violation of which is a crime, it would impose a state-mandated local program.

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

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

(5) This bill would declare that it is to take effect immediately as an urgency statute.

Vote: 2/3 Appropriation: no Fiscal Committee: yes Local Program: yes

## THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

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

(a) The Controlled Substance Utilization Review and Evaluation System (CURES) is a valuable investigative, preventive, and educational tool for law enforcement, regulatory boards, educational researchers, and the health care community. 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 60,000 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 which has proven to be a cost-effective tool to help reduce the misuse, abuse, and trafficking of those drugs.

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

**805.8.** (a) (1) 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, and the California Board of Podiatric Medicine shall increase the licensure, certification, and renewal fees charged to practitioners under their supervision who are authorized pursuant to Section 11150 of the Health and Safety Code to prescribe or dispense Schedule II, Schedule III, or Schedule IV controlled substances by up to 1.16 percent annually, but in no case shall the fee increase exceed the reasonable costs associated with maintaining CURES for the purpose of regulating prescribers and dispensers of controlled substances licensed or certificated by these boards.

(2) The California State Board of Pharmacy shall increase the licensure, certification, and renewal fees charged to wholesalers and nonresident wholesalers of dangerous drugs, licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9, by up to 1.16 percent annually, but in no case shall the fee increase exceed the reasonable costs associated with maintaining CURES for the purpose of regulating wholesalers and nonresident wholesalers of dangerous drugs licensed or certificated by that board.

(3) The California State Board of Pharmacy shall increase the licensure, certification, and renewal fees charged to veterinary food-animal drug retailers, licensed pursuant to Article 15 (commencing with Section 4196) of Chapter 9, by up to 1.16 percent annually, but in no case shall the fee increase exceed the reasonable costs associated with 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 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 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 11165 of the Health and Safety Code is amended to read:

**11165.** (a) To assist 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~~ *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 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 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 ~~from~~ *for* the Department of Justice *for the purpose of finding CURES.* The department may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. ~~Funds~~ *The department shall make information about the amount and the source of all private grant funds it receives for support of CURES available to the public. 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 CURES.

(c) 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~~ *agency*, as described in this ~~subdivision~~ *subdivision*, shall not be disclosed, sold, or transferred to any third party.

(d) 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 the following information to the Department of Justice on a weekly basis 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) 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) This section shall become operative on January 1, 2005. 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. 4.** 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~~ *shall* provide a notarized application developed by the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient maintained within the Department of Justice, ~~and~~ *and, upon approval*, the department ~~may~~ *shall* release to that practitioner or 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 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) ~~1~~ (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) and approval of the application required pursuant to subdivision (a), licensed health care practitioners eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances and pharmacists shall 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 the mandate contained in paragraph (2). The department shall provide a copy of the notification to the Secretary of the 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. 5.** Part 21 (commencing with Section 42001) is added to Division 2 of the Revenue and Taxation Code, to read:

**PART 21. Controlled Substance Utilization Review and Evaluation System (CURES) Tax Law**

**42001.** For purposes of this part, the following definitions apply:

(a) "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.

(b) "Insurer" means a health insurer licensed pursuant to Part 2 (commencing with Section 10110) of Division 2 of the Insurance Code, a health care service plan 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), and a workers' compensation insurer licensed pursuant to Part 3 (commencing with Section 11550) of Division 2 of the Insurance Code.

(c) "Qualified manufacturer" means a manufacturer of a controlled substance doing business in this state, as defined in Section 23101, 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.

**42003.** (a) For the privilege of doing business in this state, an annual tax is hereby imposed on all qualified manufacturers in an amount of \_\_\_\_ dollars (\$\_\_\_\_), for the purpose of establishing and maintaining

enforcement of the Controlled Substance Utilization Review and Evaluation System (CURES), established pursuant to Section 11165 of the Health and Safety Code.

(b) For the privilege of doing business in this state, a tax is hereby imposed on a one time basis on all insurers in an amount of \_\_\_\_ dollars (\$\_\_\_\_), for the purpose of upgrading CURES.

**42005.** Each qualified manufacturer and insurer shall prepare and file with the board a return, in the form prescribed by the board, containing information as the board deems necessary or appropriate for the proper administration of this part. The return shall be filed on or before the last day of the calendar month following the calendar quarter to which it relates, together with a remittance payable to the board for the amount of tax due for that period.

**42007.** The board shall administer and collect the tax imposed by this part pursuant to the Fee Collection Procedures Law (Part 30 (commencing with Section 55001)). For purposes of this part, the references in the Fee Collection Procedures Law (Part 30 (commencing with Section 55001)) to "fee" shall include the tax imposed by this part and references to "feepayer" shall include a person required to pay the tax imposed by this part.

**42009.** All taxes, interest, penalties, and other amounts collected pursuant to this part, less refunds and costs of administration, shall be deposited into the CURES Fund.

**42011.** The board shall prescribe, adopt, and enforce rules and regulations relating to the administration and enforcement of this part.

**SEC. 6.** 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.

**SEC. 7.** 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 this act take effect immediately.



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|                     |  |
|---------------------|--|
| <b>Bill Number:</b> | <b>SB 62</b>   |
| <b>Introduced</b>   | 1/8/13   |
| <b>Last Amend:</b>  |  |
| <b>Author:</b>      | Senator Curren Price, Jr.                                  |
| <b>Topic:</b>       | Coroners: reporting requirements:<br>prescription drug use |
| <b>Position:</b>    | SUPPORT (2/13/13)  |

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**Current Bill Status:** 4/15/13 – Hearing in Senate Business, Professions and Economic Development

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

**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:**

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 specific healing arts board, including the Board of Pharmacy. 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:**

If enacted, the board anticipates additional staffing to conduct inspections, compliance investigations, and related case support. Assuming the board receives approximately 1,800 reports a year, the board estimates 40 percent may result in a full investigation into violations of corresponding responsibility.

To perform these duties, the board will require an additional six (6) inspectors, and three (3) associate analysts. The board is not able to absorb this workload within its existing resources.

**Staff Recommendation:** Ratify the board's position taken February 13, 2013



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

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

February 13, 2013

The Honorable Curren D. Price Jr.  
Chair, Senate Committee on Business,  
Professions and Economic Development  
California State Senate  
State Capitol, Room 2059  
Sacramento, CA 95814

RE: Senate Bill 62 - SUPPORT

Dear Senator Price:

The California State Board of Pharmacy is pleased to advise you that it **SUPPORTS** Senate Bill 62 as Introduced.

This bill would require coroners to provide the Board of Pharmacy and others with a report where a death may be the result of prescription drug use, to be followed by a copy of the coroner's report, autopsy protocol and all other relevant information. Where such deaths occur, this information will enable the board to review patterns of drugs dispensed by pharmacies to identify abuses. The board believes this measure has the potential to save lives by preventing future deaths resulting from prescription drug use.

We look forward to working with you on this measure and others in the new session. Please do not hesitate to contact me at (916) 574-7911 or our Legislative Manager Carolyn Klein at (916) 574-7913 if you or your staff has any questions.

Sincerely,

A handwritten signature in black ink that reads "Virginia Herold".

VIRGINIA HEROLD  
Executive Officer

cc: Department of Consumer Affairs



## SB 62- PRICE Prescription Drug Deaths

### Summary

Senate Bill 62 guarantees state licensing boards have data as soon as possible to determine the role doctors and pharmacists may play in patient prescription drug deaths. In the event that a coroner determines cause of death to be prescription drug overdose, SB 62 requires county coroners to transmit their findings to the Medical Board of California, Osteopathic Medical Board of California, the California Board of Podiatric Medicine, the Physician Assistant Board and California State Board of Pharmacy.

### Existing Law

Existing law establishes the Medical Board of California to regulate physicians and surgeons, the Osteopathic Medical Board of California to regulate osteopathic physicians, the California Board of Podiatric Medicine to regulate podiatrists, the Physician Assistant Board to regulate physician assistants and the California State Board of Pharmacy to regulate pharmacists and pharmacies.

Existing law requires coroners to inquire into and determine the circumstances, manner, and cause of all violent, sudden, or unusual deaths.

Existing law requires coroners to transmit reports to the Medical Board of California, Osteopathic Medical Board of California, the California Board of Podiatric Medicine and the Physician Assistant Board in the event that the cause of death may be gross negligence.

### Why Is This Bill Needed?

For the past number of years, abuse of prescription drugs (taking a prescription medication that is not prescribed for you, or taking it for reasons or in dosages other than as prescribed) to get high has become increasingly prevalent. The Centers for Disease Control (CDC) has called rising rates of prescription drug abuse an epidemic and federal data shows the past year abuse of prescription pain killers now ranks second, just behind marijuana, as the nation's most widespread illegal drug problem. Data shows that individuals who misuse prescription drugs, particularly teens, believe these substances are safer than illicit drugs because they are prescribed by a health care professional and thus are safe to take under any circumstances.

While some doctors may be negligent in paying attention to signs that their patients are addicts, in most instances, boards are probably unaware that there is even any correlation between an overdose death of a patient and the drugs prescribed by their doctor. Current law only requires coroners reports to be transmitted to the Medical Board of California in the event that gross negligence by a physician is determined as the cause of death. This situation results in the Board not necessarily having the right information to begin investigating.

In a case where the coroner findings deal with a young person, who is not a cancer patient on hospice or someone in a health facility setting, who was found dead in possession of various opioid combinations, the prescribing doctor and his or her practices may need to be looked into. Particularly in instances where the same doctor is listed as the prescribing physician on the medication bottles of numerous dead patients, the licensing board should have that information readily available.

**FOR MORE INFORMATION** – Sarah Mason (916) 651-4313 [sarah.mason@sen.ca.gov](mailto:sarah.mason@sen.ca.gov)

SB 62 also responds to a recent *LA Times* series that analyzed coroners' reports for over 3000 deaths occurring in four counties (Los Angeles, Orange, Ventura and San Diego) where the cause of death was overdose by prescription drugs. The analysis found that in nearly half of the cases where prescription drug overdose was listed as the cause of death, there was a direct connection to a prescribing physician. The report also found that more than 80 of the doctors whose names were listed on prescription bottles found at the home of or on the body of a decedent had been the prescribing physician for 3 or more dead patients, including one doctor who was linked to as many as 16 dead patients.

Coroners reports are a treasure trove of data that can inform the appropriate licensing boards about where people are getting drugs, how much they have when they die of an overdose and whether they were under the care of a doctor who may have been prescribing too much.

This bill connects the dots and creates a very necessary pathway for prescription drug overdose deaths to be reported directly to the Boards that can take necessary action against their licensees who may have been directly involved. If Boards are receiving reports from coroners throughout the state, they will be better armed with the necessary tools to make a correlation to their licensees in overprescribing circumstances and take action.

**Do You Support SB 62?**

*Please send a letter of support to:*

Senator Curren Price  
State Capitol Rm. 2057  
Sacramento, CA 95814



California  
LEGISLATIVE INFORMATION

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

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**SENATE BILL**

**No. 62**

**Introduced by Senator Price**

**January 08, 2013**

**An act to amend Section 802.5 of the Business and Professions Code, relating to coroners.**

LEGISLATIVE COUNSEL'S DIGEST

SB 62, as introduced, Price. Coroners: reporting requirements: prescription drug use.

Existing law requires a coroner to make a report, as specified, when he or she receives information that indicates that a death may be the result of a physician and surgeon's, podiatrist's, or physician assistant's gross negligence or incompetence.

This bill would expand those provisions to require a coroner to make a report when he or she receives information that indicates a death may be the result of prescription drug use and to require the coroner to additionally file the report with the California State Board of Pharmacy. By increasing the duties of county officers, this bill creates a state-mandated local program.

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

This bill would provide that, if the Commission on State Mandates determines that the bill contains costs mandated by the state, reimbursement for those costs shall be made pursuant to these statutory provisions.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**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 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, *or physician assistants*, and all other relevant

information available. The initial report shall be followed, within 90 days, by copies of the coroner's report, autopsy protocol, and all other relevant information.

*(b) 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 pathologist indicating that a death may be the result of prescription drug use, 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, and shall also be filed with the California State Board of Pharmacy. The initial report shall include the name of the decedent, date and place of death, attending physicians, podiatrists, or physician assistants, and all other relevant information available. The initial report shall be followed, within 90 days, by copies of the coroner's report, autopsy protocol, and all other relevant information.*

~~(b)The~~

*(c) A* report required by this section 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) *or (b)*.

**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.



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|                        |   |
|------------------------|---|
| <b>Bill Number:</b>    | <b>AB 186</b>   |
| <b>Introduced</b>      | 1/28/2013   |
| <b>Amendment Date:</b> | <b>4/1/2013</b>   |
| <b>Author:</b>         | Assembly Member Maienschein and co-authors                      |
| <b>Topic:</b>          | Professions and vocations: Military spouses: temporary licenses |
| <b>Position:</b>       |   |

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**Affected Sections:** Section 115.5 Business and Professions Code (BPC)

Status: Re-referred to ASM Committee on Business, Professions and Consumer Protection

**EXISTING LAW:**

Section 115.5 was added to the BPC in 2012 to require boards within the Department of Consumer Affairs to expedite the licensure process for an applicant who (1) is married to or in a domestic partnership or other legal union with an active duty member of the armed forces, as specified; and (2) holds a current license in another state for which he or she is seeking a license from the board. That section further authorizes boards to adopt regulations necessary to administer the section. (AB 1904 (Block), Chapter 399, Statutes 2012 – Board Position: Support)

**THIS BILL WOULD:**

- Amend Section 115.5 to require a board to issue a provisional license to an applicant
  - Who meets requirements (1) and (2), above, provided the application includes an affidavit that the information submitted in the application is accurate and
  - Where verification from the other jurisdiction has been *requested*.
- Further amendments provide that the applicant shall not have committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under the BPC at the time the act was committed; and that
- The applicant shall not have been disciplined by a licensing entity in another jurisdiction and shall not be subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction.

**FISCAL IMPACT ON THE BOARD:**

AB 186 would result in a fiscal impact to the board, in that the measure would require the board to create additional license types that are not currently supported by the board's existing tracking system. Also, with the department's migration to a new licensing system (BreZE), the board is unable to make any changes to the existing system; thus, the board would at this time be unable to create the provisional license types through 2013 and possibly into 2014.

**STAFF COMMENTS:**

The provisions of AB 186 would apply to any board within the Department of Consumer Affairs.

The board does not have a “provisional license” category for Pharmacists, Pharmacist Interns, or Pharmacy Technicians. Also, the board is not able to modify its existing I.T. system to accommodate such changes.

Likewise, the California Board of Pharmacy does not have reciprocity with other licensing jurisdictions/states; therefore, there would be no guarantee that the applicant’s license in another state would meet the requirements for licensure in California. This may result in persons that do not meet California licensing requirements working in a pharmacy setting for up to 18 months.

AB 186 contains some previous language in last year’s AB 1904 (the enabling legislation), that was not chaptered. For example, AB 186 (b)(2)(A) specifies:

*The applicant shall not have committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under this code at the time the act was committed.*

An affidavit attesting to the truthfulness of this fact could result in harm to the public if, in fact, it was determined during the regular licensing process, this statement was untrue.

The board has previously stated that it proudly supports the men and women of the Armed Forces of the United States, and that it supports provisions that would be most effective and efficient to assist military spouses in their efforts to seek a board license.

