

Attachment 1

Senate Bill No. 294

CHAPTER 565

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

[Approved by Governor October 4, 2013. Filed with
Secretary of State October 4, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

SB 294, Emmerson. Sterile drug products.

(1) 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, commencing July 1, 2014, 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, commencing July 1, 2014, would specify requirements for the board for the issuance or renewal of a license, and requirements for the pharmacy as a licensee. The bill would require the board to adopt regulations to implement these provisions, and, on and after July 1, 2014, to review formal revisions to specified national standards relating to the compounding of sterile preparations to determine whether amendments to those regulations are necessary, as specified. 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.

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

This bill, commencing July 1, 2014, would establish the fee for the issuance or renewal of a nonresident sterile compounding pharmacy license in the amount of \$780 and would require the applicant to deposit a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing an inspection of the nonresident pharmacy location, as specified.

(3) The bill would also require the board to report to the Legislature, on or before January 1, 2018, regarding the regulation of nonresident pharmacies, including, among other things, a detailed description of board activities related to the inspection and licensure of nonresident pharmacies.

(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.

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. Sterile Drug Products

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

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

(b) The board shall adopt emergency regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to initially implement the provisions of this article that become operative on July 1, 2014. The initial adoption, amendment, or repeal of a regulation authorized by this section is deemed to address an emergency for purposes of Sections 11346.1 and 11346.6 of the Government Code, and the board is hereby exempted for that purpose from the requirements of subdivision (b) of Section 11346.1 of the Government Code. After the initial adoption, amendment, or repeal of an emergency regulation pursuant to this section, the board may request approval from the Office of Administrative Law to readopt the regulation as an emergency regulation pursuant to Section 11346.1 of the Government Code.

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

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

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

(b) The board shall adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

(c) The board shall review any formal revision to General Chapter 797 of the United States Pharmacopeia and The National Formulary (USP–NF), relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official, to determine whether amendments are necessary for the regulations adopted by the board pursuant to subdivision (b).

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

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

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

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

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

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

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

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

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

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

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

4127.1. (a) A pharmacy shall not compound sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from

the board pursuant to this section. The license shall be renewed annually and is not transferable.

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

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

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

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

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

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

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

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

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

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

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

(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

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

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

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

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

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

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

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued

to the owner of the nonresident pharmacy license at that location. A license to compound injectable sterile drug products may not be issued or renewed until the board receives the following from the nonresident pharmacy:

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

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

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

(d) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident pharmacies. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:

(1) A detailed description of board activities related to the inspection and licensure of nonresident pharmacies.

(2) The status of proposed changes to federal law that are under serious consideration and that would govern compounding pharmacies, including legislation pending before the United States Congress, administrative rules, regulations, or orders under consideration by the federal Food and Drug Administration or other appropriate federal agency, and cases pending before the courts.

(3) If applicable, recommended modifications to the board's statutory duties related to nonresident pharmacies as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.

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

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

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

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

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

pharmacy shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually pursuant to subdivision (v) of Section 4400.

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

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

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

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

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

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

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

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

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

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

(f) Adverse effects reported or potentially attributable to a nonresident pharmacy's sterile compounded drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

(g) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident pharmacies. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:

(1) A detailed description of board activities related to the inspection and licensure of nonresident pharmacies.

(2) Whether fee revenue collected pursuant to subdivision (v) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of this section provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident pharmacies.

(3) The status of proposed changes to federal law that are under serious consideration and that would govern compounding pharmacies, including legislation pending before the United States Congress, administrative rules, regulations, or orders under consideration by the federal Food and Drug Administration or other appropriate federal agency, and cases pending before the courts.

(4) If applicable, recommended modifications to the board's statutory duties related to nonresident pharmacies as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.

(h) The requirement for submitting a report imposed under subdivision (g) is inoperative on January 1, 2022, pursuant to Section 10231.5 of the Government Code.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars (\$400) and may be increased to five hundred twenty

dollars (\$520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325) for each license.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

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

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

Senate Bill No. 821

CHAPTER 473

An act to amend Sections 1613, 1915, 1926.2, 3024, 3025, 3040, 3041.2, 3051, 3057.5, 3077, 3093, 3098, 3103, 3106, 3107, 3109, 3163, 4053, 4107, 4980.36, 4980.397, 4980.398, 4980.399, 4980.40, 4980.43, 4980.50, 4984.01, 4984.7, 4984.72, 4989.68, 4992.05, 4992.07, 4992.09, 4992.1, 4996.1, 4996.3, 4996.4, 4996.9, 4996.17, 4996.18, 4996.28, 4999.33, 4999.45, 4999.46, 4999.47, 4999.50, 4999.52, 4999.53, 4999.55, 4999.64, and 4999.100 of, and to add Section 4021.5 to, the Business and Professions Code, and to amend Section 14132 of the Welfare and Institutions Code, relating to healing arts.

[Approved by Governor October 1, 2013. Filed with
Secretary of State October 1, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

SB 821, Committee on Business, Professions and Economic Development.
Healing arts.

(1) Existing law, the Dental Practice Act, establishes the Dental Board of California, which was formerly known as the Board of Dental Examiners of California. Existing law requires the board to have and use a seal bearing its name. Existing law creates, within the jurisdiction of the board, a Dental Hygiene Committee of California, that is responsible for regulation of registered dental hygienists, registered dental hygienists in alternative practice, and registered dental hygienists in extended functions.

This bill would amend those provisions to remove an obsolete reference to the former board and to make other technical changes.

(2) Existing law, the Optometry Practice Act, provides for the licensure and regulation of optometrists by the State Board of Optometry. That act refers to the authorization to practice optometry issued by the board as a certificate of registration.

This bill would instead refer to that authorization issued by the board as an optometrist license and would make other technical and conforming changes.

(3) Existing law, the Pharmacy Law, governs the business and practice of pharmacy in this state and establishes the California State Board of Pharmacy. Existing law prohibits the board from issuing more than one site license to a single premises except to issue a veterinary food-animal drug retailer license to a wholesaler or to issue a license for compound sterile injectable drugs to a pharmacy.

This bill would additionally authorize the board to issue more than one site license to a single premises to issue a centralized hospital packaging

license. The bill would also establish a definition for the term “correctional pharmacy.”

Existing law authorizes the board to issue a license as a designated representative to provide supervision in a wholesaler or veterinary food-animal drug retailer. Existing law requires an individual to meet specified requirements to obtain and maintain a designated representative license, including a minimum of one year of paid work experience related to the distribution or dispensing of dangerous drugs or devices or meet certain prerequisites.

The bill would require the one year of paid work experience to obtain a designated representative license to be in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer. The bill would also make related, technical changes.

(4) Existing law provides for the licensure and regulation of marriage and family therapists, licensed educational psychologists, licensed clinical social workers, and licensed professional clinical counselors by the Board of Behavioral Sciences. Existing law makes various changes to the licensing and associated eligibility and examination requirements for marriage and family therapists, licensed clinical social workers, and licensed professional clinical counselors, effective January 1, 2014.

This bill would delay the implementation of these and other related changes until January 1, 2016.

Existing law requires all persons applying for marriage and family therapist or licensed professional clinical counselor licensure examinations to have specified hours of experience, including experience gained by an intern or trainee as an employee or volunteer.

This bill would specify that experience shall be gained by an intern or trainee only as an employee or volunteer.

Existing law establishes a \$75 delinquent renewal fee for a licensed educational psychologist and for licensed clinical social workers.

This bill would instead specify that \$75 is the maximum delinquent renewal fee.

Existing law requires an applicant for registration as an associate clinical social worker to meet specified requirements. Existing law also defines the application of social work principles and methods.

This bill would additionally require that all applicants and registrants be at all times under the supervision of a supervisor responsible for ensuring that the extent, kind, and quality of counseling performed is consistent with the training and experience of the person being supervised, and who is responsible to the board for compliance with all laws, rules, and regulations governing the practice of clinical social work. The bill would also specify that the practice of clinical social work includes the use, application, and integration of the coursework and experience required.

Existing law requires a licensed professional clinical counselor, to qualify for a clinical examination for licensure, to complete clinical mental health experience, as specified, including no less than 1,750 hours of direct counseling with individuals or groups in specified settings and not more

falsely represents the existence or nonexistence of a state of facts constitutes unprofessional conduct.

SEC. 15. Section 3107 of the Business and Professions Code is amended to read:

3107. It is unlawful to use or attempt to use any license or certificate issued by the board that has been purchased, fraudulently issued, counterfeited, or issued by mistake, as a valid license or certificate.

SEC. 16. Section 3109 of the Business and Professions Code is amended to read:

3109. Directly or indirectly accepting employment to practice optometry from any person not having a valid, unrevoked license as an optometrist or from any company or corporation constitutes unprofessional conduct. Except as provided in this chapter, no optometrist may, singly or jointly with others, be incorporated or become incorporated when the purpose or a purpose of the corporation is to practice optometry or to conduct the practice of optometry.

The terms “accepting employment to practice optometry” as used in this section shall not be construed so as to prevent a licensed optometrist from practicing optometry upon an individual patient.

Notwithstanding the provisions of this section or the provisions of any other law, a licensed optometrist may be employed to practice optometry by a physician and surgeon who holds a license under this division and who practices in the specialty of ophthalmology or by a health care service plan pursuant to the provisions of Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

SEC. 17. Section 3163 of the Business and Professions Code is amended to read:

3163. Except as provided in Section 3078, the name of an optometric corporation and any name or names under which it may be rendering professional services shall contain and be restricted to the name or the last name of one or more of the present, prospective, or former shareholders and shall include the words optometric corporation or wording or abbreviations denoting corporate existence, provided that the articles of incorporation shall be amended to delete the name of a former shareholder from the name of the corporation within two years from the date the former shareholder dies or otherwise ceases to be a shareholder.

SEC. 18. Section 4021.5 is added to the Business and Professions Code, to read:

4021.5. “Correctional pharmacy” means a pharmacy, licensed by the board, located within a state correctional facility for the purpose of providing pharmaceutical care to inmates of the state correctional facility.

SEC. 19. Section 4053 of the Business and Professions Code is amended to read:

4053. (a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling,

storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.

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

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

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

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

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

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

(C) Knowledge and understanding of quality control systems.

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

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

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

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

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

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

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

SEC. 20. Section 4107 of the Business and Professions Code is amended to read:

4107. (a) The board may not issue more than one site license to a single premises except as follows:

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

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

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

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

Senate Bill No. 305

CHAPTER 516

An act to amend Sections 1000, 2450, 2450.3, 2530.2, 2531, 2531.06, 2531.75, 2532.6, 2533, 2570.19, 3010.5, 3014.6, 3046, 3056, 3057, 3110, 3685, 3686, 3710, 3716, and 3765 of, and to add Sections 144.5 and 3090.5 to, the Business and Professions Code, relating to healing arts.

[Approved by Governor October 3, 2013. Filed with
Secretary of State October 3, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

SB 305, Lieu. Healing arts: boards.

(1) Existing law requires specified regulatory boards within the Department of Consumer Affairs to require an applicant for licensure to furnish to the board a full set of fingerprints in order to conduct a criminal history record check.

This bill would additionally authorize those boards to request and receive from a local or state agency certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation and would authorize a local or state agency to provide those records to the board upon request.

(2) The Chiropractic Act, enacted by an initiative measure, provides for the licensure and regulation of chiropractors in this state by the State Board of Chiropractic Examiners. Existing law specifies that the law governing chiropractors is found in the act.

This bill would require that the powers and duties of the board, as provided, be subject to review by the appropriate policy committees of the Legislature as if these provisions were scheduled to be repealed on January 1, 2018. This bill would also make nonsubstantive changes to conform with the Governor's Reorganization Plan No. 2.

(3) Existing law, the Osteopathic Act, provides for the licensure and regulation of osteopathic physicians and surgeons by the Osteopathic Medical Board of California.

This bill would require that the powers and duties of the board, as provided, be subject to review by the appropriate policy committees of the Legislature. The bill would require that the review be performed as if these provisions were scheduled to be repealed as of January 1, 2018.

(4) Existing law, the Speech-Language Pathologists and Audiologists and Hearing Aid Dispensers Licensure Act, provides for the licensure and regulation of speech-language pathologists, audiologists, and hearing aid dispensers by the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board. The act authorizes the board to appoint an executive

officer. Existing law repeals these provisions on January 1, 2014, and subjects the board to review by the Joint Committee on Boards, Commissions, and Consumer Protection.

This bill would extend the operation of these provisions until January 1, 2018, and provide that the repeal of these provisions subjects the board to review by the appropriate policy committees of the Legislature.

The Speech-Language Pathologists and Audiologists and Hearing Aid Dispensers Licensure Act also authorizes the board to refuse to issue, or issue subject to terms and conditions, a license on specified grounds, including, among others, securing a license by fraud or deceit.

This bill would additionally authorize the board to refuse to issue, or issue subject to terms and conditions, a license for a violation of a term or condition of a probationary order of a license or a term or condition of a conditional license issued by the board, as provided. The bill would also delete an obsolete provision and make other technical changes.

(5) Existing law, the Occupational Therapy Practice Act, provides for the licensure and regulation of occupational therapists, as defined, by the California Board of Occupational Therapy. Existing law repeals those provisions on January 1, 2014, and subjects the board to review by the Joint Committee on Boards, Commissions, and Consumer Protection.

This bill would extend the operation of these provisions until January 1, 2018, and provide that the repeal of these provisions subjects the board to review by the appropriate policy committees of the Legislature.

(6) Existing law, the Naturopathic Doctors Act, until January 1, 2014, provides for the licensure and regulation of naturopathic doctors by the Naturopathic Medicine Committee within the Osteopathic Medical Board of California. Existing law also specifies that the repeal of the committee subjects it to review by the appropriate policy committees of the Legislature.

This bill would extend the operation of these provisions until January 1, 2018, and make conforming changes.

(7) Existing law, the Optometry Practice Act, provides for the licensure and regulation of optometrists by the State Board of Optometry. The Respiratory Care Act provides for the licensure and regulation of respiratory care practitioners by the Respiratory Care Board of California. Each of those acts authorizes the board to employ an executive officer. Existing law repeals these provisions on January 1, 2014, and subjects the boards to review by the Joint Committee on Boards, Commissions, and Consumer Protection.

This bill would extend the operation of these provisions until January 1, 2018, and provide that the repeal of these provisions subjects the boards to review by the appropriate policy committees of the Legislature.

(8) The Optometry Practice Act prescribes license eligibility requirements, including, but not limited to, not having been convicted of a crime, as specified. The act defines unprofessional conduct to include, committing or soliciting an act punishable as a sexually related crime, if that act or solicitation is substantially related to the qualifications, functions, or duties of an optometrist. Under the act, the board may take action against a licensee who is charged with unprofessional conduct, and may deny an application

for a license if the applicant has committed an act of unprofessional conduct. Under existing law, commission of any act of sexual abuse, misconduct, or relations with a patient, client, or customer constitutes unprofessional conduct and grounds for disciplinary action against any healing arts licensee, subject to a specified exception for a physician and surgeon.

This bill would add to the license eligibility requirements under the act that the applicant is not currently required to register as a sex offender, as specified. The bill would make conviction of a crime that currently requires a licensee to register as a sex offender unprofessional conduct and would expressly specify that commission of an act of sexual abuse or misconduct, as specified, constitutes unprofessional conduct, subject to an exception for an optometrist treating his or her spouse or person in an equivalent domestic relationship. The bill would also state that those acts of unprofessional conduct shall be considered crimes substantially related to the qualifications, functions, or duties of a licensee. The bill would also expressly specify that the board may revoke a license if the licensee has been found, in an administrative proceeding, as specified, to have been convicted of sexual misconduct or convicted of a crime that currently requires the licensee to register as a sex offender.

(9) The Respiratory Care Act also prohibits a person from engaging in the practice of respiratory care unless he or she is a licensed respiratory care practitioner. However, the act does not prohibit specified acts, including, among others, the performance of respiratory care services in case of an emergency or self-care by a patient.

This bill would additionally authorize the performance of pulmonary function testing by persons who are currently employed by Los Angeles County hospitals and have performed pulmonary function testing for at least 15 years.

This bill would make legislative findings and declarations as to the necessity of a special statute for the persons described above.

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

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

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

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

1000. (a) The law governing practitioners of chiropractic is found in an initiative act entitled "An act prescribing the terms upon which licenses may be issued to practitioners of chiropractic, creating the State Board of

Assembly Bill No. 512

CHAPTER 111

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

[Approved by Governor August 16, 2013. Filed with
Secretary of State August 16, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

AB 512, 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.

