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

LEGISLATION AND REGULATION COMMITTEE CHAIR REPORT

Greg Lippe, CPA, Chair, Public Member
Ramón Castellblanch, PhD, Public Member
Victor Law, RPh, Professional Member
Albert Wong, PharmD, Professional Member

The Legislation and Regulation Committee has not met since April 23, 2014.

Part 1: Legislation Report

a. Status of Board Sponsored Provisions — Attachment 1

1. SB 960 (Morrell) Pharmacy Licenses: Letters of Admonishment

Version: Amended June 19, 2014
Location: ASM Floor (on Consent as of 7/21/14)
Status: Passed from ASM Appropriations to the Floor on 7/2/14
Position: SUPPORT

Senate Bill 960 contains the board's sponsored provisions to authorize the board to issue a Letter of Admonishment (LOA) to an applicant.

The board's provisions originally appeared in AB 2131 (Morrell), and sought to enact a separate statutory provision for a letter of reprimand for applicants (modeled after a Medical Board of California provision). Since that time, the bill was amended modify existing Section 4315 BPC to authorize the board to issue a Letter of Admonishment (currently authorized for licensees) also to an applicant, which would describe the nature and facts of an individual's violations. The section affords the individual the right to contest the LOA and specifies the process and timeframe for contesting the LOA, and would require that the LOA be purged three years from the date of issuance. The board voted to Support SB 960 at the April 2014 board meeting.

On May 28, 2014 the bill was amended to specify that a LOA shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure. The most recent amendments (June 19) are technical and nonsubstantive. A copy of the June 19, 2014 amendment, and the board's support letters (April 24, June 13) are provided in Attachment 1.

Staff Recommendation: By the action of the board president and chair of the committee, the board took a Support position following the May 28 amendment. Staff requests the board ratify the Support position taken on June 13, 2014.

2. **SB 1466 (Committee on Business, Professions, and Economic Development) Omnibus Provision Relating to Requirements for a Designated Representative**

Version: July 1, 2014
Location: ASM Appropriations
Status: (No hearing date as of 7/18/14)
Position: Support

Senate Bill 1466, section 13, contains a board-sponsored provision to amend Section 4053 Business and Professions Code (BPC) to specify that a designated representative shall be at least 18 years of age.

Section 12 of the bill contains an amendment to section 4021.5 BPC to modify the definition of a "correctional pharmacy." Currently, the definition applies to "state" correctional facilities, and the bill removes "state." To implement the provision, the board will need to seek funding to modify the board's licensing system, as correctional facilities currently licensed are fee exempt. Due to the length of the bill, only portions of the Legislative Digest and those sections relevant to Pharmacy Law (sections 12 and 13) are provided in Attachment 1, along with a copy of the board's (April 24) support letter.

3. **SB 600 (Lieu) Repeal of Pedigree Requirements**

Version: June 30, 2014
Location: ASM Appropriations
Status: (No hearing date as of 7/18/14)
Position: Support

Senate Bill 600 contains the board's sponsored provisions to conform California law to federal law (the federal Drug Quality and Security Act). The board's provisions were amended into SB 600 on June 10. At that time, the bill also contained provisions to declare that drugs obtained outside of the licensed supply chain (regulated by the FDA) were deemed to be misbranded, and provided for related penalties; these provisions have since been stricken. The current version of the bill (June 30) is attached as is the ASM Committee on Business Professions and Consumer Protection analysis.

Staff Recommendation: Support Senate Bill 600

4. **AB 2605 (Bonilla) Requirements for Third Party Logistics Providers**

Version: June 17, 2014
Location: SEN Appropriations
Status: Hearing August 4, 2014
Position: Support

The federal legislation enacted to establish standards for drug chain security contained provisions to establish national standards for wholesalers and to establish specialized regulation of third party logistics providers (3PLs). The new federal law requires the FDA to establish regulation provisions regarding national standards for wholesalers and 3PLs over the next one to two years. If a state does not regulate wholesalers and 3PLs, the national registration will be required. The law specifically prohibits the regulation of 3PLs as wholesalers (which is exactly what California law currently does).

To ensure the continued oversight of these active participants in the drug supply chain, the board voted to secure legislation to implement a separate license category for third-party logistics providers. On April 23, 20414, Assembly member Bonilla, Chair of the Assembly Committee on Business Professions and Consumer Protection, amended her Assembly Bill 2605 to carry the board's provisions. The bill has been amended twice since that time and board staff continues to work with the author's office and stakeholders to refine the provisions. As reflected in the current language, a third-party logistics provider will have a "facility manager" in lieu of a designated representative, as the individual responsible for a facility's compliance with applicable laws. The board will incur costs to add this new category of licensure to the BreEZe licensing system.

The board president and chair of the committee established a Support position on the bill following the publication of the board's provisions. A copy of the June 17 version of the bill is provided in Attachment 1, along with a copy of the board's April 24, 2014 letter, and a copy of the SEN Committee on Business, Professions & Economic Development analysis of the bill.

Staff Recommendation: Ratify the Support position taken April 24, 2014, and Support the current version AB 2605.

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

Attachment 2

1. AB 186 (Maienschein) Professions and vocations: military spouses: temporary licenses

Version: June 25, 2014
Location: SEN Floor
Status: Third reading (as of 7/1/14)
Position: None

AB 186 would require DCA licensing authorities, including the Board of Pharmacy, to issue a 12-month temporary license to an applicant who is a military spouse or domestic partner while the license is being processed so long as specified requirements are met.

To implement the provisions, the board will require additional staff resources to promulgate regulations and to expedite the processing the applications, the issuance of the temporary permits and to manage the issuance of the permanent licenses –

workload the board cannot absorb. Because the bill requires additional license types (not supported by the board's systems) the bill will incur costs to add these license categories to the new licensing system (BreEZe). A copy of the June 25 version of the bill and the author's Fact Sheet are provided in Attachment 2. The board does not have a position on this bill.

2. AB 1535 (Bloom) Pharmacists: naloxone hydrochloride

Version: June 24, 2014
Location: SEN Floor
Status: Third reading (as of 7/1/14)
Position: Support (April 24, 2014)

Assembly Bill 1535 will add section 4052.01 to the BPC to authorize a pharmacist to furnish naloxone hydrochloride (NH) pursuant to a standard procedure or protocol developed by the board and the Medical Board of California (MBC), in consultation with the California Pharmacists Association, the California Society of Addiction Medicine and other appropriate entities. The bill requires specific information to be included in the procedures or protocol, prohibits a pharmacist from allowing a person receiving NH to waive consultation, and other requirements. The bill is co-sponsored by the California Pharmacist Association and the Drug Policy Alliance.

The most recent version of the bill authorizes the board to adopt emergency regulations to establish the standardized procedures or protocols. A copy of AB 1535, the author's Fact Sheet, and the board's support letter (April 24, 2014) are provided in Attachment 2.

Staff Recommendation: Support AB 1535 as Amended June 24, 2014

3. AB 1702 (Maienschein) Professions and vocations: incarceration

Version: April 23, 2014
Location: SEN Floor
Status: Third reading (as of 7/1/14)
Position: Oppose (April 24, 2014)

Existing law establishes various eligibility criteria needed to qualify for a license and also authorizes the board to deny a license on the grounds that the applicant has been convicted of a crime substantially related to the qualifications, functions, or duties of the business or profession for which application is made.

AB 1702 would provide that an individual who has satisfied any of the requirements needed to obtain a license while incarcerated, who applies for that license upon release from incarceration, and who is otherwise eligible for the license shall not be subject to a delay in processing the application or a denial of the license solely based on the prior incarceration. At its meeting held April 23, 2014, the board considered the introduced

version of the bill and determined that the measure could limit the board's discretion when making a licensing decision and may add confusion as to what criteria the board could actually consider when making those decisions.

AB 1702 was amended on April 23 to specify that an application shall not be subject to delay in processing or a denial of the license based solely on the basis that all or *some of the licensure requirements were completed while the individual was incarcerated*. The April 23 version also stated that the bill shall not be construed to limit the board's ability to deny a license pursuant to Section 480.

A copy of the April 23 amendment is provided in Attachment 2.

Staff Recommendation: Change the board's position from Oppose to "No Position"

4. AB 1727 (Rodriguez) Prescription Drugs: collection and distribution program

Last amendment: June 15, 2014
Status: Enrolled (7/8/14)
Position: Support

The Health and Safety Code (starting at section 150200) sets forth provisions for the Surplus Medication Collection and Distribution Program. This law allows counties to establish a repository and distribution program under which a pharmacy may distribute the surplus unused medications to persons that meet county-established requirements.

AB 1727 prohibits the donation of a medication that is the subject of a US FDA managed risk evaluation and mitigation strategy, if the transfer is prohibited by that strategy or if the inventory transfer requires prior authorization from the manufacturer of the medication. The bill further declares that a drug subject to a US FDA managed risk evaluation and mitigation strategy which is <u>not</u> prohibited from donation shall be managed and dispensed in accordance with the requirements of the strategy.

A copy of the enrolled bill and the board's April 24 support letter are provided in Attachment 2.

5. AB 1841 (Mullin) Medical assistants

Version: June 2, 2014
Location: Senate Floor
Status: Third Reading (as of 6/25/14)
Position: None

Assembly Bill 1841 would authorize a medical assist to hand out prepackaged prescription drugs, labeled in accordance with Section 4170 (prescriber dispensing), to patients as part of the "technical supportive services" they provide in clinics that are issued a license by the board pursuant to Section 4180 BPC (nonprofit or free clinics)

and Section 4190 BP (Clinics). The language specifies that in every instance, prior to handing the medication to a patient, a "appropriate patient consultation regarding use of the drug" shall be provided by a licensed physician and surgeon, a licensed podiatrist, a physician assistant, a nurse practitioner, or a certified nurse-midwife.

16 CCR Section 171072(c) specifies the requirements for a patient consultation by a pharmacist. While the bill provides that the patient shall receive an appropriate consultation regarding the "use of the drug" – the bill does not require that the consultation cover precautions and relevant warnings, to include common severe side or adverse effects or interactions that the patient may encounter, or other information.

A copy of the "amends the law version" of the bill is provided in Attachment 2, as is a copy of the board's regulation concerning Duty to Consult (16 CCR 1707.2), and the Senate Committee on Business, Professions and Economic Development analysis.

6. AB 2396 (Bonta) Convictions: expungement: licenses

Version: May 15, 2014
Location: Senate Appropriations
Status: Hearing August 4, 2014
Position: Oppose

Assembly Bill 2396 amends section 480 of the Business and Professions Code to prohibit a board within the DCA from denying a license based solely on a criminal conviction that has been withdrawn, set aside, or dismissed by the court. As discussed by the board at the April 2014 Board Meeting, the enactment of AB 2396 would prohibit the board from using an expunged conviction as the sole reason for a licensure denial. Based on its concern that AB 2396 will eliminate the board's discretion in making licensure decisions in these cases, it voted to Oppose AB 2396. The most recent amendment contains a technical amendment and does address the board's concerns.

If enacted, the board would be required to conduct an investigation to substantiate the underlying cause for the conviction, which could potentially increase the board's enforcement costs.

A copy of AB 2396 is provided in Attachment 2.

7. AB 2603 (V. Manuel Perez) Controlled Substances: permissive lawful possession

Version: July 1, 2014
Location: Senate Floor
Status: Third reading (as of 7/1/14)
Position: Oppose

Assembly Bill 2603 amends section 11350 of the Health & Safety Code (HSC) to allow, under certain circumstances, an individual (other than the prescription holder) to possess a controlled substance.

In April 2014, the board opposed the introduced version of the bill – which allowed another person to possess the controlled substance if they 'intended' to deliver it to the prescription holder or 'intended' to discard the controlled substance for the prescription holder.

The current version of the bill specifies that it is not unlawful to possess a controlled substance if both of the following apply: (1) the possession is at the direction or express authorization of the prescription holder **and** (2) the purpose of the possession is to deliver the prescription to the prescription holder or to discard the substance in a lawful manner. A copy of AB 2603 is provided in Attachment 2.

8. AB 2757 (Bocanegra) Centralized hospital packaging pharmacies: medication labels

Version: July 2, 2014
Location: ASM Appropriations
Status:
Position: Support

Assembly Bill 2757 is a "gut & amend" to amend sections 4128, 4128.4 and 4128.5 BPC to specify requirements for barcode and human-readable labels on drugs prepared by a hospital's centralize hospital packaging pharmacy.

The amendments would specify (in 4128.4) that a barcode shall be readable by 'barcode administration software' and that the software would verify it's the right medication, for the right inpatient, the right dose, and the right route of administration.

Amendments to Section 4128.5 would specify the requirements of human-readable labels to require: the date the medication was prepared, the beyond use date, the established name of the drug, the quantity of the active ingredients, special storage or handling requirement, the lot number or control number, and the name of the centralized packaging pharmacy. This section further specifies that for quality control and investigative purposes, a pharmacist shall be able to retrieve the following information from using the lot number or control number: the components used in the drug product, the expiration date of each component, and the NDC number. A copy of AB 2757 is provided in Attachment 2.

Board inspectors have identified one suggested technical amendment for the board's consideration: to amend 4128.5(a)(4) to specify the quantity of "each" active ingredient.

Staff Recommendation: Ratify the board's Support position.

9. SB 204 (Corbett) Prescription Drugs: labeling

Version: June 10, 2014
Location: ASM Floor (Third Reading as of 7/3/14)
Status:
Position: *None*

Senate Bill 204 would require the board to conduct surveys of pharmacists and electronic health record (EHR) vendors to evaluate the use of standardized directions on prescription labels; to report the findings at its July 2016 Board Meeting, and to publish the findings on the board's website. The board has identified an estimated cost of $50,000 to contract for the mandated surveys, which would come out of the board's Contingent Fund (license fees).

A copy of the bill is provided in Attachment 2.

10. SB 1014 (Jackson) Pharmaceutical waste: home generated

Version: June 30, 2014
Location: ASM Appropriations
Status:
Position: Support

Senate Bill 1014 would require the Department of Resources Recycling and Recovery (CalRecycle) and the board to jointly develop regulations authorizing a voluntary program to collect and properly dispose of home-generated pharmaceutical waste. The program is to be based on the model guidelines that were developed in 2008.

In April, the board established a position of Support if Amended, to specify that the board be an equal partner in the development and implementation of any requirements for pharmacy drug take-back. Staff worked with the author, and on June 10 Senator Jackson amended SB 1014 to address the board's request. Thus, a letter of support was provided on June 12.

A copy of the June 30 version of the bill and the board's support letter are provided in Attachment 2.

11. SB 1039 (Hernandez) Pharmacies: furnishing drugs

Version: June 26, 2014
Location: ASM Appropriations
Status:
Position: Support

Senate Bill 1039 will expand in an acute care health facility licensed pursuant to Health and Safety Code section 1250(a) those tasks that are authorized for a pharmacy technician to perform. At the April Board Meeting, the board established a Support if Amended position and sought to address discrepancies with Title 22 in the language.

Staff worked with the author's office and stakeholders to address the board's concerns. The bill has been amended several times since then, to also include an amendment that the pharmacist be responsible for the duties performed under his or her supervision by a technician, adds Section 4119.6 to the BPC to authorize an intern pharmacist to stock, replenish, and inspect the emergency pharmaceutical supplies container and emergency medical system supplies of a licensed general acute care hospital; and specify the facility's authority to administer, dispense or furnish dangerous drugs and dangerous devices to inpatients or patients upon discharge pursuant to preprinted or electronic standing orders, protocols, etc.

A copy of the June 26 version of the bill is provided in Attachment 2. Based on recent amendments that addressed the board's concerns, the board president and committee chair established a position of Support.

Staff Recommendation: Ratify the Support position

12. SB 1258 (DeSaulnier) Controlled substances: prescriptions: reporting

Version: April 23, 2014
Location: Sen Appropriations
Status: Died - Held in Appropriations / Suspense
Position: Support if Amended (April 23, 2014)

The Uniform Controlled Substances Act (HSC 11000 et seq.) establishes and defines the parameters and use of the CURES Program within the California Department of Justice. Under current law, prescribers and pharmacies are required to report each week to DOJ every Schedule II, III and IV prescription dispensed. Likewise the US Drug Enforcement Administration has promulgated regulations regarding the electronic transmission of schedule II controlled substances.

SB 1258 would have permitted the oral and electronic transmission of controlled substances prescriptions; establish dispensing limits; require the reporting of Schedule V

controlled substances furnished to CURES; and allow DCA investigators access to CURES data for specified investigations. The bill died in appropriations; no copy is provided.

c. Other Legislation Being Tracked by Board Staff **Attachment 3**

1. AB 1743 (Ting) Hypodermic needles and syringes

Version: May 27, 2014
Location: SEN Floor
Status: Third Reading (as of 6/26/14)
Position: Support

Existing law, until January 1, 2015, authorizes a pharmacist or physician to furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older. AB 1743 would extend these provisions to 2021.

The introduced version deleted the sunset date all together, and the board supported the bill. The current version of the bill appears to address the technical cross references to the Health & Safety Code, but now includes a sunset date of 2021.

A copy of the bill and the board's support letter are provided in Attachment 3. Staff is not recommending any change to the board's position.

2. AB 2147 (Melendez) State government Internet Web site: information practices

Version: May 1, 2014
Location: ASM Appropriations
Status: Died

No action or discussion needed. Assembly Bill 2147 would have required every state agency that uses an Internet Web site to provide specified disclosures displayed in a minimum 12-point boldface type. The bill died in the house of origin; a copy is not provided.

3. AB 2418 (Bonilla) Health care coverage: prescription drug refills

Version: July 3, 2014
Location: SEN Appropriations
Status: Hearing set 8/4/14 (as of 7/21/14)
Position: Support

Assembly Bill 2418 would allow a patients to opt out of their health plan's mandatory mail order program if they prefer to obtain their prescription drugs from a community

pharmacy, would streamline prescription medications by placing a patient's medications on the same refill schedule; and would for early refills of covered ophthalmic products at 70 percent of the predicted days of use.

The bill is sponsored by the California Pharmacists Association and the California Healthcare Institute. A copy of the bill and the board's support letter are provided in Attachment 3.

4. AB 2058 (Wilk) Open Meetings (Urgency)

Version: June 19, 2014
Location: SEN Floor
Status: Third Reading (as of 7/1/14)
Position: None

The Bagley-Keene Open Meeting Act requires that all meetings of a state body, as defined, be openand public and that all persons be permitted to attend and participate in any meeting of a state body, subject to certain conditions and exceptions. AB 2058 would amend the definition of a "state body" to exclude an advisory body with less than 3 individuals, except for certain standing committees. This bill may impact the board's Organizational Development Committee, in that it is a "standing" committee, not an advisory committee. To make this committee a public meeting would have a fiscal impact to the board of approximately $10,000 annually.

A copy of the bill is provided in Attachment 3.

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Part 2: Regulation Report

a. Board Approved – Undergoing Administrative Review Attachment 4

Update on Rulemaking to Amend Section 1707.5 of Title 16 California Code of Regulations Regarding Patient-Centered Labeling Requirements

At the October 2013 Board Meeting, the board voted to modify the board's patient-centered prescription label requirements at Section 1707.5 (a) (1) to require that only the four items listed in section 1707.5 (a) (1) be clustered into one area of the label that comprises at least 50 percent of the label and to require these items to be printed in 12-point san serif typeface.

At the January 2014 Legislation and Regulation Committee meeting, the committee motioned to make a recommendation to the board to initiate the rulemaking. At the January 2014 Board Meeting, the board approved a motion to initiate a rulemaking to amend Section 1707.5 to Title 16 of the California Code of Regulations. The rulemaking was noticed on April 11, 2014, and the 45-day public comment period will conclude on May 26, 2014.

At the June 2014 Board Meeting, the board voted to move forward with the rulemaking file and approved the draft responses to the comments received. Board staff is working on finalizing the regulation package to the Department of Consumer Affairs to complete the review process. At the July 2014 Board Meeting, an update will be provided. A copy of the proposed text is provided in Attachment 4.

b. Board Approved – Awaiting Notice Attachment 5

1. **Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements**

   At the July 2013 Board Meeting, the board voted to approve the text to amend Sections 1702, 1702.1, 1702.2, and 1702.5 to Title 16 of the California Code of Regulations. Staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking. A copy of the approved language is provided in Attachment 5.

   Proposal to Amend Section 1702 – Update Pharmacist Renewal Requirements
   The board's proposal would amend Section 1702 to add as a condition of renewal, the requirement for a pharmacist licensee to disclose on the renewal form any disciplinary action against any license issued to the individual by a government agency as well as defines disciplinary action.

Proposal to Amend Section 1702.1 – Update Pharmacy Technician Renewal Requirements

The board's proposal would amend Section 1702.1 to add as a condition of renewal a fingerprint requirement for those who have not previously submitted fingerprints as a condition of renewal of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identifier. Additionally, this proposal adds as a condition of renewal the requirement for a licensee to disclose specified convictions and disciplinary actions.

Proposal to Amend Section 1702.2 – Update Designated Representative Renewal Requirements

The board's proposal would amend Section 1702.2 to add as a condition of renewal a fingerprint requirement for those who have not previously submitted fingerprints as a condition of renewal of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identifier. Additionally, this proposal adds as a condition of renewal the requirement for a licensee to disclose specified convictions and disciplinary actions.

Proposal to Amend Section 1702.5 – Update Nonresident Wholesaler or Nonresident Pharmacy Requirements

The board's proposal would amend Section 1702.5 to add as a condition of renewal, a requirement for a nonresident wholesaler or nonresident pharmacy to disclose on the renewal form any disciplinary action against any license issued to the licensee by a government agency as well as defines disciplinary action.

2. Combined Rulemaking - Proposal to Amend Title 16 California Code of Regulations Sections 1732.05, 1732.2, and 1732.5 related to Continuing Education

The board previously approved a 45-day public comment period for three proposals related to continuing education. Due to the significant changes in pharmacy law as a result of SB 294 (Emmerson, Chapter 565, Statutes of 2013) and SB 493 (Hernandez, Chapter 469, Statutes of 2013) with regard to the changes to compounding and the addition of the advanced practice pharmacist, board staff recommended to the Legislation and Regulation Committee to revisit the three continuing education regulation proposals. At the January 2014 Legislation and Regulation Committee meeting the committee reviewed the board approved language and deemed this language meets the board's requirements. The currently approved language is provided in Attachment 5.

Proposal to Amend Section 1732.05 – Update Accreditation Agencies for Continuing Education

The board's proposal would amend Section 1732.05(a)(2) to reflect the restructuring of the Pharmacy Foundation of California and its transference of duties related to the provision of continuing education to the California Pharmacists Association.

Proposal to Amend Section 1732.2 – Board Accredited Continuing Education
Proposed amendments to Section 1732.2 would specify additional methods of obtaining board-accredited continuing education. Pharmacists are required to complete 30 hours of continuing education per renewal period. Specifically, the board's proposal would specify that a pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) may annually be awarded up to six (6) hours of CE hours for conducting a review of exam test questions; would specify that a pharmacist or pharmacy technician may be awarded up to six (6) hours of CE for attending a full-day board meeting and up to two (2) hours of CE for attending a full committee meeting of the board; and would specify that an individual may be awarded three (3) hours of CE for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Proposal to Amend Section 1732.5 – Specification of Continuing Education Credit in Specific Content Areas
The board's proposal would require continuing education in specific content areas for pharmacists. Specifically, the proposed text would require six of the 30 units required of continuing education for a pharmacist renewal to be in specified content areas.

3. Proposal to Amend Title 16 California Code of Regulations Section 1703 Related to Section 100" Regulatory Actions

During the October 2012 Board Meeting, the board voted to delegate to the Executive Officer the authority to adopt regulation changes that are deemed to be "without regulatory effect" in accordance with Section 100 of Title 1 of the California Code of Regulations. Further, the board specified that upon the adoption of any Section 100 regulatory changes, the Executive Officer shall report to the board at its next regularly scheduled Board Meeting any regulations authorized by this motion. This delegation expired December 31, 2013. Further, as part of its motion, the board directed staff to prepare draft amendments to add the "Section 100" delegation to Title 16 CCR 1703 and to bring the draft to the next meeting of the Legislation and Regulation Committee for consideration. This did not occur.

At the October 2013 Board Meeting, staff proposed language to amend Title 16 California Code of Regulations to delegate to the Executive Officer the authority to initiate a rulemaking to adopt "changes without regulatory effect." At the October 2013 Board Meeting, the board voted to direct staff to initiate the formal rulemaking process, issue the amended text as discussed at this meeting for a 45-day public comment period. If no negative comments are received, direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, delegate to the Executive Officer the authority to make any non-substantive changes to the proposed

regulations before completing the rulemaking process, and adopt the proposed regulation at Section 1703 as described in the text notice.

Staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking. The approved language is provided in Attachment 5.

ATTACHMENT 1

Board-Sponsored Legislation

AMENDED IN ASSEMBLY JUNE 19, 2014

AMENDED IN SENATE MAY 28, 2014

AMENDED IN SENATE APRIL 22, 2014

AMENDED IN SENATE APRIL 7, 2014

SENATE BILL No. 960

Introduced by Senator Morrell

February 6, 2014

An act to amend Section 4315 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 960, as amended, Morrell. Pharmacy.

Existing law, the Pharmacy Law, provides for the regulation and licensure of pharmacists by the California State Board of Pharmacy. Existing law authorizes the executive officer of the board, or his or her designee, to issue a letter of admonishment to a licensee for the failure to comply with specified requirements. Existing law requires a letter of admonishment to be in writing, and sets forth procedures ~~to~~ *by which the licensee may* contest or comply with a letter of admonishment.