Likewise, the board is charged with protection of the public in exercising its licensing regulatory and disciplinary functions and that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

The board may wish to consider if – through the provisional licensing of an individual – placing an individual in a pharmacy setting without ensuring the individual meets the requirements for licensure in California is in the best interest of the public safety.

**AVERAGE PROCESSING TIMES:**

The following average processing times were reported to the board for December 2012:

| License Type           | Average Days to Process Initial Application |
|------------------------|---|
| Pharmacist (exam apps) | 8   |
| Pharmacy Intern        | 6   |
| Pharmacy Technician    | 29  |

|                        | Average Days to Process Deficiency Documents |
|------------------------|--|
| Pharmacist (exam apps) | 2  |
| Pharmacy Intern        | 3  |
| Pharmacy Technician    | 2  |

# Assembly California Legislature



## BRIAN MAIENSCHIN ASSEMBLYMAN, SEVENTY-SEVENTH DISTRICT AB 186 – Fact Sheet

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### **Background**

Current law allows spouses of active duty military members, who have been redeployed to California from another state, to get an expedited professional license if they have a valid license for the same profession in another state.

According to a recent study by the California Research Bureau, California has around 72,500 military spouses residing in the state at any given time. It is estimated that over one third of these individuals are involved in a profession that requires some sort of licensing requirement.

A military family can receive orders to move as often as every two years. According to the Department of Defense, military spouses are ten times more likely to have moved across state lines in the last year compared to their civilian counterparts. This poses a particularly difficult problem for spouses of military personnel who work in a licensed vocation nursing.

A December article published in USAA Magazine described the process as taking many months even after all appropriate documentation has been submitted, fees being paid, and tests taken to receive the license. Often times, potential employees can't even start looking for jobs until their licenses have been received. This has all lead to an estimated 26% of military spouses being unemployed and seeking work—more than three times the national average.

With the implementation of temporary licensing through AB 186, military spouses will be able to immediately look for employment to help support their families while taking all the necessary steps to apply and receive a license from the state.

### **This Bill**

AB 186 seeks to authorize military spouses, who have moved here on active duty orders and who have a valid professional license in another state, to receive an 18-month provisional license in the same profession for which they are applying for licensure. The licensee applicant must provide sufficient evidence of being married to, or in a domestic partnership or legal union with, an active duty member of the United States Armed Forces.

### **Contacts**

Matthew Peralta

[Matthew.Peralta@asm.ca.gov](mailto:Matthew.Peralta@asm.ca.gov) or,

Erin Donnette

[Erin.Donnette@asm.ca.gov](mailto:Erin.Donnette@asm.ca.gov)

Office of Asm. Brian Maienschein

916-319-2077



California  
LEGISLATIVE INFORMATION

AB-186 Professions and vocations: military spouses: temporary licenses. (2013-2014)

AMENDED IN ASSEMBLY APRIL 01, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**ASSEMBLY BILL**

**No. 186**

**Introduced by Assembly Member Maienschein**  
**(Principal Coauthor(s): Assembly Member Hagman)**  
*(Coauthor(s): Assembly Member Dahle, Donnelly, Beth Gaines, Harkey, Olsen, Patterson)*  
*(Coauthor(s): Senator Fuller, Huff)*

January 28, 2013

**An act to amend Section 115.5 of the Business and Professions Code, relating to professions and vocations, and making an appropriation therefor.**

LEGISLATIVE COUNSEL'S DIGEST

AB 186, as amended, Maienschein. Professions and vocations: military spouses: temporary licenses.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law provides for the issuance of reciprocal licenses in certain fields where the applicant, among other requirements, has a license to practice within that field in another jurisdiction, as specified. ~~Under existing law, licensing fees imposed by certain boards within the department are deposited in funds that are continuously appropriated.~~ Existing law requires a board within the department to expedite the licensure process for an applicant who holds a current license in another jurisdiction in the same profession or vocation and who supplies satisfactory evidence of being married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active duty military orders.

This bill would authorize a board within the department to issue a provisional license to an applicant who qualifies for an expedited license pursuant to the above-described provision. *The bill would prohibit a provisional license from being provided to any applicant who has committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license at the time the act was committed, or has been disciplined by a licensing entity in another jurisdiction, or is the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction. The bill would require the board to approve a provisional license based on an application that includes an affidavit that the information submitted in the application is accurate and that verification documentation from the other jurisdiction has been requested.* The bill would require the provisional license to expire after 18 months *or at the issuance of the expedited license.*

*By creating provisional licenses for which a fee may be collected and deposited into a continuously appropriated fund, this bill would make an appropriation.*

Vote: majority Appropriation: yes Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** Section 115.5 of the Business and Professions Code is amended to read:

**115.5.** (a) A board within the department shall expedite the licensure process for an applicant who meets both of the following requirements:

(1) Supplies evidence satisfactory to the board that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders.

(2) Holds a current license in another state, district, or territory of the United States in the profession or vocation for which he or she seeks a license from the board.

(b) (1) For each applicant who is eligible for an expedited license pursuant to subdivision (a) *and meets the requirements in paragraph (2)*, the board ~~may~~ *shall* provide a provisional license while the board processes the application for licensure. *The board shall approve a provisional license based on an application that includes an affidavit that the information submitted in the application is accurate and that verification documentation from the other jurisdiction has been requested.* The provisional license shall expire 18 months after issuance *or upon issuance of the expedited license.*

(2) (A) *The applicant shall not have committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under this code at the time the act was committed.*

(B) *The applicant shall not have been disciplined by a licensing entity in another jurisdiction and shall not be the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction.*

(c) A board may adopt regulations necessary to administer this section.



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|                        |   |
|------------------------|---|
| <b>Bill Number:</b>    | <b>AB 213</b>   |
| <b>Introduced</b>      | 1/31/2013   |
| <b>Amendment Date:</b> | <b>4/1/2013</b>   |
| <b>Author:</b>         | Assembly Member Logue and co-authors  |
| <b>Topic:</b>          | Healing Arts: Licensure and certification requirements: military experience |
| <b>Position:</b>       |   |

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**Affected Sections:** Repeal and Add Section 712 to the Business and Professions Code (BPC)  
Add Section 131136 to the Health and Safety Code (HSC)

**Status:** Hearing: 4/9/13 ASM Business, Professions and Consumer Protection

**EXISTING LAW:**

Existing Pharmacy provides for the licensure of <sup>1</sup>Pharmacists, <sup>2</sup>Pharmacist Interns, <sup>3</sup>Pharmacy Technicians and other individuals and representatives related to its site licenses, and specifies the minimum requirements for licensure of these individuals.

**Title 16 CCR § 1793.6(b)** specifies that a course of training provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, shall meet the requirements of Section 4202(a) for a Pharmacy Technician applicant.

Existing Section **712 BPC** provides that a board, as specified, shall, upon the presentation of satisfactory evidence by an applicant for licensure, accept the education, training, and practical experience completed by the applicant as a member of the US Armed Forces or Military Reserves of the US, the national guard of any state, the military reserves of any state, or the naval militia of any state, toward the qualifications and requirements for licensure by that board if the board determines that the education, training, or practical experience is equivalent to the standards of the board.

Existing law at **Section 115.5 BPC** requires the board to expedite the licensure process for a spouse of an active duty member of the military, as specified.

Existing **Section 131136 HSC** relates to the licensing and certification of certified nurse assistants, home health aides and other individuals licensed or certified by the CDPH.

**ACCORDING TO THE AUTHOR:**

AB 213 would break down barriers facing returning veterans by requiring state entities that license healthcare professionals to establish policies that recognize the education, training, and

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<sup>1</sup> Minimum requirements for pharmacist licensure specified at Section 4200(a)(1-6) BPC

<sup>2</sup> Minimum requirements for licensure as a Pharmacist Intern specified at Section 4208 BPC

<sup>3</sup> Minimum requirements for licensure as a Pharmacy Technician specified at Section 4202 BPC, and at Title 16 CCR § 1793.6.

practical experience of a veteran applicant. The author states AB 213 would also require these entities to work with the college programs they approve or accredit to ensure that the colleges have procedures in place so that veteran applicants are not forced to retake classes they have already completed at a military institute.

**THIS BILL WOULD:**

Specify that not later than 7/1/14, if a board accredits or otherwise approves schools offering educational course credit for meeting licensure qualification, the board shall require a school seeking accreditation or approval to submit to the board proof that the school has procedures in place to evaluate, upon presentation of satisfactory evidence by the applicant, the applicant's military education, training, and practical experience toward the completion of a program that would qualify a person for licensure, as specified.

To determine compliance with the section, as specified, the Department of Veterans Affairs, the Chancellor of the CSU, and the Chancellor of the California Community Colleges shall provide technical assistance to the boards and to the schools as it relates to the section.

**STAFF COMMENTS:**

Existing regulation at 16 CCR 1793.5(c) specifies the minimum requirements for "any other course" that meets the minimum educational requirements for licensure as a Pharmacy Technician in California. This section does not require a school to come before the board for approval or accreditation, only that the course of instruction meets the requirements therein.

Pharmacists must pass a national exam, and individuals who are eligible for licensure as a Pharmacy Intern must meet existing educational requirements – none of which are specifically accredited by the board.

**FISCAL IMPACT ON THE BOARD:**



**DAN LOGUE**  
ASSEMBLYMAN, THIRD DISTRICT  
OFFICE - (916) 319-2003  
FAX - (916) 319-2103  
ASSEMBLYMEMBER.LOGUE@ASSEMBLY.CA.GOV

## **AB 213**

### **Veterans Healthcare Workforce Act of 2013**

#### **Purpose**

In order to honor the service of our nation's returning heroes and address California's healthcare workforce needs, this bill would ensure that veterans with healthcare education, training, and practical experience are expedited into civilian employment as healthcare professionals.

This bill would break down barriers facing returning veterans, by requiring state entities that license healthcare professionals to establish policies that recognize the education, training, and practical experience of a veteran applicant. It would also require these entities to work with the college programs they approve or accredit to ensure that the colleges have procedures in place so that veteran applicants are not forced to retake classes they have already completed at a military institute. This will ensure that veterans are able to quickly complete the additional coursework necessary for licensure, and put them on the fast track into the healthcare workforce.

#### **Background**

Under current law, most healthcare providers are regulated by either one of the healing arts boards in the Department of Consumer Affairs, or by the Department of Public Health. These regulators set standards that applicants must meet in order to obtain licensure or certification as a healthcare professional. Many of these regulators also set accreditation standards for college programs that educate students for healthcare professions. In order to maintain their accreditation with state regulators, college programs in California often must meet standards set by national professional associations.

According to the Department of Defense, during the 2011 federal fiscal year 8,854 enlisted service members with medical classifications and training separated from active duty. During the same year, 16,777 service members separated from active duty who listed California as their state of residence (10.8% of national total). Using these numbers, one could anticipate as many as 900 enlisted service members with medical classifications returning to California seeking civilian employment in the healthcare field. This is a valuable pool of skilled healthcare professionals that should be tapped into.

According to the 2008 report, "U.S. Military and California Health Personnel: Select Comparisons," by the Center for the Health Professions, University of California, San Francisco:

As California faces workforce shortages and geographic mal-distribution in many of the health care professions, policy makers are looking to expanding educational programs, rethinking practice models and improving recruitment and retention efforts among existing and new pools of workers. One potential pool of health care workers includes former military personnel returning from active duty or retiring with years available for service in the civilian labor force. ...

Individuals with military training or experience in health care may be well-positioned to meet civilian health care needs upon their separation from service. Most of the military training is nationally accredited and/or of documented high quality, and a serviceperson retiring from military duty may still want to work for many years in the civilian sector. However, current rules and regulations may present unnecessary challenges. To facilitate smooth transitions between military and civilian work, civilian policy makers and educators might want to explore better alignment of accreditation, certification and licensure standards. ...

In many instances, civilian health education programs and state professional boards' licensing criteria do not always give full credit for the health care provider education, training and experience one may have received in the military.

Veterans of the United States Armed Forces and the National Guard gain invaluable education, training and practical experience through their military service. Yet, while the national unemployment rate is approximately 8.3%, as of June 2011 one million veterans were unemployed nationally and the unemployment rate for post-9/11 veterans was 13.3%, with young male veterans (ages 18 to 24) experiencing an unemployment rate of 21.9%. Having stable employment available for a returning veteran is important not only for them, but also for their families and the communities they live in.

It is critical, both to the veteran who is seeking to transition to civilian life and to patients who live in underserved inner-city and rural areas, that the state ensure that veterans with healthcare education, training and practical experience are expedited into civilian professions.

### **Support**

Office of the Deputy Assistant Secretary of Defense (Military Community & Family Policy) (2/26)

American Legion-Department of California (3/12)

AMVETS (3/12)

California Association of County Veterans Service Officers (3/12)

California State Commanders Veterans Council (3/12)

VFW – Department of California (3/12)

Vietnam Veterans of American – California State Council (3/12)

Association of California Healthcare Districts (4/2)

### **Opposition**

None at this time.

(Updated March 12<sup>th</sup>, 2013)



California  
LEGISLATIVE INFORMATION

AB-213 Healing arts: licensure and certification requirements: military experience. (2013-2014)

AMENDED IN ASSEMBLY APRIL 01, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**ASSEMBLY BILL**

**No. 213**

**Introduced by Assembly Member Logue  
(Principal Coauthor(s): Assembly Member Pan)**

*(Coauthor(s): Assembly Member Conway, Beth Gaines, Harkey, Jones, Morrell, Nestande, Wilk)*

January 31, 2013

**An act to add Section 712 to the Business and Professions Code, and to add Section 131136 to the Health and Safety Code, relating to healing arts.**

LEGISLATIVE COUNSEL'S DIGEST

AB 213, as amended, Logue. Healing arts: licensure and certification requirements: military experience.

Existing law provides for the licensure and regulation of various healing arts professions and vocations by boards within the Department of Consumer Affairs. Existing law requires the rules and regulations of these healing arts boards to provide for methods of evaluating education, training, and experience obtained in military service if such training is applicable to the requirements of the particular profession or vocation regulated by the board. Under existing law, specified other healing arts professions *and vocations* are licensed or certified and regulated by the State Department of Public Health. In some instances, a board with the Department of Consumer Affairs or the State Department of Public Health approves schools offering educational course credit for meeting licensing or certification qualifications and requirements.

This bill would require ~~a healing arts board within the Department of Consumer Affairs and~~ the State Department of Public Health, upon the presentation of evidence by an applicant for licensure or certification, to accept education, training, and practical experience completed by an applicant in military service toward the qualifications and requirements to receive a license or certificate *for specified professions and vocations* if that education, training, or experience is equivalent to the standards of the ~~board or~~ department. If a board *within the Department of Consumer Affairs* or the State Department of Public Health accredits or otherwise approves schools offering educational course credit for meeting licensing and certification qualifications and requirements, the bill would, not later than July 1, 2014, require those schools seeking accreditation or approval to have procedures in place to evaluate an applicant's military education, training, and practical experience toward the completion of an educational program that would qualify a person to apply for licensure or certification, as specified.

Under existing law, the Department of Veterans Affairs has specified powers and duties relating to various programs serving veterans. Under existing law, the Chancellor of the California State University and the Chancellor of the California Community Colleges have specified powers and duties relating to statewide health education programs.