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, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

Assembly Bill No. 1045

CHAPTER 302

An act to amend Section 4303 of, and to add Section 4127.9 to, the Business and Professions Code, relating to pharmacy.

[Approved by Governor September 9, 2013. Filed with Secretary of State September 9, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1045, Quirk-Silva. Sterile compounding and nonresident pharmacies.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies in this state by the California State Board of Pharmacy. A violation of these provisions is a crime.

Existing law provides that a 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. Existing law prohibits a person from acting as a nonresident pharmacy unless he or she has obtained a license from the board, and authorizes the board to register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed. The law also prohibits a resident or nonresident pharmacy from compounding injectable sterile drug products for shipment into this state without a license issued by the board, and authorizes a license to compound injectable sterile drug products to be issued only for a location that is licensed as a resident or nonresident pharmacy.

This bill would require a resident or a nonresident pharmacy that issues a recall notice regarding a sterile compounded drug to contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if use of or exposure to the recalled drug may cause serious adverse health consequences or death and if the recalled drug was dispensed or is intended for use in this state. Because a violation of these requirements would be a crime, the bill would impose a state-mandated local program.

The bill would also provide that if the home state pharmacy license of a nonresident pharmacy is canceled, revoked, or suspended for any reason, any license issued pursuant to the provisions governing the licensing and registration of nonresident pharmacies or authorizing a nonresident pharmacy to compound injectable sterile drug products shall be immediately canceled, revoked, or suspended by operation of law.

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.

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

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

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

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

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

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

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

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

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

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

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

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

(c) If the home state pharmacy license of a nonresident pharmacy is canceled, revoked, or suspended for any reason, any license issued pursuant

to Section 4112 or 4127.2 shall be immediately canceled, revoked, or suspended by operation of law.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article 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.

Assembly Bill No. 1057

CHAPTER 693

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

[Approved by Governor October 10, 2013. Filed with Secretary of State October 10, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1057, 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, commencing January 1, 2015, to inquire in every application for licensure if the individual applying for licensure is serving in, or has previously served in, the military.

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. Commencing January 1, 2015, each board shall inquire in every application for licensure if the individual applying for licensure is serving in, or has previously served in, the military.

Assembly Bill No. 1136

CHAPTER 304

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

[Approved by Governor September 9, 2013. Filed with
Secretary of State September 9, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1136, Levine. Pharmacists: drug disclosures.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription 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. This requirement applies when the board determines that the drug is a drug or drug type for which this warning shall be given. A violation of the Pharmacy Law is a crime.

This bill would additionally require, on and after July 1, 2014, a pharmacist to include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel if the pharmacist, in exercising his or her professional judgment, determines that the drug may impair a person's ability to operate a vehicle or vessel, as specified. 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.

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

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

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

(1) The drug poses substantial risk to the person consuming the drug when taken in combination with alcohol or the drug may impair a person's ability to drive a motor vehicle, whichever is applicable.

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

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

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

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

(e) A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each drug given at the time of discharge and each drug given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each 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 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.

Senate Bill No. 669

CHAPTER 725

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.

[Approved by Governor October 10, 2013. Filed with
Secretary of State October 10, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

SB 669, 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 medical 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 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 approve authorized training providers and to establish and approve minimum standards for training and the use and administration of epinephrine auto-injectors. The bill would specify components to be included in the minimum training and requirements. The bill would authorize the director of the authority to deny, suspend, or revoke any approval or place any approved training provider on probation upon a finding by the director of an imminent threat to public health and safety, as prescribed. The bill would create the Specialized First Aid Training Program Approval Fund, and require the authority to assess a fee, to be deposited into the fund, to cover the reasonable costs incurred by the authority for the ongoing review and approval of training and certification.

These provisions would not apply to a school district or county office of education, or its personnel, that provides and utilizes epinephrine auto-injectors to provide emergency medical care, as specified. The bill would provide that nothing in these provisions shall be construed to limit or restrict the ability of prehospital emergency medical care personnel to

administer epinephrine, including the use of epinephrine auto-injectors, or to require additional training or certification, if the administration of epinephrine is part of their scope of practice.

The bill would authorize a pharmacy to dispense epinephrine auto-injectors to a prehospital emergency medical care person 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. The bill would require epinephrine auto-injectors obtained by prehospital emergency medical care personnel to be used only when functioning outside the course of the person's occupational duties, or as a volunteer, as specified.

(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 medical care person or lay rescuer who administers an epinephrine auto-injector, in good faith and not for compensation, to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with specified certification and training requirements and standards, except as specified.

(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.

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 medical care person or lay rescuer for the purpose of rendering emergency care in accordance with Section 1797.197a of the Health and Safety Code, if both of the following requirements are met:

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

“First Aid 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 “First Aid Purposes Only.”

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) “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 or 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 to administer an epinephrine auto-injector as a prehospital emergency medical care person or lay rescuer, pursuant to this section or any other statute or regulation.

(2) The epinephrine auto-injector is used on another, with the expressed or implied consent of that person, to treat anaphylaxis.

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

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

(5) The epinephrine auto-injectors obtained by prehospital emergency medical care personnel pursuant to Section 4119.3 of the Business and Professions Code shall be used only when functioning outside the course of the person’s occupational duties, or as a volunteer, pursuant to this section.

(6) The Emergency Medical Services System is activated as soon as practicable when an epinephrine auto-injector is used.

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

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

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

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

(C) Emergency followup procedures, including activation of the Emergency Medical Services System, by calling the emergency 9-1-1 telephone number or otherwise alerting and summoning more advanced medical personnel and services.

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

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

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

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

(4) The director of the authority may, in accordance with regulations adopted by the authority, deny, suspend, or revoke any approval issued under this subdivision or may place any approved training provider on probation upon a finding by the director of an imminent threat to public health and safety, as evidenced by any of the following:

(A) Fraud.

(B) Incompetence.

(C) The commission of any fraudulent, dishonest, or corrupt act that is substantially related to the qualifications, functions, or duties of training program directors or instructors.

(D) Conviction of any crime that is substantially related to the qualifications, functions, or duties of training program directors or instructors. The record of conviction or a certified copy of the record shall be conclusive evidence of the conviction.

(E) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this

section or the regulations promulgated by the authority pertaining to the review and approval of training programs in anaphylaxis and the use and administration of epinephrine auto-injectors, as described in this subdivision.

(d) (1) The authority shall assess a fee pursuant to regulation sufficient to cover the reasonable costs incurred by the authority for the ongoing review and approval of training and certification under subdivision (c).

(2) The fees shall be deposited in the Specialized First Aid Training Program Approval Fund, which is hereby created in the State Treasury. All moneys deposited in the fund shall be made available, upon appropriation, to the authority for purposes described in paragraph (1).

(3) The authority may transfer unused portions of the Specialized First Aid Training Program Approval Fund to the Surplus Money Investment Fund. Funds transferred to the Surplus Money Investment Fund shall be placed in a separate trust account, and shall be available for transfer to the Specialized First Aid Training Program Approval Fund, together with the interest earned, when requested by the authority.

(4) The authority shall maintain a reserve balance in the Specialized First Aid Training Program Approval Fund of 5 percent of annual revenues. Any increase in the fees deposited in the Specialized First Aid Training Program Approval Fund shall be effective upon determination by the authority that additional moneys are required to fund expenditures pursuant to subdivision (c).

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

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

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

Senate Bill No. 809

CHAPTER 400

An act to add Sections 208, 209, and 2196.8 to the Business and Professions Code, and to amend Sections 11164.1, 11165, and 11165.1 of, and to add Section 11165.5 to, the Health and Safety Code, relating to controlled substances.

[Approved by Governor September 27, 2013. Filed with
Secretary of State September 27, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

SB 809, 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, beginning April 1, 2014, require an annual fee of \$6 to be assessed on specified licensees, including licensees authorized to prescribe, order, administer, furnish, or dispense controlled substances, and require the regulating agency of each of those licensees to bill and collect that fee at the time of license renewal. The bill would authorize the Department of Consumer Affairs to reduce, by regulation, that fee to the reasonable cost of operating and maintaining CURES for the purpose of regulating those licensees, if the reasonable regulatory cost is less than \$6 per licensee. The bill would require the proceeds of the fee to be deposited into the CURES Fund for the support of CURES, as specified. The bill would also permit specified insurers, health care service plans, qualified manufacturers, and other donors to voluntarily contribute to the CURES Fund, as described.

(2) Existing law requires the Medical Board of California to periodically develop and disseminate information and educational materials regarding various subjects, including pain management techniques, to each licensed physician and surgeon and to each general acute care hospital in California.

This bill would additionally require the board to periodically develop and disseminate to each licensed physician and surgeon and to each general acute care hospital in California information and educational materials relating to the assessment of a patient's risk of abusing or diverting controlled substances and information relating to CURES.

(3) 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, by January 1, 2016, or upon receipt of a federal Drug Enforcement Administration registration, whichever occurs later, health care practitioners authorized to prescribe, order, administer, furnish, or dispense controlled substances, 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 their care. The bill would require the Department of Justice, in conjunction with the Department of Consumer Affairs and certain licensing boards, to, among other things, develop a streamlined application and approval process to provide access to the CURES database for licensed health care practitioners and pharmacists. The bill would make other related and conforming changes.

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

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

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

(2) Helping practitioners make prescribing decisions.

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

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

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

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

(2) Upgrading the CURES PDMP in California so that it is capable of operating in conjunction with all national prescription drug monitoring programs.

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

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

SEC. 2. Section 208 is added to the Business and Professions Code, to read:

208. (a) Beginning April 1, 2014, a CURES fee of six dollars (\$6) shall be assessed annually on each of the licensees specified in subdivision (b) to pay the reasonable costs associated with operating and maintaining CURES for the purpose of regulating those licensees. The fee assessed pursuant to this subdivision shall be billed and collected by the regulating agency of each licensee at the time of the licensee's license renewal. If the reasonable regulatory cost of operating and maintaining CURES is less than six dollars (\$6) per licensee, the Department of Consumer Affairs may, by regulation, reduce the fee established by this section to the reasonable regulatory cost.

(b) (1) Licensees authorized pursuant to Section 11150 of the Health and Safety Code to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances or pharmacists licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2.

(2) Wholesalers and nonresident wholesalers of dangerous drugs licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2.

(3) Nongovernmental clinics licensed pursuant to Article 13 (commencing with Section 4180) and Article 14 (commencing with Section 4190) of Chapter 9 of Division 2.

(4) Nongovernmental pharmacies licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2.

(c) The funds collected pursuant to subdivision (a) shall be deposited in the CURES Fund, which is hereby created within the State Treasury. Moneys in the CURES Fund shall, upon appropriation by the Legislature, be available to the Department of Consumer Affairs to reimburse the Department of Justice for costs to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

(d) The Department of Consumer Affairs shall contract with the Department of Justice on behalf of 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 Board of the Medical Board of California, the Osteopathic Medical Board of California, the Naturopathic Medicine Committee of the Osteopathic Medical Board, the State Board of Optometry, and the California Board of Podiatric Medicine to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

SEC. 3. Section 209 is added to the Business and Professions Code, to read:

209. The Department of Justice, in conjunction with the Department of Consumer Affairs and the boards and committees identified in subdivision (d) of Section 208, shall do all of the following:

(a) Identify and implement a streamlined application and approval process to provide access to the CURES Prescription Drug Monitoring Program (PDMP) database for licensed health care practitioners eligible to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances and for pharmacists. Every reasonable effort shall be made to implement a streamlined application and approval process that a licensed health care practitioner or pharmacist can complete at the time that he or she is applying for licensure or renewing his or her license.

(b) Identify necessary procedures to enable licensed health care practitioners and pharmacists with access to the CURES PDMP to delegate their authority to order reports from the CURES PDMP.

(c) Develop a procedure to enable health care practitioners who do not have a federal Drug Enforcement Administration (DEA) number to opt out of applying for access to the CURES PDMP.

SEC. 4. Section 2196.8 is added to the Business and Professions Code, to read:

2196.8. The board shall periodically develop and disseminate information and educational material regarding assessing a patient's risk of abusing or diverting controlled substances and information relating to the Controlled Substance Utilization Review and Evaluation System (CURES), described in Section 11165 of the Health and Safety Code, to each licensed physician and surgeon and to each general acute care hospital in this state. The board shall consult with the State Department of Public Health, the boards and committees specified in subdivision (d) of Section 208, and the Department

of Justice in developing the materials to be distributed pursuant to this section.

SEC. 5. Section 11164.1 of the Health and Safety Code is amended to read:

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

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

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

SEC. 6. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in 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, order, administer, furnish, or dispense these controlled substances.

(b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

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

(2) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that

may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(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, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, 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, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration 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, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section

208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

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

SEC. 7. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before January 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that practitioner 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).

(ii) A pharmacist shall, before January 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

(B) 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 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.

(C) Any authorized subscriber shall notify the Department of Justice within 30 days of any changes to the subscriber account.

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the

process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(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) 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.

(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. 8. Section 11165.5 is added to the Health and Safety Code, to read:

11165.5. (a) The Department of Justice may seek voluntarily contributed private funds from insurers, health care service plans, qualified manufacturers, and other donors for the purpose of supporting CURES. Insurers, health care service plans, qualified manufacturers, and other donors may contribute by submitting their payment to the Controller for deposit into the CURES Fund established pursuant to subdivision (c) of Section 208 of the Business and Professions Code. The department shall make information about the amount and the source of all private funds it receives for support of CURES available to the public. Contributions to the CURES Fund pursuant to this subdivision shall be nondeductible for state tax purposes.

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

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

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

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

(4) "Qualified manufacturer" means a manufacturer of a controlled substance, but does not mean a wholesaler or nonresident wholesaler of

dangerous drugs, regulated pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code, a veterinary food-animal drug retailer, regulated pursuant to Article 15 (commencing with Section 4196) of Chapter 9 of Division 2 of the Business and Professions Code, or an individual regulated by the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, or the California Board of Podiatric Medicine.

O



OFFICE OF THE GOVERNOR

October 4, 2013

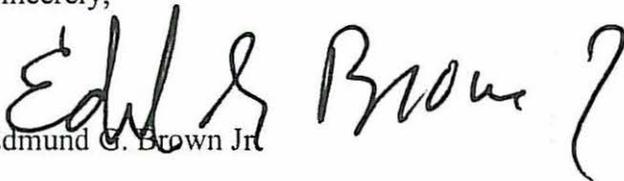
To the Members of the California State Senate:

I am returning Senate Bill 205 without my signature.

The bill would require certain parts of a prescription drug's label to be printed in at least 12-point typeface.

The Board of Pharmacy is required to provide an update of its 2010 labeling guidelines to the Legislature next month. I prefer to wait for their findings before mandating such a change.

Sincerely,

A handwritten signature in black ink that reads "Edmund G. Brown Jr." with a large question mark at the end.

Edmund G. Brown Jr

Senate Bill No. 205

Passed the Senate September 11, 2013

Secretary of the Senate

Passed the Assembly September 10, 2013

Chief Clerk of the Assembly

This bill was received by the Governor this _____ day
of _____, 2013, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

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

LEGISLATIVE COUNSEL'S DIGEST

SB 205, Corbett. Prescription drugs: labeling.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law defines a prescription as including 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, beginning January 1, 2016, would require certain portions of the required information on the prescription label, including the name of the patient or patients, to be printed in at least a 12-point typeface. Because a violation of this requirement would be a crime, the bill would impose a state-mandated local program.

This bill would incorporate additional changes in Section 4076 of the Business and Professions Code proposed by SB 493, that would become operative only if SB 493 and this bill are both chaptered and become effective on or before January 1, 2014, and this bill is chaptered last.

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.

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 with all of the following:

(1) Except when 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 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.

(e) This section shall remain in effect only until January 1, 2016, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2016, deletes or extends that date.

SEC. 1.5. Section 4076 of the Business and Professions Code is amended to read:

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

(1) Except when 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 Section 4052.1, 4052.2, or 4052.6 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 Section 4052.1, 4052.2, or 4052.6.

(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 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 Section 4052.1, 4052.2, or 4052.6.

(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.

(e) This section shall remain in effect only until January 1, 2016, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2016, deletes or extends that date.

SEC. 2. Section 4076 is added to the Business and Professions Code, to read:

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

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2

orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

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

(3) The name of the patient or patients.

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

(5) The date of issue.