This bill would further authorize the executive officer of the California State Board of Pharmacy, or his or her designee, to issue a letter of admonishment to an applicant for licensure who has committed any violation of law that the board deems, in its discretion, does not merit the denial of a license or require probationary status. The bill would authorize a letter of admonishment that is issued to an applicant for licensure to be issued concurrently with a license.

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

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

SECTION 1. Section 4315 of the Business and Professions Code is amended to read:

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with Section 733, for failure to comply with this chapter or regulations adopted pursuant to this chapter, or for failure to comply with Division 116 (commencing with Section 150200) of the Health and Safety Code, directing the licensee to come into compliance.

(b) The executive officer, or his or her designee, may issue a letter of admonishment to an applicant for licensure who has committed any violation of law that the board deems, in its discretion, does not merit the denial of a license or require probationary status under Section 4300. The letter of admonishment may be issued concurrently with a license.

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

(d) The letter of admonishment shall inform the licensee or applicant that within 30 days of service of the order of admonishment the licensee or applicant may do either of the following:

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

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or applicant or his or her legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or ~~his or her~~ authorized representative *of the licensee or applicant* may accompany the licensee or applicant to the office conference.

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

(C) The office conference is intended to be an informal proceeding and shall not be subject to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with

Section 11400), or Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

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

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

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

(e) The letter of admonishment shall be served upon the licensee or applicant personally or by certified mail at his or her address of record with the board. If the licensee or applicant is served by certified mail, service shall be effective upon deposit in the United States mail.

(f) The licensee or applicant shall maintain and have readily available a copy of the letter of admonishment and corrective action plan, if any, for at least three years from the date of issuance of the letter of admonishment.

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

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

(2) Institute disciplinary proceedings pursuant to ~~Article 19 (commencing with Section 4300).~~ *this article.*

1 (h) The issuance of a letter of admonishment pursuant to
2 subdivision (b) shall not be construed as a disciplinary action or
3 discipline for purposes of licensure or the reporting of discipline
4 for licensure.

O

California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

April 24, 2014

The Honorable Mike Morrell
California State Senate
State Capitol, Room 3056
Sacramento, CA 95814

RE: Senate Bill 960 - SUPPORT

Dear Senator Morrell:

The Board of Pharmacy thanks you for authoring Senate Bill 960, which would amend the board's current authority to issue a letter of admonishment, to also allow the board to issue such a letter to an applicant at the time a new license is issued.

Upon receipt of an application for a license, the board conducts a thorough investigation to determine whether the individual is qualified for the license being sought. We investigate all matters related to the issuance of the license that may affect the public welfare, to include a review of an individual's criminal history record information to determine prior arrests and convictions within and outside of California. The board also requires information about prior administrative actions taken by any regulatory agency against an applicant. Sometimes information gained from this background review shows serious violations and/or conduct in an individual's past.

When considering the appropriate action when making a licensing decision, the board recognizes that some violations or conduct – while serious – may not be sufficient or is so old that the board may have difficulty sustaining a denial of the license.

Senate Bill 960 would authorize the board to issue a letter of admonishment, which would describe in detail the nature and facts of an individual's conduct. Existing provisions afford an individual the right to contest a letter of admonishment and the related timeframe for doing so, and would require that a letter of admonishment be purged three years from the date of issuance.

The Board of Pharmacy believes that Senate Bill 960 would serve to protect public by licensing individuals who meet minimum qualifications for licensure, but also by documenting an individual's conduct and/or violations. Should an individual who is issued a letter of admonishment violate Pharmacy Law provisions in the three years during which the letter is on file, the conduct outlined in the letter of admonishment would be considered by the board for future possible discipline.

Thank you for your efforts on behalf of the board of pharmacy. Please do not hesitate to contact me at 574-7911 or Legislative Coordinator Carolyn Klein at 574-7913 whenever you need our assistance.

Sincerely,

/s/
VIRGINIA HEROLD
Executive Officer

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

June 13, 2014

The Honorable Susan Bonilla
Chair, Assembly Business, Professions and Consumer Protection Committee
Member, California State Assembly
State Capitol, Room 4140
Sacramento, CA 95814

RE: Senate Bill 960 (Morrell) - SUPPORT

Dear Assembly Member Bonilla:

The Board of Pharmacy, as the sponsor of Senate Bill 960, respectfully requests the support of your committee when it comes before you on June 17. This bill which would authorize the board to issue a letter of reprimand with an initial license.

This bill would provide the board with an additional tool to ensure public protection. Upon receipt of an application for a license, the board conducts a thorough investigation to determine whether the individual is qualified for the license being sought. We investigate all matters related to the issuance of the license that may affect the public welfare, to include a review of an individual's criminal history record information to determine prior arrests and convictions within and outside of California. The board also requires information about prior administrative actions taken by any regulatory agency against an applicant. Sometimes information gained from this background review shows serious violations in the individual's past.

When considering the appropriate action when making a licensing decision, the board recognizes that some violations – while serious – may not be sufficient or are so old that the board may have difficulty sustaining a denial of the license.

Senate Bill 960 would authorize the board to issue a letter of admonishment, which would describe the nature and facts of an individual's violations. Senate Bill 960 would provide the individual the right to contest the letter of admonishment and specify the process and timeframe for the contesting of the letter, and would require that a letter of admonishment be purged three years from the date of issuance.

The Board of Pharmacy believes that Senate Bill 960 would serve to protect public by licensing individuals who meet minimum qualifications for licensure, but also by documenting and making available information regarding an individual's past so that employers can make informed decisions as to those they are hiring.

Please do not hesitate to contact me at 574-7911 if you have questions.

Sincerely,

VIRGINIA HEROLD
Executive Officer

✓ cc: The Honorable Mike Morrell

AMENDED IN ASSEMBLY JULY 1, 2014

AMENDED IN ASSEMBLY JUNE 2, 2014

SENATE BILL No. 1466

Introduced by Committee on Business, Professions and Economic Development (Senators Lieu (Chair), Berryhill, Block, Corbett, Galgiani, Hernandez, Hill, Padilla, and Wyland)

March 25, 2014

An act to amend Sections 27, 655.2, 2023.5, 2089.5, 2240, 2530.5, 2532.2, 2532.7, 2936,4021.5, 4053, 4980,~~4980.36,~~ 4980.37, 4980.399, 4980.41, 4980.43, 4980.55, 4980.72, 4980.78, 4987.5, 4989.16, 4989.22, 4992.09, 4996.17, 4996.23, 4998, 4999.55, 4999.58, 4999.59, 4999.60, and 4999.123 of, to amend the heading of Chapter 13 (commencing with Section 4980) of Division 2 of,~~ to add Section 2023 to,~~ and to repeal Sections 2930.5 and 2987.3 of, the Business and Professions Code, and to amend Section 14132.55 of the Welfare and Institutions Code, relating to health care professionals.

LEGISLATIVE COUNSEL'S DIGEST

SB 1466, as amended, Committee on Business, Professions and Economic Development. Health care professionals.

(1) Existing law prohibits a physician and surgeon, licensed medical corporation, or any audiologist who is not a licensed hearing aid dispenser from employing a licensed hearing aid dispenser for the purpose of fitting or selling hearing aids.

This bill would prohibit a licensed hearing aid dispenser from employing a physician and surgeon or any audiologist who is not a licensed dispensing audiologist or hearing aid dispenser, or contracting with a licensed medical corporation, for the purpose of fitting or selling hearing aids.

(2) Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. Existing law requires the Medical Board of California to review issues and problems surrounding the use of laser or intense light pulse devices for elective cosmetic procedures, in conjunction with the Board of Registered Nursing and in consultation with other specified groups. Existing law requires the board and the Board of Registered Nursing to adopt regulations, by January 1, 2009, with regard to the use of laser or intense pulse light devices for elective cosmetic procedures, as specified. Existing law requires the board to adopt regulations, by January 1, 2013, regarding the appropriate level of physician availability needed within clinics or other settings using laser or intense pulse light devices for elective cosmetic procedures.

This bill would delete the provisions that require the board to adopt regulations by January 1, 2009, and January 1, 2013. ~~The bill would instead require the board to adopt regulations, by January 1, 2016, regarding the appropriate level of physician availability needed within all clinics or other settings.~~

(3) Existing law requires a physician and surgeon who performs a scheduled medical procedure outside of a general acute care hospital that results in the death of any patient on whom that medical treatment was performed by the physician and surgeon, or by a person acting under the physician and surgeon's orders or supervision, to report, in writing on a form prescribed by the board, that occurrence to the board within 15 days after the occurrence. A person who violates this requirement is guilty of a misdemeanor.

This bill would make that provision applicable without regard to whether the procedure was scheduled. By expanding the scope of a crime, the bill would impose a state-mandated local program.

(4) Existing law provides for the licensing and regulation of persons who are engaged in the practice of speech-language pathology or audiology, as specified, and vests the enforcement of these provisions in the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board. Among other requirements, an applicant for licensure as a speech-language pathologist or audiologist is required to submit transcripts from an educational institution approved by the board evidencing completion of specified coursework, and submit evidence of the satisfactory completion of supervised clinical practice with individuals representative of a wide spectrum of ages and communication disorders. Existing law requires the board to establish

by regulation the required number of clock hours, not to exceed 300 clock hours, of supervised clinical practice necessary for the applicant.

This bill would delete the requirement that the applicant submit transcripts from an educational institution approved by the board evidencing completion of specified coursework and would increase the maximum number of clock hours that the board may establish by regulation to 375.

(5) Existing law, the Psychology Licensing Law, provides for the licensure and regulation of psychologists by the Board of Psychology. Under certain circumstances, existing law authorizes the board to issue a fictitious-name permit to a psychologist, as specified.

This bill would repeal the provision that authorizes the issuance of a fictitious-name permit, and would make conforming changes with regard to that repeal. The bill would make other changes to update a provision related to consumer notices, as specified.

(6) Existing law, the Pharmacy Law, governs the regulation of the practice of pharmacy and establishes the California State Board of Pharmacy to administer and enforce these provisions. The law authorizes the board to issue a license to an individual to serve as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer, as specified, and requires the licensee to 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. The law also defines a correctional pharmacy to mean a pharmacy, licensed by the board, located within a state correctional facility, as specified.

This bill would require an individual who applies for a designated representative license to be at least 18 years of age. The bill would also revise the definition of a correctional pharmacy to mean a pharmacy, licensed by the board, located within a correctional facility, without regard to whether the facility is a state or local correctional facility.

~~(7) Existing law, the Licensed Marriage and Family Therapist Act, provides for the licensure and regulation of marriage and family therapists by the Board of Behavioral Sciences. Existing law sets forth the educational and training requirements for licensure as a marriage and family therapist. Existing law, among other requirements, requires an applicant for licensure to complete 75 hours of client centered advocacy or face-to-face counseling, as specified.~~

a conspicuous location in their principal psychological business office, a notice which reads as follows:

"NOTICE TO CONSUMERS: The Department of Consumer Affair's Board of Psychology receives and responds to questions and complaints regarding the practice of psychology. If you have questions or complaints, you may contact the board by email at bopmail@dca.ca.gov, on the Internet at www.psychology.ca.gov, by calling 1-866-503-3221, or by writing to the following address:

Board of Psychology
1625 North Market Boulevard, Suite –215
Sacramento, California 95834"

~~SEC. 12.~~

SEC. 11. Section 2987.3 of the Business and Professions Code is repealed.

~~SEC. 13.~~

SEC. 12. Section 4021.5 of the Business and Professions Code is amended to read:

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

~~SEC. 14.~~

SEC. 13. 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 who is at least 18 years of age 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. 15.~~

SEC. 14. The heading of Chapter 13 (commencing with Section 4980) of Division 2 of the Business and Professions Code is amended to read:

CHAPTER 13. LICENSED MARRIAGE AND FAMILY THERAPISTS

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

April 24, 2014

The Honorable Ted W. Lieu, Chair
Senate Committee on Business,
Professions & Economic Development
State Capitol, Room 4140
Sacramento, CA 95814

RE: Senate Bill 1466 - SUPPORT

Dear Senator Lieu and Committee Members:

The Board of Pharmacy is pleased to support Senate Bill 1466, which contains the board's sponsored provisions to amend Section 4053 of the Business and Professions Code related to the minimum requirements for designated representatives, and that also amends the definition of a "correctional pharmacy" specified at section 4021.5 of the Business and Professions Code.

Please do not hesitate to contact me at 574-7911 or Legislative Coordinator Carolyn Klein at 574-7913 if we can answer any questions or be of assistance to you and the committee staff.

Sincerely,

VIRGINIA HEROLD
Executive Officer

copy: Members, Senate Committee on Business,
Professions & Economic Development

AMENDED IN ASSEMBLY JUNE 30, 2014

AMENDED IN ASSEMBLY JUNE 12, 2014

AMENDED IN ASSEMBLY JUNE 10, 2014

AMENDED IN SENATE MAY 28, 2013

AMENDED IN SENATE APRIL 23, 2013

AMENDED IN SENATE APRIL 8, 2013

SENATE BILL No. 600

Introduced by Senator Lieu

February 22, 2013

An act to amend Sections 4033 and 4045 of, to repeal Sections 4034, 4034.1, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5 of, and to repeal and add Section 4163 of, the Business and Professions Code, and to amend Section 111825 of, and to add Section 111397 to, the Health and Safety Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 600, as amended, Lieu. Drugs.

(1) Existing federal law, the Federal Food, Drug, and Cosmetic Act, regulates, among other matters, the manufacture, distribution, and sale of prescription drugs in interstate commerce and is administered by the United States Food and Drug Administration.

Existing law, the federal Drug Supply Chain Security Act ~~establishes~~, *provides for* the development of a system that will require, among other things, manufacturers, wholesale drug distributors, repackagers, and dispensers in the drug supply chain to provide specified transaction information about a drug product, and prohibits a state or political

subdivision of a state from continuing in effect any requirements for tracing products through the distribution system, including any requirements with respect to electronic pedigree systems, that are inconsistent with, more stringent than, or in addition to, any requirements of federal law.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy and the sale of dangerous drugs or dangerous devices by the California State Board of Pharmacy. Existing law, commencing July 1, 2016, prohibits a wholesaler or repackager from selling, trading, or transferring a dangerous drug at wholesale without providing a pedigree, as defined, and from acquiring a dangerous drug without receiving a pedigree. Existing law imposes parallel requirements with respect to pharmacies commencing July 1, 2017. Existing law makes these pedigree requirements inoperative upon the effective date of federal law addressing pedigree or serialization measures for dangerous drugs, or as otherwise specified in the event of a conflict with federal law.

This bill would repeal the pedigree requirements and make related conforming changes.

(2) Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of drugs and devices and is administered by the State Department of Public Health. Existing law makes it unlawful to manufacture, sell, deliver, hold, or offer for sale, any drug that is misbranded, and provides that a drug or device is misbranded if its labeling is false or misleading in any particular. A violation of this law is a misdemeanor.

This bill would provide that any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is misbranded. Because a violation of this provision would be a crime, the bill would impose a state-mandated local program.

The bill would provide that any person who purchases a foreign dangerous drug or medical device, or an illegitimate product or suspect product, as those terms are defined pursuant to federal law, that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is guilty of a

misdemeanor and subject to imprisonment for not more than one year in ~~the~~ *a* county jail, a fine of not more ~~that~~ *than* $10,000 per occurrence, or both the imprisonment and fine. By creating new crimes, the bill would impose a state-mandated local program.

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

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

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

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

1 SECTION 1. Section 4033 of the Business and Professions
2 Code is amended to read:
3 4033. (a) (1) "Manufacturer" means and includes every person
4 who prepares, derives, produces, compounds, or repackages any
5 drug or device except a pharmacy that manufactures on the
6 immediate premises where the drug or device is sold to the ultimate
7 consumer.
8 (2) Notwithstanding paragraph (1), "manufacturer" shall not
9 mean a pharmacy compounding a drug for parenteral therapy,
10 pursuant to a prescription, for delivery to another pharmacy for
11 the purpose of delivering or administering the drug to the patient
12 or patients named in the prescription, provided that neither the
13 components for the drug nor the drug are compounded, fabricated,
14 packaged, or otherwise prepared prior to receipt of the prescription.
15 (3) Notwithstanding paragraph (1), "manufacturer" shall not
16 mean a pharmacy that, at a patient's request, repackages a drug
17 previously dispensed to the patient, or to the patient's agent,
18 pursuant to a prescription.
19 (b) Notwithstanding subdivision (a), "manufacturer" also means
20 a person who prepares, derives, manufactures, produces, or
21 repackages a dangerous drug, as defined in Section 4022, device,
22 or cosmetic. Manufacturer also means the holder or holders of a
23 New Drug Application (NDA), an Abbreviated New Drug
24 Application (ANDA), or a Biologics License Application (BLA),
25 provided that such application has been approved; a manufacturer's
26 third party logistics provider; a private label distributor (including

colicensed partners) for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distributor agent for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer's affiliated group (regardless of whether the member takes title to the drug) or is a contract distributor site.

SEC. 2. Section 4034 of the Business and Professions Code is repealed.

SEC. 3. Section 4034.1 of the Business and Professions Code is repealed.

SEC. 4. Section 4045 of the Business and Professions Code is amended to read:

4045. "Third-party logistics provider" or "reverse third-party logistic provider" means an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs.

SEC. 5. Section 4163 of the Business and Professions Code is repealed.

SEC. 6. Section 4163 is added to the Business and Professions Code, to read:

4163. (a) A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. ~~When~~ *If* the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

SEC. 7. Section 4163.1 of the Business and Professions Code, as added by Section 68 of Chapter 658 of the Statutes of 2006, is repealed.

SEC. 8. Section 4163.1 of the Business and Professions Code, as added by Section 9 of Chapter 713 of the Statutes of 2008, is repealed.

SEC. 9. Section 4163.2 of the Business and Professions Code is repealed.

SEC. 10. Section 4163.3 of the Business and Professions Code is repealed.

SEC. 11. Section 4163.4 of the Business and Professions Code is repealed.

SEC. 12. Section 4163.5 of the Business and Professions Code is repealed.

SEC. 13. Section 111397 is added to the Health and Safety Code, to read:

111397. Any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is misbranded.

SEC. 14. Section 111825 of the Health and Safety Code is amended to read:

111825. (a) Any person who violates any provision of this part or any regulation adopted pursuant to this part shall, if convicted, be subject to imprisonment for not more than one year in ~~the~~ *a* county jail or a fine of not more than one thousand dollars ($1,000), or both the imprisonment and fine.

(b) Notwithstanding subdivision (a), any person who violates Section 111865 by removing, selling, or disposing of an embargoed food, drug, device, or cosmetic without the permission of an authorized agent of the department or court shall, if convicted, be subject to imprisonment for not more than one year in ~~the~~ *a* county jail or a fine of not more than ten thousand dollars ($10,000), or both the fine and imprisonment.

(c) Notwithstanding subdivision (a), any person who purchases a foreign dangerous drug or medical device, illegitimate product, as defined in Section 360eee(8) of Title 21 of the United States Code, or suspect product, as defined in Section 360eee(21) of Title 21 of the United States Code, that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is guilty of a misdemeanor and subject to imprisonment for not more than one year in ~~the~~ *a* county

jail, a fine of not more ~~that~~ *than* ten thousand dollars ($10,000) per occurrence, or both the imprisonment and fine.

(d) If the violation is committed after a previous conviction under this section that has become final, or if the violation is committed with intent to defraud or mislead, or if the person committed a violation of Section 110625 or 111300 that was intentional or that was intended to cause injury, the person shall be subject to imprisonment for not more than one year in ~~the~~ *a* county jail, imprisonment in *the* state prison, or a fine of not more than ten thousand dollars ($10,000), or both the imprisonment and fine.

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

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Date of Hearing: June 24, 2014

ASSEMBLY COMMITTEE ON BUSINESS, PROFESSIONS AND CONSUMER PROTECTION
Susan A. Bonilla, Chair
SB 600 (Lieu) – As Amended: June 12, 2014

SENATE VOTE: 39-0

SUBJECT: Drugs

SUMMARY: Repeals provisions of current pharmacy law to conform to the federal Drug Quality and Security Act (DQSA) and declares any that foreign dangerous drug that is not approved by the United States Food and Drug Administration (FDA) or that is obtained outside the state-licensed supply chain is misbranded, and that anyone who purchases that drug is guilty of a misdemeanor and subject to a fine of not more than $10,000. Specifically, this bill:

1) Repeals provisions of current pharmacy law to conform to the federal DQSA.

2) Declares any foreign dangerous drug that is not approved by the United States Food and Drug Administration (FDA) or that is obtained outside of the licensed supply chain regulated by the FDA, California State Board of Pharmacy (BOP), or State Department of Public Health (DPH) to be misbranded.

3) Declares it a misdemeanor for any person to purchase a foreign dangerous drug or medical device, illegitimate product, or suspect product, as specified, that is not approved by the FDA or that is obtained outside of the licensed supply chain regulated by the FDA, BOP, or DPH. States that a person who does this is subject to imprisonment for not more than one year in the county jail, a fine of not more than $10,000 per occurrence, or both the imprisonment and fine.

4) States that no reimbursement is required by this act 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, as specified.

EXISTING FEDERAL LAW:

1) Establishes the FDA to protect the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices through the Food, Drug, and Cosmetic Act (FDCA). (21 United States Code (USC) 301 *et seq.*)

2) Establishes the Drug Supply Chain Security Act (Act), as part of the DQSA, which outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. (21 USC 351 *et seq.*)

3) Defines "illegitimate product" as a product for which credible evidence shows that the product:

a) Is counterfeit, diverted, or stolen;

b) Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

c) Is the subject of a fraudulent transaction; or,

d) Appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans. (21 USC 360eee)

4) Defines "suspect product" to mean a product for which there is reason to believe that such product:

a) Is potentially counterfeit, diverted, or stolen;

b) Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

c) Is potentially the subject of a fraudulent transaction; or,

d) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans. (21 USC 360eee)

EXISTING STATE LAW:

1) Establishes BOP to regulate the practice of pharmacy and pharmacists, including requirements for drug prescription labels. (Business and Professions Code (BPC) Sections 4000 *et seq.*)

2) Defines "dangerous drug" or "dangerous device" to mean any drug or device unsafe for self-use in humans or animals, and includes the following:

a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import;

b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device; or,

c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription, as specified.

3) Establishes the "e-pedigree" law which creates a record in electronic form containing information regarding each transaction resulting in a change of ownership of the given prescription drug, including returns. (BPC 4034 *et seq.*)

4) Establishes the Sherman Food, Drug, and Cosmetic Law, administered by DPH, which regulates the packaging, labeling, and advertising of drugs and devices. (Health and Safety Code (HSC) Sections 109875 *et seq.*)

5) Declares it unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded. (HSC 111440)

6) Declares any drug or device to be misbranded if its labeling is false or misleading in any particular. (HSC 111330)

7) Declares any drug or device to be misbranded unless it bears a label containing all of the following information:

   a) The name and place of business of the manufacturer, packer, or distributor; and,

   b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. (HSC 111340)

8) Declares any drug to be misbranded unless its label bears, to the exclusion of any other nonproprietary name except the applicable, systematic chemical name or the chemical formula, all of the following information:

   a) The established name of the drug, if any;

   b) If it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, codeine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, barbituric acid, or any derivative or preparation of any substances contained therein;

   c) For nonprescription drugs, the quantity or proportion of each active ingredient and the established name of each inactive ingredient, as specified; and,

   d) The requirement for stating the quantity of the active ingredients of any drug, including the quantity or proportion of any alcohol, and also including, whether active or not, the quantity or proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, codeine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, barbituric acid, or any derivative or preparation of any substances contained therein, shall apply to all drugs, including prescription drugs and nonprescription drugs. For any prescription drug the established name of the drug or ingredient, as the case may be, on the label and on any labeling on which a name for the drug or ingredient is used shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for the drug or ingredient. (HSC 111355)

9) States that any person who violates any provision of the Sherman Food, Drug, and Cosmetic Law, if convicted, is subject to imprisonment for not more than one year in the county jail or a fine of not more than $1,000, or both the imprisonment and fine. (HSC 111825)

FISCAL EFFECT: Unknown

COMMENTS:

1) Purpose of this bill. This bill repeals provisions of current pharmacy law to conform to federal law and also declares that anyone who purchases a foreign dangerous drug that is not approved by the FDA or that is obtained outside the state licensed supply chain is guilty of a misdemeanor. This bill is intended to reduce circumvention of approved purchasing channels by punishing the purchase of drugs that are not regulated by the state or federal government. This bill is author-sponsored.

2) Author's statement. According to the author's office, "Patients may be treated with drugs and devices that are represented as FDA-approved but are often of unknown origin and quality which can result in significant harm to these patients.

   "When a drug is illegally imported, there is no guarantee as to the active ingredients in the drug or the potency of the drug. Imported drugs may contain too little active ingredient, in which case therapeutic effects will be minimized. Alternatively, these products may contain too much active ingredient, which can result in harm to consumers and negative interactions with other medications. Manufacturing, storage, packaging and transportation of imported drugs are not regulated by the FDA. This can lead to degradation of the product and harm to consumers. Some imported medicines – even those that bear the name of a U.S.-approved product – may, in fact, be counterfeit versions that are unsafe or even completely ineffective. Some imported medicines and their ingredients, although legal in foreign countries, may not have been evaluated for safety and effectiveness in the United States. These products may be addictive or may contain other dangerous substances. Imported drugs may be labeled in languages that American consumers do not understand and may make medical claims or suggest specific uses that have not been adequately evaluated for safety and effectiveness. Additionally, imported drugs may lack information about side effects caused by the medicine."