With respect to complying with the bill's requirements and obtaining specified funds to support compliance with these provisions, this bill would require the Department of Veterans Affairs, the Chancellor of the California State University, and the Chancellor of the California Community Colleges to provide technical assistance to the healing arts boards within the Department of Consumer Affairs, the State Department of Public Health, and to the schools offering, or seeking to offer, educational course credit for meeting licensing qualifications and requirements.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

## THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** This act shall be known and may be cited as the Veterans Health Care Workforce Act of ~~2012~~ 2013.

**SEC. 2.** (a) The Legislature finds and declares all of the following:

(1) Lack of health care providers continues to be a significant barrier to access to health care services in medically underserved urban and rural areas of California.

(2) Veterans of the United States Armed Forces and the California National Guard gain invaluable education, training, and practical experience through their military service.

(3) According to the federal Department of Defense, as of June 2011, one million veterans were unemployed nationally and the jobless rate for post-9/11 veterans was 13.3 percent, with young male veterans 18 to 24 years of age experiencing an unemployment rate of 21.9 percent.

(4) According to the federal Department of Defense, during the 2011 federal fiscal year, 8,854 enlisted service members with medical classifications separated from active duty.

(5) According to the federal Department of Defense, during the 2011 federal fiscal year, 16,777 service members who separated from active duty listed California as their state of residence.

(6) It is critical, both to veterans seeking to transition to civilian health care professions and to patients living in underserved urban and rural areas of California, that the Legislature ensures that veteran applicants for licensure by healing arts boards within the Department of Consumer Affairs or the State Department of Public Health are expedited through the qualifications and requirements process.

(b) It is the intent of the Legislature to ensure that boards within the Department of Consumer Affairs and the State Department of Public Health and schools offering educational course credit for meeting licensing qualifications and requirements fully and expeditiously recognize and provide credit for an applicant's military education, training, and practical experience.

**SEC. 3.** Section 712 is added to the Business and Professions Code, to read:

~~712.(a)Notwithstanding any other provision of law, a board under this division shall, upon the presentation of satisfactory evidence by an applicant for licensure, accept the education, training, and practical experience completed by the applicant as a member of the United States Armed Forces or Military Reserves of the United States, the national guard of any state, the military reserves of any state, or the naval militia of any state, toward the qualifications and requirements for licensure by that board if the board determines that the education, training, or practical experience is equivalent to the standards of the board.~~

~~(b)~~

**712. (a)** Not later than July 1, 2014, if a board under this division accredits or otherwise approves schools offering educational course credit for meeting licensing qualifications and requirements, the board shall require a school seeking accreditation or approval to submit to the board proof that the school has procedures in place to evaluate, upon presentation of satisfactory evidence by the applicant, the applicant's military education, training, and practical experience toward the completion of an educational program that would qualify a person to apply for licensure if the school determines that the education, training, or practical experience is equivalent

to the standards of the board. A board that requires a school to be accredited by a national organization shall not impose requirements on the school that conflict with the standards of the national organization.

~~(e)~~

(b) With respect to complying with the requirements of this section including the determination of equivalency between the education, training, or practical experience of an applicant and the board's standards, and obtaining state, federal, or private funds to support compliance with this section, the Department of Veterans Affairs, the Chancellor of the California State University, and the Chancellor of the California Community Colleges shall provide technical assistance to the boards under this division and to the schools under this section.

**SEC. 4.** Section 131136 is added to the Health and Safety Code, to read:

**131136.** (a) Notwithstanding any other provision of law, the department shall, upon the presentation of satisfactory evidence by an applicant for licensure or certification in one of the professions described in subdivision (b), accept the education, training, and practical experience completed by the applicant as a member of the United States Armed Forces or Military Reserves of the United States, the national guard of any state, the military reserves of any state, or the naval militia of any state, toward the qualifications and requirements for licensure *or certification* by the department if the department determines that the education, training, or practical experience is equivalent to the standards of the department.

(b) The following professions are subject to this section:

- (1) Medical laboratory technician as described in Section 1260.3 of the Business and Professions Code.
- (2) Clinical laboratory scientist as described in Section ~~1262~~ 1261 of the Business and Professions Code.
- (3) Radiologic technologist as described in Chapter 6 (commencing with Section 114840) of Part 9 of Division 104.
- (4) Nuclear medicine technologist as described in Chapter 4 (commencing with Section 107150) of Part 1 of Division 104.
- (5) Certified nurse assistant as described in Article 9 (commencing with Section 1337) of Chapter 2 of Division 2.
- (6) Certified home health aide as described in Section 1736.1.
- (7) Certified hemodialysis technician as described in ~~Article 3.5 (commencing with Section 1247) of Chapter 3 of Division 2~~ Section 1247.61 of the Business and Professions Code.
- (8) Nursing home administrator as described in ~~Chapter 2.35 (commencing with Section 1416) of Division 2.~~ Section 1416.2.

(c) Not later than July 1, 2014, if the department accredits or otherwise approves schools offering educational course credit for meeting licensing and certification qualifications and requirements, the department shall require a school seeking accreditation or approval to submit to the board proof that the school has procedures in place to fully accept an applicant's military education, training, and practical experience toward the completion of an educational program that would qualify a person to apply for licensure or certification if the school determines that the education, training, or practical experience is equivalent to the standards of the department. If the department requires a school to be accredited by a national organization, the requirement of the department shall not, in any way, conflict with standards set by the national organization.

(d) With respect to complying with the requirements of this section including the determination of equivalency between the education, training, or practical experience of an applicant and the department's standards, and obtaining state, federal, or private funds to support compliance with this section, the Department of Veterans Affairs, the Chancellor of the California State University, and the Chancellor of the California Community Colleges shall provide technical assistance to the department, to the State Public Health Officer, and to the schools described in this section.



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|------------------------|---|
| <b>Bill Number:</b>    | <b>AB 258</b>                           |
| <b>Introduced</b>      | 2/7/13                                  |
| <b>Amendment Date:</b> |   |
| <b>Author:</b>         | Assembly Member Colonel Rocky J. Chavez |
| <b>Topic:</b>          | State Agencies: Veterans                |
| <b>Position:</b>       |   |

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

**Status:** In ASM Appropriations  
Passed out of ASM Com on Veterans Affairs on 3/11/13

**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 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 military?" The provision shall apply to written forms or publications that are newly printed on or after 1/1/14.

**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.

**FISCAL IMPACT ON THE BOARD:**

None identified

# California Legislature



Colonel Rocky J. Chávez  
Assemblymember, 76<sup>th</sup> District

## FACT SHEET

### Assemblymember Colonel Rocky J. Chávez

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#### Assembly Bill 258 – UPDATING VETERAN IDENTIFICATION QUESTION

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##### SUMMARY

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Assembly Bill 258 will update the veteran identifier question seen on forms at any state government organization which asks individuals to identify as a veteran or non-veteran. The new question will read “Have you ever served in the military?”

##### ISSUE BACKGROUND

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Currently California residents are simply asked, “Are you a veteran?” Although a very simple question many veterans believe they are not true veterans because they have never served in combat or, most commonly, because they are women.

In 2011 the California Research Bureau conducted a survey on women, 63 of the 843 respondents (7.4%), marked that they were not a veteran then included comments such as, “I served in the Air Force,” additionally the women stated “I thought veteran benefits were only for men.”

Furthermore, when the CRB held the ICV meetings in December 2011, and Jan. and Feb. 2012 both women in the services repeatedly stated that the, “Are you a veteran?” question was insufficient for identifying female veterans and men who had not served in combat.

Veterans who do not identify themselves can lose out on many Federal Benefits for which they are entitled. Such benefits include the GI Bill, disability compensation and pension, access to free or reduced cost medical care, vocational rehab, unemployment benefits, veteran home loans, burial benefits, and survivor benefits.

##### SOLUTION

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Conservatively it is anticipated that an additional 10% of women will identify as veterans simply by changing the way the question is asked, an increase of 18,500 women in CA alone.

AB 258 changes the question identifying veterans to capture more veterans, dissuading the belief that veterans are only those who have seen combat.

##### AUTHOR'S STATEMENT

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“It is a shame that many of our female veterans do not believe they are entitled to the same benefits as their male counterparts. AB 258 is a small change that will positively impact our female veterans and ensure they have access to the benefits they deserve.”  
Assemblymember Colonel Rocky J. Chávez.

##### SUPPORT

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- American Federation of State, County and Municipal Employees, AFL-CIO (AFSCME)
- American Association of University Women – California.

##### OPPOSITION

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None on file.

##### MORE INFORMATION

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Lyndsay Mitchell  
916-319-2076  
[lyndsay.mitchell@asm.ca.gov](mailto:lyndsay.mitchell@asm.ca.gov)



*California*  
LEGISLATIVE INFORMATION

AB-258 State agencies: veterans. (2013-2014)

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**ASSEMBLY BILL**

**No. 258**

**Introduced by Assembly Member Chávez**

**February 07, 2013**

**An act to add Section 11019.11 to the Government Code, relating to state agencies.**

LEGISLATIVE COUNSEL'S DIGEST

AB 258, as introduced, Chávez. State agencies: veterans.

Existing law provides for the governance and regulation of state agencies, as defined. Existing law provides certain benefits and protections for members of the Armed Forces of the United States.

This bill would require every state agency that requests on any written form or written publication, or through its Internet Web site, whether a person is a veteran, to request that information in a specified manner.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**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 military?"

(b) This section shall apply only to a written form or written publication that is newly printed on or after January 1, 2014.



**Bill Number:** AB 512  
**Introduced** 2/20/13  
**Amendment Date:**  
**Author:** Assembly Member Rendon  
**Topic:** Healing Arts: Licensure Exemption  
**Position:**

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**Affected Sections:** Amend Section 901 of the Business and Professions Code (BPC)

**Status:** Hearing: 4/9/13 in Asm Business, Professions and Consumer Protection

**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 WOULD:**

Extend the provisions of the section from 1/1/14 to 1/1/18.

**ACCORDING TO THE AUTHOR:**

AB 512 would extend the sunset on current law that allows qualified, out-of-state medical practitioners to volunteer their services on a limited basis for health care events from January 2014 to January 2018.

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.

Staff will continue to watch this measure.

**FISCAL IMPACT ON THE BOARD:**

None identified

# AB 512 (Rendon)

## Medical Volunteers

### Issue

There are more than two million uninsured people in Los Angeles County. Many individuals rely on government or non-profit sponsored health events to receive medical screenings, services and treatment.

The law that allows these health events to use out-of-state medical professionals is due to expire at the beginning of January 2014.

### Background

More than 4,900 people received free medical, vision and dental care inside the Los Angeles Memorial Coliseum during the four day CareNow Clinic. Now in its third year, CareNow is a non-profit organization, founded by healthcare professionals dedicated to serving those who are underserved and uninsured. Eight hundred doctors, dentists, optometrists, nurses, and general volunteers transformed the Los Angeles Coliseum into a medical clinic where people received on the spot medical attention.

Current law exempts out-of-state medical practitioners from California licensure when volunteering their services during a declared state of emergency or when they volunteer their services during a health care event sponsored by a non-profit organization or local government.

Services are provided only to uninsured or underinsured individuals. Practitioners can volunteer only for up to ten calendar days.

Respective healing arts boards were required to promulgate regulations before out-of-state practitioners were allowed to volunteer and the boards can also deny permission to the health care provider from volunteering for failure to comply with California's stringent practicing requirements.

The Medical Board of California promulgated the regulations in August, 2012. The regulations, however, were not done in time to allow out-of-state practitioners to volunteer at the CareNow Health Event in Los Angeles last fall. The statute that provided for these regulations now is set to expire. This program needs more time to demonstrate its success.

### Legislation

AB 512 extends the sunset on current law that allows qualified, out-of-state medical practitioners to volunteer their services on a limited basis for health care events from January 2014 to January 2018.

### Support

Los Angeles County (Sponsor)

### Contact Information

Staff: Stacey Reardon  
(916) 319-2063  
(916) 319-2163 [Fax]  
stacey.reardon@asm.ca.gov



California  
LEGISLATIVE INFORMATION

AB-512 Healing arts: licensure exemption. (2013-2014)

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**ASSEMBLY BILL**

**No. 512**

**Introduced by Assembly Member Rendon**

February 20, 2013

**An act to amend Section 901 of the Business and Professions Code, relating to healing arts.**

LEGISLATIVE COUNSEL'S DIGEST

AB 512, as introduced, Rendon. Healing arts: licensure exemption.

Existing law provides for the licensure and regulation of various healing arts practitioners by boards within the Department of Consumer Affairs. Existing law provides an exemption from these requirements for a health care practitioner licensed in another state who offers or provides health care for which he or she is licensed during a state of emergency, as defined, and upon request of the Director of the Emergency Medical Services Authority, as specified.

Existing law provides, until January 1, 2014, an exemption from the licensure and regulation requirements for a health care practitioner, as defined, licensed or certified in good standing in another state or states, who offers or provides health care services for which he or she is licensed or certified through a sponsored event, as defined, (1) to uninsured or underinsured persons, (2) on a short-term voluntary basis, (3) in association with a sponsoring entity that registers with the applicable healing arts board, as defined, and provides specified information to the county health department of the county in which the health care services will be provided, and (4) without charge to the recipient or a 3rd party on behalf of the recipient, as specified. Existing law 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 specified requirements, including payment of a fee as determined by the applicable licensing board.

This bill would delete the January 1, 2014, date of repeal, and instead allow the exemption to operate until January 1, 2018.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

**THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:**

**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 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.





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|------------------------|---|
| <b>Bill Number:</b>    | <b>AB 555</b>                                   |
| <b>Introduced</b>      | 2/20/13   |
| <b>Amendment Date:</b> | <b>3/19/13</b>                                  |
| <b>Author:</b>         | Assembly Member Salas                           |
| <b>Topic:</b>          | Professions and Vocation: Military and Veterans |
| <b>Position:</b>       |   |

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**Affected Sections:** Amend Section 35 of the Business and Professions Code (BPC)

**Status:** Re-referred to Asm Business, Professions and Consumer Protection

**EXISTING LAW:**

**Section 35 BPC** provides for the licensure and regulation of various professions and vocations by DCA boards, and that boards may adopt rules and regulations to provide for methods of evaluating education, training, and experience obtained in the armed services, if applicable to the requirements of the profession to which they are applying.

Section **712 BPC** provides that a board, as specified, shall, upon the presentation of satisfactory evidence by an applicant for licensure, accept the education, training, and practical experience completed by the applicant as a member of the US Armed Forces or Military Reserves of the US, the national guard of any state, the military reserves of any state, or the naval militia of any state, toward the qualifications and requirements for licensure by that board if the board determines that the education, training, or practical experience is equivalent to the standards of the board.

**THIS BILL WOULD:**

**Amend Section 35 PBC** to require a board to consider, and that a board may accept, any relevant training received while serving in the armed services of the United States for purposes of satisfying the requirements for a license, as specified. The measure authorizes a board to consult with the Department of Veterans Affairs and the Military Department when evaluating whether training acquired during military service is applicable to the requirements for the license being sought.

**STAFF COMMENTS:**

Board regulation at 16 CCR 1793.5 specifies that for a Pharmacy Technician applicant, an individual who possesses a certification of completion from a training program provided by a branch of the federal armed services shall meet the minimum educational requirements for a California license.

This is one of my bills that the DCA is tracking; staff will continue to watch this measure.