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

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

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

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

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

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

(i) Prescriptions dispensed by a veterinarian.

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

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

(B) This paragraph applies to outpatient pharmacies only.

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

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

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

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

(d) If a pharmacist dispenses a dangerous drug or device in a 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.

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

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

SEC. 2.5. Section 4076 is added to the Business and Professions Code, to read:

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

(1) Except when 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 Section 4052.1, 4052.2, or 4052.6 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 Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

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

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

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

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

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

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

(i) Prescriptions dispensed by a veterinarian.

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

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

(B) This paragraph applies to outpatient pharmacies only.

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

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

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

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

(d) If a pharmacist dispenses a dangerous drug or device in a 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 Section 4052.1, 4052.2, or 4052.6.

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

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

SEC. 3. Sections 1.5 and 2.5 of this bill incorporate amendments to Section 4076 of the Business and Professions Code proposed by both this bill and Senate Bill 493. They shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2014, (2) each bill amends Section 4076 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 493, in which case Sections 1 and 2 of this bill shall not become operative.

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.



OFFICE OF THE GOVERNOR

OCT 12 2013

To the Members of the California State Senate:

Senate Bill 598 would effect two changes to our state's pharmacy law. First, it would allow interchangeable "biosimilar" drugs to be substituted for biologic drugs, once these interchangeable drugs are approved by the federal Food and Drug Administration (FDA). This is a policy I strongly support.

Second, it requires pharmacists to send notifications back to prescribers about which drug was dispensed. This requirement, which on its face looks reasonable, is for some reason highly controversial. Doctors with whom I have spoken would welcome this information. CalPERS and other large purchasers warn that the requirement itself would cast doubt on the safety and desirability of more cost-effective alternatives to biologics.

The FDA, which has jurisdiction for approving all drugs, has not yet determined what standards will be required for biosimilars to meet the higher threshold for "interchangeability." Given this fact, to require physician notification at this point strikes me as premature.

For these reasons, I am returning SB 598 without my signature.

Sincerely,


Edmund G. Brown Jr.

Senate Bill No. 598

Passed the Senate September 4, 2013

Secretary of the Senate

Passed the Assembly August 26, 2013

Chief Clerk of the Assembly

This bill was received by the Governor this _____ day
of _____, 2013, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to add Section 4073.5 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 598, 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 the product has been approved by the federal Food and Drug Administration, as specified, and the prescriber does not personally indicate "Do not substitute," as specified. The bill would also require, for prescriptions filled prior to January 1, 2017, the pharmacy to, within 5 business days of the selection of a biological product or an interchangeable biosimilar, notify the prescriber or enter in a patient record whether the prescription dispensed was a biological product or an interchangeable biosimilar, except as specified. The bill would prohibit a pharmacist from selecting a biosimilar that meets the requirements of these provisions unless the cost to the patient of the biosimilar selected is the same or less than the cost of the prescribed biological product. The bill would also require that the substitution of a biosimilar be communicated to the patient. 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.

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 filling a prescription order for a prescribed biological product may select a biosimilar only if both 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 “Do not substitute,” or words of similar meaning, in the manner provided in subdivision (c).

(b) For prescriptions filled prior to January 1, 2017, the pharmacy shall, within five business days of the selection of a biological product or an interchangeable biosimilar, approved as provided in paragraph (1) of subdivision (a), notify the prescriber whether the prescription dispensed was a biological product or an interchangeable biosimilar, approved as provided in paragraph (1) of subdivision (a), or enter the information in a patient record system shared by the prescriber. No notification is required if the prescriber indicates “Do not substitute” in the manner provided in subdivision (c), if there is no FDA-approved interchangeable biosimilar pursuant to paragraph (1) of subdivision (a), or if a refill prescription is not changed from the product originally dispensed.

(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.

(d) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (c). The pharmacist who selects the biosimilar to be dispensed pursuant to this section shall assume the same responsibility for substituting the biosimilar as would be incurred in filling a prescription for a biosimilar prescribed by name. 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 select a biosimilar that meets the requirements of paragraph (1) of subdivision (a) unless the cost to the patient of the biosimilar selected is the same or less than the cost of the prescribed biological product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

(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 Medi-Cal Act set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

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

(g) 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).

(h) 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 prescription for 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.

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

(j) Nothing in this section prohibits a disability insurer or health care service plan from requiring prior authorization or imposing other appropriate utilization controls in approving coverage for any biological 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.

SUBJECT: B&P Code Section 119 - Criminal Prosecution as Sole Remedy

PROBLEM/SUMMARY:

Current law only allows DCA regulatory agencies to pursue criminal misdemeanor filings for violations of B&P Code 119. Although individuals who commit these violations represent a risk to the public and legitimate licensees, workload considerations may prevent some district attorneys from pursuing criminal charges, especially if a consumer injury directly resulting from the B&P 119 violation can't readily be established. Consequently, individuals who have, in fact, violated the law may avoid having any record of their violations.

PROPOSED CHANGE:

Work with the department to amend Section 119 to provide the board with the express authority to issue administrative citations for violations that are not pursued criminally. This also will enable the board to establish a record of violations that can be made available for the public to use in making consumer choices.

PROPOSED LANGUAGE:

119. Any person who does any of the following is guilty of a misdemeanor and is, in addition, subject to disciplinary action in accordance with the provisions of this code:

(a) Displays or causes or permits to be displayed or has in his or her possession either of the following:

(1) A canceled, revoked, suspended, or fraudulently altered license.

(2) A fictitious license or any document simulating a license or purporting to be or have been issued as a license.

(b) Lends his or her license to any other person or knowingly permits the use thereof by another.

(c) Displays or represents any license not issued to him or her as being his or her license.

(d) Fails or refuses to surrender to the issuing authority upon its lawful written demand any license, registration, permit, or certificate which has been suspended, revoked, or canceled.

(e) Knowingly permits any unlawful use of a license issued to him or her.

(f) Photographs, photostats, duplicates, manufactures, or in any way reproduces any license or facsimile thereof in a manner that it could be mistaken for a valid license, or displays or has in his or her possession any such photograph, photostat, duplicate, reproduction, or facsimile unless authorized by this code.

(g) Buys or receives a fraudulent, forged, or counterfeited license knowing that it is fraudulent, forged, or counterfeited. For purposes of this subdivision, "fraudulent" means containing any misrepresentation of fact.

As used in this section, "license" includes "certificate," "permit," "authority," and "registration" or any other indicia giving authorization to engage in a business or profession regulated by this code or referred to in Section 1000 or 3600.

Reference - Existing Law

4000. This chapter constitutes, and may be cited as, the Pharmacy Law.

1 **Business and Professions Code 4053.**

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

7 (b) An individual who is at least 18 years of age may apply for a designated
8 representative license. In order to obtain and maintain that license, the individual shall
9 meet all of the following requirements:

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

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

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

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

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

23 (C) Knowledge and understanding of quality control systems.

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

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

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

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

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

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

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

37 *(Chapter 473, Statutes 2013, Senate Bill 821, SEC. 19)*



Bill Number:	AB 467
Introduced	2/22/13
Last Amend:	9/6/2013
Author:	Assembly Member Stone
Topic:	Prescription Drugs: collection and distribution program
Current Position:	Oppose Unless Amended (<i>est 8/23/13</i>)

Current Bill Status: Referred to SEN Business, Professions & Economic Development

Affected Sections: Business & Professions Code Sections 4046 and 4169.5 and Health & Safety Code Sections 150205 and 150208

Prior Version: AB 467 (as amended 8/19/13) was a “gut & amend” where the scope of an existing bill was modified to exempt an entity (now referred to as an ‘intermediary’) from oversight by the board and would specify that such an entity’s activities would not be deemed wholesaling activities. The board thereafter established (on 8/23/13) a position of *Oppose Unless Amended* and provided the author with suggested amendments (see attached position letter).

Recommendation: For the 9/6/13 version, remove position of “Oppose Unless Amended” and be neutral at this time.

The board may wish to specify the term of the license and any subsequent renewal(s).

SUMMARY:

Assembly Bill 467 would provide for the licensure of a “Surplus Medication Collection and Distribution Intermediary” to allow such an entity to perform duties related to the movement of drugs donated through a Surplus Medication Collection and Distribution program, as provided in the Health & Safety Code. Specifically, AB 467 would

Business & Professions Code. Chapter 9. Division 2.

- **Add** Section 4046 to Article 2 (Definitions) to define a “surplus medication collection and distribution intermediary.”
- **Add** a new Article 11.5 – “Surplus Medication Collection and Distribution Intermediaries”
- **Add** a new Section 4169.5 to specify the licensure requirements of a surplus medication collection and distribution intermediary.

Health & Safety Code. Division 116. Surplus Medication Collection & Distribution

- **Amend** Section 150204 of the Health & Safety Code. This section specifies those entities that shall be held harmless from criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in accordance with the “Surplus Medication Collection and Distribution” program. This section would add a surplus medication collection and distribution intermediary as an entity that would be exempt from civil or criminal liability.
- **Add** Section 150208 to the Health & Safety Code to specify the activities of a surplus medication collection and distribution intermediary.

EXISTING LAW:

As the regulatory agency mandated to secure the drug delivery channel for California patients, entities and individuals who participate in the drug delivery chain in California fall within the board’s licensing and regulatory oversight.

Existing Pharmacy Law provides for the licensure and regulation of pharmacies, pharmacists, wholesalers of dangerous drugs or devices, and other individuals and entities. ¹Current law defines a “wholesaler” to include a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or who negotiates for distribution any drug or device.

Under existing ²law, a county may voluntarily establish a Surplus Medication Collection and Distribution (SMCD) Program through a county-owned pharmacy or a pharmacy that contracts with the county for this purpose. The provisions of this program were significantly expanded in 2012 (see SB 1329, Simitian) to (in part) allow county Public Health Officers to establish programs, to allow for a broader pool of medication donors, provide the board with the authority to prohibit an entity from participation in the program, and to allow transfers of donated medications between established programs.

THIS BILL WOULD:

Authorize the board to issue a license, charge related fees, and specify the license requirements for a “surplus medication collection and distribution intermediary” (intermediary). Those intermediaries/entities that are also a 501(c)(3) nonprofit corporation would be required to be licensed, but would be exempt from paying a fee to the board. *The bill does not specify renewal requirements for the license, nor does it specify the term of the license issued.*

Amend the Health and Safety Code to exempt intermediaries from civil or criminal penalties associated with drugs distributed under a Surplus Medication Collection and Distribution program.

STAFF COMMENTS:

Staff expects that a stakeholders meeting will be scheduled sometime in November.

As amended September 6, 2013, AB 467 does not specify the term of the license, nor does it specify any renewal requirements for the license. The board may wish to specify these provisions.

¹ Business and Professions Code Section 4043.

² Division 116 of the Health and Safety Code, Sections 150200-150207

There is one technical error (transposition error) that should be corrected in 4169.5.

FISCAL IMPACT ON THE BOARD:

The board would need to modify its existing licensing systems to add a new category of licensure (license type). This would be a one-time expense of approximately \$10,000.

The board will incur minor costs associated with the development of application forms and the processing of these applications, which will be absorbed within existing resources.



California
LEGISLATIVE INFORMATION

AB-467 Prescription drugs: collection and distribution program. (2013-2014)

"Today's Law as Amended" 9/6/13

SECTION 1. Section 4046 is added to the Business and Professions Code, to read:

4046. "Surplus medication collection and distribution intermediary" means a firm, association, partnership, corporation, limited liability company, state governmental agency or political subdivision that performs the functions specified in Section 4169.5 for the purpose of a program established pursuant to Division 116 (commencing with Section 150200) of the Health and Safety Code.

SEC. 2. Article 11.5 (commencing with Section 4169.5) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 11.5. Surplus Medication Collection and Distribution Intermediaries

4169.5. (a) A surplus medication collection and distribution intermediary established for the purpose of facilitating the connection of eligible and participating entities under a program established pursuant to Division 116 (commencing with Section 150200) of the Health and Safety Code shall be licensed by the board. The board shall enforce the requirements set forth in Section 150208 of the Health and Safety Code.

(b) An application for licensure as a surplus medication collection and distribution intermediary shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is an entity other than a natural person, the application shall state the information as to each person beneficially interested in that entity.

(c) As used in this section, and subject to subdivision (e), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(d) In any case where the applicant is a charitable organization described in Section 501 (c) (3) of the Internal Revenue Code, the applicant shall furnish the board with organizations the articles of incorporation. The applicant shall also furnish the board with the names of the controlling members.

(e) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant's entity. Upon request by the executive officer of the board, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(f) The application shall contain a statement to the effect that the applicant or persons beneficially interested have not been convicted of a felony and have not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(g) Upon the approval of the application by the board and payment of a fee in the amount of three hundred dollars (\$300), the executive officer of the board shall issue a license to operate as a surplus medication collection and distribution intermediary, if all of the provisions of this chapter have been complied with. Fees received by the board pursuant to this section shall be deposited into the Pharmacy Board Contingent Fund. An applicant for licensure as a surplus medication collection and distribution intermediary that is a nonprofit organization pursuant to subdivision (d) is exempt from the fee requirement.

(h) A surplus medication collection and distribution intermediary licensed pursuant to this section is exempt from licensure as a wholesaler.

SEC. 3. *Section 150205 of the Health and Safety Code is amended to read:*

150205. *(a) The following persons and entities shall not be subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with this division:*

~~(a)~~ *(1) A prescription drug manufacturer, wholesaler, governmental entity, or participating entity.*

~~(b)~~ *(2) A pharmacist or physician who accepts or dispenses prescription drugs.*

~~(c)~~ *(3) A licensed health or care facility, as described in Section 150202, or a pharmacy, as described in Section 150202.5.*

(b) A surplus medication collection and distribution intermediary, as described in Section 150208, shall not be subject to criminal or civil liability for injury caused when facilitating the donation of prescription drugs in compliance with this division.

SEC. 4. *Section 150208 is added to the Health and Safety Code, to read:*

150208. *(a) A surplus medication collection and distribution intermediary that is licensed pursuant to Section 4169.5 of the Business and Professions Code, established for the purpose of facilitating the connection of eligible and participating entities under a program established pursuant to this division is authorized to operate under this section.*

(b) A surplus medication collection and distribution intermediary shall comply with the following:

(1) It shall not take possession, custody, or control of dangerous drugs and devices.

(2) It shall ensure that notification is provided to participating entities that a package has been shipped when the surplus medication collection and distribution intermediary has knowledge of the shipment or provided logistical support to facilitate a shipment directly from an eligible entity to a participating entity.

(3) It shall not select, or direct an eligible entity to select, a specific participating entity to receive surplus medications.

(c) A surplus medication collection and distribution intermediary is authorized to do the following:

(1) Contract directly with a county to connect eligible entities with participating entities and provide general support in a county's implementation of a program established pursuant to this division.

(2) Charge membership, administrative, or overhead fees sufficient to cover the reasonable costs of the services provided.

(d) No participating entities shall receive donated medication directly from the surplus medication collection and distribution intermediary.

SEC. 5. *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. 6. *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:*

To ensure that California's medication donation program is allowed to continue to operate to facilitate the distribution of medications to the indigent population which would not otherwise have access to these medications, it is necessary that this act take effect immediately.



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

August 23, 2013

The Honorable Mark Stone
California State Assembly
State Capitol, Room 5155
Sacramento, CA 95814

RE: Assembly Bill 467 – Oppose Unless Amended

Dear Assemblymember Stone:

I regret to inform you that the Board of Pharmacy (board) has taken a position of oppose unless amended on your Assembly Bill 467. Assembly Bill 467 would create a significant exemption from licensure and regulation by the board by exempting any person from being licensed as a wholesaler who performs drug wholesaler activities while working with a county run drug repository program.

The board understands that the sponsor of this legislation is one such entity that performs services for counties with drug repository programs. Further, the board believes that Pharmacy Law requires licensure as a wholesaler to perform these services. As you are aware, the board has been working with the sponsors on resolving this specific compliance issue and is awaiting proposed meeting dates to continue our dialog. It is the board's assumption that the proposed legislation is designed to address the current divergence of opinions; however, the proposed solution creates several problems.

In its current form, AB 467 lacks appropriate oversight for the distribution of dangerous drugs to patients. It allows any "person" to perform the duties of a wholesaler without licensure by the board. As the regulatory agency responsible for securing the drug delivery channel for all California patients, such an exemption would remove the board's ability to perform its statutory mandate of overseeing the drug distribution system in California, putting patients at risk. The proposed definition of a "person" is far too broad and would allow anyone to serve in the capacity of a drug distributor. In addition, the duties the "person" would be authorized to perform are also far too broad. Lastly, the exemption from licensure and oversight would create significant opportunities for diversion of the medications from their intended recipients - - indigent patients receiving care from county programs.