3) California's e-Pedigree Law and DQSA. E-pedigree was California's statutory program to prevent counterfeit medicine from entering the legitimate supply chain. E-pedigree was created by SB 1307 (Figueroa), Chapter 857, Statutes of 2004, and began implementation the following year, with full operability anticipated by 2015.

   The "pedigree" was a chain of custody record in electronic form containing information regarding each transaction resulting in a change of ownership of a prescription drug. The goal of the program was for any owner or possessor of a prescription drug located at a licensed wholesaler, repackager, reverse distributor, or pharmacy in California to be able to show the lineage of the drug from the manufacturer through the drug distribution channel. The e-pedigree was required to contain specific information required by the statute, and had to be made and passed through an electronic track and trace system based on unique identification numbers affixed at the point of manufacture.

   The federal Drug Quality and Security Act was signed into law by President Obama on November 27, 2013. This bill was prompted by the fungal meningitis outbreak in 2012 linked to unsanitary conditions at a Massachusetts compounding pharmacy, as well as concerns regarding increases in counterfeit, falsified, substandard and dangerous prescription

medications. DQSA contained two parts – the Compounding Quality Act and the Drug Supply Chain Security Act.

The Compounding Quality Act created a voluntary compliance regime where compounding pharmacies that voluntarily register as "outsourcing facilities" will be subject to oversight by the FDA in much of the same way that traditional pharmaceutical manufacturers are monitored.

The Drug Supply Chain Security Act built upon California's e-pedigree efforts to create a national electronic track and trace system for prescription drugs. The Act will replace the patchwork system adopted by individual states and create a unified national program. In doing this, the Act explicitly preempted any state's requirements for tracing products through the distribution system that are inconsistent with, more stringent than, or in addition to any of the requirements under the Act. Thus, California's e-pedigree system is currently invalid by operation of law. This law repeals those invalid sections.

4) Counterfeit drugs. Counterfeit and unapproved drugs pose a serious threat to consumers. Efforts to combat the use of counterfeit and unapproved drugs have become increasingly challenging, as supply chains have become more complex and global. According to the FDA, nearly 40% of the drugs Americans take are made elsewhere, and about 80% of manufacturing sites of active pharmaceutical ingredients used in drugs manufactured inside the United States are located in more than 150 countries.

Counterfeit drugs falsely represent a product's identity through unauthorized representation of a legitimate trademark, trade name, or other likenesses. Counterfeiting can apply to both branded and generic products, and counterfeit drugs may fail to meet the quality and safety standards established by national and state regulatory authorities, and may contain dangerous substances, incorrect dosages, or no active ingredient.

According to a 2013 report from the Brookings Institution,

> Although data associated with counterfeit and unapproved drugs are limited due to the clandestine nature of counterfeiting, certain trends have emerged which may indicate that a wide spectrum of counterfeit drugs are being manufactured and distributed. While reports of counterfeit and unapproved drugs were initially associated with "lifestyle drugs" (e.g., those for erectile dysfunction, weight loss), counterfeiters have expanded into more profitable and specialty markets, including drugs for chronic and life threatening diseases. Investigations and seizures have revealed counterfeit and unapproved versions of HIV/AIDS drugs, pain drugs, antibiotics, insulin, cholesterol drugs, hormone replacement therapy, flu drugs, cancer drugs, anti-arthritic drugs, cardiac drugs, anti-parasitic drugs, and antihistamines. Research has indicated that in 2011, cancer drugs represented the eighth most commonly counterfeited medical product worldwide.
>
> In recent years, unscrupulous distributors have expanded their tactics to target clinical settings for the sale of counterfeit and unapproved drugs. Medical offices are often contacted through mass advertising campaigns via "blast faxes", phone calls, direct email, and online marketing. These distributors often target clinics and hospitals for sale of physician-administered drugs, including a variety of injectable drugs.

The report notes that most of the nationwide efforts to combat counterfeit and unapproved products have focused on the major players in the drug supply chain, such as drug manufacturers and distributors. However, there have been fewer inroads in targeting the purchasing of drugs by patients and health care professionals, who may be lured by significantly lower prices from drugs available outside the nationwide supply.

This bill targets this practice by clarifying in state law that a drug that is not approved by the FDA or obtained outside of the federal and state licensed supply chain is a "misbranded drug," and that purchasing a misbranded drug is a misdemeanor. This bill also increases the fine for violations from $1,000 to $10,000.

5) Questions for the Committee. This bill establishes that a drug not approved by the FDA or obtained outside the US and California supply chain is deemed "misbranded." It is likely that nearly all drugs purchased outside the nationwide supply chain that are not intended for the California market are already misbranded for failure to meet FDA, BOP, or Sherman Act labeling standards. As noted above, existing law already makes it unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded, and subjects the violator to a penalty of one year in jail, $1,000 fine, or both.

   However, this bill goes significantly farther than the current fine and expressly states that the penalty for purchasing a drug obtained outside the US supply chain, or if the drug is suspected to be fraudulent, is $10,000. The Committee may wish to ask whether such a dramatic escalation of the fine accurately reflects the level of danger to public safety hazard that it purports to combat. It is also unclear how penalties would be assessed, leaving it open to question whether an individual violation is accounted by the unit dose (per pill), by the prescription, or by the transaction.

6) Suggested technical amendment. On page 7, line 3, replace "that" with "than"

7) Related legislation. AB 2605 (Bonilla) of 2014 requires third party logistic providers who provide pharmaceutical storage, handling, or distribution services to be licensed by the California Board of Pharmacy. This bill is pending in the Senate Business, Professions, and Economic Development Committee.

8) Previous legislation. SB 1307 (Figueroa), Chapter 857, Statutes of 2004, created California's e-Pedigree program, which made comprehensive changes to the drug distribution system to protect the integrity of the pharmaceutical supply chain.

   SB1476 (Figueroa), Chapter 658, Statutes of 2006, delayed the implementation date for the E-pedigree component to January 1, 2009 and granted the Board the authority to extend the deadline an additional two years to allow the industry additional time to implement technologies necessary for electronic pedigrees.

REGISTERED SUPPORT / OPPOSITION:

Support

None on file

Opposition

None on file

Analysis Prepared by: Sarah Huchel / B.,P. & C.P. / (916) 319-3301

AMENDED IN SENATE JUNE 17, 2014

AMENDED IN ASSEMBLY MAY 5, 2014

AMENDED IN ASSEMBLY APRIL 23, 2014

AMENDED IN ASSEMBLY MARCH 18, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 2605

Introduced by Assembly Member Bonilla

February 21, 2014

An act to amend Sections ~~4022.5,~~ 4040.5, 4043, ~~4053,~~ 4060, 4081, 4101, 4105, 4120, 4126, 4149, 4160, 4161, 4162, 4162.5, 4164, 4165, 4166, 4167, 4168, 4169, 4201, 4305.5, 4312, 4331, and 4400 of, to amend the heading of Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of, to add ~~Section 4025.2~~ *Sections 4025.5, 4044.5, 4053.1, and 4107* to, and to repeal and add Section 4045 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2605, as amended, Bonilla. Pharmacy: third-party logistics providers.

(1) Under the Pharmacy Law, a violation of which is a crime, the California State Board of Pharmacy licenses and regulates the practice of pharmacy. Existing law restricts the purchase, trade, sale, or transfer of dangerous drugs or dangerous devices, as defined, to licensed wholesalers and other authorized persons. Under the Pharmacy Law, the board licenses and regulates entities, including third-party logistics providers, as wholesalers. The Pharmacy Law defines a "third-party logistics provider" or a "reverse third-party logistics provider" as an

entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. *Existing law requires a wholesaler to be supervised or managed by a designated representative-in-charge and requires a separate license for each place of business owned or operated by a wholesaler. Existing law also requires a wholesaler to submit a surety bond of $100,000 payable to a specified fund of the board to secure payment of any administrative fine imposed by the board.* Existing law, the federal Drug Supply Chain Security Act, prohibits a third-party logistics provider, as defined, from conducting any activities in a state unless each facility of the provider is licensed by the state from which drugs are distributed by the provider in accordance with regulations to be promulgated by the Secretary of the United States Department of Health and Human Services.

This bill would revise the definition of *the terms* "third-party logistics provider" ~~or~~ *and* "reverse third-party logistics provider" to conform to federal law, as specified, and would require a third-party logistics provider of a dangerous drug or dangerous device to be separately licensed by the board as a third-party logistics provider. *The bill would require a third-party logistics provider to be supervised and managed by a facility manager-in-charge who would be subject to similar requirements as those imposed on a designated representative-in-charge with respect to wholesalers. The bill would limit a place of business to a single board-issued license and would require that at least one designated representative, in the case of a wholesaler, or facility manager, in the case of a third-party logistics provider, be present during business hours for each licensed place of business. The bill would require a third-party logistics provider to submit a surety bond of $90,000 payable to a specified fund of the board to secure payment of any administrative fine imposed by the board.*

The bill would also require a manufacturer, wholesaler, third-party logistics provider, or pharmacy that has reasonable cause to believe that a dangerous drug or device that is or was in its possession, and has been sold or distributed in or through California, is counterfeit or the subject of a fraudulent transaction to notify the board within 72 hours of obtaining that knowledge.

(2) The Pharmacy Law requires a person located outside this state that ships, sells, mails, or delivers dangerous drugs or dangerous devices

into this state, or sells, brokers, or distributes dangerous drugs or devices within this state to be a licensed nonresident wholesaler.

This bill would, in addition, require a person located outside this state that performs those actions or that warehouses or distributes dangerous drugs or dangerous devices into this state, or warehouses dangerous drugs or devices within this state to be licensed as either a nonresident wholesaler or a nonresident third-party logistics provider. The bill would make conforming changes, and would delete obsolete cross-references and provisions.

(3) Existing law sets the fees for the issuance and renewal of licenses for wholesalers and designated representatives at specified amounts and authorizes those fees to be increased to specified higher amounts.

This bill would instead set the fees at the higher amounts.

(4) Because a violation of the requirements described in paragraphs (1) and (2) above would be a crime, the bill would impose a state-mandated local program.

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

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

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

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

1 ~~SECTION 1. Section 4022.5 of the Business and Professions~~
2 ~~Code is amended to read:~~
3 ~~4022.5. (a) "Designated representative" means an individual~~
4 ~~to whom a license has been granted pursuant to Section 4053. A~~
5 ~~pharmacist fulfilling the duties of Section 4053 shall not be~~
6 ~~required to obtain a license as a designated representative.~~
7 ~~(b) "Designated representative-in-charge" means a designated~~
8 ~~representative or a pharmacist proposed by a wholesaler, third-party~~
9 ~~logistics provider, or veterinary food-animal drug retailer and~~
10 ~~approved by the board as the supervisor or manager responsible~~
11 ~~for ensuring the compliance of the wholesaler, third-party logistics~~
12 ~~provider, or veterinary food-animal drug retailer with all state and~~
13 ~~federal laws and regulations pertaining to practice in the applicable~~
14 ~~license category.~~

~~SEC. 2. Section 4025.2 is added to the Business and Professions Code, to read:~~

~~4025.2. "Facility manager" means the individual who is designated by a third-party logistics provider to oversee the facility of the third-party logistics provider and who, in conjunction with the quality assurance department of the third-party logistics provider, is responsible for ensuring the third-party logistics provider's compliance with state and federal laws and the third-party logistics provider's customer specifications.~~

SECTION 1. Section 4025.5 is added to the Business and Professions Code, to read:

4025.5. (a) "Facility manager" means an individual licensed by the board who oversees the operations of a third-party logistics provider with respect to dangerous drugs and dangerous devices received by, stored in, or shipped from the licensed place of business of the third-party logistics provider.

(b) "Facility manager-in-charge" means a facility manager licensed by the board who is designated by a third-party logistics provider and approved by the board pursuant to Section 4160 to oversee a licensed place of business of the third-party logistics provider. The facility manager-in-charge is responsible for ensuring the compliance of the licensed placed of business with state and federal laws and with the third-party logistics provider's customer specifications.

~~SEC. 3.~~

SEC. 2. Section 4040.5 of the Business and Professions Code is amended to read:

4040.5. "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsaleable dangerous drugs.

~~SEC. 4.~~

SEC. 3. Section 4043 of the Business and Professions Code is amended to read:

4043. "Wholesaler" means and includes a person who acts 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 drug or device included in Section 4022. Unless otherwise authorized by

law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

SEC. 4. Section 4044.5 is added to the Business and Professions Code, to read:

4044.5. "Reverse third-party logistics provider" means an entity that processes or manages the disposition of an outdated or nonsaleable dangerous drug or dangerous device on behalf of a manufacturer, wholesaler, or dispenser of the dangerous drug or dangerous device, but does not take ownership of the dangerous drug or dangerous device nor have the responsibility to direct its sale or disposition. Unless otherwise specified in this chapter, every provision of this chapter that applies to a third-party logistics provider shall also apply to a reverse third-party logistics provider.

SEC. 5. Section 4045 of the Business and Professions Code is repealed.

SEC. 6. Section 4045 is added to the Business and Professions Code, to read:

4045. "Third-party logistics provider" ~~or "reverse third-party logistic provider"~~ means an entity that provides or coordinates warehousing or other logistics services ~~of a product in~~ *for a dangerous drug or dangerous device in intrastate or* interstate commerce on behalf of a manufacturer, wholesaler, or dispenser of ~~a product~~ *the dangerous drug or dangerous device*, but does not take ownership of the ~~product~~ *dangerous drug or dangerous device*, nor have responsibility to direct ~~the~~ *its* sale or disposition ~~of the product~~.

~~SEC. 7. 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, third-party logistics provider, or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, warehousing, distribution, and shipment of dangerous drugs and dangerous devices in the wholesaler, third-party logistics provider, or veterinary food-animal drug retailer.~~

~~(b) An individual who is at least 18 years of age 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, third-party logistics provider, 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 shall not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.~~

~~(c) The wholesaler, third-party logistics provider, or veterinary food-animal drug retailer 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. 7. Section 4053.1 is added to the Business and Professions Code, to read:

4053.1. (a) Notwithstanding Section 4051, the board may issue a license to a qualified individual as a facility manager to provide sufficient and qualified supervision of a third-party logistics provider's place of business. The facility manager shall protect the public health and safety in the handling, storage, warehousing, distribution, and shipment of dangerous drugs and dangerous devices in the third-party logistics provider's place of business.

(b) An individual who is at least 18 years of age may apply for a facility manager 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 meet one of the following requirements:

(A) Have a minimum of one year of paid work experience in the past three years with a third-party logistics provider.

(B) Have a minimum of one year of paid work experience in the past three years in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, performing duties related to the distribution or dispensing of dangerous drugs or dangerous devices.

(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

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

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

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

(iii) Knowledge and understanding of quality control systems.

(iv) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage, handling, and transport of dangerous drugs.

(B) The board may, by regulation, require the training program required under this paragraph to include additional material.

(C) The board shall not issue a license as a facility manager until the applicant provides proof of completion of the training required by this paragraph to the board.

(c) A third-party logistics provider shall not operate without at least one facility manager present at each of its licensed places of business as required under Section 4160.

SEC. 8. Section 4060 of the Business and Professions Code is amended to read:

4060. 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 Section 4052.1, 4052.2, or 4052.6. This section does not apply to the possession of any controlled substance by a manufacturer, wholesaler, third-party logistics provider, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, if in stock in containers correctly labeled with the name and address of the supplier or producer.

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. 9. Section 4081 of the Business and Professions Code is amended to read:

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, *facility manager-in-charge,* or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge, *facility manager-in-charge,* or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge, *facility manager-in-charge,* or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

SEC. 10. Section 4101 of the Business and Professions Code is amended to read:

4101. (a) A pharmacist may take charge of and act as the pharmacist-in-charge of a pharmacy upon application by the pharmacy and approval by the board. ~~Any~~ *A* pharmacist-in-charge who ceases to act as the pharmacist-in-charge of the pharmacy shall notify the board in writing within 30 days of the date of that change in status.

(b) A designated representative or a pharmacist may take charge of, and act as, the designated representative-in-charge of a wholesaler~~, third-party logistics provider,~~ or veterinary food-animal drug retailer upon application by the wholesaler~~, third-party logistics provider,~~ or veterinary food-animal drug retailer and approval by the board. ~~Any~~ *A* designated representative-in-charge who ceases to act as the designated representative-in-charge at that entity shall notify the board in writing within 30 days of the date of that change in status.

(c) A facility manager may take charge of, and act as, the facility manager-in-charge of a third-party logistics provider upon application by the third-party logistics provider and approval by the board. A facility manager-in-charge who ceases to act as the facility manager-in-charge at that entity shall notify the board in writing within 30 days of the date of that change in status.

SEC. 11. Section 4105 of the Business and Professions Code is amended to read:

4105. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any

entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) *(1)* Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, *or* the pharmacist on duty if the pharmacist-in-charge is not on duty, ~~or, in the case of a veterinary food-animal drug retailer, wholesaler, third-party logistics provider, or the designated representative on duty,~~ shall, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(2) In the case of a veterinary food-animal drug retailer, wholesaler, or third-party logistics provider, any records that are maintained electronically shall be maintained so that the designated representative-in-charge or the facility manager-in-charge, or the designated representative on duty or the facility manager on duty if the designated representative-in-charge or facility manager-in-charge is not on duty, shall, at all times during which the licensed place of business is open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board~~,~~ may, upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the

board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.

SEC. 12. Section 4107 is added to the Business and Professions Code, to read:

4107. If a manufacturer, wholesaler, third-party logistics provider, or pharmacy has reasonable cause to believe that a dangerous drug or dangerous device in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, third-party logistics provider, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This section shall apply to any dangerous drug or dangerous device that has been sold or distributed in or through this state.

~~SEC. 12.~~

SEC. 13. Section 4120 of the Business and Professions Code is amended to read:

4120. (a) A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler or third-party logistics provider who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler or third-party logistics provider pursuant to this chapter without registering as a nonresident pharmacy.

(b) Applications for a nonresident pharmacy registration shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section.

(c) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident pharmacy.

(d) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section

to serve as any evidence that the nonresident pharmacy is doing business within this state.

~~SEC. 13.~~

SEC. 14. Section 4126 of the Business and Professions Code is amended to read:

4126. (a) Notwithstanding any other law, a covered entity may contract with a pharmacy to provide pharmacy services to patients of the covered entity, as defined in Section 256b of Title 42 of the United States Code, including dispensing preferentially priced drugs obtained pursuant to Section 256b of Title 42 of the United States Code. Contracts between those covered entities and pharmacies shall comply with guidelines published by the Health Resources and Services Administration and shall be available for inspection by board staff during normal business hours.

(b) Drugs purchased pursuant to Section 256b of Title 42 of the United States Code and received by a pharmacy shall be segregated from the pharmacy's other drug stock by either physical or electronic means. All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records.

(c) Drugs obtained by a pharmacy to be dispensed to patients of a covered entity pursuant to Section 256b of Title 42 of the United States Code that cannot be distributed because of a change in circumstances for the covered entity or the pharmacy shall be returned to the distributor from which they were obtained. For the purposes of this section, a change in circumstances includes, but is not limited to, the termination or expiration of the contract between the pharmacy and the covered entity, the closure of a pharmacy, disciplinary action against the pharmacy, or closure of the covered entity.

(d) A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license, or both a pharmacy and a third-party logistics provider license.

(e) Neither a covered entity nor a pharmacy shall be required to obtain a license as a wholesaler or a third-party logistics provider based on acts reasonably necessary to fully participate in the drug purchase program established by Section 256b of Title 42 of the United States Code.

~~SEC. 14.~~

SEC. 15. Section 4149 of the Business and Professions Code is amended to read:

4149. (a) A nonresident distributor shall not sell or distribute hypodermic needles or syringes in this state without obtaining a license from the board pursuant to Section 4141.

(b) Notwithstanding subdivision (a), a license is not required if the nonresident distributor sells or distributes solely through a person who is licensed as a wholesaler or third-party logistics provider pursuant to Section 4160.

(c) The Legislature, by enacting this section, does not intend a license issued to any nonresident distributor pursuant to this article to serve as evidence that the entity is doing business within this state.

~~SEC. 15.~~

SEC. 16. The heading of Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code is amended to read:

Article 11. Wholesalers, Third-Party Logistics Providers, and Manufacturers

~~SEC. 16.~~

SEC. 17. Section 4160 of the Business and Professions Code is amended to read:

4160. (a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

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

(c) A separate license shall be required for each place of business owned or operated by a wholesaler or third-party logistics provider. *Each place of business may only be issued a single license by the board.* Each license shall be renewed annually and shall not be transferable. *At all times during which a place of business is open for business, at least one designated representative, in the case of a wholesaler, or facility manager, in the case of a third-party logistics provider, shall be present.*

(d) Every wholesaler ~~or third-party logistics provider~~ shall be supervised or managed by a designated representative-in-charge.

The designated representative-in-charge shall be responsible for the *wholesaler's* compliance~~ of the wholesaler or third-party logistics provider~~ with state and federal laws governing wholesalers ~~and third-party logistics providers~~. As part of its initial application for a license, and for each renewal, each wholesaler~~ or third-party logistics provider~~ shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler~~ or third-party logistics provider~~ license without identification of an approved designated representative-in-charge for the wholesaler~~ or third-party logistics provider~~.

(e) Each place of business of a third-party logistics provider shall be supervised and managed by a facility manager-in-charge. The facility manager-in-charge shall be responsible for the compliance of the place of business with state and federal laws governing third-party logistics providers and with the third-party logistics provider's customer specifications. As part of its initial application for a license, and for each renewal, each third-party logistics provider shall, on a form designated by the board, provide identifying information and the California license number for a facility manager proposed to serve as the facility manager-in-charge. The proposed facility manager-in-charge shall be subject to approval by the board. The board shall not issue or renew a third-party logistics provider license without identification of an approved facility manager-in-charge for the third-party logistics provider.

~~(e)~~

(f) A wholesaler~~ or third-party logistics provider~~ shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as the designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler ~~or third-party logistics provider~~ shall propose another replacement within 15 days of the date of disapproval, and shall continue to

name proposed replacements until a designated representative-in-charge is approved by the board.

(g) A third-party logistics provider shall notify the board in writing, on a form designed by the board, within 30 days of the date when a facility manager-in-charge ceases to act as the facility manager-in-charge, and shall on the same form propose another facility manager to take over as the facility manager-in-charge. The proposed replacement facility manager-in-charge shall be subject to approval by the board. If disapproved, the third-party logistics provider shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a facility manager-in-charge is approved by the board.

~~(f)~~

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

~~(g)~~

(i) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (f) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

~~SEC. 17.~~

SEC. 18. Section 4161 of the Business and Professions Code is amended to read:

4161. (a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.

(b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler or nonresident third-party logistics provider from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, warehoused, distributed, or delivered to a site located in this state or sold, brokered, warehoused, or distributed within this state. *Each place of business may only be issued a single license by the board.* A license shall be renewed annually and shall not be transferable.

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

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

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

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

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

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

(f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred, warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.

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

(i) The board shall not issue or renew a nonresident wholesaler or nonresident third-party logistics provider license until the nonresident wholesaler or nonresident third-party logistics provider identifies a designated representative-in-charge *or facility manger-in-charge* and notifies the board in writing of the identity and license number of the designated representative-in-charge *or facility manager-in-charge*.

(j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler ~~or nonresident third-party logistics provider~~ with state and federal laws governing wholesalers ~~and third-party logistics providers~~. *The facility manager-in-charge shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws governing third-party logistics providers.* A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge *or facility manager-in-charge* within 30 days of the date that the prior designated representative-in-charge *or facility manager-in-charge* ceases to be the designated representative-in-charge *or facility manager-in-charge*.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars ($550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180

days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

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

~~SEC. 18.~~

SEC. 19. Section 4162 of the Business and Professions Code is amended to read:

4162. (a) (1) An applicant for the issuance or renewal of a wholesaler ~~or third-party logistics provider~~ license, which is not government owned and operated, shall submit a surety bond of one hundred thousand dollars ($100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) An applicant for the issuance or renewal of a third-party logistics provider license, which is not government owned and operated, shall submit a surety bond of ninety thousand dollars ($90,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

~~(2)~~

(3) For purposes of ~~paragraph (1)~~ *paragraphs (1) and (2)*, the board may accept a surety bond less than ~~one hundred thousand dollars ($100,000)~~ *the amount required under paragraph (1) or (2)* if the annual gross receipts of the previous tax year for the wholesaler or third-party logistics provider is ten million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).

~~(3)~~

(4) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler or third-party logistics provider, shall not be required to post a surety bond as provided in paragraph (1) *or (2)*.

~~(4)~~

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

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

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

~~SEC. 19.~~

SEC. 20. Section 4162.5 of the Business and Professions Code is amended to read:

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

(2) An applicant for the issuance or renewal of a nonresident third-party logistics provider license shall submit a surety bond of ninety thousand dollars ($90,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine

imposed by the board and any cost recovery ordered pursuant to Section 125.3.

~~(2)~~

(3) For purposes of ~~paragraph (1)~~ *paragraphs (1) and (2)*, the board may accept a surety bond less than ~~one hundred thousand dollars ($100,000)~~ *the amount required under paragraph (1) or (2)* if the annual gross receipts of the previous tax year for the nonresident wholesaler or the nonresident third-party logistics provider is ten million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).

~~(3)~~

(4) For applicants who satisfy paragraph ~~(2),~~ *(3),* the board may require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler or nonresident third-party logistics provider who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

~~(4)~~

(5) A person to whom an approved new drug application or a biologics license application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application or biologics license application, and is licensed or applies for licensure as a nonresident wholesaler or a nonresident third-party logistics provider, shall not be required to post a surety bond as provided in this section.