**FISCAL IMPACT ON THE BOARD:**

None identified



California  
LEGISLATIVE INFORMATION

AB-555 Professions and vocations: military and veterans. (2013-2014)

AMENDED IN ASSEMBLY MARCH 19, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**ASSEMBLY BILL**

**No. 555**

**Introduced by Assembly Member Salas**

**February 20, 2013**

**An act to amend Section 35 of the Business and Professions Code, relating to professions and vocations.**

LEGISLATIVE COUNSEL'S DIGEST

AB 555, as amended, Salas. Professions and vocations: military and veterans.

Existing law provides for the licensure and regulation of various professions and ~~vacations~~ *vacations* by boards within the Department of Consumer Affairs. *Existing law requires these boards to adopt rules and regulations to provide for methods of evaluating education, training, and experience obtained in the armed services, if applicable to the requirements of the business, occupation, or profession regulated, and to specify how this education, training, and experience may be used to meet the licensure requirements for the particular business, occupation, or profession regulated.*

This bill would ~~state the intent of the Legislature to enact legislation that would streamline the licensure process of various professions and vocations for veterans and members of the military separating from service.~~ *require a board to consider any relevant training an applicant for a license received while serving in the armed services of the United States for purposes of satisfying the requirements for a license, if applicable to the requirements for the particular business, occupation, or profession regulated by the board. This bill would also authorize a board to consult with the Department of Veterans Affairs and the Military Department when evaluating whether training acquired during service in the armed services of the United States is applicable to requirements for the license an applicant seeks.*

Vote: majority Appropriation: no Fiscal Committee: ~~no~~yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** *Section 35 of the Business and Professions Code is amended to read:*

**35. (a)** It is the policy of this state that, consistent with the provision of high-quality services, persons with skills, knowledge, and experience obtained in the armed services of the United States should be permitted to apply this learning and contribute to the employment needs of the state at the maximum level of responsibility

and skill for which they are qualified. To this end, rules and regulations of boards provided for in this code shall provide for methods of evaluating education, training, and experience obtained in the armed services, if applicable to the requirements of the business, occupation, or profession regulated. These rules and regulations shall also specify how this education, training, and experience may be used to meet the licensure requirements for the particular business, occupation, or profession regulated. Each board shall consult with the Department of Veterans Affairs and the Military Department before adopting these rules and regulations. Each board shall perform the duties required by this section within existing budgetary resources of the agency within which the board operates.

*(b) A board provided for in this code shall consider, and may accept, any relevant training an applicant for a license received while serving in the armed services of the United States for purposes of satisfying the requirements for a license, if applicable to the requirements for the particular business, occupation, or profession regulated by the board. A board may consult with the Department of Veterans Affairs and the Military Department when evaluating whether training acquired during service in the armed services of the United States is applicable to requirements for the license an applicant seeks.*

~~SECTION 1. It is the intent of the Legislature to enact legislation that would streamline the licensure process of various professions and vocations for veterans and members of the military separating from service.~~



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|------------------------|--|
| <b>Bill Number:</b>    | <b>AB 1057</b>                                       |
| <b>Introduced</b>      | 2/22/13  |
| <b>Amendment Date:</b> |  |
| <b>Author:</b>         | Assembly Member Medina                               |
| <b>Topic:</b>          | Professions and Vocation: Licenses: Military Service |
| <b>Position:</b>       |  |

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**Affected Sections:** Add Section 114.5 to the Business and Professions Code (BPC)

**Status:** Referred to Asm Appropriations  
Passed out of Asm Business, Professions and Consumer Protection on 4/2/13 (13-0)

**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 PBC** to require every board to inquire on every application for licensure if the applicant is serving in, or has previously served in, the 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 the information required by this section. Further, and with the department's migration to a new licensing system (BreEZe), the board is unable to modify its existing licensing requirements (this is through 2013 and possibly into 2014).

Board staff will communicate with the DCA on how the department may plan to implement the provisions of the measure, if enacted. Staff will continue to monitor this legislation.

## **AB 1057 (Medina)**

### **Veteran Inquiry On Licensure Applications**

#### *Background*

Thousands of military veterans return to California from service in the United States Armed Forces each year. For many veterans, finding civilian employment can be difficult. Most veterans possess valuable professional and occupational skills that are highly sought by California employers and consumers. Ensuring a successful transition from military to civilian life includes creating an efficient process for licensing veterans in professional careers who have learned valuable work skills while in the military.

The Department of Consumer Affairs currently oversees 36 licensing programs that issue more than two million licenses, registrations, and certifications in nearly 200 professional categories. These licensing boards, bureaus, committees, commission and program are charged with regulating a particular profession through licensure and enforcement programs. Each of these entities is responsible for enforcing the minimum qualifications for licensure that are established by statute and regulation. Licensure requirements vary in their specificity and flexibility. In many cases, the stated qualifications are specific and provide the regulating entity with little to no discretion over what experience or education can be accepted. Professional and occupational licensure requirements range from completing a form and paying a licensing fee to satisfying significant experience, education and exam requirements.

#### *Problem*

Most of the Department's licensing programs already have some process for accepting military service credit towards licensure for one or all of its license types. However, there is nothing on the application for licensure that identifies military experience. This bill will allow the Department of Consumer Affairs the ability to identify veterans in the application for licensure process, further counting their military credit towards licensure.

#### *Proposal*

AB 1057 (Medina) will require an inquiry of military service to be included on licensure applications of every board within the Department of Consumer Affairs.

#### *Support*

None

#### *Opposition*

None

Staff Contact: Conrad Crump (916) 319-2506, [Conrad.crump@asm.ca.gov](mailto:Conrad.crump@asm.ca.gov)



*California*  
LEGISLATIVE INFORMATION

AB-1057 Professions and vocations: licenses: military service. (2013-2014)

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**ASSEMBLY BILL**

**No. 1057**

**Introduced by Assembly Member Medina**

February 22, 2013

**An act to add Section 114.5 to the Business and Professions Code, relating to professions and vocations.**

LEGISLATIVE COUNSEL'S DIGEST

AB 1057, as introduced, Medina. Professions and vocations: licenses: military service.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law authorizes a licensee or registrant whose license expired while the licensee or registrant was on active duty as a member of the California National Guard or the United States Armed Forces to, upon application, reinstate his or her license without penalty and without examination, if certain requirements are satisfied, unless the licensing agency determines that the applicant has not actively engaged in the practice of his or her profession while on active duty, as specified.

This bill would require each board to inquire in every application for licensure if the applicant is serving in, or has previously served in, the military.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** Section 114.5 is added to the Business and Professions Code, to read:

**114.5.** Each board shall inquire in every application for licensure if the applicant is serving in, or has previously served in, the military.



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|---------------------|-------------------------|
| <b>Bill Number:</b> | <b>AB 299</b>           |
| <b>Introduced</b>   | 2/12/13                 |
| <b>Last Amend:</b>  |                         |
| <b>Author:</b>      | Assembly Member Holden  |
| <b>Topic:</b>       | Pharmacy: Mail Order Rx |
| <b>Position:</b>    |                         |

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**Current Bill Status:** Referred to ASM Business, Professions and Consumer Protection  
(2/28/13)

**Affected Sections:** Amend Section 4112 of the Business and Professions Code (BPC)

**SUMMARY:**

SB 299 is a bill sponsored by the California Pharmacists Association, which would amend Section 4112 BPC to prohibit a resident or nonresident pharmacy that delivers prescriptions via mail from entering into, or being a party to, an agreement with a health care service plan or disability insurer that requires a plan enrollee to utilize mail order services, or that requires a plan enrollee or insured to opt out of a mail order process.

**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.

**THIS BILL WILL:**

As summarized above, this bill would **Amend Section 4112** to add a new subdivision (h) as follows:

*(h) A nonresident pharmacy or a pharmacy located in this state that delivers prescriptions via mail is prohibited from entering into, or being a party to, an agreement with a health care service plan or disability insurer that requires a plan enrollee or insured to utilize mail order services or that requires a plan enrollee or insured to opt out of a mail order process.*

**FISCAL IMPACT ON THE BOARD:**

A pharmacy that violates the provisions of Section 4112(h), would be subject to discipline by the board. The board has existing authority to issue citations containing administrative fines and orders of abatement. Related regulations at Article 9 of Title 16 of the California Code of Regulations (commencing with Section 1775) include a mechanism to contest a citation issued by the board.

As of April 2012, the board issued licenses to approximately 6,900 pharmacies, and to approximately 500 nonresident pharmacies.

Violating the provisions of Section 4112, as introduced in AB 299, may result in an increase of citations and fines, complaints, and related investigations and could require additional inspector and staff support to handle any such increase.

**Staff Comments:**

Staff has requested a Fact Sheet from the author's office.

Health Maintenance Organizations (aka HMOs) or certain Preferred Provider Organizations (PPOs) are regulated by the California Department of Managed Healthcare.

Should a health care service plan or disability insurer be precluded from *offering* agreements that would require a plan enrollee or insured to utilize mail order pharmacy services (or opt out of one) in lieu of placing such a restriction on a pharmacy?



*California*  
LEGISLATIVE INFORMATION

AB-299 Pharmacy. (2013-2014)

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**ASSEMBLY BILL**

**No. 299**

**Introduced by Assembly Member Holden**

February 12, 2013

**An act to amend Section 4112 of the Business and Professions Code, relating to pharmacy.**

LEGISLATIVE COUNSEL'S DIGEST

AB 299, as introduced, Holden. Pharmacy.

The Pharmacy Law governs the business and practice of pharmacy in this state. That law provides that any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state is considered a nonresident pharmacy. The law prohibits a person from acting as a nonresident pharmacy unless he or she has obtained a license, and imposes various disclosure and recordkeeping requirements on nonresident pharmacies. Any person who knowingly violates these provisions is guilty of a misdemeanor.

This bill would prohibit a nonresident pharmacy or a pharmacy located in this state that delivers prescriptions via mail from entering into, or being a party to, an agreement with a health care service plan or disability insurer that requires a plan enrollee or insured to utilize mail order services or that requires a plan enrollee or insured to opt out of a mail order process. By creating new crimes, the bill would impose a state-mandated local program.

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

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

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** Section 4112 of the Business and Professions Code is amended to read:

**4112.** (a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(g) A nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the board to manufacture, compound, furnish, sell, dispense, or initiate the prescription of a dangerous drug or dangerous device, or to provide any pharmacy-related service, to a person residing in California.

*(h) A nonresident pharmacy or a pharmacy located in this state that delivers prescriptions via mail is prohibited from entering into, or being a party to, an agreement with a health care service plan or disability insurer that requires a plan enrollee or insured to utilize mail order services or that requires a plan enrollee or insured to opt out of a mail order process.*

~~(h)~~

*(i) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.*

~~(i)~~

*(j) The registration fee shall be the fee specified in subdivision (a) of Section 4400.*

~~(j)~~

*(k) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.*

~~(k)~~

*(l) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.*

**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:** AB 804  
**Introduced** 2/21/13  
**Last Amend:**  
**Author:** Assembly Member Lowenthal  
**Topic:** Medi-Cal: Pharmacy Providers: Invoices  
**Position:**

**Current Bill Status:** 4/30/13 – Hearing Scheduled in Assembly Health

**Affected Sections:** Section 14105.45 of the Welfare and Institutions Code (related to Medi-Cal)

**SUMMARY:**

According to the author, AB 804 would safeguard the confidentiality of proprietary information that retail pharmacies will be required to submit to the Department of Health Care Services (DHCS) as part of establishing a new Medi-Cal Fee-For-Service reimbursement methodology.

**EXISTING LAW:**

In part, **Section 14105.45 WIC** specifies that reimbursement to Medi-Cal pharmacy providers for legend and nonlegend drugs shall not exceed the lowest of either (a) a pharmacy’s estimated acquisition cost of the drug, plus a professional fee for dispensing, or (b) the pharmacy’s usual and customary charge, as specified.

The section further defines criteria by which the CDHCS shall establish the estimated acquisition cost of legend and nonlegend drugs. When establishing a fee-for-service provider, the CDHCS requires specified information from the pharmacy provider, to include detailed drug price information (See 14105.45(b)(5)(c)(i)).

**THIS BILL WILL:**

Amend Section 14105.45(b)(5)(c)(i) to specify that pharmacy invoice information provided shall be confidential and exempt from disclosure under the California Public Records Act.

**FISCAL IMPACT ON THE BOARD:** None

**Staff Comments:** FYI only. There is no direct impact to the board; staff is watching this measure as it relates to pharmacy records.

**Support:** (see Fact Sheet)

California Retailers Association (Sponsor)  
California Pharmacists Association  
CVS  
National Association of Chain Drug Stores  
Rite-Aid  
Walgreens

**Opposition:**

None identified

# AB 804 (B. Lowenthal)

## Medi-Cal Pharmacy Providers: Invoices

### SUMMARY

Under existing law, Medi-Cal pharmacy providers are required to submit drug price information, including invoice prices, to the Department of Health Care Services (DHCS) or to a vendor designated by the department in order to establish the Average Acquisition Cost (AAC). Current law also provides that drug pricing information is confidential and exempt from public disclosure.

This bill ensures that all pharmacy invoice information is kept confidential and exempt from public disclosure. This bill also makes legislative findings expressing the need for that information to be protected.

### BACKGROUND

In 2011, DHCS' budget trailer bill, AB 102 (Budget), Chapter 29, Statutes of 2011, included language that replaced the Average Wholesale Price (AWP) formula in the Medi-Cal system with the Average Acquisition Cost (AAC) pricing structure. The AAC changed the manner in which pharmacies are reimbursed under Medi-Cal's fee-for-service program.

AB 102 authorized DHCS to collect broad pricing information not just from individual pharmacies, but also from pharmacy warehouses, nonprofit medical programs, wholesalers, and manufacturers that often purchase drugs at a significant discount.

As part of establishing and calculating the AAC, DHCS is permitted to contract with a third party vendor for the purposes of conducting a cost of dispensing study, surveying drug pricing information, and collecting data from pharmacy providers. As part of the study, Medi-Cal pharmacy providers are required to submit drug pricing information that include invoice prices, all discounts, rebates, and refunds known to the provider to DHCS or the selected third party vendor. DHCS has recently closed its Request for Proposal (RFP) search for the third party vendor, and the selection for the vendor will be made public soon.

Each pharmacy company has a unique arrangement with drug manufacturers and wholesalers in the acquisition of drugs. While current law protects the confidentiality of drug price information, invoices typically contain sensitive information that warrants the same level of protection including, information that relates to volume

discounts and other pharmacy information that goes beyond just the drug price. Much of the information is extremely sensitive and is proprietary pricing information. Therefore, it is crucial that there are specific confidentiality and privacy protections for pharmacies that are providing invoice information to DHCS or the potential outside vendor.

AB 804 would safeguard the confidentiality of proprietary information that retail pharmacies will be required to submit to DHCS as part of establishing a new Medi-Cal Fee-For-Service reimbursement methodology.

### AB 804

- Ensures that pharmacy invoice information is kept confidential and exempt from public disclosure.