We believe that it is not the intent of your office to create such an open exemption and the board requests consideration of a more balanced approach. The board proposes an alternative resolution that will address the concerns of the sponsors and allow county

The Honorable Mark Stone

August 23, 2013

Page 2

programs to use an intermediary to assist with the distribution of drugs. Suggested language is enclosed that will achieve your goals including:

- Allowing an intermediary to assist with the redistribution of donated medications
- Removing any financial barriers, including fees and bonding requirements, to obtaining licensure to perform the specified functions
- Allowing the board the ability to appropriately regulate, via licensure, all persons involved in the distribution of medications throughout the drug delivery system.

Board staff would like to work with you and the sponsors of AB 467 to ensure that drug distribution to indigent patients has necessary safeguards to prevent the diversion of drugs. The balanced approach suggested by the board would achieve this goal.

The board is committed to working with you and all other stakeholders to ensure that all California patients have access to necessary medications.

Sincerely,



Anne Sodergren
Assistant Executive Officer

Enclosure

cc: Department of Consumer Affairs
George Wang, SIRUM
Senate Business Professions and Economic Development Committee
Assembly Business, Professions and Consumer Protection Committee
Assembly Health Committee

Board of Pharmacy
Proposed Amendments to AB 467

SECTION 1.

Section 150201 of the Health and Safety Code is amended to read:

150201.

For purposes of this division:

(a) "Eligible entity" means all of the following:

(1) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is county owned or that contracts with the county pursuant to this division and is not on probation with the California State Board of Pharmacy.

(2) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is owned and operated by a primary care clinic, as defined in Section 1204, that is licensed by the State Department of Public Health and is not on probation with the California State Board of Pharmacy.

(3) A primary care clinic, as defined in Section 1204, that is licensed by the State Department of Public Health and licensed to administer and dispense drugs pursuant to subparagraph (A) of paragraph (1) of subdivision (a) of Section 4180 of the Business and Professions Code and is not on probation with the California State Board of Pharmacy.

(b) "Medication" or "medications" means a dangerous drug, as defined in Section 4022 of the Business and Professions Code.

(c) "Participating entity" means an eligible entity that has received written or electronic documentation from the county health department pursuant to paragraph (3) of subdivision (a) of Section 150204 and that operates a repository and distribution program pursuant to this division.

~~(d) "Person" includes a firm, association, partnership, corporation, limited liability company, state governmental agency, or political subdivision.~~

SEC. 2.

Section 150208 is added to the Health and Safety Code, to read:

150208.

A charitable organization described in Section 501(c)(3) of the Internal Revenue Code of 1954, a state governmental agency or a state political subdivision, conducting ~~Activities~~ activities solely relating to the donation or distribution of medications, including, but not limited to, facilitating or negotiating the donation or distribution of medications, pursuant to this division shall ~~not be deemed a drug repository wholesaler for these purposes. To perform as a drug repository wholesaler, such entity must first be licensed as a wholesaler licensed pursuant to Business and Professions Code Section 4160 et seq. but, shall not be required to comply with the surety bond requirements detailed in Business and Professions Section 4162 and shall not be required to pay the application or renewal fee established in Business and Professions Code Section 4400 (f).~~ wholesaling activities required to comply with the licensing requirements for a wholesaler. Any person that is not otherwise a wholesaler, as defined in Section 4043 of the Business and Professions Code, shall not be deemed a wholesaler or required to be licensed as a wholesaler under the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code) when performing those activities pursuant to this division.

SEC. 3.

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:

To ensure that California's medication donation program is allowed to continue to operate to facilitate the distribution of medications to the indigent population which would not otherwise have access to these medications, it is necessary that this act take effect immediately.



California
LEGISLATIVE INFORMATION

AB-467 Prescription drugs: collection and distribution program. (2013-2014)

AMENDED IN SENATE AUGUST 19, 2013

AMENDED IN SENATE AUGUST 12, 2013

AMENDED IN ASSEMBLY APRIL 11, 2013

AMENDED IN ASSEMBLY MARCH 19, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

ASSEMBLY BILL

No. 467

Introduced by Assembly Member Stone
(Principal coauthor: Senator Hill)

February 19, 2013

~~An act to amend Section 14581 of the Food and Agricultural Code, relating to the Fertilizer Inspection Advisory Board.~~ *An act to amend Section 150201 of, and to add Section 150208 to, the Health and Safety Code, relating to pharmaceuticals, and declaring the urgency thereof, to take effect immediately.*

LEGISLATIVE COUNSEL'S DIGEST

AB 467, as amended, Stone. ~~Fertilizer Inspection Advisory Board.~~ *Prescription drugs: collection and distribution program.*

Existing law authorizes a county to establish, by ordinance, a repository and distribution program under which specified pharmacies and primary care clinics may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Existing law authorizes specified health and care facilities, pharmacies, drug manufacturers, and pharmacy wholesalers to donate unused medications to the program. Existing law requires a county that has established a program to establish procedures to, among other things, ensure proper safety and management of any medications collected and maintained by a participating entity.

This bill would provide that activities relating to the donation or distribution of medications under the program are not wholesaling activities, and any person, as defined, that is not otherwise a wholesaler shall not be deemed a wholesaler or required to be licensed as a wholesaler when performing those activities.

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

~~Existing law governs the manufacture and distribution of fertilizing materials, as defined, including licensing, labeling, and inspection, and requires the Secretary of Food and Agriculture to enforce these provisions. Existing law establishes, within the Department of Food and Agriculture, the Fertilizer Inspection Advisory Board to advise the secretary and make recommendations on all matters pertaining to these provisions, as specified.~~

~~The board consists of 9 persons appointed by the secretary, 8 of whom are required to be licensed pursuant to these provisions and subject to the payment of a specified inspection fee, and one of whom is required to be a public member.~~

~~This bill would revise the composition of the board to require only 3 members of the board to be licensed pursuant to these provisions and subject to the payment of the inspection fee. The bill would require the board to be composed of 3 farmers or farmer representatives, at least one of whom is an organic farmer or the representative of an organic farming program, one member who represents the academic community, one member who is an environmental expert with knowledge relevant to the board's function, and one public member who represents a community whose primary source of drinking water exceeds the maximum contaminant level for nitrate.~~

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

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

SECTION 1. *Section 150201 of the Health and Safety Code is amended to read:*

150201. For purposes of this division:

(a) "Eligible entity" means all of the following:

(1) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is county owned or that contracts with the county pursuant to this division and is not on probation with the California State Board of Pharmacy.

(2) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is owned and operated by a primary care clinic, as defined in Section 1204, that is licensed by the State Department of Public Health and is not on probation with the California State Board of Pharmacy.

(3) A primary care clinic, as defined in Section 1204, that is licensed by the State Department of Public Health and licensed to administer and dispense drugs pursuant to subparagraph (A) of paragraph (1) of subdivision (a) of Section 4180 of the Business and Professions Code and is not on probation with the California State Board of Pharmacy.

(b) "Medication" or "medications" means a dangerous drug, as defined in Section 4022 of the Business and Professions Code.

(c) "Participating entity" means an eligible entity that has received written or electronic documentation from the county health department pursuant to paragraph (3) of subdivision (a) of Section 150204 and that operates a repository and distribution program pursuant to this division.

(d) "Person" includes a firm, association, partnership, corporation, limited liability company, state governmental agency, or political subdivision.

SEC. 2. *Section 150208 is added to the Health and Safety Code, to read:*

150208. Activities relating to the donation or distribution of medications, including, but not limited to, facilitating or negotiating the donation or distribution of medications, pursuant to this division shall not be deemed wholesaling activities. Any person that is not otherwise a wholesaler, as defined in Section 4043 of the Business and Professions Code, shall not be deemed a wholesaler or required to be licensed as a wholesaler under the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code) when performing those activities pursuant to this division.

SEC. 3. *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:*

To ensure that California's medication donation program is allowed to continue to operate to facilitate the distribution of medications to the indigent population which would not otherwise have access to these medications, it is necessary that this act take effect immediately.

~~SECTION 1. Section 14581 of the Food and Agricultural Code is amended to read:~~

~~14581.(a)There is, in the department, a Fertilizer Inspection Advisory Board consisting of nine persons appointed by the secretary, which shall be composed of the following individuals:~~

~~(1)Three members who are licensed under this chapter and subject to payment of the inspection fee.~~

~~(2)Three members who are farmers or farmer representatives, at least one of whom is an organic farmer or a representative of an organic farming program.~~

~~(3)One member who represents the academic community.~~

~~(4)One member who is an environmental expert with knowledge relevant to the board's function.~~

~~(5)One member of the public who represents a community whose primary source of drinking water exceeds the maximum contaminant level for nitrate.~~

~~(b)The members of the board shall receive no compensation, but are entitled to payment of necessary traveling expenses in accordance with the rules of the Department of Human Resources. These expenses shall be paid out of appropriations made to the department pursuant to this chapter.~~

AMENDED IN ASSEMBLY JUNE 27, 2013

AMENDED IN SENATE MAY 23, 2013

AMENDED IN SENATE APRIL 24, 2013

SENATE BILL

No. 204

Introduced by Senator Corbett

February 8, 2013

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

LEGISLATIVE COUNSEL'S DIGEST

SB 204, as amended, 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, commencing January 1, 2016, require translations of the directions for use in non-English languages published on the board's Internet Web site to be used, as applicable, when labeling a prescription container. The bill would, notwithstanding these provisions, authorize a pharmacy to ~~provide use~~ its own translations of the *board's English language* directions for ~~use established by regulation of the board in the non-English languages published on the board's Internet Web site~~ use, as specified, if a trained and qualified translator or translation service, as defined, is utilized to complete the additional translations. The bill would authorize the directions for use, as specified, to be translated into additional non-English languages if ~~certified~~

~~translation services are a trained and qualified translator or translation service, as defined, is~~ utilized to complete the additional translations. The bill would authorize a pharmacist to ~~provide use~~ the English language directions for use, as specified, if he or she reasonably believes a translation of the directions for use contains an error due to software or equipment malfunction. The bill would also provide that a pharmacist that reasonably uses the translations of the directions for use in non-English languages published on the board’s Internet Web site has not breached his or her legal duty if the published translations contain an error and the pharmacist did not know, or did not have reason to know, of the error. *The bill would require that the board’s English language directions for use be provided in each instance in which a non-English translation of the directions for use is used.* Because a violation of this requirement would be a crime, the bill would impose a state-mandated local program.

This bill would define “translation” and “trained and qualified translator or translation service” for purposes of the provisions described above.

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

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

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

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

- 1 SECTION 1. Section 4076.3 is added to the Business and
- 2 Professions Code, to read:
- 3 4076.3. (a) Translations of the directions for use in non-English
- 4 languages published on the board’s Internet Web site shall be used,
- 5 as applicable, when labeling a prescription container pursuant to
- 6 Section 4076.
- 7 (b) The *English language* directions for use established by
- 8 regulation of the board may be translated into additional
- 9 non-English languages if ~~certified translation services are a trained~~
- 10 *and qualified translator or translation service is* utilized to
- 11 complete the additional translations.

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

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

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

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

21 (g) *For purposes of this section, “translation” means the*
22 *conversion of written text to the corresponding written text in a*
23 *different language.*

24 (h) *For purposes of this section, “trained and qualified*
25 *translator or translation service” means any of the following:*

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

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

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

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

36 (B) *He or she commits to abide by the American Translators*
37 *Association’s Code of Professional Conduct and Business*
38 *Practices.*

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

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

7 (f)

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

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



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

Current Bill Status: 2-Year Bill – Last location was ASM Health (7/23/13)

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

SUMMARY

Existing Pharmacy Law requires that a prescription container dispensed to a patient include the directions for use of the drug (Section 4076). Board regulation at 16 CCR 1707.5 specifies standardized “directions for use” that shall be used, if they are applicable to the prescription. In addition, the board maintains on its website translations in five languages of the “directions for use” that are found at 16 CCR 1707.5(a)(4).

SB 204 would add Section 4076.5 to require a pharmacist to use the translations for the “directions for use” available on the board’s website, as applicable, when labeling a prescription. The section would also authorize a pharmacist to translate the directions for use into additional non-English languages if certified translation services are utilized to complete the translations.

At the Legislation and Regulation Committee meeting held July 30, 2013, and at the Board Meeting held later that day, board members discussed whether or not to take a position, as it was unclear if Senator Corbett would be moving the bill or make it a 2-year bill. Likewise, the board conveyed concern over mandating translations prior to the completion of the board’s review of the patient-centered label requirements. Senator Corbett sent the board a letter at that meeting where in she stated her intention to amend SB 204 to clarify the bill as it relates to having the English directions for use on the label, where translated directions for use is also on the label.

The board’s Communication and Public Education Committee is heading up the board’s review of its patient-centered label requirements, which will be complete by December 2013.

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 website¹ 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 be operative on January 1, 2016, to

- Require that the translated directions for use in non-English Languages (as published on the board's web site) shall be used, as applicable, when labeling a prescription drug container.
- Allow for the translation of the English standard directions for use (as specified in board Regulation) into additional non-English languages if a trained and qualified translator or translation service is utilized to complete additional translations.
- Permit a pharmacy to use its own translations of the standardized directions for use, if a trained and qualified translator or translation service is utilized.
- Allow a pharmacist to use the English language directions for use (board regulation) if the pharmacist reasonably believes that a translation contains an error due to a software or equipment malfunction.
- Require that the English directions for use be provided in each instance where a non-English translation is used.
- Define "translation" and "trained and qualified translator or translation service" and require a pharmacy to establish policies and determine and document an individual's qualifications related to providing these translations.

FISCAL IMPACT ON THE BOARD:

If enacted as introduced, the board may need to update its regulation at 16 CCR § 1707.5.

Support:

California Pan-Ethnic Health Network.
Center for the Pacific Asian Family
Asian Americans Advancing Justice
American Cancer Society Cancer Action Network
National Asian Pacific American Families Against Substance Abuse, Inc.
Cal-Islanders Humanitarian Association

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

MAGNA Systems Incorporated
Guam Communications Network
California Rural Legal Assistance Foundation
APAIT Health Center
Asian American Drug Abuse Program, Inc.
Asian Pacific Policy & Planning Council
Madera Coalition for Community Justice
Pacific Asian Counseling Services
Korean Community Center of the East Bay
Asian Law Alliance
Vision y Compromiso
Thai Health and Information Services, Inc.
Street Level Health Project
3 Individuals

Opposition:

California Pharmacists Association

CAPITOL OFFICE
State Capitol, Room 313
Sacramento, CA 95814-4900
TEL (916) 651-4010
FAX (916) 327-2433

DISTRICT OFFICES
1057 MacArthur Blvd., Suite 206
San Leandro, CA 94577
TEL (510) 577-2310
FAX (510) 577-2308

39155 Liberty St., Suite F-610
Fremont, CA 94538
TEL (510) 794-3900
FAX (510) 794-3940

California State Senate

SENATOR ELLEN M. CORBETT MAJORITY LEADER

REPRESENTING ALAMEDA AND SANTA CLARA COUNTIES



STANDING COMMITTEES

Business, Professions &
Economic Development
Energy, Utilities &
Communications
Environmental Quality
Insurance
Judiciary

SELECT COMMITTEES

Emerging Technology:
Biotechnology and
Green Energy Jobs, Chair
California's Wine Industry
Mental Health

JOINT COMMITTEE

Rules

July 30, 2013

Ms. Virginia Herold, Executive Officer
California Board of Pharmacy
1625 N Market Drive, Suite N219
Sacramento, CA 95834

Dear Ms. Herold:

I wish to address some concerns that were raised in today's Legislation/Regulation Committee Meeting of the Board of Pharmacy (Board) with regards to my Senate Bill 204 related to translated prescription directions and Senate Bill 205 related to 12 point font prescription labels.

I understand that the Board's committee members were concerned with space on the label if translated directions and their English counterparts were both required to be printed in 12 point font on the label. In order to assuage the concerns of the opposition with regards to patient safety and liability, I agreed to have the English directions printed on the prescription container, not necessarily on the prescription label, when translated directions are provided. It was not my intention to have both directions printed on the label in 12 point font, and I am working on amendments to clarify that in the bill. I explicitly chose not to dictate where or how the English directions needed to be placed on the prescription container, as I feel it would be best for the Board to make that decision.