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

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

~~SEC. 20.~~

SEC. 21. Section 4164 of the Business and Professions Code is amended to read:

4164. (a) A wholesaler or third-party logistics provider licensed by the board that distributes controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all distributions of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

(b) Each wholesaler shall develop and maintain a system for tracking individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. The system shall be capable of identifying purchases of any dangerous drug at preferential or contract prices by customers that vary significantly from prior ordering patterns for the same customer, including by identifying purchases in the preceding 12 calendar months by that customer or similar customers and identifying current purchases that exceed prior purchases by either that customer or similar customers by a factor of 20 percent.

(c) Upon written, oral, or electronic request by the board, a wholesaler shall furnish data tracked pursuant to subdivision (b) to the board in written, hardcopy, or electronic form. The board shall specify the dangerous drugs, the customers, or both the dangerous drugs and customers for which data are to be furnished, and the wholesaler shall have 30 calendar days to comply with the request.

(d) As used in this section, "preferential or contract prices" means and refers to purchases by contract of dangerous drugs at prices below the market wholesale price for those drugs.

~~SEC. 21.~~

SEC. 22. Section 4165 of the Business and Professions Code is amended to read:

4165. A wholesaler or third-party logistics provider licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.

~~SEC. 22.~~

SEC. 23. Section 4166 of the Business and Professions Code is amended to read:

4166. (a) Any wholesaler that uses the services of any third-party logistics provider or carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that provider or carrier until the drugs

or devices are delivered to the transferee at its board-licensed premises.

(b) Nothing in this section is intended to affect the liability of a wholesaler, third-party logistics provider, or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

~~SEC. 23.~~

SEC. 24. Section 4167 of the Business and Professions Code is amended to read:

4167. A wholesaler or third-party logistics provider shall not obtain, by purchase or otherwise, any dangerous drugs or dangerous devices that it cannot maintain, in a secure manner, ~~on the premises~~ *at the place of business* licensed by the board.

~~SEC. 24.~~

SEC. 25. Section 4168 of the Business and Professions Code is amended to read:

4168. A county or municipality shall not issue a business license for any establishment that requires a wholesaler or third-party logistics provider license unless the establishment possesses a current wholesaler or third-party logistics provider license issued by the board. For purposes of this section, an "establishment" is the licensee's physical location in California.

~~SEC. 25.~~

SEC. 26. Section 4169 of the Business and Professions Code is amended to read:

4169. (a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health.

~~SEC. 26.~~

SEC. 27. Section 4201 of the Business and Professions Code is amended to read:

4201. (a) Each application to conduct a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, 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 other than a natural person, the application shall state the information as to each person beneficially interested therein.

(b) As used in this section, and subject to subdivision (c), 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.

(c) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and 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 entity. Upon request by the executive officer, 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.

(d) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has 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.

(e) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

(f) Notwithstanding any other law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(g) Notwithstanding any other law, the wholesaler license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(h) Notwithstanding any other law, the third-party logistics provider license shall authorize the holder to provide or coordinate warehousing, distribution, or other similar services of dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(i) Notwithstanding any other law, the veterinary food-animal drug retailer license shall authorize the holder to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(j) For licenses referred to in subdivisions (f), (g), (h), and (i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

~~SEC. 27.~~

SEC. 28. Section 4305.5 of the Business and Professions Code is amended to read:

4305.5. (a) A person that is licensed as a wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of the designated representative-in-charge *or facility manager-in-charge*. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(b) A person that is licensed as a wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, that willfully fails to notify the board of the termination of employment of the designated representative-in-charge *or facility manager-in-charge* at its licensed place of business, and that continues to operate the place of business in the absence of the designated representative-in-charge *or facility manager-in-charge* for that place of business shall be subject to summary suspension or revocation of its license as a wholesaler, third-party logistics provider, or veterinary food-animal drug retailer at that place of business.

(c) A designated representative-in-charge of a wholesaler~~,~~ ~~third-party logistics provider,~~ or veterinary food-animal drug retailer, *or a facility manager-in-charge of a third-party logistics provider,* who terminates his or her employment at the licensed place of business, shall notify the board within 30 days of the termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

~~SEC. 28.~~

SEC. 29. Section 4312 of the Business and Professions Code is amended to read:

4312. (a) The board may cancel the license of a wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer if the licensed premises remain closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may cancel a license after a shorter period of closure. To cancel a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If a written objection is not received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may cancel the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings

shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.

(b) If the license of a wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer is canceled pursuant to subdivision (a) or revoked pursuant to Article 19 (commencing with Section 4300), or a wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.

(c) If a wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer is located, authorizing the board to enter the wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer.

(d) If the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.

(1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) If a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

(e) For the purposes of this section, "closed" means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.

(f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

~~SEC. 29.~~

SEC. 30. Section 4331 of the Business and Professions Code is amended to read:

4331. (a) A person who is neither a pharmacist nor a designated representative and who ~~does either of the following,~~ *takes charge of a wholesaler or veterinary food-animal drug retailer or who dispenses a prescription or furnishes dangerous devices,* except as otherwise provided in this chapter, is guilty of a ~~misdemeanor:~~ *misdemeanor.*

~~(1) Takes charge of a wholesaler, third-party logistics provider, or veterinary food-animal drug retailer.~~

~~(2) Coordinates the warehousing or distribution of dangerous drugs or dangerous devices or dispenses a prescription or furnishes dangerous devices.~~

(b) A person who is not a facility manager who takes charge of a third-party logistics provider or coordinates the warehousing or distribution of dangerous drugs or dangerous devices within a third-party logistics provider, except as otherwise provided in this chapter, is guilty of a misdemeanor.

~~(b)~~

(c) A person licensed as a veterinary food-animal drug retailer that fails to place in charge of that veterinary food-animal drug retailer a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

~~(c)~~

(d) A person licensed as a wholesaler ~~or third-party logistics provider~~ that fails to place in charge of that wholesaler ~~or third-party logistics provider~~ a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(e) A person licensed as a third-party logistics provider that fails to place in charge of a licensed place of business of the third-party logistics provider a facility manager, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a facility manager, or as otherwise provided in this chapter, is guilty of a misdemeanor.

~~SEC. 30.~~

SEC. 31. Section 4400 of the Business and Professions Code, as added by Section 9 of Chapter 565 of the Statutes of 2013, 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 or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(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 *a* license as a designated representative pursuant to Section 4053, *or as a facility manager pursuant to Section 4053.1,* shall be three hundred thirty dollars ($330) and may be decreased to no less than two hundred fifty-five dollars ($255).

(2) The fee for the annual renewal of a license as a designated representative *or facility manager* shall be one hundred ninety-five dollars ($195) and may be decreased to no less than one hundred fifty dollars ($150).

(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 three hundred thirty dollars ($330) and may be decreased to no less than two hundred fifty-five dollars ($255).

(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 ninety-five dollars ($195) and may be decreased to no less than one hundred fifty dollars ($150).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600).

(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. 31.~~

SEC. 32. 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.

O

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www.pharmacy.ca.gov

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

April 24, 2014

The Honorable Susan Bonilla
Member, California State Assembly
State Capitol, Room 4140
Sacramento, CA 95814

RE: AB 2605 (Support)

Dear Assemblymember Bonilla,

On behalf of the Board of Pharmacy, it is my pleasure to thank you for agreeing to author AB 2605. This bill would establish regulatory and licensure requirements for third party logistics providers, which are businesses that ship, store, select and distribute prescription medication and devices to patients and providers. As such, these businesses provide vital services necessary to ensure the integrity of the pharmaceutical supply chain. It is of upmost importance to the public health that they be regulated as are all other members of the supply chain.

Until recently third party logistic providers (or as they are more frequently called – 3PLs) were required to be licensed as drug wholesalers by this board if they were handling product intended for California patients or practitioners. However, recently enacted federal law requires a separate licensure program for 3PLs, and specifically directs that they not be licensed as wholesalers. As such provisions in AB 2605 would establish requirements for these distributors of prescription drugs and devices that are appropriate to entities that distribute and select medication. The federal Food and Drug Administration will ultimately develop general requirements for these businesses; however, the FDA has 18 more months before they are required to develop the parameters. Well thought out legislative action by California is thus likely to establish national parameters for the regulation of these distributors.

The board is pleased to have the opportunity to work with you and Sarah Huchel on this proposal. We commit to provide whatever support you need in order to secure its successful enactment, which will ensure the ongoing quality of California's prescription drugs and devices.

Please do not hesitate to contact Executive Officer Virginia Herold (916-574-7911) whenever the board can be of any assistance. Thank you once again for your efforts in carrying this proposal.

Sincerely,
/s/
STAN WEISSER
President

cc: Sarah Huchel

Hearing Date: June 23, 2014 Bill No: AB 2605

SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT
Senator Ted W. Lieu, Chair

Bill No: AB 2605 Author: Bonilla
As Amended: June 17, 2014 Fiscal: Yes

SUBJECT: Pharmacy: third-party logistics providers.

SUMMARY: Requires third party logistic providers who provide storage, handling, or distribution services, to be licensed by the California Board of Pharmacy.

Existing law:

1) Establishes the practice of pharmacy and provides for the licensing and regulation of pharmacies and pharmacists by the Board of Pharmacy (Board). (Business and Professions Code (BPC) § 4000 et seq.)

2) Defines "wholesaler" to mean a person who acts 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 device. (BPC § 4043)

3) Defines "third party logistic provider" (3PL) or "reverse third party logistics provider" (reverse 3PL) to mean an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. (BPC § 4045)

4) Requires wholesalers and nonresident wholesalers to have a designated representative in charge, maintain a surety bond, and adhere to certain distribution, administrative, and storage requirements as specified. (BPC §§ 4160 – 4169)

This bill:

1) Defines "facility manager" as an individual licensed by the Board who oversees the operations of a 3PL with respect to dangerous drugs and dangerous devices received by, stored in or shipped from the licensed place of business of the 3PL.

2) Defines "facility manager in charge" as a facility manager licensed by the Board designated by a 3PL and approved by the Board to oversee a licensed place of business of the 3PL.

3) Provides that the facility manager in charge is responsible for ensuring the compliance of the licensed place of business with state and federal laws and with the 3PL customer specifications.

4) Repeals and recasts the definition of 3PL to mean an entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce, on behalf of a manufacturer, wholesaler or dispenser of a product but does not take ownership of the products, nor have responsibility to direct the sale or disposition of the product.

5) Defines "reverse 3PL" as an entity that processes or manages the disposition of an outdated or nonsaleable dangerous drug or dangerous device on behalf of a manufacturer, wholesaler or dispenser of the dangerous drug or dangerous device but does not take ownership of the dangerous drug or dangerous device nor have the responsibility to direct its sale or disposition. Specifies that provisions under Pharmacy Law that apply to a 3PL shall also apply to a reverse 3PL.

6) Authorizes the Board to issue a license to a qualified individual as a facility manager to provide sufficient and qualified supervision of a 3PL's place of business. Provides that the facility manager shall protect the public health and safety in the handling, storage, warehousing, distribution and shipment of dangerous drugs and dangerous devices in the 3PL's place of business.

7) Requires the facility manager applicant to meet the same requirements as those set forth for a designated representative under current law. Prohibits a 3PL from operating without at least one facility manager present at each of its licensed places of business.

8) Provides that a facility manager may take charge of and act as the facility manager in charge of a 3PL upon application by the 3PL and with Board approval. Requires Board notification within 30 days in writing if a facility manager in charge is no longer operating in that capacity.

9) Provides that if a manufacturer, wholesaler, 3PL or pharmacy has reasonable cause to believe that a dangerous drug or dangerous device that has been sold or distributed in California that is in or has been in its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, 3PL or pharmacy shall notify the Board within 72 hours.

10) Requires a 3PL to keep records of the manufacture, acquisition, or disposition of dangerous drugs, and current inventory, as specified.

11) Requires a 3PL that is not government owned and operated to post a surety bond of $90 thousand.

12) Establishes fees for a 3PL and nonresident 3PL license, as specified.

13) Makes other conforming and technical changes, as specified.

FISCAL EFFECT: This bill is keyed "fiscal"l by Legislative Counsel. According to the Assembly Committee on Appropriations analysis dated May 14, 2014, this bill will result in one-time costs of $20,000 to add a new license type to the DCA licensing and enforcement system information technology system (BreEZe). The analysis also cites minor revenue loss to the Controlled Substance Utilization Review and Evaluation System (CURES) Fund since currently, wholesalers are assessed a $6 per year fee on each license or at renewal and the new 3PL licensees, who were previously licensed as wholesalers, would not be subject to this fee. According to the analysis, oversight workload for the Board should remain at a similar level, as the bill does not add new regulatory duties.

COMMENTS:

1. **Purpose.** This bill is sponsored by the Board of Pharmacy. According to the Author, California has regulated 3PLs as drug wholesalers for years, but recent federal legislation, the Drug Quality and Security Act (DQSA), preempts California law and requires that if California wants to license 3PLs, they must be licensed as a distinct entity. The Author notes that DQSA permits states or the FDA to license 3PLs. However, regulations implementing a federal licensing program are not anticipated until late 2015, and will likely be completed later than that. The Author notes that until then, 3PLs which are not state licensed are "deemed" federally licensed unless FDA finds that a specific 3PL provider is practicing unsafely. This means that there are no safety, storage, handling, or recordkeeping standards for 3PLs to adhere to until FDA develops regulations. According to the Author, 3PLs are essentially unregulated until either California or FDA develops a licensing scheme.

2. **Drug Supply Regulation.** The Food, Drug and Cosmetic Act (FDCA) was passed by Congress to ensure public confidence in our drug distribution system and to require that drugs are both safe and effective. The FDCA requires FDA to regulate drug manufacturers and to approve drugs for sale but also requires state governments to regulate the drug distribution system by licensing and regulating drug wholesalers. In the simplest situation, a manufacturer sells drugs directly to one of the major wholesalers who then sell the drugs to a hospital or pharmacy. However, this simple distribution pattern is not the only distribution route taken through the supply chain. Typically, there is more than one wholesaler who receives the drugs before they reach the pharmacy. These transactions include transfers between separate facilities owned by major wholesalers and transfers between the major wholesalers and the large drug store chains that have their own wholesale facilities in the company distribution system. Common carriers may transport the drugs between licensed entities and in some cases will store, select and then ship products to pharmacies at the direction of manufacturers.

   The distribution system is further complicated by the practice of "repackaging." Unlike European countries and Canada, most drugs in the United States are not packaged in a "unit of use" size by the drug manufacturers. Instead, many drugs are sold by the manufacturers in large bulk containers and then are repackaged by additional companies into smaller containers for resale to the pharmacy. And the distribution system is complicated yet again by the existence of a "secondary" wholesale market. "Secondary" wholesalers are smaller companies (often regional down to small family owned companies) that focus their business on selling drugs to other wholesalers and serving smaller niche clients that are not routinely served by the major wholesalers (individual practitioners, small clinics, rural locations, etc.).

Drugs routinely move between both primary and secondary wholesalers and from pharmacies to secondary wholesalers as well. These intermediate steps pose the greatest opportunities for compromising the integrity of the drug distribution system. The primary threat to system integrity is the introduction of counterfeit products. Counterfeit drugs are most likely to be introduced into a distribution system that involves multiple wholesalers because drugs are largely untraceable unless they are only handled by a major wholesaler who purchases directly from the manufacturer. Without being able to trace a drug back, there is no assurance to the consumer that the drug has been stored and handled appropriately to preserve its potency and safety.

In response to a growing threat to the pharmaceutical supply chain from counterfeit, misbranded, adulterated or diverted drugs, California enacted SB 1307 (Figueroa, Chapter 857, Statutes of 2004) which made comprehensive changes to the drug distribution system to protect the integrity of the pharmaceutical supply chain. That legislation enacted the nation's strongest pharmaceutical consumer protection measure and included provisions pertaining to the licensure and qualifications of wholesalers, restrictions on furnishing and the requirement, beginning January 1, 2007, of an electronic pedigree (e-pedigree) to accompany and validate drug distributions for the purpose of tracking each prescription drug at the saleable unit (item) level through the distribution system. Subsequent Board sponsored legislation, SB1476 (Figueroa, Chapter 658, Statutes of 2006) delayed the implementation date for the e-pedigree component to January 1, 2009 and granted the Board the authority to extend the deadline an additional two years to allow the industry additional time to implement technologies necessary for electronic pedigrees. In 2008, the Board sponsored SB 1307 (Ridley-Thomas, Chapter 713, Statutes of 2008), which amended the law to resolve implementation issues, specifically staggering and extending the implementation dates for e-pedigree compliance, establishing grandfathering of existing stock in the supply chain, allowing the Board to establish criteria for inference, and preempting California's requirements in the event federal legislation is enacted in this area. Per SB 1307, California's e-pedigree requirements for prescription drugs would have taken effect on a staggered basis from January 1, 2015 through July 1, 2017: 50 percent of a manufacturer's products by 2015 would have had to have an e-pedigree; the remaining 50 percent of the manufacturer's products would have had to have an e-pedigree by 2016; wholesalers and repackagers would have had to accept and forward products with the e-pedigree by July 1, 2016 and; pharmacy and pharmacy warehouses would have had to accept and pass e-pedigrees by July 1, 2017.

In 2013, Congress passed and President Obama signed H.R. 3034, the DQSA. Among other provisions, the bill created a national set of standards to track pharmaceuticals through the distribution chain, aimed at curbing illegal importation and patient harm caused by counterfeit drugs and devices. The new law requires the FDA to implement an electronic system to trace pharmaceuticals throughout the supply chain at the unit level and, as a result, preempts California's E-pedigree law established in 2005. DQSA also defines a 3PL as "an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or disperser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product." Major companies, such as UPS, DHL, and others provide these services.

The duties of a 3PL can vary from contract to contract, but the comment element is that a 3PL never holds title to the product it is contracted to manage. DQSA authorizes states to continue licensing programs for wholesale distributors and 3PLs, although it explicitly states that "No State shall regulate 3PLs as wholesale distributors."

This bill creates a separate licensing system for 3PLs to be in conformance with DQSA. While DQSA does provide for a federal licensing system for 3PLs beginning in late 2015, until that time, 3PLs will be unregulated unless the FDA makes a specific finding that a 3PL does not utilize good handling and distribution practices. This bill will provide for ongoing licensing of 3PLs according to California law to maintain the integrity of the drug supply system.

3. **Related Legislation This Year.** SB 600 (Lieu) of 2014 conforms to DQSA by repealing California's E-pedigree law, strengthening definitions for misbranded drugs and devices under California's Sherman, Food, Drug and Cosmetics Act and ensuring appropriate penalties for purchasing a foreign dangerous drug or medical device, illegitimate product, or suspect product. (Status: *This measure is pending a hearing in Assembly Business, Professions and Consumer Protection Committee*.)

4. **Prior Related Legislation.** SB 294 (Emmerson, Chapter 565, Statutes of 2013), expanded the types of sterile compounded drugs for which a license is required and requires inspection of nonresident sterile compounding pharmacies by the Board.

   SB 1307 (Ridley-Thomas, Chapter 713, Statutes of 2008) extended the implementation dates for e-pedigree compliance, establishing grandfathering of existing stock in the supply chain, allowing the Board to establish criteria for inference, and preempted California's requirements in the event federal legislation is enacted in this area.

   SB 1476 (Figueroa, Chapter 658, Statutes of 2006) delayed the implementation date for the e-pedigree component to January 1, 2009 and granted the Board the authority to extend the deadline an additional two years to allow the industry additional time to implement technologies necessary for electronic pedigrees.

   SB 1307 (Figueroa, Chapter 857, Statutes of 2004) required, beginning January 1, 2007, an electronic pedigree to accompany and validate drug distributions for the purpose of tracking each prescription drug at the saleable unit level through the distribution system.

SUPPORT AND OPPOSITION:

Support:

Board of Pharmacy

Opposition:

None on file as of June 18, 2014.

Consultant: Sarah Mason

ATTACHMENT 2

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

AMENDED IN SENATE JUNE 25, 2014

AMENDED IN SENATE MAY 29, 2014

AMENDED IN SENATE JUNE 24, 2013

AMENDED IN ASSEMBLY MAY 24, 2013

AMENDED IN ASSEMBLY APRIL 22, 2013

AMENDED IN ASSEMBLY APRIL 1, 2013

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 186

Introduced by Assembly Member Maienschein
(Principal coauthor: Assembly Member Hagman)
(Coauthors: Assembly Members Chávez, Dahle, Donnelly, Beth Gaines, Garcia, *Gorell,* Grove, Harkey, Olsen, Patterson, and V. Manuel Pérez)
(Coauthors: Senators Fuller and Huff)

January 28, 2013

An act to add Section 115.6 to the Business and Professions Code, relating to professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

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

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law provides for the issuance of reciprocal licenses in certain fields where the applicant, among other requirements, has a

license to practice within that field in another jurisdiction, as specified. Existing law requires that the licensing fees imposed by certain boards within the department be deposited in funds that are continuously appropriated. Existing law requires a board within the department to expedite the licensure process for an applicant who holds a current license in another jurisdiction in the same profession or vocation and who supplies satisfactory evidence of being married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active duty military orders.

This bill would, in addition to the expedited licensure provisions described above, establish a temporary licensure process for an applicant who holds a ~~current~~ *current, active, and unrestricted* license in another jurisdiction, as specified, and who supplies satisfactory evidence of being married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active duty military orders. The bill would require a temporary license to expire 12 months after issuance, upon issuance of an expedited license, or upon denial of the application for expedited licensure by the board, whichever occurs first.

This bill would require an applicant seeking a temporary license as a civil engineer, geotechnical engineer, structural engineer, land surveyor, professional geologist, professional geophysicist, certified engineering geologist, or certified hydrogeologist to successfully pass the appropriate California specific examination or examinations required for licensure in those respective professions by the Board for Professional Engineers, Land Surveyors, and Geologists. The bill would also authorize a board to require an applicant to successfully pass an examination in jurisprudence or California law and ethics for the issuance of a temporary license if successfully passing the examination is a requirement for all applicants for full licensure.

This bill would exclude the California Architects Board, *the Landscape Architects Technical Committee, the Contractors' State License Board,* the State Board of Chiropractic Examiners, ~~or~~ *and* a board that established a temporary licensing process before January 1, 2014, from these provisions.

Because the bill would authorize the expenditure of continuously appropriated funds for a new purpose, the bill would make an appropriation.

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

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

SECTION 1. Section 115.6 is added to the Business and Professions Code, to read:

115.6. (a) A board within the department shall, after appropriate investigation, issue a temporary license to an applicant if he or she meets the requirements set forth in subdivision (c). The temporary license shall expire 12 months after issuance, upon issuance of an expedited license pursuant to Section 115.5, or upon denial of the application for expedited licensure by the board, whichever occurs first.

(b) The board may conduct an investigation of an applicant for purposes of denying or revoking a temporary license issued pursuant to this section. This investigation may include a criminal background check.

(c) An applicant seeking a temporary license pursuant to this section shall meet the following requirements:

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

(2) The applicant shall hold ~~a current license~~ *current, active, and unrestricted license that confers upon him or her the authority to practice,* in another state, district, or territory of the United ~~States in~~ *States,* the profession or vocation for which he or she seeks a temporary license from the board.

(3) The applicant shall submit an application to the board that shall include a signed affidavit attesting to the fact that he or she meets all of the requirements for the temporary license and that the information submitted in the application is accurate, to the best of his or her knowledge. The application shall also include written verification from the applicant's original licensing jurisdiction stating that the applicant's license is in good standing in that jurisdiction.

(4) The applicant shall not have committed an act in any jurisdiction that would have constituted grounds for denial,

suspension, or revocation of the license under this code at the time the act was committed. A violation of this paragraph may be grounds for the denial or revocation of a temporary license issued by the board.

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

(6) The applicant shall, upon request by a board, furnish a full set of fingerprints for purposes of conducting a criminal background check.

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

(e) A temporary license issued pursuant to this section for the practice of medicine may be immediately terminated upon a finding that the temporary licenseholder failed to meet any of the requirements described in subdivision (c) or provided substantively inaccurate information that would affect his or her eligibility for temporary licensure. Upon termination of the temporary license, the board shall issue a notice of termination that shall require the temporary licenseholder to immediately cease the practice of medicine upon receipt.

(f) An applicant seeking a temporary license as a civil engineer, geotechnical engineer, structural engineer, land surveyor, professional geologist, professional geophysicist, certified engineering geologist, or certified hydrogeologist pursuant to this section shall successfully pass the appropriate California-specific examination or examinations required for licensure in those respective professions by the Board for Professional Engineers, Land Surveyors, and Geologists.

(g) A board within the department may require an applicant to successfully pass an examination in jurisprudence or California law and ethics for the issuance of a temporary license pursuant to this section if successfully passing the examination is a requirement for all applicants for full licensure.

(h) This section shall not apply to the California Architects ~~Board~~ *Board, the Landscape Architects Technical Committee, the Contractors' State License Board,* or the State Board of Chiropractic Examiners.

1 (i) This section shall not apply to a board that established a
2 temporary licensing process before January 1, 2014.