### SUPPORT

- California Retailers Association (Sponsor)
- California Pharmacists Association
- CVS
- National Association of Chain Drug Stores
- Rite-Aid
- Walgreens

### STAFF CONTACT

Mary June G. Flores  
Legislative Aide  
Assemblymember Bonnie Lowenthal (916) 319-2070  
[MaryJune.Flores@asm.ca.gov](mailto:MaryJune.Flores@asm.ca.gov)



*California*  
LEGISLATIVE INFORMATION

AB-804 Medi-Cal: pharmacy providers: invoices. (2013-2014)

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**ASSEMBLY BILL**

**No. 804**

**Introduced by Assembly Member Lowenthal**

**February 21, 2013**

**An act to amend Section 14105.45 of the Welfare and Institutions Code, relating to Medi-Cal.**

LEGISLATIVE COUNSEL'S DIGEST

AB 804, as introduced, Lowenthal. Medi-Cal: pharmacy providers: invoices.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid Program provisions. Existing law requires reimbursement to Medi-Cal pharmacy providers for drugs, as prescribed, and authorizes the department to establish a new reimbursement methodology based on average acquisition cost, as defined. Under existing law, Medi-Cal pharmacy providers are required to submit drug price information, including invoice prices, to the department or a vendor designated by the department for the purposes of establishing the average acquisition cost. Under existing law, drug pricing information is confidential and exempt from public disclosure, as specified.

This bill would provide that pharmacy invoice information is confidential and exempt from public disclosure, as specified.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

Vote: majority Appropriation: no Fiscal Committee: no Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** Section 14105.45 of the Welfare and Institutions Code is amended to read:

**14105.45.** (a) For purposes of this section, the following definitions shall apply:

(1) "Average acquisition cost" means the average weighted cost determined by the department to represent the actual acquisition cost paid for drugs by Medi-Cal pharmacy providers, including those that provide specialty

drugs. The average acquisition cost shall not be considered confidential and shall be subject to disclosure pursuant to the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(2) "Average manufacturers price" means the price reported to the department by the federal Centers for Medicare and Medicaid Services pursuant to Section 1927 of the Social Security Act (42 U.S.C. Sec. 1396r-8).

(3) "Average wholesale price" means the price for a drug product listed as the average wholesale price in the department's primary price reference source.

(4) "Estimated acquisition cost" means the department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package.

(5) "Federal upper limit" means the maximum per unit reimbursement when established by the federal Centers for Medicare and Medicaid Services and published by the department in Medi-Cal pharmacy provider bulletins and manuals.

(6) "Generically equivalent drugs" means drug products with the same active chemical ingredients of the same strength and dosage form, and of the same generic drug name, as determined by the United States Adopted Names—~~(USAN)~~ Council (USAN Council) and accepted by the federal Food and Drug Administration (FDA), as those drug products having the same chemical ingredients.

(7) "Legend drug" means any drug whose labeling states "Caution: Federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(8) "Maximum allowable ingredient cost" (MAIC) means the maximum amount the department will reimburse Medi-Cal pharmacy providers for generically equivalent drugs.

(9) "Innovator multiple source drug," "noninnovator multiple source drug," and "single source drug" have the same meaning as those terms are defined in Section 1396r-8(k)(7) of Title 42 of the United States Code.

(10) "Nonlegend drug" means any drug whose labeling does not contain the statement referenced in paragraph (7).

(11) "Pharmacy warehouse," as defined in Section 4163 of the Business and Professions Code, means a physical location licensed as a wholesaler for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of those drugs to a group of pharmacies under common ownership and control.

(12) "Specialty drugs" means drugs determined by the department pursuant to subdivision (f) of Section 14105.3 to generally require special handling, complex dosing regimens, specialized self-administration at home by a beneficiary or caregiver, or specialized nursing facility services, or may include extended patient education, counseling, monitoring, or clinical support.

(13) "Volume weighted average" means the aggregated average volume for a group of legend or nonlegend drugs, weighted by each drug's percentage of the group's total volume in the Medi-Cal fee-for-service program during the previous six months. For purposes of this paragraph, volume is based on the standard billing unit used for the legend or nonlegend drugs.

(14) "Wholesaler" means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail pharmacies in California.

(15) "Wholesaler acquisition cost" means the price for a drug product listed as the wholesaler acquisition cost in the department's primary price reference source.

(b) (1) Reimbursement to Medi-Cal pharmacy providers for legend and nonlegend drugs shall not exceed the lowest of either of the following:

(A) The estimated acquisition cost of the drug plus a professional fee for dispensing.

(B) The pharmacy's usual and customary charge as defined in Section 14105.455.

(2) The professional fee shall be seven dollars and twenty-five cents (\$7.25) per dispensed prescription. The professional fee for legend drugs dispensed to a beneficiary residing in a skilled nursing facility or intermediate care facility shall be eight dollars (\$8) per dispensed prescription. For purposes of this paragraph "skilled nursing facility" and "intermediate care facility" shall have the same meaning as defined in Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations. If the department

determines that a change in dispensing fee is necessary pursuant to this section, the department shall establish the new dispensing fee through the budget process and implement the new dispensing fee pursuant to subdivision (d).

(3) The department shall establish the estimated acquisition cost of legend and nonlegend drugs as follows:

(A) For single source and innovator multiple source drugs, the estimated acquisition cost shall be equal to the lowest of the average wholesale price minus 17 percent, the average acquisition cost, the federal upper limit, or the MAIC.

(B) For noninnovator multiple source drugs, the estimated acquisition cost shall be equal to the lowest of the average wholesale price minus 17 percent, the average acquisition cost, the federal upper limit, or the MAIC.

(C) Average wholesale price shall not be used to establish the estimated acquisition cost once the department has determined that the average acquisition cost methodology has been fully implemented.

(4) For purposes of paragraph (3), the department shall establish a list of MAICs for generically equivalent drugs, which shall be published in pharmacy provider bulletins and manuals. The department shall establish a MAIC only when three or more generically equivalent drugs are available for purchase and dispensing by retail pharmacies in California. The department shall update the list of MAICs and establish additional MAICs in accordance with all of the following:

(A) The department shall base the MAIC on the mean of the average manufacturer's price of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the department to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California.

(B) If average manufacturer prices are unavailable, the department shall establish the MAIC in one of the following ways:

(i) Based on the volume weighted average of wholesaler acquisition costs of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the department to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California.

(ii) Pursuant to a contract with a vendor for the purpose of surveying drug price information, collecting data, and calculating a proposed MAIC.

(iii) Based on the volume weighted average acquisition cost of drugs generically equivalent to the particular innovator drug adjusted by the department to represent the average purchase price paid by Medi-Cal pharmacy providers.

(C) The department shall update MAICs at least every three months and notify Medi-Cal providers at least 30 days prior to the effective date of a MAIC.

(D) The department shall establish a process for providers to seek a change to a specific MAIC when the providers believe the MAIC does not reflect current available market prices. If the department determines a MAIC change is warranted, the department may update a specific MAIC prior to notifying providers.

(E) In determining the average purchase price, the department shall consider the provider-related costs of the products that include, but are not limited to, shipping, handling, storage, and delivery. Costs of the provider that are included in the costs of the dispensing shall not be used to determine the average purchase price.

(5) (A) The department may establish the average acquisition cost in one of the following ways:

(i) Based on the volume weighted average acquisition cost adjusted by the department to ensure that the average acquisition cost represents the average purchase price paid by retail pharmacies in California.

(ii) Based on the proposed average acquisition cost as calculated by the vendor pursuant to subparagraph (B).

(iii) Based on a national pricing benchmark obtained from the federal Centers for Medicare and Medicaid Services or on a similar benchmark listed in the department's primary price reference source adjusted by the department to ensure that the average acquisition cost represents the average purchase price paid by retail pharmacies in California.

(B) For the purposes of paragraph (3), the department may contract with a vendor for the purposes of surveying drug price information, collecting data from providers, wholesalers, or drug manufacturers, and calculating a proposed average acquisition cost.

(C) (i) Medi-Cal pharmacy providers shall submit drug price information to the department or a vendor designated by the department for the purposes of establishing the average acquisition cost. The information submitted by pharmacy providers shall include, but not be limited to, invoice prices and all discounts, rebates, and refunds known to the provider that would apply to the acquisition cost of the drug products purchased during the calendar quarter. Pharmacy warehouses shall be exempt from the survey process, but shall provide drug cost information upon audit by the department for the purposes of validating individual pharmacy provider acquisition costs. *Pharmacy invoice information shall be confidential and shall be exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).*

(ii) Pharmacy providers that fail to submit drug price information to the department or the vendor as required by this subparagraph shall receive notice that if they do not provide the required information within five working days, they shall be subject to suspension under subdivisions (a) and (c) of Section 14123.

(D) (i) For new drugs or new formulations of existing drugs, ~~where~~ *if* drug price information is unavailable pursuant to clause (i) of subparagraph (C), drug manufacturers and wholesalers shall submit drug price information to the department or a vendor designated by the department for the purposes of establishing the average acquisition cost. Drug price information shall include, but not be limited to, net unit sales of a drug product sold to retail pharmacies in California divided by the total number of units of the drug sold by the manufacturer or wholesaler in a specified period of time determined by the department.

(ii) Drug products from manufacturers and wholesalers that fail to submit drug price information to the department or the vendor as required by this subparagraph may not be a reimbursable benefit of the Medi-Cal program for those manufacturers and wholesalers until the department has established the average acquisition cost for those drug products.

(E) Drug pricing information provided to the department or a vendor designated by the department for the purposes of establishing the average acquisition cost pursuant to this section shall be confidential and shall be exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(F) Prior to the implementation of an average acquisition cost methodology, the department shall collect data through a survey of pharmacy providers for purposes of establishing a professional fee for dispensing in compliance with federal Medicaid requirements.

(i) The department shall seek stakeholder input on the retail pharmacy factors and elements used for the pharmacy survey relative to both average acquisition costs and dispensing costs. Any adjustment to the dispensing fee shall not exceed the aggregate savings associated with the implementation of the average acquisition cost methodology.

(ii) For drug products provided by pharmacy providers pursuant to subdivision (f) of Section 14105.3, a differential professional fee or payment for services to provide specialized care may be considered as part of the contracts established pursuant to that section.

(G) When the department implements the average acquisition cost methodology, the department shall update the Medi-Cal claims processing system to reflect the average acquisition cost of drugs not later than 30 days after the department has established average acquisition cost pursuant to subparagraph (A).

(H) Notwithstanding any other provision of law, if the department implements average acquisition cost pursuant to clause (i) or (ii) of subparagraph (A), the department shall update actual acquisition costs at least every three months and notify Medi-Cal providers at least 30 days prior to the effective date of any change in an actual acquisition cost.

(I) The department shall establish a process for providers to seek a change to a specific average acquisition cost when the providers believe the average acquisition cost does not reflect current available market prices. If the department determines an average acquisition cost change is warranted, the department may update a specific average acquisition cost prior to notifying providers.

(c) The director shall implement this section in a manner that is consistent with federal Medicaid law and regulations. The director shall seek any necessary federal approvals for the implementation of this section. This section shall be implemented only to the extent that federal approval is obtained.

(d) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.

(e) The department may enter into contracts with a vendor for the purposes of implementing this section on a bid or nonbid basis. In order to achieve maximum cost savings, the Legislature declares that an expedited process for contracts under this section is necessary. Therefore, contracts entered into to implement this section, and all contract amendments and change orders, shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

(f) (1) The rates provided for in this section shall be implemented only if the director determines that the rates will comply with applicable federal Medicaid requirements and that federal financial participation will be available.

(2) In determining whether federal financial participation is available, the director shall determine whether the rates comply with applicable federal Medicaid requirements, including those set forth in Section 1396a(a)(30) (A) of Title 42 of the United States Code.

(3) To the extent that the director determines that the rates do not comply with applicable federal Medicaid requirements or that federal financial participation is not available with respect to any rate of reimbursement described in this section, the director retains the discretion not to implement that rate and may revise the rate as necessary to comply with federal Medicaid requirements.

(g) The director shall seek any necessary federal approvals for the implementation of this section.

(h) This section shall not be construed to require the department to collect cost data, to conduct cost studies, or to set or adjust a rate of reimbursement based on cost data that has been collected.

(i) Adjustments to pharmacy drug product payment pursuant to Section 14105.192 shall no longer apply when the department determines that the average acquisition cost methodology has been fully implemented and the department's pharmacy budget reduction targets, consistent with payment reduction levels pursuant to Section 14105.192, have been met.

(j) Prior to implementation of this section, the department shall provide the appropriate fiscal and policy committees of the Legislature with information on the department's plan for implementation of the average acquisition cost methodology pursuant to this section.

**SEC. 2.** The Legislature finds and declares that Section 1 of this act imposes a limitation on the public's right of access to meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following finding to demonstrate the interest protected by this limitation and the need for protecting that interest: the Legislature finds and declares that in order to protect the privacy of pharmacy providers who disclose sensitive information, it is necessary to treat that information as confidential.



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| <b>Bill Number:</b> | <b>SB 146</b>  |
| <b>Introduced</b>   | 1/31/13  |
| <b>Amended:</b>     | <b>3/6/13</b>  |
| <b>Author:</b>      | Senator Lara   |
| <b>Topic:</b>       | Workers' Compensation: medical treatment:<br>billing |
| <b>Position:</b>    |  |

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**Current Bill Status:** As amended, passed out of the Senate (3/18/13)  
In the Assembly. First Reading. Held at Desk.

**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 introduced 1/31/13, the measure struck the requirement for a copy of a prescription to be submitted with such a request for payment.

**AS AMENDED, THIS BILL WOULD:**

Provide that a copy of a prescription for pharmaceutical services is not necessary unless required under a written agreement between an employer, insurer, or third-party claims administrator and a pharmacy.

Allow an employer insurer, or third-party claims administrator to request a copy of the prescription during a review of any records of prescription drugs dispensed by a pharmacy.

Provides that any entity submitting a pharmacy bill for payment on or after 1/1/13 and denied payment for not including a copy of the prescription from the treating physician, shall have 90 days after 1/1/14 to resubmit those bills for payment.

**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. Staff will continue to watch this measure.

**FISCAL IMPACT ON THE BOARD:**

None identified.

**SUPPORT:**

CompPharma (sponsor)

**OPPOSITION:** None known



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*Fact Sheet*  
*Senator Ricardo Lara*  
*SB 146 – Efficiency in Pharmacy Billing*

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**Summary:** SB 146 ensures access to medically necessary medications for injured workers and provides regulatory relief to the workers' compensation (WC) system.

Specifically, this bill removes an unnecessary requirement for WC pharmacy claims to include a prescription or prescription copy. The requirement is unnecessary because it provides duplicative information.

**Background:** SB 863 (Ch. 363, Statutes of 2012), among other changes to the WC system, requires pharmacy claims to include a prescription or prescription copy. The inclusion of a prescription or prescription copy provides no new information, as pharmacy claims currently capture all the information included on a prescription. There is no additional value in attaching a prescription or prescription copy. Therefore, the requirement is unnecessary and yields duplicative information.

Furthermore, pharmacies and pharmacy billers are not able to comply with the requirement under the electronic billing standard. The billing standard does not support the inclusion of attachments. Therefore, attaching a prescription copy to an electronic claim is not feasible. (The billing standard is a set of rules and regulations adopted by the state for paper and electronic medical billing.)

Compliance with the requirement is possible under the paper billing standard, but patient access to medically necessary medications could be delayed because paper billing would significantly slow the system and remove the real-time processing that allows for immediate dispensing of medication.

Despite the lack of compliance with the new requirement, patients are currently able to get their WC prescriptions only because prescriptions are being dispensed with the understanding among WC providers that the requirement will be repealed.

**Problem:** SB 863 requires a pharmacy or pharmacy biller to include a prescription or prescription copy with a WC pharmacy claim. This requirement is unnecessary, as it provides no information that was not already provided. Additionally, compliance under the electronic billing standard is not feasible. Lack of compliance could deem a bill incomplete, and therefore offers reason to deny a claim.