Similarly, there was a concern about SB 205 raised that as the Board considers making the purpose for the prescription a required part of the label, its presence on the label in 12 point font could provide less room. According to current regulations, pharmacies must already be able print the purpose for the prescription in 12 point font, upon request, when it is provided. SB 205 would simply require all prescription labels to be printed in a manner that is already possible under current regulations.

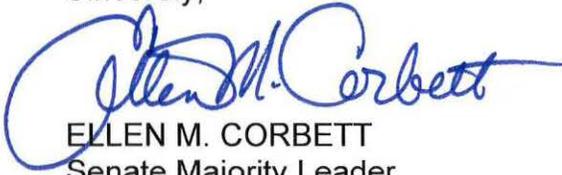
During discussions of SB 204, the idea of liability was also raised. I wish to state that SB 204 has three separate provisions addressing liability. First, those pharmacists who reasonably use the provided translations will not have breached their legal duty if the translation is found to contain an error. Second, the English directions for use will also

Ms. Virginia Herold
July 30, 2013
Page 2

be on the container, eliminating confusion for the pharmacist. Third, instead of using the published translations, those pharmacies that wish to provide their own translations using trained and qualified translation services may do so. This will enable them to take on the amount of liability they feel is appropriate in their contract with the third party.

Finally, I wish to state that simply allowing the free market to guide the process may not be in the best interest of the millions of California consumers that these bills will affect. The free market does not always produce the best results for protecting consumers, which is why we need to provide safeguards so patients can safely take their medication. SB 204 and SB 205 are about protecting consumers and ensuring that they can read and understand their prescription labels. I respectfully request that the Board withhold taking a position on SB 204 and SB 205 at this time and work with my office to address the concerns raised.

Sincerely,



ELLEN M. CORBETT
Senate Majority Leader

EMC:jvl

AMENDED IN ASSEMBLY JUNE 20, 2013

AMENDED IN SENATE MAY 7, 2013

AMENDED IN SENATE APRIL 18, 2013

SENATE BILL

No. 306

Introduced by Senator ~~Price Torres~~
(Principal coauthor: Assembly Member ~~Gordon~~ Cooley)

February 15, 2013

An act to amend Sections ~~1000, 2530.2, 2531, 2531.75, 2533, 2570.19, 2602, and 2607.5~~ 4170, 4180, and 4186 of the Business and Professions Code, relating to ~~healing arts~~ pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 306, as amended, ~~Price Torres. Healing arts: boards. Pharmacy: dangerous drugs and dangerous devices: automated drug delivery systems.~~

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies in this state by the California State Board of Pharmacy. A violation of the Pharmacy Law is a crime.

Among other provisions, the Pharmacy Law prohibits a prescriber from dispensing dangerous drugs or dangerous devices, as defined, to patients in his or her office unless specified conditions are met. Existing law defines a prescriber for purposes of this provision to mean a person who holds a physician's and surgeon's certificate, or one of other specified health care licenses or certificates, and who is registered to engage in that practice with the appropriate board of this state. Existing law authorizes certain health care professionals, including a certified nurse-midwife or a nurse practitioner, as specified, to hand to a patient of the supervising physician and surgeon a properly labeled prescription

drug prepackaged by a physician and surgeon, a manufacturer, as defined, or a pharmacist.

This bill would revise the conditions under which a prescriber may dispense dangerous drugs and dangerous devices. The bill would require a health care professional who is licensed as specified, or his or her designee, to physically furnish the dangerous drug or device to the patient, to be identified, except as specified, by the drug or device manufacturer or wholesaler supplying the drug or device as the recipient of the drug or device, and as the recipient in all invoices, bills of lading, state or federal order forms, and other documentation, and to provide the patient with an oral consultation, as specified. The bill would revise the definition of a prescriber to apply to a person who is licensed to prescribe and dispense dangerous drugs, including, but not limited to, the licensed health care professionals authorized pursuant to existing law. The bill would also authorize a registered nurse who functions within a licensed primary care clinic, federal or state government operated clinic, community or free clinic to hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer, as defined, or a pharmacist.

Existing law authorizes clinics to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic. Existing law also authorizes an automated drug delivery system, as defined, to be located in any clinic licensed by the board, as specified. Existing law requires an automated drug delivery system to collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

This bill would authorize an automated drug delivery to be located in a group practice, as specified. The bill would authorize specified entities, including a group practice, that uses an automated drug delivery system, as described, to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon or other prescriber when permitted by law, and would make conforming and related changes.

The bill would also impose new conditions on an automated drug delivery system. Among other requirements, the bill would require that an automated drug delivery system be located within the clinic or office of the group practice, that its contents be secure from access or removal by unauthorized individuals, and that it maintain a readily retrievable

electronic record to identify all pharmacists, registered pharmacy technicians, prescribers, and all other personnel involved in the dispensing of a drug. The bill would also require that the record of transactions conducted through the automated drug delivery system be made available to authorized agents of the board. The bill would authorize the board to adopt regulations permitting the use of an automated drug delivery system that delivers dispensed medications directly to a patient.

Because of violation of the bill's requirements 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.

~~The Chiropractic Act, enacted by an initiative measure, provides for the regulation and licensing of chiropractors in this state by the State Board of Chiropractic Examiners. Existing law specifies that the law governing chiropractors is found in the act.~~

~~This bill would require that the powers and duties of the board, as provided, be subject to review by the appropriate policy committees of the Legislature. The bill would require that the review of the board be performed as if these provisions were scheduled to be repealed on January 1, 2018.~~

~~Existing law, the Speech-Language Pathologists and Audiologists and Hearing Aid Dispensers Licensure Act, provides for the licensure and regulation of speech-language pathologists, audiologists, and hearing aid dispensers by the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board. The act authorizes the board to appoint an executive officer. Existing law repeals these provisions on January 1, 2014, and subjects the board to review by the Joint Committee on Boards, Commissions, and Consumer Protection.~~

~~This bill would extend the operation of these provisions until January 1, 2018, and provide that the repeal of these provisions subjects the board to review by the appropriate policy committees of the Legislature.~~

~~The Speech-Language Pathologists and Audiologists and Hearing Aid Dispensers Licensure Act also authorizes the board to refuse to issue, or issue subject to terms and conditions, a license on specified grounds, including, among others, securing a license by fraud or deceit.~~

~~This bill would additionally authorize the board to refuse to issue, or issue subject to terms and conditions, a license for a violation of a term or condition of a probationary order of a license issued by the board, as provided:~~

~~Existing law, the Occupational Therapy Practice Act, provides for the licensure and regulation of occupational therapists, as defined, by the California Board of Occupational Therapy. Existing law repeals those provisions on January 1, 2014, and subjects the board to review by the Joint Committee on Boards, Commissions, and Consumer Protection:~~

~~This bill would extend the operation of these provisions until January 1, 2018, and provide that the repeal of these provisions subjects the board to review by the appropriate policy committees of the Legislature.~~

~~Existing law, the Physical Therapy Practice Act, provides for the licensure and regulation of physical therapists by the Physical Therapy Board of California. The act authorizes the board to appoint an executive officer. Existing law repeals these provisions on January 1, 2014.~~

~~This bill would extend the operation of these provisions until January 1, 2018.~~

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

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

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

3 4170. (a) No prescriber shall dispense *dangerous* drugs or
 4 dangerous devices to patients in his or her office or place of
 5 practice unless all of the following conditions are met:

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

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

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

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

9 ~~(5) The prescriber does not use a dispensing device unless he~~
10 ~~or she personally owns the device and the contents of the device,~~
11 ~~and personally dispenses the dangerous drugs or dangerous devices~~
12 ~~to the patient packaged, labeled, and recorded in accordance with~~
13 ~~paragraph (4).~~

14 (5) *Unless the prescriber is employed by or under contract to*
15 *a clinic or group practice that is licensed by the board pursuant*
16 *to Section 4180, the prescriber is identified by the drug*
17 *manufacturer or wholesaler supplying the drugs as the recipient*
18 *of the drugs and identified by name and registration number as*
19 *the recipient in all invoices, bills of lading, state or federal order*
20 *forms, and other documentation. As the recipient of the drugs, the*
21 *prescriber is responsible for ensuring that the drugs are securely*
22 *and safely stored prior to dispensing and is responsible for*
23 *maintaining all required records regarding the receipt, storage,*
24 *and dispensing or other disposition of all drugs and devices.*

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

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

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

38 ~~(8)~~

39 (9) A certified nurse-midwife who functions pursuant to a
40 standardized procedure or protocol described in Section 2746.51,

1 a nurse practitioner who functions pursuant to a standardized
2 procedure described in Section 2836.1, or protocol, a physician
3 assistant who functions pursuant to Section 3502.1, *a registered*
4 *nurse who functions pursuant to Section 2725.1*, or a naturopathic
5 doctor who functions pursuant to Section 3640.5, may hand to a
6 patient of the supervising physician and surgeon a properly labeled
7 prescription drug prepackaged by a physician and surgeon, a
8 manufacturer as defined in this chapter, or a pharmacist. *Nothing*
9 *in this section shall preclude the use of an automated drug delivery*
10 *system described in Section 4186.*

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

20 (c) “Prescriber,” as used in this section, means *a person who is*
21 *licensed to prescribe and dispense dangerous drugs and devices,*
22 *including, but not limited to, a*~~person~~*, person who holds a*
23 *physician’s and surgeon’s certificate, a license to practice*
24 *optometry, a license to practice naturopathic medicine, a license*
25 *to practice dentistry, a license to practice veterinary medicine, or*
26 *a certificate to practice podiatry, and who is duly registered by the*
27 *Medical Board of California, the State Board of Optometry, the*
28 *Bureau of Naturopathic Medicine, the Dental Board of California,*
29 *the Veterinary Medical Board, or the Board of Osteopathic*
30 *Examiners of this state.*

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

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

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

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

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

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

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

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

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

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

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

35 4180. (a) (1) *Notwithstanding any provision of this chapter,*
36 *any of the following ~~clinics~~ entities may purchase drugs at*
37 *wholesale for administration or dispensing, under the direction of*
38 *a physician and surgeon, or other prescriber when permitted by*
39 *law, to patients registered for care at the clinic:*

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

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

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

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

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

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

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

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

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

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

33 4186. (a) ~~Automated~~ *An automated drug delivery systems*
34 *system, as defined in subdivision (h) (i), may be located in any*
35 *clinic or group practice licensed by the board pursuant to as*
36 *described in Section 4180.* ~~If~~

37 (b) (1) *If an automated drug delivery system is located in a*
38 *clinic, the clinic shall develop and implement written policies and*
39 *procedures to ensure safety, accuracy, accountability, security,*
40 *patient confidentiality, and maintenance of the quality, potency,*

1 and purity of drugs. All policies and procedures shall be maintained
2 at the location where the automated drug system is being used.

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

15 ~~(b)~~

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

24 ~~(e)~~

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

28 ~~(d)~~

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

39 ~~(e)~~

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

7 ~~(f) The~~

8 (g) A pharmacist operating the automated drug delivery system
9 shall be ~~located~~ *licensed* in California.

10 ~~(g)~~

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

13 ~~(h)~~

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

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

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

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

38 (4) *The clinic or group practice shall employ a process of filling*
39 *and stocking the system with drugs. The stocking or restocking of*
40 *a drug shall only be completed by a pharmacist, prescriber, or*

1 *personnel designated by the pharmacist or prescriber and all of*
2 *the following shall apply:*

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

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

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

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

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

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

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

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

37 (A) *Name of the patient.*

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

40 (C) *Quantity of drug dispensed.*

- 1 (D) Date and time of dispensing.
- 2 (E) Prescription number or other unique serial number assigned
- 3 to the transaction.
- 4 (F) Name of prescriber.
- 5 (G) Identity of the pharmacist who approved the prescription,
- 6 or of the prescriber.
- 7 (H) Identity of the person to whom the drug was released.
- 8 (9) Unless the prescriber provides consultation pursuant to
- 9 regulations adopted by the board pursuant to Section 4005, the
- 10 system shall provide patients with telephonic access to consultation
- 11 by a California-licensed pharmacist.
- 12 (10) In the case of dangerous drugs that require reconstitution,
- 13 the prescriber or his or her designee shall reconstitute the
- 14 medication for the patient.

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

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

28 SECTION 1. ~~Section 1000 of the Business and Professions~~
 29 ~~Code is amended to read:~~

30 ~~1000. The law governing practitioners of chiropractic is found~~
 31 ~~in an initiative act entitled “An act prescribing the terms upon~~
 32 ~~which licenses may be issued to practitioners of chiropractic,~~
 33 ~~creating the State Board of Chiropractic Examiners and declaring~~
 34 ~~its powers and duties, prescribing penalties for violation hereof,~~
 35 ~~and repealing all acts and parts of acts inconsistent herewith,”~~
 36 ~~adopted by the electors November 7, 1922. Notwithstanding any~~
 37 ~~other law, the powers and duties of the State Board of Chiropractic~~
 38 ~~Examiners, as set forth in this article and under the act creating~~
 39 ~~the board, shall be subject to review by the appropriate policy~~

Note: the remaining pages were deleted 96



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

August 9, 2013

The Honorable Norma J. Torres
California State Senate
State Capitol, Room 4053
Sacramento, CA 95814

RE: Senate Bill 306 – Oppose Unless Amended

Dear Senator Torres:

I regret to inform you that the Board of Pharmacy has taken a position of oppose unless amended on your Senate Bill 306. Senate Bill 306 would make significant changes to Pharmacy Law allowing physician-owned group practices to acquire a board-issued clinic license, and thus to allow these medical groups to purchase prescription drugs at wholesale, have a comingled drug supply, and provide for potential widespread drug dispensing in a clinic setting with no pharmacist involvement. The board believes that such a significant policy modification warrants meaningful analysis and thoughtful discussion, which requires more time than can be allowed this late in the legislative session. We thank you for your action yesterday to make SB 306 a two-year bill.

The board has been working with the sponsors of the bill for several months, and we have provided technical assistance related to existing pharmacy law. We understand the sponsor's concerns to address underserved patient populations and allow for point-of-care dispensing. However, the current version of SB 306 goes far beyond the sponsor's stated intentions by allowing unspecified groups of physicians to dispense unspecified amounts of dangerous drugs from a comingled drug stock.

As currently drafted, we believe that SB 306 would create a system that lacks appropriate oversight for the widespread distribution of dangerous drugs to patients. It allows "designees" to receive drugs from wholesalers and stock automated dispensing machines, and allows those individuals to label and dispense dangerous drugs to patients, without direct professional medical or pharmacist intervention. Also, while Senate Bill 306 fosters the use of automated dispensing systems, it eliminates existing patient protections that provide for visual pharmacist review of patient records and interaction with patients to provide counseling.

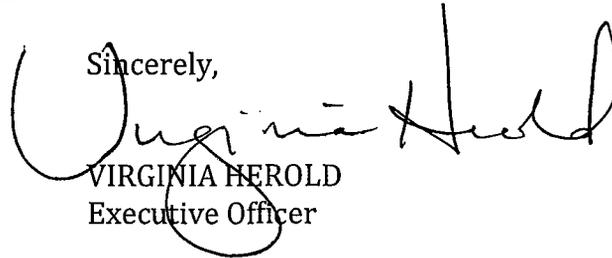
The Honorable Norma J. Torres

August 9, 2013

Page 2

We look forward to working with you and your staff to address the board's concerns related to drug distribution in clinic settings, the use of automated dispensing systems, and to ensuring California patients have access to necessary medications and receive appropriate care. To that end, the board remains committed to working with you and other stakeholders to achieve these goals.

Sincerely,

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

VIRGINIA HEROLD
Executive Officer

cc: Department of Consumer Affairs
Maureen O'Haren



Bill Number:	SB 306
Introduced	
Last Amend:	June 20, 2013
Author:	Senator Norma Torres
Topic:	Automated Drug Delivery Systems (Sponsor: Molina Healthcare of California, InstyMeds)
Position:	Oppose Unless Amended (7/30/13)

Current Bill Status: 2-Year Bill. Last location: ASM Business, Professions and Consumer Protection

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

BILL HISTORY:

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

Board staff has met with the sponsors of the bill a couple of times to provide technical assistance on Pharmacy Law provisions, and in June 2013 provided a possible draft that might allow a group to have a comingled drug supply (a model that was similar to that which is used for surgical clinics). The version amended on 6/20/13 does not reflect the board's draft.