O

Assembly
California Legislature

BRIAN MAIENSCHEIN
ASSEMBLYMAN, SEVENTY-SEVENTH DISTRICT

AB 186 – Fact Sheet

Background

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

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

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

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

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

This Bill

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

Contacts

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916-319-2077

AMENDED IN SENATE JUNE 24, 2014

AMENDED IN ASSEMBLY APRIL 1, 2014

AMENDED IN ASSEMBLY MARCH 18, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 1535

Introduced by Assembly Member Bloom
(Coauthor: Senator Pavley)

January 21, 2014

An act to add Section 4052.01 to the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

AB 1535, as amended, Bloom. Pharmacists: naloxone hydrochloride.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law, generally, authorizes a pharmacist to dispense or furnish drugs only pursuant to a valid prescription. Existing law authorizes a pharmacist to furnish emergency contraceptives and hormonal contraceptives pursuant to standardized procedures or protocols developed and approved by both the board and the Medical Board of California, as specified, or developed by the pharmacist and an authorized prescriber. Existing law also authorizes a pharmacist to furnish nicotine replacement products pursuant to standardized procedures or protocols developed and approved by both the board and the Medical Board of California, as specified. Existing law authorizes a licensed health care provider who is permitted to prescribe an opioid antagonist and is acting with reasonable care to prescribe and dispense or distribute an opioid antagonist for the treatment of an opioid overdose

to a person at risk of an opioid-related overdose or a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose.

This bill would authorize a pharmacist to furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California, in consultation with specified entities. The bill would require the board and the Medical Board of California, in developing those procedures and protocols, to include procedures requiring the pharmacist to provide a consultation to ensure the education of the person to whom the drug is furnished, as specified, and notification of the patient's primary care provider of drugs or devices furnished to the patient, as specified. The bill would prohibit a pharmacist furnishing naloxone hydrochloride pursuant to its provisions from permitting the person to whom the drug is furnished to waive the consultation described above. The bill would require a pharmacist to complete a training program on the use of opioid antagonists prior to performing this procedure. The bill would require each board to enforce these provisions with respect to its respective licensees.

This bill would authorize the California State Board of Pharmacy to adopt emergency regulations to establish the standardized procedures or protocols that would remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted as described above.

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

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

1 SECTION 1. Section 4052.01 is added to the Business and
2 Professions Code, to read:
3 4052.01. (a) Notwithstanding any other provision of law, a
4 pharmacist may furnish naloxone hydrochloride in accordance
5 with standardized procedures or protocols developed and approved
6 by both the board and the Medical Board of California, in
7 consultation with the California Society of Addiction Medicine,
8 the California Pharmacists Association, and other appropriate
9 entities. In developing those standardized procedures or protocols,
10 the board and the Medical Board of California shall include the
11 following:

(1) Procedures to ensure education of the person to whom the drug is furnished, including, but not limited to, opioid overdose prevention, recognition, and response, safe administration of naloxone hydrochloride, potential side effects or adverse events, and the imperative to seek emergency medical care for the patient.

(2) Procedures to ensure the education of the person to whom the drug is furnished regarding the availability of drug treatment programs.

(3) Procedures for the notification of the patient's primary care provider with patient consent of any drugs or devices furnished to the patient, or entry of appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider, and with patient consent.

(b) A pharmacist furnishing naloxone hydrochloride pursuant to this section shall not permit the person to whom the drug is furnished to waive the consultation required by the board and the Medical Board of California.

(c) Prior to performing a procedure authorized under this section, a pharmacist shall complete a training program on the use of opioid antagonists that consists of at least one hour of approved continuing education on the use of naloxone hydrochloride.

(d) The board and the Medical Board of California are each authorized to ensure compliance with this section. Each board is specifically charged with enforcing this section with respect to its respective licensees. This section does not expand the authority of a pharmacist to prescribe any prescription medication.

(e) The board may adopt emergency regulations to establish the standardized procedures or protocols. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The emergency regulations authorized by this subdivision are exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted pursuant to subdivision (a).

O

AB 1535 (Bloom)
Overdose Antidote Furnished by Pharmacists
Fact Sheet

SUMMARY

Due to increases in the use and abuse of prescription painkillers in our state, prescription drug overdose is now the leading cause of accidental death in California—killing more people than car accidents or gunshots. Naloxone hydrochloride is a safe and effective antidote to opioid overdose that when administered by a family member or another witness, can prevent death or disability. Currently naloxone is available only by prescription, or from programs operating under standing orders from a physician. This bill would improve access to this life-saving medication by allowing pharmacists to furnish naloxone in accordance with standardized procedures developed and approved by the Medical Board of California and the Board of Pharmacy.

EXISTING LAW

Generally, pharmacists dispense drugs pursuant to a prescription from a physician or another authorized medical professional. Pharmacists are also allowed to furnish specified prescription medications including emergency contraception, hormonal contraception, and nicotine replacement products pursuant to protocols developed and approved by the Medical Board of California and the Board of Pharmacy.

BACKGROUND

Naloxone hydrochloride is a low-cost generic medication available only by prescription, first approved by the FDA in 1971. As an "opioid antagonist," it reverses the effects of opioid medications, including oxycodone, oxymorphone, Vicodin, Percocet, methadone, and heroin. Naloxone does not produce intoxication, and has no potential for addiction or abuse. It is safe to administer, either by injection or intranasally.

Public health experts agree that increasing access to naloxone is a key strategy in preventing drug overdose deaths. The American Medical Association, the White House Office of National Drug Control Policy, the Director of the National Institutes of Drug Abuse, among others, have called for providing naloxone to at-risk patients, first responders, and persons likely to witness a potentially fatal opioid overdose.

Programs in some California cities and other parts of the US provide naloxone and training to laypeople including law enforcement officers, EMTs and other first responders, pain patients and their caregivers, and persons addicted to prescription or illegal opiates. A recent publication of US Centers for Disease Control and Prevention profiled programs that provided over 50,000 doses to laypersons, with over 10,000 life-saving reversals reported, and no negative outcomes.

Furthering the policy of increasing access to naloxone, last year the Legislature passed AB 635 (Ammiano) to allow physicians to prescribe naloxone to family members and friends of persons at-risk for overdose, or by standing order without a prior examination of the patient.

The logical next step in combating the epidemic of opioid overdose in California is to allow community pharmacists to provide naloxone and counseling to at-risk patients pursuant to standards developed by the Medical Board and the Board of Pharmacy.

FISCAL

Minimal and absorbable costs for development of protocols by the Board of Pharmacy and the Medical Board of California.

SUPPORT

California Pharmacist Association (Sponsor)
Drug Policy Alliance (Sponsor)
Health Officers Association of California
California Society of Addiction Medicine
California Narcotics Officers Association
A New PATH--Parents for Addiction Treatment and Healing
Bay Area Addiction Recovery Treatment
Broken No More
County Alcohol and Drug Program Administrators Association of California
Center for Living and Learning
Cri-Help, Inc.
Families ACT!
Fred Brown Recovery Services

Office of Assemblymember Richard Bloom Contact: Theresa Pena (916) 319-2050

GRASP--Grief Recovery After a Substance Passing
HealthRight 360
Health Officers Association of California
Homeless Health Care Los Angeles
Hope of the Valley Recovery Home
Los Angeles Community Action Network
Los Angeles HIV Drug and Alcohol Task Force
Mary Magdalene Project
Primary Purpose Sober Living Homes
Safer Alternatives Through Networking and Education
San Fernando Recovery Center

OPPOSITION

None on file

Contacts:

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bwarren@cpha.com 916-606-8016

Glenn Backes, Drug Policy Alliance
glennbackes@mac.com 916-202-2538

California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

April 24, 2014

The Honorable Richard H. Bloom
California State Assembly
State Capitol, Room 2179
Sacramento, CA 95814

RE: Assembly Bill 1535 - Support

Dear Assembly Member Bloom:

The Board of Pharmacy is pleased to Support your Assembly Bill 1535, which would allow a pharmacist to furnish naloxone hydrochloride to a person pursuant to a standardized procedure or protocol developed by the Board of Pharmacy and the Medical Board of California (MBC), and to require pharmacists furnishing naloxone to complete specified training. Assembly Bill 1535 would ensure persons receiving naloxone would receive appropriate education regarding opioid overdose prevention, recognition, and response; potential side effects or adverse events; and education and information related to drug treatment programs.

The board supports your efforts to expand access to this life-saving drug to those who are at risk of an opioid-related overdose, or to those who may assist a person at risk.

Please don't hesitate to contact me at (916) 574-7911 or the board's legislative manager Carolyn Klein at (916) 574-7913 if you have any questions.

Sincerely,

VIRGINIA HEROLD
Executive Officer

AMENDED IN ASSEMBLY APRIL 23, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 1702

Introduced by Assembly Member Maienschein
(Coauthor: Senator Mitchell)

February 13, 2014

An act to add Section 480.5 to the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 1702, as amended, Maienschein. Professions and vocations: incarceration.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs, among other entities. Existing law establishes various eligibility criteria needed to qualify for a license and authorizes a board to deny a license on the grounds that the applicant has been convicted of a crime substantially related to the qualifications, functions, or duties of the business or profession for which application is made.

This bill would provide that an individual who has satisfied any of the requirements needed to obtain a license while incarcerated, who applies for that license upon release from incarceration, and who is otherwise eligible for the license shall not be subject to a delay in processing the application or a denial of the license solely ~~based on the prior incarceration, except when the incarceration was for a crime substantially related to the qualifications, functions, or duties of the business or profession.~~ *on the basis that some or all of the licensure requirements were completed while the individual was incarcerated.*

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

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

1 SECTION 1. Section 480.5 is added to the Business and
2 Professions Code, to read:
3 480.5. (a) An individual who has satisfied any of the
4 requirements needed to obtain a license regulated under this ~~code~~
5 *division* while incarcerated, who applies for that license upon
6 release from incarceration, and who is otherwise eligible for the
7 license shall not be subject to a delay in processing his or her
8 application or a denial of the license solely ~~based on the prior~~
9 ~~incarceration, except as provided in Section 480.~~ *on the basis that*
10 *some or all of the licensure requirements were completed while*
11 *the individual was incarcerated.*
12 (b) Nothing in this section shall be construed to apply to a
13 petition for reinstatement of a license *or to limit the ability of a*
14 *board to deny a license pursuant to Section 480.*
15 (c) This section shall not apply to the licensure of individuals
16 under the initiative act referred to in Chapter 2 (commencing with
17 Section 1000) of Division 2.

O

Assembly Bill No. 1727

Passed the Assembly July 3, 2014

_____

Chief Clerk of the Assembly

Passed the Senate June 30, 2014

_____

Secretary of the Senate

This bill was received by the Governor this _____ day of _____, 2014, at _____ o'clock ____M.

_____

Private Secretary of the Governor

Corrected 7-9-14

CHAPTER _____

An act to amend Section 150204 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 1727, Rodriguez. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish a repository and distribution program under which a pharmacy that is owned by, or contracts with, the county may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Under existing law, only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet the United States Pharmacopoeia standards is eligible for donation to the repository and distribution program. Existing law also prohibits the donation of controlled substances to the repository and distribution program.

This bill would also prohibit the donation to a county repository and distribution program of a medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy that prohibits that inventory transfer or requires the inventory transfer to receive prior authorization from the manufacturer of the medication.

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

SECTION 1. Section 150204 of the Health and Safety Code is amended to read:

150204. (a) (1) A county may establish, by an action of the county board of supervisors or by an action of the public health officer of the county, as directed by the county board of supervisors, a repository and distribution program for purposes of this division. The county shall advise the California State Board of Pharmacy within 30 days from the date it establishes a repository and distribution program.

(2) Only an eligible entity, pursuant to subdivision (a) of Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department and the California State Board of Pharmacy in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4) (A) A participating entity shall disclose to the county health department on a quarterly basis the name and location of the source of all donated medication it receives.

(B) A participating primary care clinic, as described in paragraph (3) of subdivision (a) of Section 150201 shall disclose to the county health department the name of the licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division. This physician shall be the professional director, as defined in subdivision (c) of Section 4182 of the Business and Professions Code.

(C) The county board of supervisors or public health officer of the county shall, upon request, make available to the California State Board of Pharmacy the information in this division.

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. If the county board of supervisors, the public health officer of the county, or the California State Board of Pharmacy prohibits an eligible or participating entity from participating in the program, it shall provide written notice to the prohibited entity within 15 days of making this determination. The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy shall ensure that this notice also is provided to one another.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish written procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a participating entity.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a health or care facility, as described in Section 150202, shall have been under the control of a staff member of the health or care facility who is licensed in California as a health care professional or has completed, at a minimum, the training requirements specified in Section 1569.69.

(d) (1) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program, and once identified, shall be quarantined immediately and handled and disposed of in accordance with the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104).

(2) (A) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code shall not be donated if this inventory transfer is prohibited by that strategy, or if the inventory transfer requires prior authorization from the manufacturer of the medication.

(B) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code, the donation of which is not prohibited pursuant to subparagraph (A), shall be managed and dispensed according to the requirements of that strategy.

(e) A pharmacist or physician at a participating entity shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist or physician shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor or licensed waste hauler.

(4) (A) Transferred to another participating entity within the county to be dispensed to eligible patients pursuant to this division. Notwithstanding this paragraph, a participating county-owned pharmacy may transfer eligible donated medication to a participating county-owned pharmacy within another adjacent county that has adopted a program pursuant to this division, if the pharmacies transferring the medication have a written agreement between the entities that outlines protocols and procedures for safe and appropriate drug transfer that are consistent with this division.

(B) Medication donated under this division shall not be transferred by any participating entity more than once, and after it has been transferred, shall be dispensed to an eligible patient, destroyed, or returned to a reverse distributor or licensed waste hauler.

(C) Medication transferred pursuant to this paragraph shall be transferred with documentation that identifies the drug name, strength, and quantity of the medication, and the donation facility from where the medication originated shall be identified on medication packaging or in accompanying documentation. The document shall include a statement that the medication may not be transferred to another participating entity and must be handled

pursuant to subparagraph (B). A copy of this document shall be kept by the participating entity transferring the medication and the participating entity receiving the medication.

(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed or transferred under this program and shall be either destroyed or returned to a reverse distributor. This medication shall not be sold, dispensed, or otherwise transferred to any other entity.

(i) Medication donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.

(j) Medication donated to the repository and distribution program shall be segregated from the participating entity's other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.

(k) A participating entity shall keep complete records of the acquisition and disposition of medication donated to, and transferred, dispensed, and destroyed under, the repository and distribution program. These records shall be kept separate from the participating entity's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

(*l*) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, shall include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating entity shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

April 24, 2014

The Honorable Freddie Rodriguez
California State Assembly
State Capitol, Room 2160
Sacramento, CA 95814

RE: Assembly Bill 1727 - Support

Dear Assembly Member Rodriguez:

The Board of Pharmacy is pleased to Support your Assembly Bill 1727, which would prohibit those drugs that can only be dispensed to a patient registered with the drug's manufacturer in accordance with FDA requirements, from being donated to a county drug repository and distribution program.

Please don't hesitate to contact me at (916) 574-7911 or the board's legislative manager Carolyn Klein at (916) 574-7913 if you have any questions.

Sincerely,

VIRGINIA HEROLD
Executive Officer

California LEGISLATIVE INFORMATION

AB-1841 Medical assistants. (2013-2014)

As amended June 2, 2014 "amends the Law"

SECTION 1. Section 2069 of the Business and Professions Code is amended to read:

2069. (a) (1) Notwithstanding any other law, a medical assistant may administer medication only by intradermal, subcutaneous, or intramuscular injections and perform skin tests and additional technical supportive services upon the specific authorization and supervision of a licensed physician and surgeon or a licensed podiatrist. A medical assistant may also perform all these tasks and services upon the specific authorization of a physician assistant, a nurse practitioner, or a certified nurse-midwife.

(2) The supervising physician and surgeon may, at his or her discretion, in consultation with the nurse practitioner, certified nurse-midwife, or physician assistant, provide written instructions to be followed by a medical assistant in the performance of tasks or supportive services. These written instructions may provide that the supervisory function for the medical assistant for these tasks or supportive services may be delegated to the nurse practitioner, certified nurse-midwife, or physician assistant within the standardized procedures or protocol, and that tasks may be performed when the supervising physician and surgeon is not onsite, if either of the following apply:

(A) The nurse practitioner or certified nurse-midwife is functioning pursuant to standardized procedures, as defined by Section 2725, or protocol. The standardized procedures or protocol, including instructions for specific authorizations, shall be developed and approved by the supervising physician and surgeon and the nurse practitioner or certified nurse-midwife.

(B) The physician assistant is functioning pursuant to regulated services defined in Section 3502, including instructions for specific authorizations, and is approved to do so by the supervising physician and surgeon.

(b) As used in this section and Sections 2070 and 2071, the following definitions apply:

(1) "Medical assistant" means a person who may be unlicensed, who performs basic administrative, clerical, and technical supportive services in compliance with this section and Section 2070 for a licensed physician and surgeon or a licensed podiatrist, or group thereof, for a medical or podiatry corporation, for a physician assistant, a nurse practitioner, or a certified nurse-midwife as provided in subdivision (a), or for a health care service plan, who is at least 18 years of age, and who has had at least the minimum amount of hours of appropriate training pursuant to standards established by the board. The medical assistant shall be issued a certificate by the training institution or instructor indicating satisfactory completion of the required training. A copy of the certificate shall be retained as a record by each employer of the medical assistant.

(2) "Specific authorization" means a specific written order prepared by the supervising physician and surgeon or the supervising podiatrist, or the physician assistant, the nurse practitioner, or the certified nurse-midwife as provided in subdivision (a), authorizing the procedures to be performed on a patient, which shall be placed in the patient's medical record, or a standing order prepared by the supervising physician and surgeon or the supervising podiatrist, or the physician assistant, the nurse practitioner, or the certified nurse-midwife as provided in subdivision (a), authorizing the procedures to be performed, the duration of which shall be consistent with accepted medical practice. A notation of the standing order shall be placed on the patient's medical record.

(3) "Supervision" means the supervision of procedures authorized by this section by the following practitioners, within the scope of their respective practices, who shall be physically present in the treatment facility during the performance of those procedures:

(A) A licensed physician and surgeon.

(B) A licensed podiatrist.

(C) A physician assistant, nurse practitioner, or certified nurse-midwife as provided in subdivision (a).

(4) *(A)* "Technical supportive services" means simple routine medical tasks and procedures that may be safely performed by a medical assistant who has limited training and who functions under the supervision of a licensed physician and surgeon or a licensed podiatrist, or a physician assistant, a nurse practitioner, or a certified nurse-midwife as provided in subdivision (a).

(B) Notwithstanding any other law, in a facility licensed by the California State Board of Pharmacy under Section 4180 or 4190, other than a facility operated by the state, "technical supportive services" also includes handing to a patient a prepackaged prescription drug, excluding a controlled substance, that is labeled in compliance with Section 4170 and all other applicable state and federal laws and ordered by a licensed physician and surgeon, a licensed podiatrist, a physician assistant, a nurse practitioner, or a certified nurse-midwife in accordance with subdivision (a). In every instance, prior to handing the medication to a patient pursuant to this subparagraph, the properly labeled and prepackaged prescription drug shall have the patient's name affixed to the package and a licensed physician and surgeon, a licensed podiatrist, a physician assistant, a nurse practitioner, or a certified nurse-midwife shall verify that it is the correct medication and dosage for that specific patient and shall provide the appropriate patient consultation regarding use of the drug.

(c) Nothing in this section shall be construed as authorizing any of the following:

(1) The licensure of medical assistants.

(2) The administration of local anesthetic agents by a medical assistant.

(3) The board to adopt any regulations that violate the prohibitions on diagnosis or treatment in Section 2052.

(4) A medical assistant to perform any clinical laboratory test or examination for which he or she is not authorized by Chapter 3 (commencing with Section 1200).

(5) A nurse practitioner, certified nurse-midwife, or physician assistant to be a laboratory director of a clinical laboratory, as those terms are defined in paragraph (8) of subdivision (a) of Section 1206 and subdivision (a) of Section 1209.

(d) A nurse practitioner, certified nurse-midwife, or physician assistant shall not authorize a medical assistant to perform any clinical laboratory test or examination for which the medical assistant is not authorized by Chapter 3 (commencing with Section 1200). A violation of this subdivision constitutes unprofessional conduct.

(e) Notwithstanding any other law, a medical assistant shall not be employed for inpatient care in a licensed general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

16 CCR § 1707.2

§ 1707.2. Duty to Consult.

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:
(1) upon request; or
(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:
(A) whenever the prescription drug has not previously been dispensed to a patient; or
(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.
(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:
(A) of his or her right to request consultation; and
(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.
(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or

(b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:
(1) directions for use and storage and the importance of compliance with directions; and
(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:
(1) the name and description of the medication;
(2) the route of administration, dosage form, dosage, and duration of drug therapy;
(3) any special directions for use and storage;
(4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;
(5) prescription refill information;
(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;
(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.
Note: Authority cited: Sections 4005, 4076 and 4122, Business and Professions Code. Reference: Sections 4005, 4076 and 4122, Business and Professions Code.

Hearing Date: June 23, 2014 Bill No: AB 1841

SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT
Senator Ted W. Lieu, Chair

Bill No: AB 1841 Author: Mullin
As Amended: June 2, 2014 Fiscal: No

SUBJECT: Medical assistants.

SUMMARY: Authorizes a medical assistant to hand out properly labeled and prepackaged prescription drugs to patients as part of their existing authorization to provide "technical supportive services."

Existing law:

1) Establishes the Medical Practice Act (Act) which licenses and regulates physicians and surgeons as well as regulating medical assistants (MAs) by the Medical Board of California (MBC) within the Department of Consumer Affairs (DCA). (Business and Professions Code (BPC) § 2000 et seq.)

2) Defines a MA as a person who may be unlicensed, who performs basic administrative, clerical, and technical supportive services, as specified, for a licensed physician and surgeon or a licensed podiatrist, a physician or podiatrist group, a medical or podiatry corporation, a physician assistant, a nurse practitioner, a certified nurse-midwife or for a health care service plan. (BPC § 2069 (b) (1))

3) Requires a MA to be at least 18 years of age and have at least the minimum amount of hours of appropriate training pursuant to standards established MBC, and further requires a MA to have a certificate by the training institution or instructor indicating satisfactory completion of the required training, and for each employer to retain a copy of this certificate. (BPC § 2069 (b) (1))

4) Authorizes a MA to administer medication only by intradermal, subcutaneous, or intramuscular injections and perform skin tests and additional technical supportive services upon the specific authorization and supervision of a licensed physician and surgeon or podiatrist. A MA may also perform all these tasks and services upon the specific authorization of a physician assistant, nurse practitioner, or certified nurse-midwife. (BPC § 2069 (a) (1))

5) Permits a supervising physician and surgeon to provide written instructions to be followed by a MA in performing tasks or supportive services. The written instructions may delegate the supervision of the MA in performing the tasks or services to a nurse practitioner, certified nurse-midwife, or physician assistant within the standardized procedures or protocols. (BPC § 2069 (a) (2)

6) Defines "technical supportive services" as simple routine medical tasks and procedures that may be safely performed by a MA who has limited training and who functions under the supervision of a licensed physician and surgeon, podiatrist, physician assistant, nurse practitioner or a certified nurse-midwife, as specified. (BPC § 2069 (b) (4))

7) Permits a MA to perform venipuncture or skin puncture for the purposes of withdrawing blood upon specific authorization and supervision of a licensed physician and surgeon, podiatrist, physician assistant, nurse practitioner or nurse-midwife if the MA has met minimum training requirements established by MBC. (BPC § 2070)

8) Establishes the Pharmacy Law which provides for the licensure and regulation of pharmacies, pharmacists and wholesalers of dangerous drugs or devices by the Board of Pharmacy (BOP) within the DCA.

9) Governs the prescribing, dispensing, or furnishing of dangerous drugs by prescribers, defined to include a physician and surgeon, podiatrist and certified nurse-midwife, as specified. (BPC § 4170).

10) Authorizes a pharmacy to employ a non-licensed person to type a prescription label or otherwise enter prescription information into a computer record system, but the responsibility for the accuracy of the prescription information and the prescription as dispensed lies with the registered pharmacist who initials the prescription or prescription record. At the direction of the registered pharmacist, a non-licensed person may also request and receive refill authorization. (California Code of Regulations, Title 16, Division 17, Article 11, Section 1793.3 (a))

11) Authorizes a licensed nonprofit community clinic or free clinic, a county owned or operated primary care clinic, a clinic operated by a federally recognized Indian tribe or tribal organization, a clinic operated by primary care community or free clinic, a student health center, a nonprofit multispecialty clinic, as specified, to be licensed by the BOP 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, as specified. (BPC § 4180)

12) Authorizes a surgical clinic, as specified, to be licensed by the BOP to purchase drugs 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, as specified. (BPC § 4190)

This bill:

1) Expands the definition of "technical supportive services" carried out by a MA in a clinic described in Items 11 and 12 above, other than a facility operated by the state, to include the following:

   a) Handing a patient a properly labeled and prepackaged prescription drug, excluding a controlled substance, ordered by a licensed physician and surgeon, podiatrist, physician assistant, nurse practitioner or certified nurse-midwife, as specified.

   b) Requires that prior to a MA handing the medication to a patient, a licensed physician and surgeon, podiatrist, physician assistant, nurse practitioner, or certified nurse-midwife shall

verify that the medication and dosage for that specific patient is correct, that the patient's name is affixed to the package and shall provide the appropriate patient consultation regarding the use of the drug.

FISCAL EFFECT: This bill has been keyed "non-fiscal" by Legislative Counsel.

COMMENTS:

1. **Purpose.** This bill is sponsored by Planned Parenthood Affiliates of California to increase patient access to care by specifying medical assistants' ability to include handing to a patient medication that has already been packaged and labeled by the dispensing provider. This authority is limited to facilities that are licensed by the State Board of Pharmacy, excluding those operated by the state. The bill also excludes controlled substances, and requires the medication be properly labeled by the ordering provider who has appropriately counseled the patient on the medication.