Furthermore, should this requirement not be removed, it could lead to delayed or denied payments which would ultimately impact access to medications for injured workers through a reduction in willing pharmacy participants.

**Solution:** SB 146 ensures access to medically necessary medications for injured workers and provides regulatory relief for pharmacy providers.

Specifically, this bill:

- Removes the requirement to include a copy of a prescription with request for payment on workers' compensation pharmacy claims.
- Grants pharmacy providers the ability to re-bill for any claims denied for not including a copy of the prescription, which will allow pharmacies to continue processing WC prescriptions until this correction can be implemented.

**Sponsor:** CompPharma

**Staff Contact:** Michael Nguyen, 651- 4033



California  
LEGISLATIVE INFORMATION

SB-146 Workers' compensation: medical treatment: billing. (2013-2014)

AMENDED IN SENATE MARCH 06, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**SENATE BILL**

**No. 146**

**Introduced by Senator Lara**

**January 31, 2013**

**An act to amend Section 4603.2 of the Labor Code, relating to workers' compensation.**

LEGISLATIVE COUNSEL'S DIGEST

SB 146, as amended, Lara. Workers' compensation: medical treatment: billing.

Existing law establishes a workers' compensation system, administered by the Administrative Director of the Division of Workers' Compensation, to compensate an employee for injuries sustained in the course of his or her employment. Existing law requires an employer to provide all medical services reasonably required to cure or relieve the injured worker from the effects of the injury, and generally provides for the reimbursement of medical providers for services rendered in connection with the treatment of a worker's injury. *Existing law requires a pharmacy to 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.*

This bill would ~~delete the requirement that a pharmacy 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.~~ *The bill would* prohibit a copy of the prescription from being required with a request for payment of pharmacy services, *unless otherwise agreed to by the provider of services*, and would give any entity 90 days after January 1, 2014, to resubmit pharmacy bills for payment, originally submitted on or after January 1, 2013, where payment was denied because the bill did not include a copy of the prescription from the treating physician. *The bill would also clarify that an employer, insurer, pharmacy benefits manager, or 3rd-party claims administrator would not be precluded from requesting a copy of a prescription during a review of any records of prescription drugs dispensed by a pharmacy.*

Vote: majority Appropriation: no Fiscal Committee: no Local Program: no

## THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**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 otherwise agrees to follow the requirements of this paragraph.*

(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, shall have 90 days after January 1, 2014, to resubmit those bills for payment.

*(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 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.



**Bill Number:** SB 445  
**Introduced** 2/21/13  
**Amendment Date:**  
**Author:** Senator Current Price, Jr.  
**Topic:** Controlled Substances Advertising  
**Position:**

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**Affected Sections:** Amend Section 4121 of the Business and Professions Code (BPC)

**Status:** Hearing: 4/15/13 in SEN Business, Professions and Economic Development

**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.



## SB 445- PRICE Controlled Substances Advertising

### Summary

In an effort to combat the rising tide of prescription drug abuse and drug seeking behavior by organized crime and addicts, Senate Bill 445 seeks to prohibit pharmacies from advertising the sale of controlled substances.

### Existing Law

The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacies by the California Board of Pharmacy (BOP). Additionally, the Pharmacy Law requires advertisements for prescription drugs to be limited to quantities consistent with good medical practice and include the strength, dosage form and effective dates of the advertised price.

There currently are no prohibitions on the advertisement of controlled substances.

### Why Is This Bill Needed?

The Centers for Disease Control and Prevention (CDC) has called rising rates of prescription drug abuse an epidemic.

Prescription drug abuse is the intentional use of a medication without a prescription, or taking a drug for reasons or in dosages other than as prescribed.

The National Institute of Drug Abuse estimates there are seven million prescription drug users in the United States. Federal data also shows abuse of prescription pain killers now ranks second, just behind marijuana, as the nation's most widespread illegal drug problem. The CDC reports that

prescription drug overdoses has risen for the 11<sup>th</sup> consecutive year and those deaths accounted for 60% of drug overdose deaths, overwhelming outnumber the combined deaths from illicit drug deaths (marijuana, heroin, cocaine et al).

Additionally, the data shows that individuals who misuse prescription drugs, particularly teens, believe these substances are safer than illicit drugs because they are prescribed by a health care professional and thus are safe to take under any circumstances.

Concurrent with increased rates of prescription drug abuse are increased robberies at pharmacies, which are being targeted for their inventories of prescription painkillers, anti-anxiety drugs and other controlled medications. National data shows that since 2006, pharmacy robberies have increased 82%. Unfortunately, pharmacies have become targets, often jeopardizing the safety of pharmacy staff and patrons, for individuals seeking drugs for either personal use or for sale on the streets (single pills can be worth up to \$80 on the black market).

These types of robberies have occurred in California as recently as this year. In January, there were three separate pharmacy robberies – two in South San Francisco and one in Amador County. In the fall of 2010, there was a pharmacy robbery in Sacramento County in which two pharmacy workers were shot and one ultimately died.

This measure attempts to limit drug seeking behavior at pharmacies by prohibiting the advertisement of controlled substances.

### Controlled Substances

**FOR MORE INFORMATION** – Sarah Mason (916) 651-4313 [sarah.mason@sen.ca.gov](mailto:sarah.mason@sen.ca.gov)

Through the Controlled Substances Act of 1970, the federal government regulates the manufacture, distribution and dispensing of controlled substances. The act ranks into five schedules those drugs known to have potential for physical or psychological harm, based on three considerations: (a) their potential for abuse; (b) their accepted medical use; and, (c) their accepted safety under medical supervision.

Schedule I controlled substances have a high potential for abuse and no generally accepted medical use such as heroin, cocaine and LSD.

Schedule II controlled substances have a currently accepted medical use in treatment, or a currently accepted medical use with severe restrictions, and have a high potential for abuse and psychological or physical dependence.

Schedule II drugs can be narcotics or non-narcotic. Examples of Schedule II controlled substances include morphine, methadone, Ritalin, Demerol, Dilaudid, Percocet, Percodan, and Oxycontin.

Schedule III and IV drugs include Vicodin, Zanax, Ambien and other anti-anxiety drugs that generally have less potential for abuse than Schedule II drugs, but are known to be mixed in specific ways to achieve a narcotic-like end product.

Schedule V drugs are available over the counter.

**Do You Support SB 445?**

*Please send a letter of support to:*  
Senator Curren Price  
State Capitol Rm. 2057  
Sacramento, CA 95814



California  
LEGISLATIVE INFORMATION

SB-445 Pharmacies: advertising: controlled substances. (2013-2014)

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

**SENATE BILL**

**No. 445**

**Introduced by Senator Price**

**February 21, 2013**

**An act to amend Section 4121 of the Business and Professions Code, relating to pharmacy.**

LEGISLATIVE COUNSEL'S DIGEST

SB 445, as introduced, Price. Pharmacies: advertising: controlled substances.

The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy. A knowing violation of the law is a crime. Existing law provides that 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, except as specified.

This bill would prohibit advertisements by pharmacies that specifically promote the sale or dispensing of any controlled substances, as defined.

Because a knowing violation of this provision would be a crime, this bill would impose a state-mandated local program.

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

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

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

**THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:**

**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.



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|---------------------|--|
| <b>Bill Number:</b> | <b>SB 727</b>  |
| <b>Introduced</b>   | 2/22/13  |
| <b>Last Amend:</b>  | <b>4/3/13</b>  |
| <b>Author:</b>      | Senator Hannah-Beth Jackson                                  |
| <b>Topic:</b>       | Solid Waste: Drug Abuse Prevention and Safe Disposal Program |
| <b>Position:</b>    |  |

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**Current Bill Status:** Referred to SEN Environmental Quality (3/3/13, re-referred 4/3/13)

**Affected Sections:** Add Section 117670.1 Health and Safety Code (HSC) and add Article 3.4 (starting with Section 47122) to the Public Resources Code

**SUMMARY:**

According to the author, SB 727 would establish a pharmaceutical collection program to address the home storage and improper and illegal disposal of home-generated pharmaceuticals that has exacerbated concerns over increased drug abuse and impacts on water quality.

The author states that SB 727 is an Extended Producer Responsibility (EPR) policy approach for home-generated pharmaceuticals, which would require producers (manufacturers) to develop and implement a collection system which would be approved by and have oversight of CalRecycle. Such a system would be designed and operated by the private sector and follows models in Canada and Europe.

**EXISTING LAW:**

Establishes the Medical Waste Management Act (MWMA), administered by the State Department of Public Health (DPH) (Health and Safety Code § 117600 et seq.).

**THIS BILL WILL:**

Make declarations related to unused and unwanted pharmaceuticals.

Would add the “Drug Abuse Prevention and Safe Disposal Program to the Public Resources Code. This article would set forth definitions, requirements for stewardship plans, to include the minimum number of collection sites for each plan submitted. The program would require that a stewardship plan include the number of collection services, and that there shall be on and after January 1, 2016 one collection service within 10 miles per person in the state, with a 20 percent increase in the number of collection services one year thereafter, and other information. The plan shall also include a description of the methods to be used to **collect, transport and process** home-generated pharmaceuticals in this state.

Security and handling of returned drugs are not specifically described.

**FISCAL IMPACT ON THE BOARD:**

Unknown.

**COMMENTS:**

Current law defines pharmacy waste as biohazardous waste, which in turn (in another code section) is designated as medical waste. The Medical Waste Management Act (MWMA) prescribes the methods for treating such waste because of the potential harm to public health and safety and the environment if not managed properly. The MWMA establishes rigorous management and tracking requirements for medical waste; including requiring the use of hazardous or medical waste haulers and strict manifesting requirements. Regulation of the MWMA is performed by the California Department of Public Health.

In dealing with drug take-back issues in the past, the board has sought amendments to pharmacy law to allow for the safe return and disposal/destruction of dispensed prescription drugs.

As of 4/5/13, the bill has not been scheduled for hearing, and staff continues to gather information on this proposal.

**Staff Comments:**      Recommendation: **WATCH**

**Support:** *(See Fact Sheet)*

- California Product Stewardship Council (co-sponsor)
- Clean Water Action (co-sponsor)
- East Bay Municipal Utility District
- Contra Costa County Board of Supervisors
- Marin County Hazardous & Solid Waste Management Joint Powers Authority
- Breast Cancer Fund
- Sacramento Regional County Sanitation District
- City of Monterey
- City of Covina
- City of Sunnyvale

# Senate Bill 727 (as proposed to be amended)

## Solid Waste: Drug Abuse Prevention and Safe Disposal Program

### Senator Hannah-Beth Jackson

#### SUMMARY

SB 727 would establish a pharmaceutical collection program to address the home storage and improper and illegal disposal of home-generated pharmaceuticals that has exacerbated concerns over increased drug abuse and impacts on water quality.

#### BACKGROUND

Some pharmaceuticals are banned from solid waste disposal sites and there are very few safe and convenient disposal options available to consumers. Serious social and environmental problems persist:

- The stockpiling of unused medications in the home allow for easier access for children and teens, thus fueling youth drug abuse. According to a National Institute on Drug Abuse-sponsored 2012 study by the University of Michigan, teens who abuse drugs are either obtaining them from friends or stealing them from friends or relatives without their knowledge. Researchers concluded, "...having leftover pills from an earlier prescription is a significant source for non-medically-supervised use."<sup>1</sup>
- Poisoning is the fastest rising cause of accidental death among older adults, particularly from overdoses of prescription drugs and over-the-counter medications.
- Unintentional poisoning of adults over 60 resulting in hospitalization increased by 43% in Alameda County from 1998 to 2006.
- Unused pharmaceuticals--like toxic waste--need to be kept out of the municipal waste stream because they can leach into groundwater.
- Flushing medications into sewage systems harms the environment and contaminates the water we drink. As with other hazardous chemicals, these drugs cannot be screened by most wastewater treatment processes, thus creating a buildup of these chemicals in California waterways.
- A 2010 Associated Press investigation found 9 medications in watersheds near Los Angeles, Riverside, and Long Beach, leading to increased public health concerns about bacterial resistance to antibiotics and endocrine disruption in aquatic organisms.

<sup>1</sup> <http://monitoringthefuture.org/data/12data.html#2012data-drugs>

- According to the National Association of Water Agencies, birth control products in waterways have interfered with endocrine function, leading to decreased reproductive success and declines in fish populations. Antibiotics pose the threat of killing microbes and disrupting the entire food chain.

#### Solution – SB 727

SB 727 is a pure Extended Producer Responsibility (EPR) policy approach for home-generated pharmaceuticals. It would require the producers (manufacturers) of pharmaceuticals to develop and implement a collection system with oversight by CalRecycle, thereby establishing an effective and convenient collection program described in a stewardship plan and approved by CalRecycle.

Producers have the primary responsibility to design, operate and publicize a collection program for home-generated pharmaceutical products. Allowing the private sector to design and operate the program ensures it will be the most cost-effective and efficient system. SB 727 follows highly successful models in Canada and Europe that are very cost-effective and convenient programs for pharmaceuticals and hazardous and hard to handle waste, including, but not limited to: e-waste, paint, tires, batteries, compact fluorescent bulbs, sharps, mercury thermostats, and other mercury containing products. The bill also follows the efforts of Alameda County which recently became the first local government in the country to require producers of home-generated pharmaceuticals to develop and implement a collection system for the safe and proper disposal of these products.

#### SUPPORT

- California Product Stewardship Council (co-sponsor)
- Clean Water Action (co-sponsor)
- East Bay Municipal Utility District
- Contra Costa County Board of Supervisors
- See attached for continued list of supporters

#### CONTACTS

Linda Barr, Office of Senator Jackson, 916-651-4019, [linda.barr@sen.ca.gov](mailto:linda.barr@sen.ca.gov)  
Justin Malan, CA Product Stewardship Council, 916-448-1015, [justin@econsult.biz](mailto:justin@econsult.biz)  
Andria Ventura, Clean Water Action, 415-369-9166, [Aventura@cleanwater.org](mailto:Aventura@cleanwater.org)

**Continued list of support as of 4/5/13:**

Marin County Hazardous & Solid Waste Management  
Joint Powers Authority  
Breast Cancer Fund  
Sacramento Regional County Sanitation District  
City of Monterey  
City of Covina  
City of Sunnyvale





California  
LEGISLATIVE INFORMATION

SB-727 Medical waste: pharmaceutical product stewardship program. (2013-2014)

AMENDED IN SENATE APRIL 03, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

SENATE BILL

No. 727

Introduced by Senator Jackson  
(Coauthor(s): *Senator Hancock*)

February 22, 2013

An act to add Section ~~117647 to, and to add Chapter 12 (commencing with Section 118365) to Part 14 of Division 104 of, the Health and Safety Code, relating to public health.~~ *117670.1 to the Health and Safety Code, and to add Article 3.4 (commencing with Section 47122) to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, relating to waste management.*

LEGISLATIVE COUNSEL'S DIGEST

SB 727, as amended, Jackson. Medical waste: pharmaceutical product stewardship program.