The sponsors of SB 306 envision a model where new technologies (i.e., automated drug dispensing systems) can be used in medical offices for the purpose of increasing patient access to prescription medications for acute conditions, and to designate a “responsible prescriber” as one who is responsible for the stocking and re-stocking, policies and procedures and maintenance of the system. To do this, the proposal seeks to

- Amend Section 4170 to remove ownership limitations on drugs and devices to allow joint ownership by a physician group practice.
- Amend Sections 4170 and 4186 to allow the use of automated drug dispensing systems in physician offices, where a group practice maintains control of the system, and where designees of a physician can stock, re-stock and access the drugs.
- Allow a “physician group” to purchase and own a stock of dangerous drugs or dangerous devices, including controlled substances, from which multiple prescribers would dispense.
- Allow physician group practices to utilize an automated drug dispensing system.
- Provide for board licensure of a physician group practice that is not eligible for licensure under Section 1204 of the Health & Safety Code, or that meets the criteria for licensure as a nonprofit or free.

- Authorize a physician group practice to own an automated delivery device system from which multiple physicians would dispense dangerous drugs and devices – and where one physician would be responsible.

Discussion

Existing pharmacy provisions allow pharmacies and clinics to utilize automated dispensing drug systems within certain settings.

SB 306 would allow a pharmacist that is not located in California to supervise and be responsible for a drug supply within an automated drug delivery system in California.

SB 306 would allow individuals other than pharmacists to maintain and control inventories of dangerous drugs and dangerous devices, for dispensing to patients. The board has a vested interest in maintaining the scope of practice of a pharmacist, and not delegating those roles / functions to other individuals, especially “designees” of another.

Does the use of an “inventory of dangerous drugs and dangerous devices” from which multiple prescribers dispense drugs and devices to patients, within a group practice, conflict with the existing law that states a prescriber cannot keep a pharmacy for the retailing of dangerous drugs and dangerous devices? (§ 4170(c), § 4111)

While not inclusive, below are many concerns related to SB 306 as Amended 6/20/13:

SB 306

- Allows a prescriber’s “designee” to dispense a drug or device to a patient.
- Allows “designees” to receive drugs from wholesalers and stock automated dispensing machines.
- Allows “designees” to label prescription drug containers without direct professional medical or pharmacist intervention or check.
- Eliminates existing patient protections that provide for visual pharmacist review of patient records and interaction with patients to provide counseling.
- Has no limit on the number of prescribers in a “group” or their prescriber contracts that can use a single machine.
- Has no requirement that the prescriber be present in the facility in which the automated dispensing machine is utilized.
- Has no requirement that a patient be a patient of that facility to receive drugs from the automated dispensing machine.
- Has no requirement that the patient or the patient’s representative has to pick up the medication from the facility where the machine is located.
- Lacks specificity as to the consultation that occurs with a patient, whether the consult has to be in person, or if it is done in the same facility / location which the patient accesses the drugs.
- Leaves to any designated “unlicensed” person the task of labeling a prescription vial. This could place patients at risk, especially where more than one drug is dispensed for a patient (i.e., improperly labeled prescription vials).

Related to automated drug delivery systems,

- Should automated drug delivery systems be authorized outside of a pharmacy or clinic?
- Should the board individually license or register any automated drug delivery system in use, or proposed for use outside of a pharmacy or clinic setting.

- Should only a pharmacist be authorized to stock and re-stock the device? Should a physician, a “designee” of the physician, and/or a wholesaler be authorized to stock and restock an automated drug delivery system?
- Should a pharmacist that operates an automated drug delivery system be “located in” California?
- Would the provisions of the bill that specify the drugs are “owned” upon delivery, regardless of who pays for them, comply with e-Pedigree requirements?
- Is it necessary to retain existing provisions that provide for 2-way telephonic **and video** at an automated drug delivery system, even if a physician provides a consultation to a patient?
- Should an automated delivery system ensure the proper labeling of the drug before it is dispensed from the machine?
- Should the capacity of these machines be specified, in terms of drug formulary, quantity, and how many prescribers use it (and if they should be in the same location as the drug delivery system)?
- Should each automated drug delivery system be separately licensed or registered by the board?

EXISTING LAW:

Existing law (Article 3, Sections 4050-4068) specifies the scope of practice for a pharmacist and provides for the licensure of those individuals. Article 3 specifies the conduct restricted to a pharmacist, and the California Legislature has declared the practice of pharmacy to be 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, drug-related therapy, and communication for clinical and consultative purposes.

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

Existing law (§ 4037) defines a “Pharmacy” as a place that is licensed by the board and includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Further, existing law specifies entities and individuals to which a pharmacy may furnish dangerous drugs and dangerous devices.

Existing law (B&PC ⁱ§ 4111) specifies restrictions on prescriber ownership of a pharmacy. This statute precludes the board from issuing a license to conduct a pharmacy to

- Any person authorized to prescribe or write a prescription;
- A person or persons which whom a prescriber shares a community or other financial interest in the permit sought;
- Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership.

Existing law provides for the licensure of ⁱⁱwholesalers – to include those who act as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any dangerous drug or dangerous

device. Licensed wholesalers must have a designated representative-in-charge, subject to approval by the board, who is responsible for the wholesaler's compliance with state and federal laws related to wholesalers.

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

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

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

Existing law (§ 1204 of the Health and Safety Code) provides for the licensure of clinics by the California Department of Public Health. This section provides for the licensing of clinics operated by a tax-exempt, nonprofit corporation, as well as specialty clinics, as specified. Additional provisions of the Health and Safety Code ^{iv}(§ 1206) specify entities that are exempt from licensure as a clinic by the CDPH.

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

Existing law (§ 4186) specifies requirements for ^vautomated delivery device systems, which may be located in any Nonprofit or Free clinic that is licensed by the board. Only upon authorization by a pharmacist may drugs be removed from an automated drug delivery system, and they shall be provide to the patient by a health professional licensed pursuant to Division 2 of the Business and Professions Code. *Only a pharmacist shall restock an automated delivery device system.*

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

Section 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.

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

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

² Business and Professions Code § 4022.

THIS BILL WOULD:

In *general*, this bill would

- Provide for board licensure of a physician group practice that is not eligible for licensure under Section 1204 of the Health & Safety Code, or that meets the criteria for licensure as a nonprofit or free clinic, or a specialty clinic as specified in Sections 4180 and 4190 of the Business and Professions Code (i.e., those that are for profit, and/or owned by a physicians).
- Allow a “physician group” to own a stock of dangerous drugs or dangerous devices, including controlled substances, from which multiple prescribers would dispense.
- Authorize a physician group practice to own an automated delivery device system from which multiple physicians would dispense dangerous drugs and devices – and where one physician would be “responsible.”
- Strike existing law that requires a physician to personally own the dispensing device from which he or she dispenses dangerous drugs and dangerous devices that he or she personally owns.
- Allow for a comingled drug supply in a physician group practice, with no consulting pharmacist, in which individuals “designated” by a physician may access those drugs and devices.

Specifically, SB 306, as amended June 20, 2013, would

Amend **Section 4170 (Prescriber Dispensing)** to

- Remove the restriction that specifies that a nurse or physician attendant do not furnish the physician’s drugs or devices to a patient.
- Specify that a nurse or a prescriber’s “designee” be authorized to physically furnish a dangerous drug or device to a patient. (“Designees” are not defined, and there is no criterion for which the individual must abide.) This section specifically states that an automated drug delivery system may be utilized.
- Specify that the prescriber is responsible for the safe and secure storage of drugs and devices, *unless* they are employed by or under a contract to a clinic or group practice that is licensed by the board.
- Strike provisions that require a physician to personally own the dispensing device from which he or she dispenses dangerous drugs or devices that he or she personally owns.
- Add a requirement that when a physician dispenses a dangerous drug or device, that the physician provide the patient with an oral consultation regarding *issues that the physician deems necessary*, to ensure the safe and effective use of the drug or device; and that the consultation shall include all subjects that pharmacists are required to discuss during a patient consultation.
- Adds a registered nurse to those who may provide drugs or dangerous devices to patients in the physician group practice.
- Authorize a physician group practice to utilize an automated drug delivery system.
- Amend the definition of “prescriber” to be one who “is licensed to prescribe and dispense dangerous drugs and devices...”
- Allow a group practice to own an “inventory of dangerous drugs and devices” and dispense those drugs and devices, as specified.
- Requires the physician group practice to designate a “responsible prescriber” within the practice as one who is authorized to receive drugs and devices from a manufacturer or wholesaler, and who is responsible for all recordkeeping. (There is no requirement that the responsible prescriber actually be on site at the group practice.)
- Provide for specified recordkeeping and daily inventory of the drugs. (Note: there is no requirement that the “responsible prescriber” perform these functions.)

- Allows a prescriber who is employed by, or under contract to, the group practice to dispense drugs out of the inventory of drugs and devices of the group practice.
- Specify that the drugs are “owned” if they are “delivered to the possession of” the clinic or group practice, “regardless of the person or entity responsible for payment for the dangerous drug inventory.”
- Defines a group practice as more than one prescriber practicing under a single professional corporation or license, including a medical group or risk-bearing organization (as defined at Health and Safety Code Section 1340).

Amend Section 4180 (Clinics) to

- Specify that certain “entities” (not clinics”) be authorized to purchase drugs at wholesale for administration or dispensing.
- Add a “group practice” that uses an automated drug delivery system as an entity that is authorized to purchase drugs at wholesale for administration or dispensing.

Amend Section 4186 (Automated Drug Delivery Systems) to

- Defines “group practice” as more than one prescriber practicing under a single professional corporation or license, including a medical group or risk-bearing organization as defined in the Knox-Keene Health Care Service Plan Act of 1975.
- Require a group practice that uses an automated drug delivery system to develop and implement policies and procedures to ensure the safety, accuracy, accountability, security, patient-confidentiality, and maintenance of the drugs.
- Specify that all person who are authorized to stock, refill or retrieve the drug inventory from an automated drug delivery system comply with the policies and procedures developed.
- Allow a prescriber or “an individual” under a prescriber’s supervision to remove drugs from the automated drug delivery system.
- Specify that a prescriber or “prescriber’s designee” be authorized to stock an automated drug delivery system.
- Specify that the “responsible prescriber” be responsible for the review of the drugs contained in, and the operation and maintenance of the automated drug delivery system.
- Remove the 2-way audio and video requirement for the automated drug delivery system, where a prescriber provides consultation to a patient.
- Remove the requirement that a pharmacist operating the drug delivery system be “located” in California (rather, be “licensed” in California).
- Amend the definition of an automated drug delivery system to also include one that is used “to facilitate prescriber dispensing by a prescriber>”
- Specify requirements for the security, access, and procedures of an automated drug delivery system in a “clinic or office of the group practice.”
- Specifies that a wholesaler can stock or restock an automated drug delivery system, and that the wholesaler have a method of receiving and disposing of rejected, expired, or unused medications.
- Require that drug cartridges (used to stock or restock) be transported in tamper-evident packaging.
- Require bar code, electronic, weight, or radio frequency identification (or similar processes) to ensure the device is accurately stocked or restocked, and that alerts be provided to the responsible pharmacist or prescriber if a cartridge or container is not recorded in the automated system.
- Specify that the pharmacist or responsible prescriber is responsible if the device is incorrectly stocked or restocked by the “personnel designated” to load cartridges or containers.
- Provide for electronic recordkeeping and for the system to be able to comply with product recalls.
- Specify information that shall be maintained in the records of transactions>

- Provides for telephonic access to a California-licensed pharmacist, unless the prescriber provides consultation.
- Provides that the prescriber or his or her designee shall reconstitute medications that require reconstitution.
- Authorize the board to adopt regulations authorizing the use of an automated drug delivery system that delivers dispensed medications directly to a patient and that the regulations shall be based, in part, upon the board's assessment of the safety of the systems.

FISCAL IMPACT ON THE BOARD:

SB 306 would result in a fiscal impact to the board to implement a new license category for a "Physician Group Practice." For each new license category/type, there is an approximate cost of \$10,000 to modify the BreEZe licensing system.

Also, the board may need to promulgate regulations to clarify the requisite fee and licensure requirements for such a group practice. It is not known how many "physician group practices" would be eligible for such a license in California; the MBC does not have or maintain data on these group practices.

SUPPORT:

Molina Healthcare of California (Sponsor)

InstyMeds (Sponsor)

DRAFT LANGUAGE OFFERED TO MOLINA AS A STARTING POINT FOR DISCUSSION

Article 13.5 Medical Professional Corporations Licensed as Clinics

4187

(a) A professional corporation comprised of physicians may apply for a clinic license under this article provided at least 75 percent of the patients served by the corporation at the premises to be licensed as a clinic are provided medical services funded through a MediCal Managed Care Program.

(b) No entity shall be entitled to the benefits of this article until it has obtained a license from the board.

(c) A separate license shall be required for each clinic location. No clinic may be located in a home. A clinic shall notify the board of any change in the clinic's address on a form furnished by the board at least 30 days in advance of a move.

(d) The license shall be renewed annually.

(e) After a clinic is licensed by the board, any proposed change in ownership or beneficial interest in the licensed premises shall be reported to the board, on a form furnished by the board, at least 30 days before the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or before any transfer of ownership or beneficial interest, whichever occurs earlier.

(f) If at any time the percentage of MediCal Managed Care patients being served at the clinic decreases below 75 percent of all patients served at the clinic's premises, the corporation shall notify the board and shall have 90 days to resume serving MediCal Managed Care patients in a proportion that is at least 75 percent of all patients served. If the _____ percentage of MediCal Managed Care patients stays below 75 percent for more than three consecutive months, the medical professional corporation is no longer eligible for a clinic permit under this section, and the permit may be cancelled by the board.

4187.1

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

4187.2

(a) For the purposes of this article, "professional director" means a physician and surgeon acting in his or her capacity as medical director.

(b) Each clinic that makes an application for a license under Section 4187 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this article shall prohibit the consulting pharmacist from visiting more frequently than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(c) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate.

(d) A clinics licensed under this article shall notify the board within 30 days of any change in professional director on a form furnished by the board.

4187.3

(a) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

(b) Prior to the issuance of a clinic license authorized under Section 4187, the clinic shall comply with all applicable laws and regulations of the board relating to the drug distribution service to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the

laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

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

(d) The board shall have the authority to inspect a clinic that is licensed pursuant to this article at any time in order to determine whether the clinic is, or is not, operating in compliance with this article and all other provisions of the law

4187.4 No clinic dispensing drugs pursuant to this article shall be eligible for any professional dispensing fee that may be authorized under the Medi-Cal Program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

4187.5 (a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4187. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided only to a patient and only by a health professional licensed pursuant to this division.

(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.

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

(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.

(f) The pharmacist operating the automated drug delivery system shall be located in California.

(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Sections 4076 and 4076.5.

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

4187.6 The drug distribution service of a clinic shall be limited to the use of drugs for administration to the patients of the clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

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

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

ⁱ **4111. Restrictions on Prescriber Ownership**

(a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under 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 qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to either Section 4052.1 or 4052.2.

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

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

A prescriber must ensure that dangerous drugs dispensed by the prescriber meet specified conditions:

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

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

- "Free clinics" that are owned or leased and operated as a clinic or office by one or more licensed health care practitioners and used as an office for the practice of their profession.
- Community clinics, Tribal clinics, and clinics conducted, operated, or maintained as outpatient departments of hospitals.
- Clinics operated by a nonprofit corporation exempt from federal income taxation, as specified.

-
- A clinic that provides health care services to patients covered under Medicare, or through physicians and surgeons who, in the aggregate, devote no more than 30 percent of their professional time to direct patient care activities for which charges for professional services are paid.
 - A freestanding clinic, as specified

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

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

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

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

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

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

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

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



Bill Number:	SB 727
Introduced	2/22/13
Last Amend:	4/3/13
Author:	Senator Hannah-Beth Jackson
Topic:	Solid Waste: Drug Abuse Prevention and Safe Disposal Program
Position:	<i>None</i>

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.

At the April Board Meeting, the board encouraged staff to work with the author's office to ensure the board's concerns related to the safety of the drugs are addressed.

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.

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.

Support: *(as of April 2013)*

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

Today's Law As Amended 4/3/13



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: **yesno**

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.~~

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."¹
- 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.