2. **Background.** According to the Author, "Medical Assistants are currently allowed to provide a range of supportive and medical services like administer medication (including narcotics) orally, topically, or through injection; perform skin tests; apply bandages, remove casts and stitches, perform simple lab/ screening tests; and perform technical supportive services upon training and authorization of a licensed physician and surgeon. MAs cannot dispense and are not allowed to hand over medication of any kind to patients."

   The Author further states that current practice in community health centers relies on the use of MAs to support physicians and clinicians (nurse practitioners, certified nurse-midwives, and physician assistants). Since MAs are not permitted to hand medication to a patient, that administrative task must be done by the physician or clinician, taking their time away from seeing more patients and focusing on the care they have been trained to provide. The Author states, "After examining a patient, diagnosing them, discussing options and providing education on any recommended medication, the clinician must go back to the locked pharmacy closet to select, package and label the appropriate medication and then returns to the patient exam room to physically hand the patient the medication. This bill would allow a MA to take the medication, after it has been pulled, packaged, and labeled, and physically hand it to the patient."

   The Author indicates that although this takes only several minutes for each patient, it adds up significantly over time ultimately limiting patient access. "This minor increase in MAs ability to hand over medication will free up other providers to see additional patients. More fully utilizing the abilities of [MAs] will increase efficiency in health facilities like community health centers and by seeing more patients, health facilities will be able to reduce waiting times and expand patient access to care.

   With millions of Californians newly enrolled in health care coverage under the ACA [Affordable Care Act] and millions more eligible for coverage, expanding access to care is essential to ensuring that these individuals have meaningful coverage. California needs to utilize all health care professionals and those that assist them to the fullest extent of their abilities and

potential to increase access, improving our health care delivery system to better serve the newly enrolled population and providing coverage for the remaining uninsured."

3. **Medical Assistants**. MAs are unlicensed, but certificated, individuals. MAs must have a high school diploma or GED equivalent and take a certificate course at an approved school. Prior to performing technical supportive services, a medical assistant must receive training, as necessary, and it is the responsibility of the supervising physician, podiatrist or instructor to assure the MA's competence in performing that service at the appropriate standard of care.

   The MBC regulations establish the requirements which allow certifying organizations to certify medical assistants. According to the MBC, the training may be administered under a licensed physician, podiatrist, registered nurse, licensed vocational nurse, physician assistant or qualified medical assistant, or in a secondary, post-secondary, or adult education program in a public school authorized by the Department of Education, in a community college program, or a post-secondary institution accredited or approved by the Bureau for Private Postsecondary Education. To administer medications by intramuscular, subcutaneous and intradermal injections, perform skin tests, perform venipuncture or skin puncture to withdraw blood, a MA must complete specified training prescribed by the MBC regulations.

   MA's may perform specific functions as part of "technical supportive" services in addition to administrative functions, including:

   a) Administer medications orally, sublingually, topically, vaginally or rectally, or by providing a single dose to a patient for immediate self-administration;

   b) Administer medication by inhalation;

   c) Perform electrocardiogram, electroencephalogram, or plethysmography tests;

   d) Apply and remove bandages and dressings;

   e) Remove sutures or staples from superficial incisions or lacerations;

   f) Collect by non-invasive techniques and preserve specimens for testing, including urine, sputum, semen and stool;

   g) Prepare patients for and assist the physician, podiatrist, physician assistant or registered nurse in examinations or procedures including positioning, draping, shaving and disinfecting treatment sites, and prepare a patient for gait analysis testing;

   h) As authorized by the physician or podiatrist, provide patient information and instructions;

   i) Collect and record patient data including height, weight, temperature, pulse, respiration rate and blood pressure, and basic information about the presenting and previous conditions;

   j) Perform simple laboratory and screening tests customarily performed in a medical office.

This bill clarifies that MAs may hand out properly labeled and prepackaged prescription drugs to patients as part of "technical supportive services" in specified types of clinics. Based upon currently authorized abilities, this appears to be well within a MA's scope of practice.

4. **Related Legislation.** SB 352 (Pavley, Chapter 352, Statutes of 2013) authorized MAs to perform technical supportive services in any medical setting upon specific authorization of a physician assistant, nurse practitioner, or certified nurse-midwife without a physician on the premises. This bill removed the requirement that a MA be supervised by a physician assistant, nurse practitioner, or certified nurse-midwife only in specified community clinics.

   SB 1852 (Alpert, 2000) would have allowed MAs to perform specified tasks and services which they were only permitted to perform upon the specific authorization and under the direct supervision of a physician or podiatrist upon the specific authorization of a physician's assistant, a nurse practitioner or a nurse-midwife in a licensed clinic, as specified, that is enrolled as a Medi-Cal provider in the Family Planning, Access, Care, and Treatment Waiver Program. (Status: *SB 1852 died in Assembly Health Committee.*)

   SB 252 (Alpert, Chapter 234, Statutes of 2003) specified that MAs are not authorized to perform a clinical laboratory test or examination and does not authorize a nurse practitioner, nurse-midwife or physician assistant to be a laboratory director of a clinical laboratory. (*Note: This bill originally included a provision for MAs to provide technical supportive services under the supervision of a physician assistant, nurse practitioner or nurse midwife, but those provisions were removed from the bill in response to opposition.*)

   SB 111 (Alpert, Chapter 358, Statues of 2001) authorized a medical assistant to perform specified services in community and free clinics under the supervision of a physician assistant, nurse practitioner or nurse-midwife. This bill authorized a physician and surgeon in these specified clinics to provide written instructions for MAs, regarding the performance of tasks or duties, while under the supervision of a physician assistant, nurse practitioner or nurse midwife when the supervising physician and surgeon was not on site.

5. **Arguments in Support.** In sponsoring the bill, Planned Parenthood Affiliates of California writes that this minor expansion of MA duties will increase access to care in health care settings, including Planned Parenthood, by reducing waiting times caused, in part, by clinicians who must package the medications and then themselves hand it to the patient. "Authorizing MAs to hand over pre-packaged/pre-labeled medication is consistent with (if not less complicated than) the level and complexity and range of medical and technical support services they are already authorized to perform, including administering narcotics and giving injections." Finally, Planned Parenthood argues that authorizing MAs to hand over medication frees up the clinician from this administrative duty and allows them to see more patients and spend more time with each patient answering questions.

   Medical Board of California (MBC) believes the bill will help further the Board's mission of increasing access to care, and writes in support that allowing MAs to hand over properly labeled, pre-packaged medication is a minor increase in the MAs duties, and one that does not compromise consumer protection, since the physician would have to label the medication for the patient, package the medication, and provide the appropriate consultation.

California Association for Nurse Practitioners (CANP) states that with millions of Californians entering the health care system due to ACA implementation, healthcare providers' ability to deliver care as efficiently as possible is essential to meet the often pent-up demand for services of these newly eligible individuals. The already strained delivery system is experiencing increased pressure, particularly in underserved areas, where NPs play a critical role in providing care. AB 1841 will assist with this problem by allowing medical assistants to furnish patients with pre-labeled, pre-packaged medication, only after the medication has been selected and packaged by a physician or advanced practice clinician, such as an NP. This will allow primary care practitioners, including NPs, to dedicate more time to providing patient care.

The Association of California Healthcare Districts (ACHD) states that millions of Californians rely on public health facilities and programs for vital health care services. Additionally, many of our Community Based Healthcare Districts specialize in promoting community health care, focusing on prevention, food access, and disease management. In many parts of California, Healthcare Districts act as the sole provider of health care services in their communities. ACHD states: "As more Californians are now eligible for care, it is important that health care staff is utilized efficiently to accommodate patients as they seek care and medical services. AB 1841 creates greater staffing efficiency by utilizing medical assistants to assist with handing patients a pre-packaged and pre-authorized prescription. By allowing medical assistants to assist in this responsibility, doctors, nurses and other medical staff can focus on other patient needs"

6. **Oppose Unless Amended.** California Society of Health-System Pharmacists (CSHP) opposes this bill unless it is amended, stating, "we support the intent of the bill to reduce waiting times, expand access, and improve patient care and satisfaction in community clinics, and we appreciate the recent amendments to specify patient education, we are still concerned by the language, especially as it lacks recognition of pharmacists as providers in community clinics." CSHP indicates that with the passage of SB 493 (Hernandez, Chapter 469, Statutes of 2013) pharmacists are recognized as providers and may offer certain services that are often provided telephonically and collaboratively with physicians in clinic settings. CSHP has indicated a willingness to work with the Author in his efforts to expand access and improve patient care.

7. **Arguments in Opposition.** California Right to Life Committee, Inc. argues that allowing unlicensed healthcare professionals to hand a patient "a properly labeled and prepackaged prescription drug," creates a completely unnecessary barrier to Doctor/ patient communication.

   "Even the most educated Medical Assistants with the highest certifications do not receive pharmacy training, neither are Medical Assistants allowed to diagnose or to perform any task that requires assessment – including commenting on the safety and/or efficacy of a prescribed drug. This bill makes it much harder for a patient to obtain a consultation with a professional qualified to address their questions and assess their health needs."

   Committee staff notes that the bill explicitly requires the licensed physician and surgeon, podiatrist, physician assistant, nurse practitioner, or certified nurse-midwife to provide the appropriate patient consultation regarding the use of the drug prior to the MA handing it to the patient.

SUPPORT AND OPPOSITION:

Support:

Planned Parenthood Affiliates of California (Sponsor)
Association of California Healthcare Districts
California Association for Nurse Practitioners
Medical Board of California

Oppose Unless Amended:

California Society of Health-System Pharmacists

Opposition:

California Right to Life Committee, Inc.

Consultant: G. V. Ayers

AMENDED IN ASSEMBLY MAY 15, 2014

AMENDED IN ASSEMBLY APRIL 21, 2014

AMENDED IN ASSEMBLY MARCH 28, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 2396

Introduced by Assembly Member Bonta
(Coauthor: Assembly Member Skinner)

February 21, 2014

An act to amend Section 480 of the Business and Professions Code, relating to expungement.

LEGISLATIVE COUNSEL'S DIGEST

AB 2396, as amended, Bonta. Convictions: expungement: licenses.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law authorizes a board to deny, suspend, or revoke a license on various grounds, including, but not limited to, conviction of a crime if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued. Existing law prohibits a board from denying a license on the ground that the applicant has committed a crime if the applicant shows that he or she obtained a certificate of rehabilitation in the case of a felony, or that he or she has met all applicable requirements of the criteria of rehabilitation developed by the board, as specified, in the case of a misdemeanor.

Existing law permits a defendant to withdraw his or her plea of guilty or plea of nolo contendere and enter a plea of not guilty in any case in which a defendant has fulfilled the conditions of probation for the entire

period of probation, or has been discharged prior to the termination of the period of probation, or has been convicted of a misdemeanor and not granted probation and has fully complied with and performed the sentence of the court, or has been sentenced to a county jail for a felony, or in any other case in which a court, in its discretion and the interests of justice, determines that a defendant should be granted this or other specified relief and requires the defendant to be released from all penalties and disabilities resulting from the offense of which he or she has been convicted.

This bill would prohibit a board from denying a license based solely on a conviction that has been dismissed pursuant to the above provisions.

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

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

1 SECTION 1. Section 480 of the Business and Professions Code
2 is amended to read:
3 480. (a) A board may deny a license regulated by this code
4 on the grounds that the applicant has one of the following:
5 (1) Been convicted of a crime. A conviction within the meaning
6 of this section means a plea or verdict of guilty or a conviction
7 following a plea of nolo contendere. Any action that a board is
8 permitted to take following the establishment of a conviction may
9 be taken when the time for appeal has elapsed, or the judgment of
10 conviction has been affirmed on appeal, or when an order granting
11 probation is made suspending the imposition of sentence,
12 irrespective of a subsequent order under the provisions of Section
13 1203.4, 1203.4a, or 1203.41 of the Penal Code.
14 (2) Done any act involving dishonesty, fraud, or deceit with the
15 intent to substantially benefit himself or herself or another, or
16 substantially injure another.
17 (3) (A) Done any act that if done by a licentiate of the business
18 or profession in question, would be grounds for suspension or
19 revocation of license.
20 (B) The board may deny a license pursuant to this subdivision
21 only if the crime or act is substantially related to the qualifications,
22 functions, or duties of the business or profession for which
23 application is made.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license solely on the basis that he or she has been convicted of a felony if he or she has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code or that he or she has been convicted of a misdemeanor if he or she has met all applicable requirements of the criteria of rehabilitation developed by the board to evaluate the rehabilitation of a person when considering the denial of a license under subdivision (a) of Section 482.

(c) Notwithstanding any other provisions of this code, a person shall not be denied a license solely on the basis of a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 *of the Penal Code*.

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

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AMENDED IN SENATE JULY 1, 2014

AMENDED IN ASSEMBLY MAY 23, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 2603

Introduced by Assembly Member V. Manuel Pérez
(Coauthor: Assembly Member Chesbro)

February 21, 2014

An act to amend Sections 11350 and 11377 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 2603, as amended, V. Manuel Pérez. Controlled substances: permissive lawful possession.

Existing law, subject to certain exceptions, provides that it is a crime for any person to possess specified controlled substances, punishable by a fine or imprisonment in a county jail, as specified, unless it is upon the written prescription of a physician, dentist, podiatrist, or veterinarian licensed to practice in this state.

This bill would create an exception from these prohibitions for possession of those controlled substances by a person other than the prescription holder if the possession of the controlled substance is at the direction or with the express authorization of the prescription holder and the ~~possessor of the controlled substance intends to deliver the prescription to the prescription holder within a reasonable period of time for the prescribed use by the prescription holder, or intends to discard the controlled substance in a lawful manner.~~ *sole purpose of the possession is to deliver the prescription to the prescription holder for its prescribed use or to discard the substance in a lawful manner.*

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

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

SECTION 1. Section 11350 of the Health and Safety Code is amended to read:

11350. (a) Except as otherwise provided in this division, every person who possesses (1) any controlled substance specified in subdivision (b) or (c), or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, or specified in subdivision (b) or (c) of Section 11055, or specified in subdivision (h) of Section 11056, or (2) any controlled substance classified in Schedule III, IV, or V which is a narcotic drug, unless upon the written prescription of a physician, dentist, podiatrist, or veterinarian licensed to practice in this state, shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code.

(b) Except as otherwise provided in this division, every person who possesses any controlled substance specified in subdivision (e) of Section 11054 shall be punished by imprisonment in a county jail for not more than one year or pursuant to subdivision (h) of Section 1170 of the Penal Code.

(c) Except as otherwise provided in this division, whenever a person who possesses any of the controlled substances specified in subdivision (a) or (b), the judge may, in addition to any punishment provided for pursuant to subdivision (a) or (b), assess against that person a fine not to exceed seventy dollars ($70) with proceeds of this fine to be used in accordance with Section 1463.23 of the Penal Code. The court shall, however, take into consideration the defendant's ability to pay, and no defendant shall be denied probation because of his or her inability to pay the fine permitted under this subdivision.

(d) Except in unusual cases in which it would not serve the interest of justice to do so, whenever a court grants probation pursuant to a felony conviction under this section, in addition to any other conditions of probation which may be imposed, the following conditions of probation shall be ordered:

(1) For a first offense under this section, a fine of at least one thousand dollars ($1,000) or community service.

(2) For a second or subsequent offense under this section, a fine of at least two thousand dollars ($2,000) or community service.

(3) If a defendant does not have the ability to pay the minimum fines specified in paragraphs (1) and (2), community service shall be ordered in lieu of the fine.

(e) It is not unlawful for a person other than the prescription holder to possess a controlled substance described in subdivision (a) if both of the following apply:

(1) The possession of the controlled substance is at the direction or with the express authorization of the prescription holder.

~~(2) The possessor of the controlled substance intends to deliver the prescription to the prescription holder within a reasonable period of time for the prescribed use by the prescription holder, or intends to discard the controlled substance in a lawful manner.~~

(2) The sole purpose of the possession is to deliver the prescription to the prescription holder for its prescribed use or to discard the substance in a lawful manner.

(f) This section does not permit the use of a controlled substance by a person other than the prescription holder or permit the distribution or sale of a controlled substance that is otherwise inconsistent with the prescription.

SEC. 2. Section 11377 of the Health and Safety Code is amended to read:

11377. (a) Except as authorized by law and as otherwise provided in subdivision (b) or Section 11375, or in Article 7 (commencing with Section 4211) of Chapter 9 of Division 2 of the Business and Professions Code, every person who possesses any controlled substance which is (1) classified in Schedule III, IV, or V, and which is not a narcotic drug, (2) specified in subdivision (d) of Section 11054, except paragraphs (13), (14), (15), and (20) of subdivision (d), (3) specified in paragraph (11) of subdivision (c) of Section 11056, (4) specified in paragraph (2) or (3) of subdivision (f) of Section 11054, or (5) specified in subdivision (d), (e), or (f) of Section 11055, unless upon the prescription of a physician, dentist, podiatrist, or veterinarian, licensed to practice in this state, shall be punished by imprisonment in a county jail for a period of not more than one year or pursuant to subdivision (h) of Section 1170 of the Penal Code.

(b) (1) Any person who violates subdivision (a) by unlawfully possessing a controlled substance specified in subdivision (f) of

Section 11056, and who has not previously been convicted of a violation involving a controlled substance specified in subdivision (f) of Section 11056, is guilty of a misdemeanor.

(2) Any person who violates subdivision (a) by unlawfully possessing a controlled substance specified in subdivision (g) of Section 11056 is guilty of a misdemeanor.

(3) Any person who violates subdivision (a) by unlawfully possessing a controlled substance specified in paragraph (7) or (8) of subdivision (d) of Section 11055 is guilty of a misdemeanor.

(4) Any person who violates subdivision (a) by unlawfully possessing a controlled substance specified in paragraph (8) of subdivision (f) of Section 11057 is guilty of a misdemeanor.

(c) In addition to any fine assessed under subdivision (b), the judge may assess a fine not to exceed seventy dollars ($70) against any person who violates subdivision (a), with the proceeds of this fine to be used in accordance with Section 1463.23 of the Penal Code. The court shall, however, take into consideration the defendant's ability to pay, and no defendant shall be denied probation because of his or her inability to pay the fine permitted under this subdivision.

(d) It is not unlawful for a person other than the prescription holder to possess a controlled substance described in subdivision (a) if both of the following apply:

(1) The possession of the controlled substance is at the direction or with the express authorization of the prescription holder.

~~(2) The possessor of the controlled substance intends to deliver the prescription to the prescription holder within a reasonable period of time for the prescribed use by the prescription holder, or intends to discard the controlled substance in a lawful manner.~~

(2) The sole purpose of the possession is to deliver the prescription to the prescription holder for its prescribed use or to discard the substance in a lawful manner.

(e) This section does not permit the use of a controlled substance by a person other than the prescription holder or permit the distribution or sale of a controlled substance that is otherwise inconsistent with the prescription.

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AMENDED IN SENATE JULY 2, 2014

AMENDED IN ASSEMBLY APRIL 10, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 2757

Introduced by ~~Committee on Revenue and Taxation (Bocanegra (Chair), Gordon, Mullin, Pan, V. Manuel Pérez, and Ting)~~ *Assembly Member Bocanegra*

March 24, 2014

An act to amend ~~Sections 60501 and 60505.5 of the Revenue and Taxation Code, relating to taxation~~ *Sections 4128, 4128.4, and 4128.5 of the Business and Professions Code, relating to pharmacy.*

LEGISLATIVE COUNSEL'S DIGEST

AB 2757, as amended, ~~Committee on Revenue and Taxation~~ *Bocanegra.* ~~Diesel Fuel Tax Law: reimbursements.~~ *Centralized hospital packaging pharmacies: medication labels.*

The Pharmacy Law provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law authorizes a centralized hospital packaging pharmacy to prepare medications for administration to inpatients within its own general acute care hospital or certain other commonly owned hospitals. Existing law requires that these medications be barcoded to be readable at the inpatient's bedside in order to retrieve certain information, including the date that the medication was prepared and the components used in the drug product.

This bill would instead require that this information be displayed on a human-readable label or be retrievable using the lot number or control

number of the medication, rather than by reading the barcode. The bill would require that a medication's barcode be machine readable using medication administration software, and that the software compare the information contained in the barcode to the electronic medical record of the inpatient in order to verify that the medication to be given is the correct medication, dosage, and route of administration for that patient. Because a knowing violation of these provisions 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 Diesel Fuel Tax Law imposes a tax upon the removal, entry, sale, delivery, or specified use of diesel fuel, at a specified rate per gallon. That law provides for a reimbursement of the amount of that tax to persons who have used that tax-paid fuel in specified nontaxable uses, which is allowed through a claim for refund.~~

~~This bill would allow a claim for refund for amounts of tax paid on the biodiesel fuel portion of dyed blended biodiesel fuel removed from an approved terminal at the terminal rack, as provided, to the extent a supplier can show that the tax on that biodiesel fuel has been paid by the same supplier.~~

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 4128 of the Business and Professions*
2 *Code is amended to read:*
3 4128. (a) Notwithstanding Section 4029, a centralized hospital
4 packaging pharmacy may prepare medications, by performing the
5 following specialized functions, for administration only to
6 inpatients within its own general acute care hospital and one or
7 more general acute care hospitals if the hospitals are under common
8 ownership and located within a 75-mile radius of each other:
9 (1) Preparing unit dose packages for single administration to
10 inpatients from bulk containers, if each unit dose package is

barcoded *pursuant* to ~~contain at least the information required by~~ Section 4128.4.

(2) Preparing *sterile* compounded unit dose drugs for ~~parenteral therapy for~~ administration to inpatients, if each compounded unit dose drug is barcoded *pursuant* to ~~contain at least the information required by~~ Section 4128.4.

(3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded *pursuant* to ~~contain at least the information required by~~ Section 4128.4.

(b) For purposes of this article, "common ownership" means that the ownership information on file with the board pursuant to Section 4201 for the licensed pharmacy is consistent with the ownership information on file with the board for the other licensed pharmacy or pharmacies for purposes of preparing medications pursuant to this section.

SEC. 2. Section 4128.4 of the Business and Professions Code is amended to read:

4128.4. *(a)* Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be *machine* readable at the inpatient's bedside *using barcode medication administration software*. ~~Upon reading the barcode, the following information shall be retrievable:~~

~~(a) The date the medication was prepared.~~

~~(b) The components used in the drug product.~~

~~(c) The lot number or control number.~~

~~(d) The expiration date.~~

~~(e) The National Drug Code Directory number.~~

~~(f) The name of the centralized hospital packaging pharmacy.~~

(b) The barcode medication administration software shall permit health care practitioners to ensure that, before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration. The software shall verify that the medication satisfies these criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient.

(c) For purposes of this section, "barcode medication administration software" means a computerized system designed to prevent medication errors in health care settings.

SEC. 3. Section 4128.5 of the Business and Professions Code is amended to read:

4128.5. ~~The label for each~~ *(a) Any* unit dose medication produced by a centralized hospital packaging pharmacy shall ~~contain~~ *display a human-readable label that contains all of the following:*

(1) The date that the medication was prepared.

~~(a)~~

(2) The~~ expiration~~ *beyond-use* date.

~~(b)~~

(3) The established name of the drug.

~~(c)~~

(4) The quantity of the active ingredient.

~~(d)~~

(5) Special storage or handling requirements.

(6) The lot number or control number assigned by the centralized hospital packaging pharmacy.

(7) The name of the centralized hospital packaging pharmacy.

(b) For quality control and investigative purposes, a pharmacist shall be able to retrieve all of the following information using the lot number or control number described in subdivision (a):

(1) The components used in the drug product.

(2) The expiration date of each of the drug's components.

(3) The National Drug Code Directory number.

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.