The ~~existing~~ Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, including pharmaceutical waste, as defined. Existing law requires, among other things, that all medical waste be hauled by either a registered hazardous waste hauler or by a person with an approved limited-quantity exemption granted pursuant to specified provisions of law. ~~Under the law, an enforcement agency may bring an action to enjoin the violation or threatened violation of these provisions or issue a specified order to a person who is responsible for a violation or threatened violation. A violation of that order, and other provisions of law, is a crime.~~

*Existing law requires a pharmaceutical manufacturer selling or distributing medication that is intended to be self-injected at home to submit, on an annual basis, to the Department of Resources Recycling and Recovery a plan supporting the safe collection and proper disposal of specified waste devices.*

*This bill would require a producer of a pharmaceutical sold in the state to, individually or through a stewardship organization, to submit a plan, on or before January 1, 2015, to the Department of Resources Recycling and Recovery. The bill would require the plan to provide for the development of a program to collect, transport, and process home-generated pharmaceutical drugs and to include specified aspects, including the minimum amount of collection sites, including by January 1, 2016, at least one collection service within 10 miles per person in the state.*

*The bill would require the department to post on its Internet Web site a list of the producers or stewardship organizations that have submitted a plan within 10 days of receipt of the plan. The bill would provide for the*

*review and approval of the plan by the department, within 90 days of receipt of the plan. The bill would require the department to post on its Internet Web site a list of producers for which the department has approved a plan and the bill would require the department to update this list no less than once every 6 months.*

*The bill would require a producer or stewardship organization, on or after April 1, 2016, and every year thereafter, to prepare and submit to the department an annual report describing the activities carried out pursuant to the plan during the previous calendar year.*

*The bill would require the producer or stewardship organization to pay the department an annual administrative fee in an amount that is sufficient to cover the department's costs of administering and enforcing these provisions. The bill would require the department to deposit the fees in the Drug Abuse Prevention and Safe Disposal Program Account, which the bill would establish in the Integrated Waste Management Fund, and the department would be authorized to expend the moneys in that account upon appropriation by the Legislature, to administer and enforce the bill's requirement.*

*The bill would require the department to enforce these provisions and would authorize the department to impose an administrative civil penalty on a person who violates the bill's requirements or impose a fine on a producer or stewardship organization if a stewardship plan is not submitted by January 1, 2015. The bill would require the department to deposit these fines and penalties into the Drug Abuse Prevention and Safe Disposal Program Penalty Account, which this bill would establish in the Integrated Waste Management Fund, and the department would be authorized to expend the moneys in that account upon appropriation by the Legislature, to enforce the bill's requirements.*

~~This bill would, effective January 1, 2015, prohibit a producer of a pharmaceutical that is a cover drug, as defined, from selling or distributing that pharmaceutical in the state unless it is included in a product stewardship plan that is approved by the department. This bill would require each producer to operate, individually or jointly with other producers, an approved product stewardship program or to enter into an agreement with a stewardship organization, as defined, to operate that program on the producer's behalf. This bill would require a producer, group of producers, or stewardship organization, if applicable, to pay all associated costs with its product stewardship program, as specified, including the costs incurred by the state for administration and enforcement of the program. The bill would prohibit the producer from charging specified fees to recover the costs of its program.~~

~~This bill would require a producer, individually or jointly with other producers, in consultation with specified entities, to develop a product stewardship plan that includes, among other things, certification that the product stewardship program will accept all unwanted products, except as specified, contact information for the individual or entity submitting the plan and for each producer participating in the program, and a description of the methods by which unwanted products will be collected in the state. This bill would require the producer, group of producers, or stewardship organization operating the program to prepare and submit a written report to the department, as prescribed. This bill would require the department to administer any penalties under those provisions. By expanding the definition of a crime, this bill would impose a state-mandated local program.~~

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

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

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: **yes/no**

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

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

*(a) The stockpiling of unused and unwanted pharmaceuticals has increased rapidly in recent years, creating access to potentially dangerous drugs to children and adults alike. Accidental poisoning from ingestion of drugs among children often occurs in homes where medicine is easily accessible. The Partnership for a Drug-Free America released a report in February 2010 indicating that over 60 percent of teenagers are able to obtain prescription painkillers free of charge from family and friends.*

*(b) Poisoning is the fastest rising cause of accidental death among older adults, particularly from overdoses of prescription drugs and over-the-counter medications. Unintentional poisoning of adults over 60 years of age resulting in hospitalization increased by 43 percent in the County of Alameda from 1998 to 2006.*

*(c) Pharmaceutical residues have been accumulating in groundwater and drinking water. Drugs enter the environment through multiple sources, including flushing toilets or through leaks in landfills. Even the most advanced wastewater treatment plants are not currently able to account for these chemicals. The cost of developing this waste treatment for wastewater is extremely high. Thus, many drugs will continue to pass through wastewater treatment systems and contaminate receiving waters unless the source of the problem is addressed.*

*(d) Safe and convenient medical waste recovery programs are critical in reducing the negative social and environmental health impacts of improper or illegal disposal.*

*(e) Product stewardship programs in Canada and Europe for hazardous wastes, medical wastes, and hard-to-handle wastes, including electronic waste, packaging, beverage containers, batteries, mercury-containing lamps, and other mercury-containing products have demonstrated that shared producer responsibility results in significant improvements in safe end-of-life management and reductions in taxpayer and ratepayer costs.*

**SEC. 2.** *Section 117670.1 is added to the Health and Safety Code, to read:*

**117670.1.** "Home-generated pharmaceutical waste" means a prescription or over-the-counter human or veterinary drug, including, but not limited to, a drug as defined in Section 109925 or in Section 321 (g)(1) of Title 21 of the United States Code, that is a waste, as defined in Section 25124, derived from a household, including, but not limited to, a multifamily residence or household. Home-generated pharmaceutical waste may be handled through a home-generated pharmaceutical waste stewardship plan pursuant to Article 3.4 (commencing with Section 47122) of the Public Resources Code.

**SEC. 3.** *Article 3.4 (commencing with Section 47122) is added to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, to read:*

**Article 3.4. Drug Abuse Prevention and Safe Disposal Program**

**47122.** The purpose of the Drug Abuse Prevention and Safe Disposal Program established pursuant to this article is to require the producers of pharmaceuticals to develop and implement a program to collect, transport, and process home-generated pharmaceutical drug waste to reduce the costs, public health risk, and environmental impacts of the illegal and unsafe disposal of this medical waste.

**47123.** For purposes of this article, the following terms have the following meanings:

(a) "Consumer" means a purchaser or owner of home-generated pharmaceuticals, including a person, business, corporation, limited partnership, nonprofit organization, or governmental entity.

(b) "Department" means the Department of Resources Recycling and Recovery.

(c) "Distributor" means a person that sells or provides for free pharmaceuticals to the general public, which may include, but is not limited to, retailers, hospitals, veterinarians, and health clinics.

(d) "Drug abuse prevention and safe disposal plan" or "plan" means a plan written by an individual producer, or stewardship organization, on behalf of one or more producers.

(e) "Home-generated pharmaceutical waste" means pharmaceutical waste as defined in Section 117670.1 of the Health and Safety Code.

(f) "Pharmaceutical" means a prescription or over-the-counter human or veterinary drug as defined in Section 117747 of the Health and Safety Code. For purposes of this article, "pharmaceutical" includes any pharmaceutical that is regulated pursuant to (1) the federal Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. Sec. 6901 et seq.), and (2) the Radiation Control Law (Chapter 8 (commencing with Section 114960) of Part 9). For purposes of this article, "pharmaceutical" does not include the following items:

(1) Vitamins or supplements.

(2) Herbal-based remedies and homeopathic drugs.

(3) Cosmetics, soap (with or without germicidal agents), laundry detergent, bleach, household cleaning products, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.).

(4) Drugs for which the producers provide a take-back program as part of a federal Food and Drug Administration managed risk evaluation and mitigation strategy (21 U.S.C. Sec. 355-1).

(5) Drugs that are biological products as defined by Section 600-3(h) of Title 21 of the Code of Federal Regulations as it exists on January 1, 2014 if the producer already provides a take-back program.

(6) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other delivery systems.

(g) "Prescription drug" means any drug that by federal or state law may be dispensed lawfully only on prescription.

(h) (1) "Producer" shall be determined with regard to a pharmaceutical that is sold, offered for sale, or distributed in California as meaning one of the following:

(A) The person that manufactures a pharmaceutical and that sells, offers for sale, or distributes that pharmaceutical in California under that person's own name or brand.

(B) If there is no person who sells, offers for sale, or distributes the pharmaceutical in California under the person's own name or brand, the producer of the pharmaceutical is the owner or licensee of a trademark or brand under which the pharmaceutical is sold or distributed in California, whether or not the trademark is registered.

(C) If there is no person who is a producer of the pharmaceutical for purposes of subparagraphs (A) and (B), the producer of that pharmaceutical is the person who brings the pharmaceutical into California for sale or distribution.

(2) "Producer" does not include (A) a retailer that puts its store label on a pharmaceutical or (B) a pharmacist who dispenses prescription drugs to, or compounds a prescribed individual drug product for a consumer.

(i) "Retailer" means a person that sells a pharmaceutical in the state to a consumer. A sale includes, but is not limited to, transactions conducted through sales outlets, catalogs, or the Internet or any other similar electronic means.

(j) "Stewardship organization" means a nonprofit organization created by the producers, including at a minimum, four representatives one each from local government, a distributor, a waste hauler, and a consumer health organization, to implement the Drug Abuse Prevention and Safe Disposal Program stewardship program.

**47124.** A producer of any pharmaceutical sold in this state shall, individually or through a stewardship organization, submit a drug abuse prevention and safe disposal stewardship plan pursuant to Section 47125 to the department to develop and implement a recovery program to manage home-generated pharmaceutical waste in an environmentally sound and medically safe fashion, including collection, transportation, processing, and disposal.

**47125.** (a) (1) On or before January 1, 2015, a producer or the designated stewardship organization for producers of pharmaceuticals shall submit a stewardship plan to the department.

(2) The plan shall be posted on the producer or stewardship organization's Internet Web site.

(b) A producer, group of producers, or stewardship organization shall consult with stakeholders during the development of the stewardship plan, including soliciting stakeholder comments, and responding to stakeholder comments, and document the comments and responses in the plan prior to submitting the stewardship plan.

(c) A stewardship plan shall include, at a minimum, all of the following elements:

(1) Contact information for all participating producers.

(2) The number of collection services for the home-generated pharmaceuticals subject to the plan. A baseline of the number of home-generated pharmaceutical collection services shall be at least one collection service within 10 miles per person in the state.

(d) The minimum number of collection sites for each plan submitted to the department shall be as follows:

(1) On and after January 1, 2016, there shall be at least one collection service within 10 miles per person in the state.

(2) On and after January 1, 2017, the number of collection services shall increase 20 percent from the reported number of collection services in 2016.

(e) On January 1, 2018, and annually thereafter, the department shall consult with the producers and stewardship organizations, local government, haulers, health community, and all stakeholders on how the program is performing, and to set fair and reasonable collection services for each year forward toward the goal of ultimately achieving safe management of all home-generated pharmaceuticals. The producer shall demonstrate to the department that it has achieved maximum improvement in the collection services.

(f) A baseline of the number of home-generated pharmaceuticals collected by all producers, or stewardship organizations, subject to a plan, shall be calculated by weight based on the percentage of home-generated pharmaceuticals collected during the preceding three years.

(g) The plan shall address collecting both solid and liquid home-generated pharmaceuticals.

(h) The methods of collection must be consistent with the requirements of Section 47115.5. Collection shall involve the use of two-key system whereby two individuals are needed to unlock the disposal bin, or if a one-key system is used, whereby only one person is needed to unlock the bin, the bin system shall render the medication unusable.

(i) The plan shall demonstrate sufficient funding for the stewardship program as described in the plan, including a funding mechanism for securing and dispersing funds to cover administrative, operational, and capital costs.

(j) The plan shall address the coordination of the stewardship program with existing local medical waste collection programs as much as is reasonably feasible and is mutually agreeable between those programs.

(k) The plan shall include goals to reduce the number of home-generated pharmaceuticals that are improperly disposed, and to maximize the proper end-of-life management of home-generated pharmaceuticals, including collection of home-generated pharmaceuticals, as practical, based on current medical waste program information.

(l) The plan shall include consumer, medical community, and retailer education and outreach efforts to promote the collection of home-generated pharmaceuticals. This information may include, but is not limited to, developing, and updating as necessary, educational and other outreach materials aimed at all distributors of pharmaceuticals. These materials shall be made available to those parties. These materials may include, but are not limited to, one or more of the following:

(1) Signage that is prominently displayed and easily visible to the consumer.

(2) Written materials and templates of materials for reproduction by retailers to be provided to the consumer at the time of purchase or delivery, or both. Written materials shall include information on proper disposal of home-generated pharmaceuticals.

(3) Advertising or other promotional materials, or both, that include references to home-generated pharmaceuticals collection opportunities.

(m) Any retailer may participate, on a voluntary basis, at a home-generated pharmaceuticals collection point pursuant to the home-generated pharmaceuticals stewardship program.

**47126.** (a) The department shall post on its Internet web-site a list of the producers or stewardship organizations that have submitted a stewardship plan within 10 days of receipt of the plan.

(b) The department shall review the plan within 90 days of receipt, and make a determination whether or not to approve the plan. The department shall approve the plan if it provides for the establishment of a home-generated pharmaceuticals stewardship program that meets the requirements of Section 47125.

(c) (1) The approved plan shall be a public record, except that financial, production, or sales data reported to the department by a producer or the stewardship organization is not a public record under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code) and shall not be open to public inspection.

(2) Notwithstanding paragraph (1), the department may release a summary form of financial, production, or sales data if it does not disclose financial, production, or sales data of a producer or stewardship organization.

(d) Three months after a plan is approved, the producer or stewardship organization shall implement the home-generated pharmaceuticals stewardship program described in the approved plan.

(e) (1) Within five days of the department approving the plan, the department shall post on its Internet Web site a list of producers for which the department has approved a plan pursuant to subdivision (b). The department shall update this posting that includes a list of producers that are in compliance with this article no less than once every six months thereafter.

(2) A producer that is not listed on the department's Internet Web site pursuant to this section, but demonstrates to the satisfaction of the department that it is in compliance with this article before the next update of the list of compliant producers by the department, pursuant to paragraph (1), may request a certification letter from the department stating that the producer is in compliance. The producer who receives the letter shall be deemed to be in compliance with this article.

**47127.** (a) On or before April 1, 2016, and every year thereafter, a producer or stewardship organization implementing a stewardship plan shall prepare and submit to the department an annual report describing the activities carried out pursuant to the plan during the previous calendar year. The annual report shall include, but is not limited to, all of the following elements:

(1) The number of home-generated pharmaceuticals collected by the program in the prior year and the collection services achieved in the prior year.

(2) A report of the total sales data for pharmaceuticals sold to distributors in the state for the previous calendar year.

(3) A report on the feedback from a stakeholders' meeting, hosted by producers or the stewardship organization, that was made available by Web cast, prior to submittal of the annual report.

(4) Independently audited financial statements that detail the financing method selected to sustainably fund the implementation of the plan to achieve the identified collection services described in the plan, pursuant to Section 47125.

(5) A description of methods used to collect, transport, and process home-generated pharmaceuticals in this state.

(6) A description of how solid and liquid home-generated pharmaceuticals are collected.

(7) A description of how pharmaceuticals regulated pursuant to the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. Sec. 6901 et seq.), and the Radiation Control Law (Chapter 8 (commencing with Section 114960) of Part 9 of the Health and Safety Code) are collected.

(8) Locations, hours, and contact information for all California collection points set up by the producers covered by the plan.

(9) Examples and descriptions of educational materials distributed to various stakeholders aimed to increase collection.

(10) An evaluation of the effectiveness of the program specific to collection, public awareness, convenience, and reduced improper disposal by both legal and illegal drug use.