¹ <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
Justin Malan, CA Product Stewardship Council, 916-448-1015, justin@econsult.biz
Andria Ventura, Clean Water Action, 415-369-9166, 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





Bill Number:	SB 493
Introduced	2/21/13
Last Amend:	9/6/13 (version prior to Enactment)
Author:	Senator Hernandez
Topic:	Pharmacy Practice
Position:	Support

Status: Approved by the Governor October 1, 2013 – Chapter 469, Statutes of 2013

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 establishes a “advanced practice pharmacist” recognition, allowing such pharmacists to perform physical assessments; order and interpret medication-related tests; refer patients to other providers; initiate, adjust, and discontinue medications under physician protocol or as part of an integrated system such as an ACO; and participate in the evaluation and management of health conditions in collaboration with other providers. The sponsor stated that SB 493 would align California law more consistently with federal programs such as the Department of Defense, the Veterans Administration, and Indian Health Service, where pharmacists have been practicing in this collaborative way for over 40 years.

The bill had double-jointing language to Senate Bill 205 as it related to amendments to Section 4076 of the Business and Professions Code. SB 205 was vetoed, so the changes made to Section 4076 (as reflected in SB 493) were enacted without further modification.

IMPLEMENTATION:

The board will be adding a new license category of “Advanced Practice Pharmacist,” is developing an application for this specialty permit, and is developing processes by which the license applications will be processed.

The board will need to promulgate regulations to set the fee for the issuance and renewal of the license.

Senate Bill No. 493

CHAPTER 469

An act to amend Sections 733, 4040, 4050, 4051, 4052, 4052.3, 4060, 4076, 4111, and 4174 of, and to add Sections 4016.5, 4052.6, 4052.8, 4052.9, 4210, and 4233 to, the Business and Professions Code, relating to pharmacy.

[Approved by Governor October 1, 2013. Filed with
Secretary of State October 1, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

SB 493, 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. The law specifies the functions pharmacists are authorized to perform, including to administer, orally or topically, drugs and biologicals pursuant to a prescriber's order, and to administer immunizations pursuant to a protocol with a prescriber. Pharmacists may also furnish emergency contraception drug therapy pursuant to standardized procedures if they have completed a training program. A violation of the Pharmacy Law is a crime.

This bill, instead, would authorize a pharmacist to administer drugs and biological products that have been ordered by a prescriber. The bill would authorize pharmacists to perform other functions, including, among other things, to furnish self-administered hormonal contraceptives, nicotine replacement products, and prescription medications not requiring a diagnosis that are recommended for international travelers, as specified. Additionally, the bill would authorize pharmacists to order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies, and to independently initiate and administer routine vaccinations, as specified. This bill also would establish board recognition for an advanced practice pharmacist, as defined, would specify the criteria for that recognition, and would specify additional functions that may be performed by an advanced practice pharmacist, including, among other things, performing patient assessments, and certain other functions, as specified. The bill would authorize the board, by regulation, to set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to these provisions, not to exceed \$300.

Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program.

The bill would make other conforming and technical changes.

This bill would incorporate additional changes in Section 4076 of the Business and Professions Code proposed by SB 205, that would become

operative only if SB 205 and this bill are both chaptered and become effective on or before January 1, 2014, and this bill is chaptered last.

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.

SECTION 1.

Section 733 of the Business and Professions Code is amended to read:

733.

(a) ~~No~~ A licentiate shall *not* obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other ~~provision of~~ law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (l) of Section 12940 of the Government Code.

(c) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022.

(d) ~~The provisions of this section shall apply to the drug therapy~~ *This section applies to emergency contraception drug therapy and self-administered hormonal contraceptives* described in Section 4052.3.

(e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third-party payer accepted by the licentiate or payment of any required copayment by the patient.

(f) The notice to consumers required by Section 4122 shall include a statement that describes patients' rights relative to the requirements of this section.

SEC. 2.

Section 4016.5 is added to the Business and Professions Code, to read:

4016.5.

"Advanced practice pharmacist" means a licensed pharmacist who has been recognized as an advanced practice pharmacist by the board, pursuant to Section 4210. A board-recognized advanced practice pharmacist is entitled to practice advanced practice pharmacy, as described in Section 4052.6, within or outside of a licensed pharmacy as authorized by this chapter.

SEC. 3.

Section 4040 of the Business and Professions Code is amended to read:

4040.

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to ~~either~~ Section ~~4052.1~~ 4052.1, 4052.2, or ~~4052.2~~ 4052.6.

(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to ~~either~~ Section ~~4052.1~~ 4052.1, 4052.2, or ~~4052.2~~ 4052.6 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any

additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

SEC. 4.

Section 4050 of the Business and Professions Code is amended to read:

4050.

(a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a ~~dynamic~~ *dynamic*, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

(c) The Legislature further declares that pharmacists are health care providers who have the authority to provide health care services.

SEC. 5.

Section 4051 of the Business and Professions Code is amended to read:

4051.

(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense ~~any a~~ dangerous drug or dangerous device, or to dispense or compound ~~any a~~ prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052.1, 4052.2, ~~4052.3~~, or ~~4052.3, 4052.6~~, and otherwise provide clinical ~~advice or information or patient consultation~~ *advice, services, information, or patient consultation, as set forth in this chapter*, if all of the following conditions are met:

(1) The clinical ~~advice or information~~ *advice, services, information*, or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

SEC. 6.

Section 4052 of the Business and Professions Code is amended to read:

4052.

(a) Notwithstanding any other ~~provision of~~ law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) ~~Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.~~ *Administer drugs and biological products that have been ordered by a prescriber.*

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

(6) Perform procedures or functions as authorized by Section 4052.6.

~~(6)~~ (7) Manufacture, measure, fit to the patient, or sell and repair dangerous ~~devices~~ *devices*, or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(8) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.

~~(7)~~ (9) Provide ~~consultation to patients and~~ professional information, including clinical or pharmacological information, advice, or consultation to other health care ~~professionals.~~ *professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.*

(10) Furnish the medications described in subparagraph (A) in accordance with subparagraph (B):

~~(8)~~ (A) ~~Furnish~~ (1) ~~-emergency-~~ *Emergency* contraception drug therapy *and self-administered hormonal contraceptives*, as authorized by Section 4052.3.

(2) Nicotine replacement products, as authorized by Section 4052.9.

(3) Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.

(B) The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.

~~(9)~~ (11) Administer immunizations pursuant to a protocol with a prescriber.

(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) ~~Nothing in this section shall~~ *This section does not* affect the *applicable* requirements of ~~existing~~ law relating to ~~maintaining the confidentiality of medical records~~. *either of the following:*

(1) Maintaining the confidentiality of medical records.

~~(d) (2) Nothing in this section shall affect the requirements of existing law relating to the~~ *The* licensing of a health care facility.

SEC. 7.

Section 4052.3 of the Business and Professions Code is amended to read:

4052.3.

(a) (1) Notwithstanding any other law, a pharmacist may furnish self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized procedure or protocol shall require that the patient use a self-screening tool that will identify patient risk factors for use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the federal Centers for Disease Control and Prevention, and that the pharmacist refer the patient to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics, upon furnishing a self-administered hormonal contraceptive pursuant to this subdivision, or if it is determined that use of a self-administered hormonal contraceptive is not recommended.

(2) The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically charged with the enforcement of this subdivision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

~~(a) (b) (1)~~ Notwithstanding any other ~~provision of~~ law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

~~(+)~~ (A) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

~~(2)~~ (B) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American ~~College Congress~~ of Obstetricians and Gynecologists, the California ~~Pharmacist~~ *Pharmacists* Association, and other appropriate entities. ~~Both the~~ *The* board and the Medical Board of California ~~shall have authority~~ *are both authorized* to ensure compliance with this clause, and ~~both boards are~~ *each board is* specifically charged with the enforcement of this provision with respect to ~~their respective licensees~~. ~~Nothing in this clause shall be construed to~~ *its*

respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

~~(b)~~ (2) Prior to performing a procedure authorized under this ~~paragraph, subdivision~~, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

~~(c)~~ (3) A pharmacist, pharmacist's employer, or pharmacist's agent ~~may shall~~ not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this ~~paragraph, subdivision~~, but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this ~~subparagraph, paragraph~~, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. ~~The provisions of this subparagraph shall cease to be operative- This paragraph shall become inoperative~~ for dedicated emergency contraception drugs ~~when if~~ these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

~~(d)~~ (4) A pharmacist ~~may shall~~ not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this ~~section, subdivision~~.

~~(e)~~ (c) For each emergency contraception drug therapy *or self-administered hormonal contraception* initiated pursuant to this section, the pharmacist shall provide the recipient of the ~~emergency contraception drugs- drug~~ with a standardized factsheet that includes, but is not limited to, the indications *and contraindications* for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Public Health, the American ~~College Congress~~ of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. ~~The provisions of this section do~~ *This section does* not preclude the use of existing publications developed by nationally recognized medical organizations.

SEC. 8.

Section 4052.6 is added to the Business and Professions Code, to read:

4052.6.

(a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:

(1) Perform patient assessments.

(2) Order and interpret drug therapy-related tests.

(3) Refer patients to other health care providers.

(4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.

(5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.

(b) A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, as permitted by that prescriber. A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider.

(c) This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.

(d) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.

(e) A pharmacist who orders and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

SEC. 9.

Section 4052.8 is added to the Business and Professions Code, to read:

4052.8.

(a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older.

(b) In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:

(1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

(2) Be certified in basic life support.

(3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.

(c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.

SEC. 10.

Section 4052.9 is added to the Business and Professions Code, to read:

4052.9.

(a) A pharmacist may furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with standardized procedures and protocols developed and approved by both the board and the Medical Board of California in consultation with other appropriate entities and provide smoking cessation services if all of the following conditions are met:

(1) The pharmacist maintains records of all prescription drugs and devices furnished for a period of at least three years for purposes of notifying other health care providers and monitoring the patient.

(2) The pharmacist notifies the patient's primary care provider of any drugs or devices furnished to the patient, or enters the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist provides the patient with a written record of the drugs or devices furnished and advises the patient to consult a physician of the patient's choice.

(3) The pharmacist is certified in smoking cessation therapy by an organization recognized by the board.

(4) The pharmacist completes one hour of continuing education focused on smoking cessation therapy biennially.

(b) The board and the Medical Board of California are both authorized to ensure compliance with this section, and each board is specifically charged with the enforcement of this section with respect to their respective licensees. Nothing in this section shall be construed to expand the authority of a pharmacist to prescribe any other prescription medication.

SEC. 11.

Section 4060 of the Business and Professions Code is amended to read:

4060.

~~No~~ A person shall *not* possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to ~~either~~ Section ~~4052.1~~ ~~4052.1~~, ~~4052.2~~, or ~~4052.2~~ ~~4052.6~~. This section ~~shall~~ *does* not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, ~~when if~~ in stock in containers correctly labeled with the name and address of the supplier or producer.

~~Nothing in this section authorizes~~ *This section does not authorize* a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

SEC. 12.

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

4076.

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

(1) Except ~~where~~ *when* 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~~ *4052.1*, *4052.2*, or ~~4052.2~~ *4052.6* 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~~ *4052.1*, *4052.2*, or ~~4052.2~~ *4052.6*.

(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 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~~ 4052.1, 4052.2, or ~~4052.2~~ 4052.6.

(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. 12.5.

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

4076.

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

(1) Except ~~where~~ *when* 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~~ 4052.1, 4052.2, or ~~4052.2~~ 4052.6 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~~ 4052.1, 4052.2, or ~~4052.2~~ 4052.6.

(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~~ 4052.1, 4052.2, or ~~4052.2~~ 4052.6.

(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.

(e) This section shall remain in effect only until January 1, 2016, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2016, deletes or extends that date.

SEC. 12.7.

Section 4076 is added to the Business and Professions Code, to read:

4076.

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

(1) Except when 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 Section 4052.1, 4052.2, or 4052.6 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 Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

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

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

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

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

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

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

(i) Prescriptions dispensed by a veterinarian.

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

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

(B) This paragraph applies to outpatient pharmacies only.

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

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

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

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

(d) If a pharmacist dispenses a dangerous drug or device in a 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 Section 4052.1, 4052.2, or 4052.6.

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

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

SEC. 13.

Section 4111 of the Business and Professions Code is amended to read:

4111.

(a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under 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 qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to ~~either~~ Section ~~4052.1~~ 4052.1, 4052.2, or ~~4052.2~~ 4052.6.

SEC. 14.

Section 4174 of the Business and Professions Code is amended to read:

4174.

Notwithstanding any other ~~provision of~~ law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, 4052.3, or ~~4052.3~~ 4052.6.

SEC. 15.

Section 4210 is added to the Business and Professions Code, to read:

4210.

(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:

(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.

(2) Satisfy any two of the following criteria:

(A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

(3) File an application with the board for recognition as an advanced practice pharmacist.

(4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.

(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.

(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars (\$300).

SEC. 16.

Section 4233 is added to the Business and Professions Code, to read:

4233.

A pharmacist who is recognized as an advanced practice pharmacist shall complete 10 hours of continuing education each renewal cycle in addition to the requirements of Section 4231. The subject matter shall be in one or more areas of practice relevant to the pharmacist's clinical practice.

SEC. 17.

Sections 12.5 and 12.7 of this bill incorporate amendments to Section 4076 of the Business and Professions Code proposed by both this bill and Senate Bill 205. They shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2014, (2) each bill amends Section 4076 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 205, in which case Section 12 of this bill shall not become operative.



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

September 20, 2013

The Honorable Edmund G. Brown Jr.
Governor
State of California
State Capitol
Sacramento, CA 95814

RE: Senate Bill 493 - Support

Dear Governor Brown:

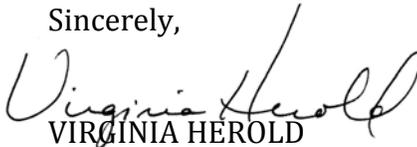
The Board of Pharmacy supports Senate Bill 493 (Hernandez) and respectfully requests your signature on this important legislation that will provide for greater health care access to Californians.

As Enrolled, Senate Bill 493 would enable a pharmacist with specified education and training to attain an Advanced Practice Pharmacist designation from the Board of Pharmacy. Such a permit will allow a pharmacist to perform patient assessments, order and interpret tests for the purpose of monitoring and managing medication therapies, and to independently initiate and administer routine vaccinations, among other things. Senate Bill 493 will also allow these pharmacists to provide consultation, training and education to patients about drug therapy, disease management, and disease prevention –health care services that pharmacists are uniquely educated and skilled to provide. Under existing law, pharmacists currently provide many of these health care services to patients in specified settings.

As California implements the Affordable Care Act, Senate Bill 493 will provide for greater health care access to millions of Californians. Moreover, Senate Bill 493 will align California law more consistently with federal programs such as the Department of Defense, the Veterans Administration and Indian Health Service, where pharmacists have been practicing collaboratively for more than 40 years.

Thank you for your thoughtful consideration of Senate Bill 493, on which the board respectfully requests your signature. Please don't hesitate to contact me at (916) 574-7911 if you have any questions.

Sincerely,


VIRGINIA HEROLD
Executive Officer

cc: Senator Ed Hernandez
Department of Consumer Affairs

California Law Changes for 2014

Provided below are code sections that were added or amended during the 2013 Legislative Session. Unless otherwise indicated, all of the provisions go into effect on January 1, 2014.

(~~Strikeout~~ indicates text that has been removed. Underlined text indicates new or added text.)

Section 114.5 is added to the Business and Professions Code, to read:

Commencing January 1, 2015, each board shall inquire in every application for licensure if the individual applying for licensure is serving in, or has previously served in, the military.

Section 144.5 is added to the Business and Professions Code, to read:

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

Section 208 is added to the Business and Professions Code, to read:

(a) Beginning April 1, 2014, a CURES fee of six dollars (\$6) shall be assessed annually on each of the licensees specified in subdivision (b) to pay the reasonable costs associated with operating and maintaining CURES for the purpose of regulating those licensees. The fee assessed pursuant to this subdivision shall be billed and collected by the regulating agency of each licensee at the time of the licensee's license renewal. If the reasonable regulatory cost of operating and maintaining CURES is less than six dollars (\$6) per licensee, the Department of Consumer Affairs may, by regulation, reduce the fee established by this section to the reasonable regulatory cost.

(b) (1) Licensees authorized pursuant to Section 11150 of the Health and Safety Code to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances or pharmacists licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2.

(2) Wholesalers and nonresident wholesalers of dangerous drugs licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2.

(3) Nongovernmental clinics licensed pursuant to Article 13 (commencing with Section 4180) and Article 14 (commencing with Section 4190) of Chapter 9 of Division 2.