~~SECTION 1. Section 60501 of the Revenue and Taxation Code is amended to read:~~

~~60501. Persons who have paid a tax for diesel fuel lost, sold, or removed as provided in paragraph (4) of subdivision (a), or used in a nontaxable use, other than on a farm for farming purposes or in an exempt bus operation, shall, except as otherwise provided in this part, be reimbursed and repaid the amount of the tax.~~

~~(a) Except as otherwise provided in subdivision (b), a claim for refund with respect to diesel fuel is allowed under this section only if all of the following apply:~~

~~(1) Tax was imposed on the diesel fuel to which the claim relates.~~

~~(2) The claimant bought or produced the diesel fuel and did not sell or resell it in this state except as provided in paragraph (4).~~

~~(3) The claimant has filed a timely claim for refund that contains the information required under subdivision (b) and the claim is supported by the original invoice or original invoice facsimile retained in an alternative storage media showing the purchase. If no original invoice was created, electronic invoicing shall be accepted as reflected by a computerized facsimile when accompanied by an original copy of the bill of lading or fuel manifest that can be directly tied to the electronic invoice.~~

~~(4) The diesel fuel was any of the following:~~

~~(A) Used for purposes other than operating motor vehicles upon the public highways of the state.~~

~~(B) Exported for use outside of this state. Diesel fuel carried from this state in the fuel tank of a motor vehicle is not deemed to be exported from this state unless the diesel fuel becomes subject to tax as an import under the laws of the destination state.~~

~~(C) Used in any construction equipment that is exempt from vehicle registration pursuant to the Vehicle Code, while operated within the confines and limits of a construction project.~~

~~(D) Used in the operation of a motor vehicle on any highway that is under the jurisdiction of the United States Department of Agriculture and with respect to the use of the highway the claimant pays, or contributes to, the cost of construction or maintenance thereof pursuant to an agreement with, or permission of, the United States Department of Agriculture.~~

~~(E) Used in any motor vehicle owned by any county, city and county, city, district, or other political subdivision or public agency when operated by it over any highway constructed and maintained by the United States or any department or agency thereof within a military reservation in this state. If the motor vehicle is operated both over the highway and over a public highway outside the military reservation in a continuous trip the tax shall not be refunded as to that portion of the diesel fuel used to operate the vehicle over the public highway outside the military reservation.~~

~~Nothing contained in this section shall be construed as a refund of the tax for the use of diesel fuel in any motor vehicle operated upon a public highway within a military reservation, which highway is constructed or maintained by this state or any political subdivision thereof.~~

~~As used in this section, "military reservation" includes any establishment of the United States Government or any agency thereof used by the Armed Forces of the United States for military, air, or naval operations, including research projects.~~

~~(F) Sold by a supplier and which was sold to any consulate officer or consulate employee under circumstances which would have entitled the supplier to an exemption under paragraph (6) of subdivision (a) of Section 60100 if the supplier had sold the diesel fuel directly to the consulate officer or consulate employee.~~

~~(G) Lost in the ordinary course of handling, transportation, or storage.~~

~~(H) (i) Sold by a person to the United States and its agencies and instrumentalities under circumstances that would have entitled that person to an exemption from the payment of diesel fuel tax under Section 60100 had that person been the supplier of this diesel fuel.~~

~~(ii) Sold by a supplier and which was sold by credit card to the United States and its agencies and instrumentalities under circumstances which would have entitled the supplier to an exemption under Section 60100 if the supplier had sold the diesel fuel directly to the United States and its agencies and instrumentalities.~~

~~(I) Sold by a person to a train operator for use in a diesel-powered train or for other off-highway use under circumstances that would have entitled that person to an exemption from the payment of diesel fuel tax under Section 60100 had that person been the supplier of this diesel fuel.~~

~~(J) Removed from an approved terminal at the terminal rack, but only to the extent that the supplier can show that the tax on the same amount of diesel fuel has been paid more than one time by the same supplier.~~

~~(b) Where tax is not imposed on dyed blended biodiesel fuel upon removal from an approved terminal at the terminal rack, if tax was previously imposed on the biodiesel fuel portion of the dyed blended biodiesel fuel, then, pursuant to paragraph (1) of~~

~~subdivision (a), a claim for refund is allowed for the tax that was paid on that biodiesel fuel, but only to the extent a supplier can show that the tax on that biodiesel fuel has been paid by the same supplier.~~

~~(c) Each claim for refund under this section shall contain the following information with respect to all of the diesel fuel covered by the claim:~~

~~(1) The name, address, telephone number, and permit number of the person that sold the diesel fuel to the claimant and the date of the purchase.~~

~~(2) A statement by the claimant that the diesel fuel covered by the claim did not contain visible evidence of dye.~~

~~(3) A statement, which may appear on the invoice, original invoice facsimile, or similar document, by the person that sold the diesel fuel to the claimant that the diesel fuel sold did not contain visible evidence of dye.~~

~~(4) The total amount of diesel fuel covered by the claim.~~

~~(5) The use made of the diesel fuel covered by the claim described by reference to specific categories listed in paragraph (4) of subdivision (a).~~

~~(6) If the diesel fuel covered by the claim was exported, a statement that the claimant has the proof of exportation.~~

~~(d) Each claim for refund under this section shall be made on a form prescribed by the board and shall be filed for a calendar year. If, at the close of any of the first three quarters of the calendar year, more than seven hundred fifty dollars ($750) is refundable under this section with respect to diesel fuel used or exported during that quarter or any prior quarter during the calendar year, and for which no other claim has been filed, a claim may be filed for the quarterly period. To facilitate the administration of this section, the board may require the filing of claims for refund for other than yearly periods.~~

~~SEC. 2. Section 60505.5 of the Revenue and Taxation Code is amended to read:~~

~~60505.5. The claim for refund forms prescribed in subdivision (d) of Section 60501 and subdivision (d) of Section 60502 may include, but not be limited to, electronic media. The claim for refund forms shall be authenticated in a form or pursuant to methods as may be prescribed by the board.~~

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AMENDED IN ASSEMBLY JUNE 10, 2014

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 *and repeal* Section 4076.3 ~~to~~ *of* 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.~~ *Existing regulations of the board provide standardized directions for use that are required to be used on drug container labels, as specified.*

This bill would require the board to conduct a survey of a representative sample of licensed pharmacists to determine the usage of the directions for use described above. The bill would require this survey to address certain issues, including, but not limited to, whether and how often the pharmacist utilizes the directions for use, barriers to utilizing the directions for use, and other directions for use utilized by the pharmacist. The bill would also require the board to conduct a similar survey of vendors that provide electronic health records (EHR)

to pharmacies and prescribers to determine the type of directions for use included in the vendor's EHR programming, as specified. The bill would authorize these surveys to be conducted with other routine surveys conducted by the board during its regular course of business. The bill would require the board to report the survey findings at its July 2016 board meeting and to publish the findings on the board's Internet Web site, as specified.

~~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 use its own translations of the board's English language directions for 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 a trained and qualified translator or translation service, as defined, is utilized to complete the additional translations. The bill would authorize a pharmacist to 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~~ *no*.

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

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

4076.3. (a) The board shall conduct a survey of a representative sample of licensed pharmacists to determine the utilization of the standardized directions for use provided in paragraph (4) of subdivision (a) of Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations. The survey shall address, but not be limited to, all of the following issues:

(1) Whether the pharmacist utilizes the standardized directions for use.

(2) How often the pharmacist utilizes the standardized directions for use.

(3) Challenges or barriers to utilizing the standardized directions for use.

(4) Other directions for use utilized by the pharmacist.

(b) The board shall conduct a survey of vendors that provide electronic health records (EHR) to pharmacies and prescribers to determine the type of directions for use included in the vendor's EHR programming. The survey shall address, but not be limited to, all of the following issues:

(1) Whether the standardized directions for use described in subdivision (a) are included in the vendor's EHR programming.

(2) Challenges or barriers to utilizing the standardized directions for use in the vendor's EHR programming.

(3) Other directions for use utilized by the vendor in its EHR programming.

(c) The surveys required by this section may be conducted with other routine surveys conducted by the board during its regular course of business.

(d) The board shall report the findings of the surveys required by this section in the aggregate at its July 2016 board meeting and publish these findings on its Internet Web site.

This section shall remain in effect only until January 1, 2020, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2020, deletes or extends that date.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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AMENDED IN ASSEMBLY JUNE 30, 2014

AMENDED IN ASSEMBLY JUNE 18, 2014

AMENDED IN ASSEMBLY JUNE 10, 2014

AMENDED IN SENATE MAY 27, 2014

AMENDED IN SENATE APRIL 21, 2014

AMENDED IN SENATE APRIL 1, 2014

SENATE BILL No. 1014

Introduced by Senator Jackson
(Principal coauthor: Senator Leno)
(Coauthors: Senators Evans, Hancock, Liu, and Pavley)
(Coauthors: Assembly Members Ammiano, Skinner, and Williams)

February 13, 2014

An act to add Section 4068.1 to the Business and Professions Code, to amend Section 117700 of, and to add Section 117670.1 to, the Health and Safety Code, and to add Article 3.4 (commencing with Section 47120) to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 1014, as amended, Jackson. Pharmaceutical waste: home generated: collection.

(1) The Department of Resources Recycling and Recovery was required, pursuant to provisions repealed on January 1, 2013, to develop, in consultation with appropriate state, local, and federal agencies, model programs for the collection and proper disposal of drug waste.

This bill would require the department and the California State Board of Pharmacy, on or before January 1, 2016, to jointly develop and adopt regulations to authorize a participant to establish a program to collect and properly dispose of home-generated pharmaceutical waste, based upon the model guidelines developed by the department pursuant to those repealed provisions and to include specified ~~requirements and~~ provisions in those regulations. The bill would deem a participant operating a program in accordance with those regulations to be in compliance with all state laws and regulations concerning the handling, management, and disposal of home-generated pharmaceutical waste. ~~The bill would, however, allow an entity with a home-generated pharmaceutical waste program, existing as of January 1, 2015, to continue operating that program.~~

(2) The 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 defines the term medical waste and excludes certain types of waste from that definition.

This bill would define the term "home-generated pharmaceutical waste" for purposes of that act. The bill would exclude, from the definition of medical waste, home-generated pharmaceutical waste that is handled by a collection and disposal program operating in accordance with the regulations specified above.

(3) The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy establishments by the California State Board of Pharmacy, and makes a knowing violation of that law a misdemeanor.

The bill would also authorize a pharmacy to accept the return of home-generated pharmaceutical waste from a consumer, consistent with specified federal laws. Because a knowing violation of this provision would be a crime, the bill would impose a state-mandated local program.

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

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

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

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

SECTION 1. Section 4068.1 is added to the Business and Professions Code, to read:

4068.1. A pharmacy may accept the return of home-generated pharmaceutical waste, as defined in Section 117670.1 of the Health and Safety Code, from a consumer, consistent with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) and the federal Controlled Substances Act (21 U.S.C. Sec. 801 et seq.).

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 home-generated pharmaceutical, 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.

SEC. 3. Section 117700 of the Health and Safety Code is amended to read:

117700. Medical waste does not include any of the following:

(a) Waste generated in food processing or biotechnology that does not contain an infectious agent as defined in Section 117675.

(b) Waste generated in biotechnology that does not contain human blood or blood products or animal blood or blood products suspected of being contaminated with infectious agents known to be communicable to humans.

(c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomitus, unless it contains fluid blood, as provided in subdivision (d) of Section 117635.

(d) Waste ~~which~~ *that* is not biohazardous, such as paper towels, paper products, articles containing nonfluid blood, and other medical solid waste products commonly found in the facilities of medical waste generators.

(e) Hazardous waste, radioactive waste, or household waste, including, but not limited to, home-generated sharps waste, as defined in Section 117671.

(f) Waste generated from normal and legal veterinarian, agricultural, and animal livestock management practices on a farm or ranch.

(g) Home-generated pharmaceutical waste, including, but not limited to, consolidated home-generated pharmaceutical waste, that is handled by a collection and disposal program operating in accordance with the regulations adopted by the Department of Resources Recycling and Recovery *and the California State Board of Pharmacy* pursuant to Article 3.4 (commencing with Section 47120) of Chapter 1 of Part 7 of Division 30 of the Public Resources Code.

SEC. 4. Article 3.4 (commencing with Section 47120) is added to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, to read:

Article 3.4. Home-Generated Pharmaceutical Waste Collection and Disposal

47120. For the purposes of this article, the following terms have the following meanings, unless the context clearly requires otherwise:

(a) "Consumer" means an individual purchaser or owner of a pharmaceutical. "Consumer" does not include a business, corporation, limited partnership, or an entity involved in a wholesale transaction between a distributor and retailer.

(b) "Entity" means a state or local public agency, pharmacy, veterinarian clinic, or other office or facility.

(c) "Home-generated pharmaceutical waste" has the same meaning as defined in Section 117670.1 of the Health and Safety Code, and includes all of the following:

(1) Articles recognized in the official United States Pharmacopoeia, the official National Formulary, the official Homeopathic Pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias.

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

(3) Articles, excluding food, intended to affect the structure or function of the body of humans or other animals.

(4) Articles intended for use as a component of an article specified in paragraph (1), (2), or (3).

(d) "Participant" means an entity that the department *and the California State Board of Pharmacy* deems appropriate for implementing and evaluating a program in accordance with the

regulations adopted pursuant to this article and that chooses to participate.

(e) "Sale" includes, but is not limited to, transactions conducted through sales outlets, catalogs, or the Internet, or any other similar electronic means, but does not include a sale that is a wholesale transaction with a distributor or retailer.

47121. ~~(a)~~ On or before January 1, 2016, the department and the California State Board of Pharmacy shall jointly develop regulations, to be approved by both agencies before adoption, authorizing a participant to establish a program to collect and properly dispose of home-generated pharmaceutical waste. The regulations shall be based upon the model guidelines developed by the department pursuant to former Section 47122, as that section read on January 1, 2012, ~~shall include the requirements specified in subdivision (b),~~ and shall include ~~the provisions specified in subdivisions (c) and (d).~~ *both of the following:*

(a) Provisions that do all of the following:

(1) Specify the types of participants authorized to maintain permanent collection locations.

(2) Specify any requirements for obtaining state permits or approvals.

(3) Specify which home-generated pharmaceutical wastes may be included in a program, including requirements for the collection of a controlled substance, as defined in Section 11007 of the Health and Safety Code.

(4) Require participants to enter into arrangements with medical or hazardous waste haulers, including ensuring that all home-generated pharmaceutical waste included in a program is appropriately picked up and transported by registered waste haulers.

(5) Specify methods for handling wastes commingled in containers with other household waste or hazardous waste.

(6) Provide methods for collecting and storing home-generated pharmaceutical waste included in a program, including the use of secured containers, and ensure that collected home-generated pharmaceutical waste is not resold, reused, sold, donated, or provided to anyone other than a registered medical or hazardous waste hauler.

(7) Provide that a facility that collects home-generated pharmaceutical waste included in a program is responsible for

ensuring that the storage, removal, and transportation of containers and the disposal of the waste are in compliance with state laws and regulations.

(8) Require the collection and retention of detailed information and invoices for each collection site.

(9) Impose requirements for one-time or periodic collection events.

(10) Impose requirements for mail-back collection and disposal programs.

(11) Impose requirements for the appropriate public education and management of consolidated home-generated pharmaceutical waste included in a program to ensure the public health and safety.

(b) ~~The regulations adopted pursuant to this section shall require~~ *Provisions requiring* a participant to take all of the following actions:

(1) Provide, at no additional cost to the consumer, for the safe take back and proper disposal of pharmaceuticals.

(2) Ensure the protection of the public health and safety, the environment, and the health and safety of consumers and employees.

(3) Report *annually* to the department, for purposes of ~~evaluation,~~ *evaluating* the safety, efficiency, and effectiveness of the implemented program on an annual basis. The report shall contain both qualitative and quantitative measures, as determined by the department *and the California State Board of Pharmacy*.

(4) Protect against the potential for the diversion of pharmaceutical waste *included in a program* for unlawful use or sale.

~~(5) Provide notices and materials to consumers that provide information about the potential impacts of improper disposal of home-generated pharmaceutical waste and the return opportunities for the proper disposal of home-generated pharmaceutical waste. Those materials shall include, but are not limited to, all of the following:~~

~~(A) Internet Web site links.~~

~~(B) Telephone numbers placed on an invoice or purchase order, or packaged with a pharmaceutical.~~

~~(C) Information about the opportunities and locations for no-cost home-generated pharmaceutical waste disposal.~~

~~(D) Signage that is prominently displayed and easily visible to the consumer.~~

~~(E) Written materials provided to the consumer at the time of purchase or delivery.~~

~~(F) Reference to the home-generated pharmaceutical waste take back opportunity in advertising or other promotional materials.~~

~~(G) Direct communications with the consumer at the time of purchase.~~

~~(c) The regulations adopted pursuant to this section shall include provisions that do all of the following:~~

~~(1) Specify the types of participants authorized to maintain permanent collection locations.~~

~~(2) Specify any requirements for obtaining state permits or approvals.~~

~~(3) Require participants to enter into arrangements with medical or hazardous waste haulers, including ensuring that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers.~~

~~(4) Specify which home-generated pharmaceutical wastes may be included in a program, including requirements for the collection of a controlled substance, as defined in Section 11007 of the Health and Safety Code.~~

~~(5) Specify methods for handling wastes commingled in containers with other household waste or hazardous waste.~~

~~(6) Provide methods for collecting and storing home-generated pharmaceutical waste, including the use of secured containers, and ensure that collected home-generated pharmaceutical waste is not resold, reused, sold, donated, or provided to anyone other than a registered medical or hazardous waste hauler.~~

~~(7) Provide that a facility that collects home-generated pharmaceutical waste is responsible for ensuring that the storage, removal, and transportation of containers and the disposal of the waste are in compliance with state laws and regulations.~~

~~(8) Require the collection and retention of detailed information and invoices for each collection site.~~

~~(9) Impose requirements for one-time or periodic collection events.~~

~~(10) Impose requirements for mail-back collection and disposal programs.~~

~~(d) The department shall include, in the regulations adopted pursuant to this section, provisions for the appropriate management of consolidated home-generated pharmaceutical waste to ensure the public health and safety.~~

47122. A participant operating a program in accordance with the regulations adopted pursuant to this article shall be deemed in compliance with all state laws and regulations concerning the handling, management, and disposal of home-generated pharmaceutical waste.

~~47123. Nothing in this article shall prohibit an entity with a home-generated pharmaceutical waste program, existing as of January 1, 2015, from continuing to operate that program.~~

47123. Regulations adopted pursuant to this article shall conform to any requirements of a federal drug take-back program.

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.

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

June 12, 2014

The Honorable Hannah-Beth Jackson
Member, California State Senate
State Capitol, Room 5080
Sacramento, CA 95814

RE: SB 1014 (as amended June 10, 2014) – Support

Dear Senator Jackson,

I am pleased to advise you that with the June 10, 2014 amendments to SB 1014, the board now supports this bill. This bill would direct this board and CalRecycle to develop regulations for drug take-back programs in California.

Prescription drug abuse has been declared an epidemic by the Centers for Disease Control. One source of medicine that becomes abused is unused medicine stored in households. Once standardized requirements for appropriate disposal methods of these medicines are in place in California, we believe that voluntary participation by pharmacies under the developed standards will provide patients with one means to dispose of the unwanted medication.

We look forward on collaborating with CalRecycle on these standards. Thank you for making this possible.

Sincerely,

/s/

VIRGINIA HEROLD
Executive Officer

AMENDED IN ASSEMBLY JUNE 26, 2014

AMENDED IN ASSEMBLY JUNE 18, 2014

AMENDED IN ASSEMBLY JUNE 5, 2014

AMENDED IN SENATE MAY 5, 2014

AMENDED IN SENATE APRIL 10, 2014

AMENDED IN SENATE MARCH 28, 2014

SENATE BILL No. 1039

Introduced by Senator Hernandez

February 18, 2014

An act to amend Sections 4052.6 and 4115 of, and to add Sections 4119.6 and 4119.7 to, the Business and Professions Code, and to amend Sections 11150 and 11210 of, and to add Section 1250.06 to, the Health and Safety Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1039, as amended, Hernandez. Pharmacy.

(1) Existing law, the Pharmacy Law, the violation of which is a crime, provides for the licensure and regulation of pharmacies, pharmacists, intern pharmacists, and pharmacy technicians by the California State Board of Pharmacy. The Pharmacy Law authorizes an intern pharmacist to perform all functions of a pharmacist, and authorizes a pharmacy technician to perform packaging, manipulative, repetitive, or other nondiscretionary tasks, in each case under supervision of a pharmacist, as specified.

This bill would authorize a pharmacy technician to perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while

assisting and while under the direct supervision and control of a pharmacist, as specified. This bill would also authorize, in a licensed health care facility, as defined, a pharmacy technician's duties to include, among other things, sealing emergency containers for use in the health care facility.

(2) Existing law authorizes a pharmacy to furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Public Health and other existing law requirements, as specified.

This bill would authorize an intern pharmacist, under the direct supervision and control of a pharmacist, to stock, replenish, and inspect the drugs maintained in the emergency pharmaceutical supplies container and the emergency medical system supplies of a licensed general acute care hospital, as defined.

This bill would authorize an intern pharmacist to inspect the drugs maintained in a licensed health care facility, as defined, pursuant to policies and procedures of the health care facility. This bill would also authorize a licensed health care facility to dispense or furnish dangerous drugs and dangerous devices to inpatients and patients upon discharge pursuant to preprinted or electronic standing orders, order sets, and protocols, as specified. This bill would require licensed health care facilities to store and maintain drugs in accordance with national standards regarding the storage area and refrigerator or freezer temperature and in accordance with the manufacturers' guidelines.

Because a violation of certain provisions of the bill would be a crime, the bill would create a state-mandated local program.

(3) Existing law authorizes a pharmacist recognized by the board as an advanced practice pharmacist to perform specified functions, including performing patient assessments *and ordering and interpreting drug therapy-related tests, and requires a pharmacist who orders and interprets those tests to ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber*.

This bill would also authorize a pharmacist recognized by the board as an advanced practice pharmacist to order patient assessments *and would require a pharmacist that orders and performs patient assessments to ensure that the ordering of those assessments is done*

in coordination with the patient's primary care provider or diagnosing prescriber.

(4) Existing law authorizes a pharmacist to initiate or adjust the drug regimen of a patient under specified circumstances. Existing law authorizes specified practitioners, including a pharmacist acting within the scope of an authorized pilot project, to prescribe, furnish, or administer controlled substances to a patient suffering from a disease, ailment, injury, or infirmity, but only when in good faith he or she believes the disease, ailment, injury, or infirmity requires the treatment, and only in the quantity and for the length of time as reasonably necessary.

This bill would modify that list of practitioners to include a pharmacist initiating or adjusting the drug regimen of a patient as authorized under existing law.

(5) Existing law provides for the licensure and inspection of health facilities, including general acute care hospitals, by the State Department of Public Health. Existing regulations require a hospital to have a pharmacy on the premises or a pharmacy license, as specified. Existing regulations also require the hospital to consult the pharmacist on the proper methods of, among other things, repackaging and labeling bulk cleaning agents.

This bill would instead provide that a licensed general acute care hospital or an acute psychiatric hospital, as defined, is not required to consult a pharmacist regarding repackaging and labeling of bulk cleaning agents, solvents, chemicals, and nondrug hazardous substances except for areas where sterile compounding is performed.

(6) 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 4052.6 of the Business and Professions
2 Code is amended to read:
3 4052.6. (a) A pharmacist recognized by the board as an
4 advanced practice pharmacist may do all of the following:

(1) Order and 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 performs patient assessments pursuant to paragraph (1) of subdivision (a)* and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those *assessments or* 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. 2. Section 4115 of the Business and Professions Code is amended to read:

4115. (a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.

(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(e) No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her

professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(g) Notwithstanding subdivisions (a) and (b), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. Nothing in this subdivision shall be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (f).

(h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(i) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following.

(1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system as authorized under Section 4119.

(2) Sealing emergency containers for use in the health care facility.

(3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist in charge and the director or

chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

SEC. 3. Section 4119.6 is added to the Business and Professions Code, to read:

4119.6. An intern pharmacist under the direct supervision and control, as defined in Section 4023.5, of a pharmacist may stock, replenish, and inspect the emergency pharmaceutical supplies container and the emergency medical system supplies of a licensed general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

SEC. 4. Section 4119.7 is added to the Business and Professions Code, to read:

4119.7. (a) A health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, may administer, dispense, or furnish dangerous drugs and dangerous devices to inpatients or patients upon discharge pursuant to preprinted or electronic standing orders, order sets, and protocols established under the policies and procedures of the health care facility, if the order is dated, timed, and authenticated in the medical record of the patient to whom the dangerous drug or dangerous device will be provided.

(b) A health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code shall store and maintain drugs in accordance with national standards regarding the storage area and refrigerator or freezer temperature, and otherwise pursuant to the manufacturer's guidelines. The health care facility's policies and procedures shall specify these storage parameters.

(c) An intern pharmacist under the direct supervision and control, as defined in Section 4023.5, of a pharmacist, shall inspect the drugs maintained in the health care facility at least once per month. The health care facility shall establish specific written policies and procedures for inspections pursuant to this paragraph.

SEC. 5. Section 1250.06 is added to the Health and Safety Code, immediately following Section 1250.05, to read:

1250.06. A licensed general acute care hospital, as defined pursuant to subdivision (a) of Section 1250, or an acute psychiatric hospital, as defined pursuant to subdivision (b) of Section 1250, is not required to consult a pharmacist regarding repackaging and labeling of bulk cleaning agents, solvents, chemicals, and nondrug

hazardous substances used throughout the hospital except for areas where sterile compounding is performed.

SEC. 6. Section 11150 of the Health and Safety Code is amended to read:

11150. No person other than a physician, dentist, podiatrist, or veterinarian, or naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and Professions Code, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, a naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

SEC. 7. Section 11210 of the Health and Safety Code is amended to read:

11210. A physician, surgeon, dentist, veterinarian, naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and Professions Code, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an

optometrist acting within the scope of Section 3041 of the Business and Professions Code may prescribe for, furnish to, or administer controlled substances to his or her patient when the patient is suffering from a disease, ailment, injury, or infirmities attendant upon old age, other than addiction to a controlled substance.

The physician, surgeon, dentist, veterinarian, naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and Professions Code, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code shall prescribe, furnish, or administer controlled substances only when in good faith he or she believes the disease, ailment, injury, or infirmity requires the treatment.

The physician, surgeon, dentist, veterinarian, or naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and Professions Code, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or a naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code shall prescribe, furnish, or administer controlled substances only in the quantity and for the length of time as are reasonably necessary.

1 SEC. 8. No reimbursement is required by this act pursuant to
2 Section 6 of Article XIII B of the California Constitution because
3 the only costs that may be incurred by a local agency or school
4 district will be incurred because this act creates a new crime or
5 infraction, eliminates a crime or infraction, or changes the penalty
6 for a crime or infraction, within the meaning of Section 17556 of
7 the Government Code, or changes the definition of a crime within
8 the meaning of Section 6 of Article XIII B of the California
9 Constitution.

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ATTACHMENT 3

Other Legislation

AMENDED IN SENATE MAY 27, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 1743

Introduced by Assembly Member Ting
(Coauthor: Senator Monning)

February 14, 2014

An act to amend Sections 4144.5, 4145.5, and 4148.5 of, and to repeal Sections 4144, 4145, 4148, and 4149.5 of, the Business and Professions Code, and to amend Section ~~11364.1~~ *11364* of, and to repeal Section ~~11364~~ *11364.1* of, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1743, as amended, Ting. Hypodermic needles and syringes.

Existing law, until January 1, 2015, authorizes a pharmacist or physician to furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older solely for his or her personal use.