(11) Any programmatic changes the producer, the stewardship organization, or both recommend based on new data provided in the annual report.

(b) The department shall review an annual report by doing all of the following:

(1) For the reports submitted for the 2016 calendar year, and each year thereafter, producers and stewardship organizations shall certify the accuracy of the collection points listed in the annual report and that they are located in every county in the state and established at a minimum of one site per 5,000 people.

(2) Reviewing sales data and collection numbers provided for the state to verify collection services.

(3) If a collection service pursuant to Section 47125 is not achieved, the department shall direct the producer or the stewardship organization to determine the most effective way to improve collection services.

(4) Verifying that all annual report elements specified in subdivision (a) have been addressed in the report.

(c) If the department does not act on a report within 45 days of receipt, the report shall be approved.

(d) The department shall make all reports submitted pursuant to this section available to the public on the department's Internet Web site.

(e) If the collection service for the home-generated pharmaceuticals subject to the plan meets the collection service, specified in Section 47125, or if the producer or stewardship organization demonstrates compliance with this article that is consistently and significantly above mandated performance levels, the department may reduce the frequency of reporting pursuant to this section.

(f) The department shall review the annual report required pursuant to this section and, within 90 days of receipt, shall adopt a finding of compliance or noncompliance with this article.

**47128.** (a) The department shall enforce this chapter.

(b) (1) The producer or stewardship organization shall pay the department an annual administrative fee pursuant to paragraph (2).

(2) The department shall impose fees in an amount that is sufficient to cover the department's full costs of administering and enforcing this chapter, including any program development costs or regulatory costs incurred by the department prior to the submittal of the stewardship plans. Fee revenues collected pursuant to this section shall only be used to administer and enforce this article. The total fee revenue collected shall not exceed \$500,000 per year.

(3) The department shall deposit all fees collected pursuant to this subdivision into the Drug Abuse Prevention and Safe Disposal Program Account, which is hereby created in the Integrated Waste Management Fund. Upon appropriation by the Legislature, moneys deposited into the account may be expended by the department to administer and enforce this article.

(c) (1) A civil penalty may be administratively imposed by the department on any person who violates this article in an amount of up to one thousand dollars (\$1,000) per violation per day.

(2) A person who intentionally, knowingly, or negligently violates this article may be assessed a civil penalty by the department of up to ten thousand dollars (\$10,000) per violation per day.

(A) In assessing any fine and penalty, the department shall consider any exigent circumstance that contributed to the stewardship organization or individual producer not meeting the required recovery targets.

(B) The department may require the producer or stewardship organization to increase expenditure on program compliance in lieu of part of any fine or penalty to be imposed for not meeting the required recovery targets.

(d) (1) The department shall impose a fine on a producer or stewardship organization if a stewardship plan required pursuant to Section 47125 is not submitted by January 1, 2015.

(2) The fine in paragraph (1) shall be effective on the 120th day after the list described in Section 47126 is posted on the department's Internet Web site, and shall apply to any producer that is not listed on the department's Internet Web site, and shall remain in effect until the producer is listed on the department's Internet Web site or can demonstrate compliance with the requirements of Section 47125. A two-thousand-five-hundred-dollar (\$2,500) fine will be imposed on the first day, and will increase by 50 percent with interest each day thereafter until a plan is submitted.

(e) The department shall deposit all fines and penalties collected pursuant to subdivisions (c) and (d) into the Drug Abuse Prevention and Safe Disposal Program Penalty Account, which is hereby created in the Integrated Waste Management Fund. Upon appropriation by the Legislature, moneys deposited into the account may be expended by the department to enforce this article.

**47129.** (a) Except as provided in subdivision (c), an action solely to increase the collection of home-generated pharmaceuticals by a producer, stewardship organization, or retailer that affects the types or quantities being recycled, or the cost and structure of any return program, is not a violation of the statutes specified in subdivision (b).

(b) The following statutes are not violated by an action specified in subdivision (a):

(1) The Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code).

(2) The Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code).

(c) Subdivision (a) shall not apply to any agreement establishing or affecting the price of home-generated pharmaceuticals, except for the home-generated pharmaceuticals stewardship assessment, or the output or production of home-generated pharmaceuticals, or any agreement restricting the geographic area or customers to which home-generated pharmaceuticals will be sold.

~~SECTION 1. Section 117647 is added to the Health and Safety Code, to read: 117647-~~

~~(a) "Covered drugs" means all drugs as defined in Section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 321(g)(1)), and covered under Section 503 of the act (21 U.S.C. Section 353(b)(1)), including both brand name and generic drugs-~~

~~(b) Covered drugs do not include any of the following-~~

~~(1) Vitamins or supplements-~~

~~(2) Herbal-based remedies, or homeopathic drugs, products, or remedies-~~

~~(3) Cosmetics, soap, with or without germicidal agents, laundry detergent, bleach, household cleaning products, shampoo, sunscreen, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the FFDCA-~~

~~(4) Drugs for which a producer provides a take-back program as part of an FFDCA managed risk evaluation and mitigation strategy-~~

~~(5) Drugs that are biological products, as defined in Section 262(i) of Title 42 of the United States Code, if the producer already provides a take-back program~~

~~(6) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other delivery systems-~~

~~(7) Nonprescription drugs-~~

~~SEC. 2. Chapter 12 (commencing with Section 118365) is added to Part 14 of Division 104 of the Health and Safety Code, to read: 12. Pharmaceutical Product Stewardship Program 118365-~~

~~For purposes of this chapter, "stewardship organization" means a nonprofit organization created by a producer to implement the pharmaceutical product stewardship program described in Section 118365.1-~~

~~118365.1.(a) Effective January 1, 2015, a producer of a pharmaceutical that is a covered drug shall not sell or distribute that pharmaceutical in the state unless it is included in a product stewardship plan approved by the department-~~

~~(b) Each producer shall do one of the following-~~

~~(1) Operate, individually or jointly with other producers, a product stewardship program approved by the department-~~

~~(2) Enter into an agreement with a stewardship organization to operate, on the producer's behalf, a product stewardship program approved by the department-~~

~~(c)(1) A producer, group of producers, or stewardship organization shall pay all administrative and operational fees associated with its product stewardship program, including the costs of collecting, transporting, and disposing of unwanted products collected from residential generators and the recycling or disposal, or both, of packaging collected with the unwanted product-~~

~~(2) A producer, group of producers, or stewardship organization shall pay for all fees associated with obtaining compliance with the California Environmental Quality Act (Division 13 (commencing with Section 21000) of the Public Resources Code), if required, for a product stewardship program and product stewardship plan-~~

~~(3) A person or producer shall not charge a specific point-of-sale fee to a consumer to recover the costs of its product stewardship program, and shall not charge a specific point-of-collection fee at the time the unwanted products are collected from residential generators or delivered for disposal-~~

~~(4) A producer, group of producers, or stewardship organization shall pay all costs incurred by the state, including, but not limited to, the department's costs, for the administration and enforcement of its pharmaceutical product stewardship program. Exclusive of any fines, the state shall only recover the actual~~

~~costs of administration and enforcement under this chapter, and shall not charge any amounts under this chapter in excess of the actual administrative and enforcement costs.~~

~~118365.2. In consultation with local governments, water districts, sanitation districts, pharmacies, waste haulers, environmental health officers, and all interested stakeholders, the producers, individually or jointly with other producers, shall develop a product stewardship plan.~~

~~(a) Each product stewardship plan required under Section 118365.1 shall contain all of the following:~~

~~(1) Certification that the product stewardship program will accept all unwanted products, regardless of who produced them under a joint plan, unless excused from this requirement by the department as part of its approval of the plan.~~

~~(2) Contact information for the individual and the entity submitting the plan and for each of the producers participating in the product stewardship program.~~

~~(3) A description of the methods by which unwanted products from residential generators will be collected in the state and an explanation of how the collection system will be convenient and adequate to serve the needs of all California residents.~~

~~(4) A description of how the product stewardship plan will provide collection services for unwanted products in all areas of California that are convenient to the public and adequate to meet the needs of the population in the area being served.~~

~~(5) If applicable, the location of each collection site and locations where envelopes for a mail-back program are available.~~

~~(6) A list containing the name, location, permit status, and record of any penalties, violations, or regulatory orders received in the previous five years by each person that will be involved in transporting unwanted products and each medical waste or hazardous disposal facility proposed to participate in the product stewardship program.~~

~~(7) A description of how the unwanted products will be safely and securely tracked and handled from collection through final disposal, and the policies and procedures to be followed to ensure security and adherence to highest management standards.~~

~~(8) A description of public education and outreach activities that are consistent with this chapter, and how the effectiveness of those programs and activities will be evaluated.~~

~~(9) A description of how the scope and extent of the product stewardship program is reasonably related to the amount of covered drugs that are sold in the state by the producer, or group of producers.~~

~~(10) A starting date for the collection of unwanted products.~~

~~(11) If applicable, a description of how support will be provided to any law enforcement agencies within the state that operate, or later agree to operate, a collection program for controlled substances, including the provision of a collection kiosk with appropriate accessories and signage, the ability to accept controlled substances and other covered drugs, and technical support, up to and including an appropriate person to provide on-site assistance with the sorting and separation of controlled substances at no cost to a participating law enforcement agency. Otherwise, controlled substances are expressly excluded from this chapter, notwithstanding any other provision.~~

~~(12) A description of how collection sites for unwanted products may be placed at appropriate retail stores in the state, including a description of the involvement of the retail store. Retailers are not required or mandated to host collection sites, and nothing in this chapter shall be interpreted as requiring that participation.~~

~~(13) If more than one producer will be involved in a proposed product stewardship program, the plan for that program shall include a fair and reasonable manner for allocating the costs of the program among the participants in that program, so that the portion of costs paid by each producer is reasonably related to the amount of covered drugs that producer sells in the state.~~

~~118365.3. On or before January 1, 2016, or at a later date as approved in writing by the department, and in each subsequent year, each producer, group of producers, or stewardship organization operating a product stewardship program shall prepare and submit to the department an annual written report describing the program's activities during the previous reporting period.~~

~~118365.4. The department shall administer the penalty provisions for this chapter.~~

~~SEC. 3. 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.~~



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|---------------------|-------------------|
| <b>Bill Number:</b> | <b>SB 493</b>     |
| <b>Introduced</b>   | 2/21/13           |
| <b>Last Amend:</b>  | <b>4/1/13</b>     |
| <b>Author:</b>      | Senator Hernandez |
| <b>Topic:</b>       | Pharmacy Practice |
| <b>Position:</b>    |                   |

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**Current Bill Status:** 4/22/13 – Hearing in SEN Business, Professions and Economic Development

**Affected Sections:** Section 733 Business and Professions Code (BPC)  
**Amend Sections 4050, 4051, 4052, 4052.3, and 4060 BPC**  
**Add Sections 4016.5, 4052.6, 4052.8, 4052.9, 4210 and 4233 BPC**

**SUMMARY:**

SB 493 would create a board designation of “Advanced Practice Pharmacist” to be recognized by the Board of Pharmacy; would declare that pharmacists are health care providers who have the authority to provide health care services; would specify expand the types of services that may be provided by a pharmacist to include immunizations and other functions, as specified; and make conforming changes to Sections 4052 and 4060 to effect the provisions of the bill.

**EXISTING LAW:**

Article 3 of the Business and Professions Code (commencing with Section 4050) provides for the scope of practice, and exemptions, for a pharmacist licensed by the board.

**THIS BILL WILL:**

Amend **Section 733 BPC** to clarify the reference to Section 4052.3 (emergency contraception and self-administered hormonal contraceptives).

Add **Section 4016.5** to define “Advanced practice pharmacist.”

Amend **Section 4050 BPC** to declare that pharmacists are health care providers who have the authority to provide health care services.

Amend **Section 4052 BPC** to

- Allow a pharmacist to administer drugs and biological products ordered by a prescriber (not limited to orally or topically).
- Perform procedures as specified in Section 4052.6 (functions of an Advanced Practice Pharmacist)
- Provide consultation, training and education to patients, as specified
- Allow a pharmacist to participate in multidisciplinary review of patient progress, including appropriate access to medical records
- Furnish emergency contraception and self-administered hormonal contraceptives as authorized by Section 4052.3

- Furnish prescription smoking-cessation drugs and devices, as authorized by Section 4052.9
- Furnish prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the US.
- Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies

Amend **Section 4052.3 BPC** to specify standardized procedures or protocols by which a pharmacist may furnish self-administered hormonal contraceptives, as specified.

Add **Section 4052.6 BPC** which would establish an “Advanced Practice Pharmacist” and specify the functions that may be performed by a pharmacist with such a designation. (See related Section 4210)

Add **Section 4052.8 BPC** to authorize a pharmacist to initiate and administer immunizations, as specified, and to also initiate and administer epinephrine or diphenhydramine by injection as needed for the treatment of a severe allergic reaction.

Add **Section 4052.9 BPC** to authorize a pharmacist to furnish prescription smoking-cessation drugs and devices, and provide smoking-cessation services if specified criteria are met.

Amend **Sections 4051 and 4060 BPC** to make conforming changes to provide consistency of the section with the provisions of the bill.

Add **Section 4210 BPC** to specify requirements for board recognition (licensure) of an advanced practice pharmacist, to include:

- Hold an active license that is in good standing
- Satisfy specified criteria (post-graduate residency; certification in a relevant area of practice; managed patients under a collaborative practice agreement or protocol – as specified)
- File an application with the board
- Pay an applicable fee to the board
- Specify that the advanced practice pharmacist recognition shall be valid for a 2-year period, conterminous with the holder’s license to practice pharmacy.

Add **Section 4233 BPC** to specify that in addition to the 30 hours of continuing education required for the renewal of a pharmacist license, to also require the completion of 10 additional hours for a pharmacist recognized as an advanced practice pharmacist.

#### **FISCAL IMPACT ON THE BOARD:**

SB 493 would result in a fiscal impact to the board to implement a new license category for an “Advanced Practice Pharmacist.” With the implementation of BreEZe, the board faces challenges in that system modifications cannot be made at this time.

Also, the board may need to promulgate regulations to clarify the requisite fee and licensure requirements for an Advanced Practice Pharmacist.

**Staff Comments:** Staff has requested a Fact Sheet from the author’s office.

**Support / Opposition:**

## SENATE BILL

No. 493

## Introduced by Senator Hernandez

February 21, 2013

An act to amend Section 4050 of the Business and Professions Code, relating to pharmacies.

## LEGISLATIVE COUNSEL'S DIGEST

SB 493, as introduced, Hernandez. Pharmacy practice.

The Pharmacy Law provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy in the Department of Consumer Affairs, and states that pharmacy practice is a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use and drug-related therapy.

This bill would make a technical, nonsubstantive change to that provision.

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

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

- P1 1 SECTION 1.  
 2 Section 4050 of the *Business and Professions*  
 3 *Code* is amended to read:  
 4 4050.  
 5 (a) In recognition of and consistent with the decisions  
 6 of the appellate courts of this state, the Legislature hereby declares  
 7 the practice of pharmacy to be a profession.  
 8 (b) Pharmacy practice is a dynamic, patient-oriented health  
 9 service that applies a scientific body of knowledge to improve and  
 P2 1 promote patient health by means of appropriate drug use,  
 2 drug-related therapy, and communication for clinical and  
 3 consultative purposes. Pharmacy practice is continually evolving  
 4 to include more sophisticated and comprehensive patient care  
 5 activities.

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