(4) Nongovernmental pharmacies licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2.

(c) The funds collected pursuant to subdivision (a) shall be deposited in the CURES Fund, which is hereby created within the State Treasury. Moneys in the CURES Fund shall, upon appropriation by the Legislature, be available to the Department of Consumer Affairs to reimburse the Department of Justice for costs to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

(d) The Department of Consumer Affairs shall contract with the Department of Justice on behalf of 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 Board of the Medical Board of California, the Osteopathic Medical Board of California, the Naturopathic Medicine Committee of the Osteopathic Medical Board, the State Board of Optometry, and the California Board of Podiatric Medicine to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

Section 209 is added to the Business and Professions Code, to read:

The Department of Justice, in conjunction with the Department of Consumer Affairs and the boards and committees identified in subdivision (d) of Section 208, shall do all of the following:

(a) Identify and implement a streamlined application and approval process to provide access to the CURES Prescription Drug Monitoring Program (PDMP) database for licensed health care practitioners eligible to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances and for pharmacists. Every reasonable effort shall be made to implement a streamlined application and approval process that a licensed health care practitioner or pharmacist can complete at the time that he or she is applying for licensure or renewing his or her license.

(b) Identify necessary procedures to enable licensed health care practitioners and pharmacists with access to the CURES PDMP to delegate their authority to order reports from the CURES PDMP.

(c) Develop a procedure to enable health care practitioners who do not have a federal Drug Enforcement Administration (DEA) number to opt out of applying for access to the CURES PDMP.

Section 733 of the Business and Professions Code is amended to read:

(a) ~~No~~ A licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other ~~provision of~~ law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (l) of Section 12940 of the Government Code.

(c) For the purposes of this section, “prescription drug or device” has the same meaning as the definition in Section 4022.

(d) ~~The provisions of this section shall apply to the drug therapy~~ This section applies to emergency contraception drug therapy and self-administered hormonal contraceptives described in Section 4052.3.

(e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third-party payer accepted by the licentiate or payment of any required copayment by the patient.

(f) The notice to consumers required by Section 4122 shall include a statement that describes patients’ rights relative to the requirements of this section.

Section 4016.5 is added to the Business and Professions Code, to read:

“Advanced practice pharmacist” means a licensed pharmacist who has been recognized as an advanced practice pharmacist by the board, pursuant to Section 4210. A board-recognized advanced practice pharmacist is entitled to practice advanced practice pharmacy, as described in Section 4052.6, within or outside of a licensed pharmacy as authorized by this chapter.

Section 4040 of the Business and Professions Code is amended to read:

(a) “Prescription” means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order

pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to ~~either Section 4052.1, 4052.2, or 4052.2, 4052.6.~~

(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to ~~either Section 4052.1, 4052.2, or 4052.2, 4052.6~~ by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

Section 4050 of the Business and Professions Code is amended to read:

(a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a ~~dynamic~~ dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and

consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

(c) The Legislature further declares that pharmacists are health care providers who have the authority to provide health care services.

Section 4051 of the Business and Professions Code is amended to read:

(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense ~~any a~~ dangerous drug or dangerous device, or to dispense or compound ~~any a~~ prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052.1, 4052.2, ~~4052.3~~, or ~~4052.3~~, 4052.6, and otherwise provide clinical ~~advice or information or patient consultation~~ advice, services, information, or patient consultation, as set forth in this chapter, if all of the following conditions are met:

(1) The clinical ~~advice or information~~ advice, services, information, or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

Section 4052 of the Business and Professions Code is amended to read:

(a) Notwithstanding any other ~~provision of~~ law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) ~~Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.~~ Administer drugs and biological products that have been ordered by a prescriber.

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or

services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

(6) Perform procedures or functions as authorized by Section 4052.6.

~~(6)~~ (7) Manufacture, measure, fit to the patient, or sell and repair dangerous devices devices, or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(8) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.

~~(7)~~ (9) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals, professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.

(10) Furnish the medications described in subparagraph (A) in accordance with subparagraph (B):

~~(8)~~ (A) Furnish (1) emergency Emergency contraception drug therapy and self-administered hormonal contraceptives, as authorized by Section 4052.3.

(2) Nicotine replacement products, as authorized by Section 4052.9.

(3) Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.

(B) The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.

~~(9)~~ (11) Administer immunizations pursuant to a protocol with a prescriber.

(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

~~(c) Nothing in this section shall~~ This section does not affect the applicable requirements of existing law relating to maintaining the confidentiality of medical records, either of the following:

(1) Maintaining the confidentiality of medical records.

~~(d) (2) Nothing in this section shall affect the requirements of existing law relating to the~~ The licensing of a health care facility.

Section 4052.3 of the Business and Professions Code is amended to read:

(a) (1) Notwithstanding any other law, a pharmacist may furnish self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized procedure or protocol shall require that the patient use a self-screening tool that will identify patient risk factors for use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the federal Centers for Disease Control and Prevention, and that the pharmacist refer the patient to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics, upon furnishing a self-administered hormonal contraceptive pursuant to this subdivision, or if it is determined that use of a self-administered hormonal contraceptive is not recommended.

(2) The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically charged with the enforcement of this subdivision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

~~(a) (b) (1)~~ (1) Notwithstanding any other provision of law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

~~(1) (A)~~ (A) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

~~(2) (B)~~ (B) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College Congress of Obstetricians and Gynecologists, the California Pharmacist Pharmacists Association, and other appropriate entities. Both the ~~The~~ board and the Medical Board of California shall have authority ~~are both authorized~~ to ensure compliance with this clause, and both boards are each board is ~~specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to~~ its respective

licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

~~(b)~~ (2) Prior to performing a procedure authorized under this ~~paragraph, subdivision,~~ a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

~~(c)~~ (3) A pharmacist, pharmacist's employer, or pharmacist's agent ~~may shall~~ not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this ~~paragraph, subdivision,~~ but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this ~~subparagraph, paragraph,~~ total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. ~~The provisions of this subparagraph shall cease to be operative. This paragraph shall become inoperative~~ for dedicated emergency contraception drugs ~~when~~ if these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

~~(d)~~ (4) A pharmacist ~~may shall~~ not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this ~~section, subdivision.~~

~~(e)~~ (c) For each emergency contraception drug therapy or self-administered hormonal contraception initiated pursuant to this section, the pharmacist shall provide the recipient of the ~~emergency contraception drugs- drug~~ with a standardized factsheet that includes, but is not limited to, the indications and contraindications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Public Health, the American College Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. ~~The provisions of this section do~~ This section does not preclude the use of existing publications developed by nationally recognized medical organizations.

Section 4052.6 is added to the Business and Professions Code, to read:

(a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:

(1) Perform patient assessments.

(2) Order and interpret drug therapy-related tests.

(3) Refer patients to other health care providers.

(4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.

(5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.

(b) A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, as permitted by that prescriber. A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider.

(c) This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.

(d) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.

(e) A pharmacist who orders and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

Section 4052.8 is added to the Business and Professions Code, to read:

(a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older.

(b) In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:

(1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

(2) Be certified in basic life support.

(3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.

(c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.

Section 4052.9 is added to the Business and Professions Code, to read:

(a) A pharmacist may furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with standardized procedures and protocols developed and approved by both the board and the Medical Board of California in consultation with other appropriate entities and provide smoking cessation services if all of the following conditions are met:

(1) The pharmacist maintains records of all prescription drugs and devices furnished for a period of at least three years for purposes of notifying other health care providers and monitoring the patient.

(2) The pharmacist notifies the patient's primary care provider of any drugs or devices furnished to the patient or enters the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist provides the patient with a written record of the drugs or devices furnished and advises the patient to consult a physician of the patient's choice.

(3) The pharmacist is certified in smoking cessation therapy by an organization recognized by the board.

(4) The pharmacist completes one hour of continuing education focused on smoking cessation therapy biennially.

(b) The board and the Medical Board of California are both authorized to ensure compliance with this section, and each board is specifically charged with the enforcement

of this section with respect to their respective licensees. Nothing in this section shall be construed to expand the authority of a pharmacist to prescribe any other prescription medication.

Section 4060 of the Business and Professions Code is amended to read:

~~No~~ A person shall not possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to ~~either~~ Section ~~4052.1- 4052.1, 4052.2, or 4052.2. 4052.6.~~ This section ~~shall~~ does not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, ~~when~~ if in stock in containers correctly labeled with the name and address of the supplier or producer. ~~Nothing in this section authorizes~~ This section does not authorize a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

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

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

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

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

(b) In addition to the requirement described in subdivision (a), on and after July 1, 2014, if a pharmacist exercising his or her professional judgment determines that a drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a

written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label required by this subdivision may be printed on an auxiliary label that is affixed to the prescription container.

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

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

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

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

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

(1) Except ~~where~~ when 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~~ 4052.1, 4052.2, or 4052.2 4052.6 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~~ 4052.1, 4052.2, or ~~4052.2~~ 4052.6.

(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 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~~ 4052.1, 4052.2, or ~~4052.2~~ 4052.6.

(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.

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

(Repealed January 1, 2016)

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

(1) Except ~~where~~ when 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~~ 4052.1, 4052.2, or ~~4052.2~~ 4052.6 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~~ 4052.1, 4052.2, or ~~4052.2~~ 4052.6.

(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~~ 4052.1, 4052.2, or 4052.2, 4052.6.

(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.

(e) This section shall remain in effect only until January 1, 2016, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2016, deletes or extends that date.

Section 4111 of the Business and Professions Code is amended to read:

(a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under 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 qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to ~~either~~ Section 4052.1- 4052.1, 4052.2, or 4052.2: 4052.6.

Section 4119.3 is added to the Business and Professions Code, to read:

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

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

Section 4174 of the Business and Professions Code is amended to read:

Notwithstanding any other ~~provision of~~ law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, 4052.3, or ~~4052.3~~ 4052.6.

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

(Becomes inoperative on July 1, 2014)

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

(b) The board shall adopt emergency regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to initially implement the provisions of this article that become operative on July 1, 2014. The initial adoption, amendment, or repeal of a regulation authorized by this section is deemed to address an emergency for purposes of Sections 11346.1 and 11346.6 of the Government Code, and the board is hereby exempted for that purpose from the requirements of subdivision (b) of Section 11346.1 of the Government Code. After the initial adoption, amendment, or repeal of an emergency regulation pursuant to this section, the board may request approval from the Office of Administrative Law to readopt the regulation as an emergency regulation pursuant to Section 11346.1 of the Government Code.

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

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

(Becomes operative on July 1, 2014)

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

(b) The board shall adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the

Government Code) to establish policies, guidelines, and procedures to implement this article.

(c) The board shall review any formal revision to General Chapter 797 of the United States Pharmacopeia and The National Formulary (USP–NF), relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official, to determine whether amendments are necessary for the regulations adopted by the board pursuant to subdivision (b).

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

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

(Becomes inoperative on July 1, 2014)

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

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

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

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

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

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

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

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

Section 4127.1 is added to the Business and Professions Code, to read:

(Becomes operative July 1, 2014)

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

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

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

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

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

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

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

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

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

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

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

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

(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

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

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

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

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

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

(Becomes inoperative on July 1, 2014)

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

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

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

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

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

(d) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident pharmacies. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:

(1) A detailed description of board activities related to the inspection and licensure of nonresident pharmacies.

(2) The status of proposed changes to federal law that are under serious consideration and that would govern compounding pharmacies, including legislation pending before the United States Congress, administrative rules, regulations, or orders under consideration by

the federal Food and Drug Administration or other appropriate federal agency, and cases pending before the courts.

(3) If applicable, recommended modifications to the board's statutory duties related to nonresident pharmacies as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.

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

Section 4127.2 is added to the Business and Professions Code, to read:

(Becomes operative on July 1, 2014)

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

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

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

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

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

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

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

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

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

- (1) Provide to the board a copy of any disciplinary or other action taken by its state of residence or another state within 10 days of the action.
- (2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.
- (3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.
- (4) Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.
- (f) Adverse effects reported or potentially attributable to a nonresident pharmacy's sterile compounded drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.
- (g) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident pharmacies. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:
- (1) A detailed description of board activities related to the inspection and licensure of nonresident pharmacies.
- (2) Whether fee revenue collected pursuant to subdivision (v) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of this section provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident pharmacies.
- (3) The status of proposed changes to federal law that are under serious consideration and that would govern compounding pharmacies, including legislation pending before the United States Congress, administrative rules, regulations, or orders under consideration by the federal Food and Drug Administration or other appropriate federal agency, and cases pending before the courts.
- (4) If applicable, recommended modifications to the board's statutory duties related to nonresident pharmacies as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.
- (h) The requirement for submitting a report imposed under subdivision (g) is inoperative on January 1, 2022, pursuant to Section 10231.5 of the Government Code.
- (i) This section shall become operative on July 1, 2014.

Section 4210 is added to the Business and Professions Code, to read:

(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:

(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.

(2) Satisfy any two of the following criteria:

(A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

(3) File an application with the board for recognition as an advanced practice pharmacist.

(4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.

(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.

(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars (\$300).

Section 4233 is added to the Business and Professions Code, to read:

A pharmacist who is recognized as an advanced practice pharmacist shall complete 10 hours of continuing education each renewal cycle in addition to the requirements of Section 4231. The subject matter shall be in one or more areas of practice relevant to the pharmacist's clinical practice.

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

(Becomes inoperative on July 1, 2014, and as of January 1, 2015 is repealed.)

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

- (a) The fee for a nongovernmental pharmacy license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).
- (b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).
- (c) The fee for the pharmacist application and examination shall be two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).
- (d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.
- (e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).
- (f) The fee for a nongovernmental wholesaler license and annual renewal shall be six hundred dollars (\$600), and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).
- (g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars (\$125) and may be increased to one hundred sixty-five dollars (\$165).
- (h) (1) The fee for application, investigation, and issuance of license as a designated representative pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).
- (2) The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).
- (i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 4400 is added to the Business and Professions Code, to read:

(Becomes operative on July 1, 2014)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 4127.9 is added to the Business and Professions Code, to read:

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

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

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

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

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

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

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

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

(a) The board may report any violation by a nonresident pharmacy of the laws and regulations of this state, any other state, or of the United States, including, but not limited

to, any violation of this chapter or of the regulations established by the board, to any appropriate state or federal regulatory or licensing agency, including, but not limited to, the regulatory or licensing agency of the state in which the nonresident pharmacy is a resident or in which the pharmacist is licensed.

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

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

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

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

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

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

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

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

(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical

analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds ~~from the 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,~~ in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to ~~prescribe~~ prescribe, order, administer, furnish, or dispense these controlled substances.

(b) ~~The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The department~~ Department of Justice may seek and use grant funds to pay the costs incurred ~~from the reporting of controlled substance prescriptions to CURES. Funds 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~~ by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

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

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

(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~~ pharmacy, clinic, or

other dispenser shall report the following information to the Department of Justice on a weekly basis and as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, ~~and the~~ and, if available, 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;~~ licensure, license number, national provider identifier (NPI) number, if applicable, 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, NPI number, and federal controlled substance registration number.

(4) ~~NDC (National Drug Code)~~ National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ~~ICD-9 (diagnosis code),~~ International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005. The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

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

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

(a) (1) ~~(A) (i)~~ A licensed health care practitioner ~~eligible to prescribe~~ authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances ~~or a pharmacist may provide a notarized~~ pursuant to Section 11150 shall, before January 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information ~~stored on the Internet~~ online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, ~~and~~ and, upon approval, the department may shall release to that practitioner ~~or pharmacist,~~ 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).

(ii) A pharmacist shall, before January 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

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

~~(2) To allow sufficient time for licensed health care practitioners eligible to prescribe A health care practitioner authorized to prescribe, order, administer, furnish, or dispense 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 pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES. has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.~~

(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) 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.

(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.

Section 11165.5 is added to the Health and Safety Code, to read:

(a) The Department of Justice may seek voluntarily contributed private funds from insurers, health care service plans, qualified manufacturers, and other donors for the purpose of supporting CURES. Insurers, health care service plans, qualified manufacturers, and other donors may contribute by submitting their payment to the Controller for deposit into the CURES Fund established pursuant to subdivision (c) of Section 208 of the Business and Professions Code. The department shall make information about the amount and the source of all private funds it receives for support of CURES available to the public. Contributions to the CURES Fund pursuant to this subdivision shall be nondeductible for state tax purposes.

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

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

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

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

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