This bill would delete that January 1, 2015, date of repeal and would, *until January 1, 2021,* authorize a pharmacist or physician to provide an unlimited number of hypodermic needles and syringes to a person 18 years of age or older solely for his or her personal use.

Under existing law it is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphanelia used for unlawfully injecting or smoking specified controlled substances. Existing law, until January 1, 2015, exempts from this prohibition the possession of 30 or fewer hypodermic needles and syringes if acquired from an authorized source, *and from January 1, 2015, through December 31, 2018, inclusive, exempts from this prohibition possession solely for personal*

use of 10 or fewer hypodermic needles or syringes if acquired from an authorized source.

This bill would ~~delete that January 1, 2015, date of repeal and would~~, *instead, and until January 1, 2021,* exempt the possession of any amount of hypodermic needles and syringes that are acquired from an authorized source.

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

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

1 SECTION 1. Section 4144 of the Business and Professions
2 Code is repealed.
3 SEC. 2. Section 4144.5 of the Business and Professions Code
4 is amended to read:
5 4144.5. A person may sell or obtain hypodermic needles and
6 hypodermic syringes without a prescription or permit, for uses that
7 the board determines are industrial, and that person shall not be
8 required to comply with Section 4145.5 or 4146.
9 SEC. 3. Section 4145 of the Business and Professions Code is
10 repealed.
11 SEC. 4. Section 4145.5 of the Business and Professions Code
12 is amended to read:
13 4145.5. (a) Notwithstanding any other provision of law, a
14 pharmacist or physician may, without a prescription or a permit,
15 furnish hypodermic needles and syringes for human use, and a
16 person may, without a prescription or license, obtain hypodermic
17 needles and syringes from a pharmacist or physician for human
18 use, if the person is known to the furnisher and the furnisher has
19 previously been provided a prescription or other proof of a
20 legitimate medical need requiring a hypodermic needle or syringe
21 to administer a medicine or treatment.
22 (b) Notwithstanding any other provision of law *and until*
23 *January 1, 2021*, as a public health measure intended to prevent
24 the transmission of HIV, viral hepatitis, and other bloodborne
25 diseases among persons who use syringes and hypodermic needles,
26 and to prevent subsequent infection of sexual partners, newborn
27 children, or other persons, a physician or pharmacist may, without
28 a prescription or a permit, furnish hypodermic needles and syringes
29 for human use to a person 18 years of age or older, and a person

18 years of age or older may, without a prescription or license, obtain hypodermic needles and syringes solely for personal use from a physician or pharmacist.

(c) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to Section 4141 for use on animals, providing that no needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.

(d) A pharmacy that furnishes nonprescription hypodermic needles and syringes shall store hypodermic needles and syringes in a manner that ensures that they are available only to authorized personnel, and are not accessible to other persons.

(e) In order to provide for the safe disposal of hypodermic needles and syringes, a pharmacy or hypodermic needle and syringe exchange program that furnishes nonprescription hypodermic needles and syringes shall *counsel consumers on safe disposal and* provide consumers with one or more of the following disposal options:

(1) It shall establish an onsite, safe, hypodermic needle and syringe collection and disposal program that meets applicable state and federal standards for collection and disposal of medical sharps waste.

(2) It shall furnish, or make available, mail-back sharps containers authorized by the United States Postal Service that meet applicable state and federal requirements for the transport of medical sharps waste, and shall provide tracking forms to verify destruction at a certified disposal facility.

(3) It shall furnish, or make available, a sharps container that meets applicable state and federal standards for collection and disposal of medical sharps waste.

(f) ~~A~~ *Until January 1, 2021, a* pharmacy that furnishes nonprescription syringes shall provide written information or verbal counseling to consumers at the time of furnishing or sale of nonprescription hypodermic needles or syringes on how to do the following:

(1) Access drug treatment.

(2) Access testing and treatment for HIV and hepatitis C.

(3) Safely dispose of sharps waste.

SEC. 5. Section 4148 of the Business and Professions Code is repealed.

SEC. 6. Section 4148.5 of the Business and Professions Code is amended to read:

4148.5. All stocks of hypodermic needles or syringes shall be confiscated if found outside the licensed premises of any person holding a permit under Section 4141 and found not in the possession or under the control of a person entitled to an exemption under Section 4143, 4144.5, or 4145.5, or under Section ~~11364.5~~ *11364*, 121349, or 121349.1 of the Health and Safety Code.

SEC. 7. Section 4149.5 of the Business and Professions Code is repealed.

~~SEC. 8. Section 11364 of the Health and Safety Code is repealed.~~

SEC. 8. Section 11364 of the Health and Safety Code is amended to read:

11364. (a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e) or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance ~~which~~ *that* is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.

~~(c) Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within the city, for the period commencing January 1, 2005, and ending December 31, 2018, subdivision (a) shall not apply to the possession solely for personal use of 10 or fewer hypodermic needles or syringes if acquired from an authorized source.~~

~~(d) This section shall be inoperative until January 1, 2015.~~

(c) Until January 1, 2021, as a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other

bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, this section shall not apply to the possession solely for personal use of hypodermic needles or syringes if acquired from a physician, pharmacist, hypodermic needle and syringe exchange program, or any other source that is authorized by law to provide sterile syringes or hypodermic needles without a prescription.

~~SEC. 9. Section 11364.1 of the Health and Safety Code is amended to read:~~

~~11364.1. (a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance which is a narcotic drug classified in Schedule III, IV, or V.~~

~~(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.~~

~~(c) As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, this section shall not apply to the possession solely for personal use of hypodermic needles or syringes if acquired from a physician, pharmacist, hypodermic needle and syringe exchange program, or any other source that is authorized by law to provide sterile syringes or hypodermic needles without a prescription.~~

SEC. 9. Section 11364.1 of the Health and Safety Code is repealed.

~~11364.1. (a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of~~

~~subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance which is a narcotic drug classified in Schedule III, IV, or V.~~

~~(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.~~

~~(c) As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, this section shall not apply to the possession solely for personal use of 30 or fewer hypodermic needles or syringes if acquired from a physician, pharmacist, hypodermic needle and syringe exchange program, or any other source that is authorized by law to provide sterile syringes or hypodermic needles without a prescription.~~

~~(d) This section shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends that date.~~

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California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

April 24, 2014

The Honorable Philip Y. Ting
California State Assembly
State Capitol, Room 3173
Sacramento, CA 95814

RE: Assembly Bill 1743 - Support

Dear Assembly Member Ting:

The Board of Pharmacy is pleased to Support your Assembly Bill 1743, which would remove the limit on the number of syringes a pharmacist is able to sell to an individual 18 years of age or older, without a prescription, and to remove the sunset date of the existing provisions.

The board historically has supported efforts that improve access to syringes and hypodermic needles for the purpose of reducing the spread of communicable diseases and protection of the public health through programs, such as the Disease Prevention Demonstration Project.

Please don't hesitate to contact me at (916) 574-7911 or the board's legislative manager Carolyn Klein at (916) 574-7913 if you have any questions.

Sincerely,

VIRGINIA HEROLD
Executive Officer

AMENDED IN SENATE JULY 3, 2014

AMENDED IN SENATE JULY 1, 2014

AMENDED IN ASSEMBLY MAY 27, 2014

AMENDED IN ASSEMBLY MAY 7, 2014

AMENDED IN ASSEMBLY APRIL 23, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 2418

Introduced by Assembly Members Bonilla and Skinner (Coauthors: Assembly Members Bonta, Maienschein, Nazarian, and Nestande)

February 21, 2014

An act to add Sections 1367.247, 1367.248, and 1367.249 to the Health and Safety Code, and to add Sections 10123.207, 10123.208, and 10123.209 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2418, as amended, Bonilla. Health care coverage: prescription drugs: refills.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law imposes various requirements on contracts and policies that cover prescription drug benefits. Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board

of Pharmacy and prohibits the refilling of a prescription without the authorization of the prescriber, except as specified.

This bill would require a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits and imposes a mandatory mail-order restriction for ~~all or some covered prescription drugs~~ *a drug that has a monthly cost to the health care service plan or health insurer that is less than twice the Medicare minimum specialty tier eligibility threshold* to establish a process allowing enrollees and insureds to opt out of the restriction *for that drug*, as ~~specified, except that the opt-out requirement would not apply to a high-cost drug, as defined.~~ *specified.* This bill would require a health care service plan or health insurer to establish and implement a process to authorize emergency refills at a participating specialty or community pharmacy when ~~a high-cost drug subject to a mandatory mail-order restriction~~ *any drug that is dispensed to an enrollee or an insured through mail order* is delivered in a condition that is unsafe to use, not delivered, or delayed for a period of time that would cause the enrollee or insured to not have the drug in time to comply with the prescribed dosage instructions. The bill would require a health care service plan contract or a health insurance policy issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits to permit and apply a prorated daily cost-sharing rate to refills of prescriptions that are dispensed by a participating pharmacy for less than the standard refill amount if the prescriber or pharmacist indicates that the refill is in the best interest of the enrollee or insured and is for the purpose of synchronizing the refill dates of the enrollee's or insured's medications, provided that certain requirements are satisfied. The bill would also require a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits to allow for the early refill of covered topical ophthalmic products at 70% of the predicted days of use. Because a willful violation of the bill's requirements by a health care service plan would be a crime, the bill would impose a state-mandated local program.

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

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

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

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

1 SECTION 1. The Legislature hereby finds and declares all of
2 the following:
3 (a) As many as 75 percent of patients do not take their
4 medications as prescribed. Poor adherence to prescribed treatments
5 poses serious health risks to nonadhering patients, particularly
6 those with chronic diseases.
7 (b) Poor adherence to prescribed treatments leads to unnecessary
8 disease progression, avoidable utilization of inpatient and outpatient
9 medical care, higher mortality rates, and increased medical
10 spending. According to the New England Healthcare Institute,
11 poor adherence to medication results in $100 billion in excess
12 hospital visits and a total of $290 billion in avoidable medical
13 spending each year — 13 percent of all health care expenditures
14 in the United States. Adherence to prescription medication prevents
15 these unnecessary complications and is a cost-effective and simple
16 tool in the treatment of health conditions.
17 (c) Given the evidence showing benefits to patients, the federal
18 Centers for Medicare and Medicaid Services requires Medicare
19 Part D plans to permit beneficiaries to choose between mail-order
20 delivery or community pharmacy access to prescription drugs,
21 requires Part D plans to allow for the synchronization of refill dates
22 for patients with multiple prescriptions, and recommends that Part
23 D plans authorize early refills of topical ophthalmic products at
24 70 percent of the predicted days of use.
25 (d) It is the intent of the Legislature to enact legislation that
26 promotes policies designed to improve patient medication
27 adherence.
28 SEC. 2. Section 1367.247 is added to the Health and Safety
29 Code, to read:
30 1367.247. (a) A health care service plan contract issued,
31 amended, or renewed on or after January 1, 2016, that provides
32 coverage for prescription drug benefits and that imposes a
33 mandatory mail-order restriction for some or all covered
34 prescription drugs shall establish a process for enrollees to opt out
35 of that restriction. The opt out process may require the use of a

plan's participating specialty or community pharmacy that is not a mail-order-only pharmacy, at the discretion of the plan. The opt out process may require 30 days' written notice before the election to opt out is effective. The opt out process shall comply with all of the following requirements:

(1) Not impose conditions or restrictions on an enrollee opting out of the mandatory mail-order restriction. For purposes of this subparagraph, "conditions or restrictions" include, but are not limited to, requiring prescriber approval or submission of documentation by the enrollee or prescriber.

(2) Allow an enrollee to opt out of the mandatory mail-order restriction, and revoke his or her prior opt out of the restriction, at any time.

(3) The choice by an enrollee to opt out shall be valid for the duration of the plan year or until the enrollee elects to revoke the opt out, whichever occurs first, provided that the enrollee remains enrolled in the same product with either the same subscriber, with respect to individual plan contracts, or the same plan sponsor, with respect to group plan contracts.

(4) A health care service plan shall provide an enrollee who obtains a covered prescription drug that is subject to the mandatory mail-order restriction with a separate written notice of the restriction and any exceptions upon dispensing of the first fill of the drug or no less than 30 days prior to the restriction taking effect for the first refill of the drug. This written notice shall be in addition to any information contained in the plan's evidence of coverage or evidence of benefits. The notice shall inform the enrollee of the right to opt out of the mandatory mail-order restriction and instructions on how to do so.

(b) This section shall not apply to a drug that is not available at a participating community pharmacy due to any of the following:

(1) An industry shortage listed on the Current Drug Shortages Index maintained by the federal Food and Drug Administration (FDA).

(2) A manufacturer's instructions or restrictions.

(3) Any risk evaluation and management strategy approved by the FDA.

(4) A special shortage affecting the plan's network of participating pharmacies.

(c) (1) The opt out requirement in subdivision (a) ~~does not apply to a high-cost drug.~~ *shall only apply to a drug that has a monthly cost to the health care service plan of less than twice the Medicare minimum specialty tier eligibility threshold.*

(2) For ~~a high-cost drug that is subject to a mandatory mail-order restriction,~~ *any drug that is dispensed to an enrollee through mail order,* a health care service plan shall establish and implement a process to authorize emergency refills at a plan's participating specialty or community pharmacy when the drug is delivered in a condition that is unsafe to use, not delivered, or delayed for a period of time that would cause the enrollee to not have the drug in time to comply with the prescribed dosage instructions.

(d) Nothing in this section shall be construed to establish a new mandated benefit or to prevent the application of deductible or copayment provisions in a plan contract.

(e) Nothing in this section shall be construed to limit or prohibit differential copayments in the form of financial incentives whereby an enrollee's cost sharing is reduced when he or she uses mail order rather than a community pharmacy.

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

~~(1) "High-cost drug" means a drug that has a monthly cost to the health care service plan of twice the Medicare minimum speciality tier eligibility threshold.~~

~~(2)~~

(1) For group health care service plan contracts, "plan year" has the meaning set forth in Section 144.103 of Title 45 of the Code of Federal Regulations.

~~(3)~~

(2) For individual health care service plan contracts, "plan year" means the calendar year.

SEC. 3. Section 1367.248 is added to the Health and Safety Code, to read:

1367.248. (a) A health care service plan contract issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits shall permit and apply a prorated daily cost-sharing rate to the refills of prescriptions that are dispensed by a participating pharmacy for less than the standard refill amount if the prescriber or pharmacist indicates that the refill for less than the standard amount is in the best interest of the

enrollee and is for the purpose of synchronizing the refill dates of the enrollee's medications and all of the following apply:

(1) The prescription drugs being synchronized are covered and authorized by the health care service plan contract.

(2) The prescription drugs being refilled for less than the standard amount are not subject to quantity limits or other utilization management controls that are inconsistent with the synchronization plan, including, but not limited to, controlled substance prescribing and dispensing guidelines intended to prevent misuse or abuse.

(3) The prescription drugs being synchronized are dispensed by a single participating pharmacy.

(4) The patient has completed at least 90 consecutive days on the prescription drugs being synchronized.

(5) The prescription drugs being refilled for less than the standard amount are of a formulation that can be effectively split over the required short fill period to achieve synchronization.

(6) The prescriber has not done either of the following with respect to the prescription drugs being refilled for less than the standard amount:

(A) Indicated, either orally or in his or her own handwriting, "No change to quantity," or words of similar meaning.

(B) Checked a box on the prescription marked "No change to quantity," and personally initialed the box or checkmark.

(b) This section shall not apply to a drug that is not available at a participating community pharmacy due to any of the following:

(1) An industry shortage listed on the Current Drug Shortages Index maintained by the federal Food and Drug Administration (FDA).

(2) A manufacturer's instructions or restrictions.

(3) Any risk evaluation and management strategy approved by the FDA.

(4) A special shortage affecting the plan's network of participating pharmacies.

(c) Nothing in this section shall be construed to establish a new or mandated benefit or to prevent the application of deductible or copayment provisions in a plan contract.

SEC. 4. Section 1367.249 is added to the Health and Safety Code, to read:

1367.249. (a) A health care service plan contract issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits shall allow for early refills of covered topical ophthalmic products at 70 percent of the predicted days of use.

(b) Nothing in this section shall be construed to establish a new mandated benefit or to prevent the application of deductible or copayment provisions in a plan contract.

SEC. 5. Section 10123.207 is added to the Insurance Code, to read:

10123.207. (a) A health insurance policy issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits and that imposes a mandatory mail-order restriction for some or all covered prescription drugs shall establish a process for insureds to opt out of that restriction. The opt out process may require the use of a health insurer's participating specialty or community pharmacy that is not a mail-order-only pharmacy, at the discretion of the health insurer. The opt out process may require 30 days' written notice before the election to opt out is effective. The opt out process shall comply with all of the following requirements:

(1) Not impose conditions or restrictions on an insured opting out of the mandatory mail-order restriction. For purposes of this subparagraph, "conditions or restrictions" include, but are not limited to, requiring prescriber approval or submission of documentation by the insured or prescriber.

(2) Allow an insured to opt out of the mandatory mail-order restriction, and revoke his or her prior opt out of the restriction, at any time.

(3) The choice by an insured to opt out shall be valid for the duration of the plan year or until the insured elects to revoke the opt out, whichever occurs first, provided that the insured remains enrolled in the same product with either the same policyholder, with respect to individual policies, or the same plan sponsor, with respect to group policies.

(4) A health insurer shall provide an insured who obtains a covered prescription drug that is subject to the mandatory mail-order restriction with a separate written notice of the restriction and any exceptions upon dispensing of the first fill of the drug or no less than 30 days prior to the restriction taking effect

for the first refill of the drug. This written notice shall be in addition to any information contained in the insurer's evidence of coverage or evidence of benefits. The notice shall inform the insured of the right to opt out of the mandatory mail-order restriction and instructions on how to do so.

(b) This section shall not apply to a drug that is not available at a participating community pharmacy due to any of the following:

(1) An industry shortage listed on the Current Drug Shortages Index maintained by the federal Food and Drug Administration (FDA).

(2) A manufacturer's instructions or restrictions.

(3) Any risk evaluation and management strategy approved by the FDA.

(4) A special shortage affecting the insurer's network of participating pharmacies.

(c) (1) The opt out requirement in subdivision (a)~~ does not apply to a high-cost drug.~~ *shall only apply to a drug that has a monthly cost to the health insurer of less than twice the Medicare minimum specialty tier eligibility threshold.*

(2) For~~ a high-cost drug that is subject to a mandatory mail-order restriction,~~ *any drug that is dispensed to an insured through mail order,* a health insurer shall establish and implement a process to authorize emergency refills at a health insurer's participating specialty or community pharmacy when the drug is delivered in a condition that is unsafe to use, not delivered, or delayed for a period of time that would cause the insured to not have the drug in time to comply with the prescribed dosage instructions.

(d) Nothing in this section shall be construed to establish a new mandated benefit or to prevent the application of deductible or copayment provisions in a policy.

(e) Nothing in this section shall be construed to limit or prohibit differential copayments in the form of financial incentives whereby an insured's cost sharing is reduced when he or she uses mail order rather than a community pharmacy.

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

~~(1) "High-cost drug" means a drug that has a monthly cost to the health insurer of twice the Medicare minimum specialty tier eligibility threshold.~~

~~(2)~~

(1) For group health insurance policies, "plan year" has the meaning set forth in Section 144.103 of Title 45 of the Code of Federal Regulations.

~~(3)~~

(2) For individual health insurance policies, "plan year" means the calendar year.

SEC. 6. Section 10123.208 is added to the Insurance Code, to read:

10123.208. (a) A health insurance policy issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits shall permit and apply a prorated daily cost-sharing rate to the refills of prescriptions that are dispensed by a participating pharmacy for less than the standard refill amount if the prescriber or pharmacist indicates that the refill for less than the standard amount is in the best interest of the insured and is for the purpose of synchronizing the refill dates of the insured's medications and all of the following apply:

(1) The prescription drugs being synchronized are covered and authorized by the health insurance policy.

(2) The prescription drugs being refilled for less than the standard amount are not subject to quantity limits or other utilization management controls that are inconsistent with the synchronization plan, including, but not limited to, controlled substance prescribing and dispensing guidelines intended to prevent misuse or abuse.

(3) The prescription drugs being synchronized are dispensed by a single participating pharmacy.

(4) The insured has completed at least 90 consecutive days on the prescription drugs being synchronized.

(5) The prescription drugs being refilled for less than the standard amount are of a formulation that can be effectively split over the required short fill period to achieve synchronization.

(6) The prescriber has not done either of the following with respect to the prescription drugs being refilled for less than the standard amount:

(A) Indicated, either orally or in his or her own handwriting, "No change to quantity," or words of similar meaning.

(B) Checked a box on the prescription marked "No change to quantity," and personally initialed the box or checkmark.

(b) This section shall not apply to a drug that is not available at a participating community pharmacy due to any of the following:

(1) An industry shortage listed on the Current Drug Shortages Index maintained by the federal Food and Drug Administration (FDA).

(2) A manufacturer's instructions or restrictions.

(3) Any risk evaluation and management strategy approved by the FDA.

(4) A special shortage affecting the insurer's network of participating pharmacies.

(c) Nothing in this section shall be construed to establish a new or mandated benefit or to prevent the application of deductible or copayment provisions in a policy.

SEC. 7. Section 10123.209 is added to the Insurance Code, to read:

10123.209. (a) A health insurance policy issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits shall allow for early refills of covered topical opthalmic products at 70 percent of the predicted days of use.

(b) Nothing in this section shall be construed to establish a new mandated benefit or to prevent the application of deductible or copayment provisions in a policy.

SEC. 8. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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

April 24, 2014

The Honorable Susan Bonilla
California State Assembly
State Capitol, Room 4140
Sacramento, CA 95814

RE: Assembly Bill 2418 - SUPPORT

Dear Assembly Member Bonilla:

The Board of Pharmacy is pleased to support your Assembly Bill 2418 which would promote better health outcomes for patients by making it easier for a pharmacist to synchronize refill dates for a patients with multiple prescriptions; by ensuring that patients who run out of eye drops early can easily obtain a refill so they do not experience a gap in therapy; and by protecting a patient's right to choose between obtaining their prescription medications from an in-network community pharmacy or via mail order delivery.

The board appreciates your efforts to promote medication adherence and enact provisions that provide patients with the choice to receive their medications in a way that works best for them.

Please do not hesitate to contact me at 574-7911 or Legislative Coordinator Carolyn Klein at 574-7913 if we can be of any assistance to you and your staff.

Sincerely,

VIRGINIA HEROLD
Executive Officer

AMENDED IN SENATE JUNE 19, 2014

AMENDED IN ASSEMBLY APRIL 9, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 2058

Introduced by Assembly Member Wilk
(Coauthors: Assembly Members ~~Hagman and Harkey~~ *Hagman, Harkey, and Olsen*)
(Coauthors: Senators DeSaulnier, Gaines, and Vidak)

February 20, 2014

An act to amend Section 11121 of the Government Code, relating to state government, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 2058, as amended, Wilk. Open meetings.

The Bagley-Keene Open Meeting Act requires that all meetings of a state body, as defined, be open and public and that all persons be permitted to attend and participate in any meeting of a state body, subject to certain conditions and exceptions.

This bill would modify the definition of "state body" to exclude an advisory body with less than 3 individuals, except for certain standing committees.

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

Vote: ⅔. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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

SECTION 1. Section 11121 of the Government Code is amended to read:

11121. As used in this article, "state body" means each of the following:

(a) Every state board, or commission, or similar multimember body of the state that is created by statute or required by law to conduct official meetings and every commission created by executive order.

(b) A board, commission, committee, or similar multimember body that exercises any authority of a state body delegated to it by that state body.

(c) An advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body of a state body, if created by formal action of the state body or of any member of the state body. An advisory body created to consist of fewer than three individuals is not a state body, except that a standing committee of a state body, irrespective of its composition, which has a continuing subject matter jurisdiction, or a meeting schedule fixed by resolution, policies, bylaws, or formal action of a state body is a state body for the purposes of this chapter.

(d) A board, commission, committee, or similar multimember body on which a member of a body that is a state body pursuant to this section serves in his or her official capacity as a representative of that state body and that is supported, in whole or in part, by funds provided by ~~the~~ *that* state body, whether the multimember body is organized and operated by the state body or ~~by~~ a private corporation.

SEC. 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to avoid unnecessary litigation and ensure the people's right to access of the meetings of public bodies pursuant to Section 3 of Article 1 of the California Constitution, it is necessary that act take effect immediately.

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AMENDED IN SENATE JUNE 19, 2014

AMENDED IN ASSEMBLY APRIL 9, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 2058

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

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(b) A board, commission, committee, or similar multimember body that exercises any authority of a state body delegated to it by that state body.

(c) An advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body of a state body, if created by formal action of the state body or of any member of the state body. An advisory body created to consist of fewer than three individuals is not a state body, except that a standing committee of a state body, irrespective of its composition, which has a continuing subject matter jurisdiction, or a meeting schedule fixed by resolution, policies, bylaws, or formal action of a state body is a state body for the purposes of this chapter.

(d) A board, commission, committee, or similar multimember body on which a member of a body that is a state body pursuant to this section serves in his or her official capacity as a representative of that state body and that is supported, in whole or in part, by funds provided by ~~the~~ *that* state body, whether the multimember body is organized and operated by the state body or ~~by~~ a private corporation.

SEC. 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to avoid unnecessary litigation and ensure the people's right to access of the meetings of public bodies pursuant to Section 3 of Article 1 of the California Constitution, it is necessary that act take effect immediately.

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ATTACHMENT 4

Board-Approved Regulations

Undergoing Administrative Review

Title 16. Board of Pharmacy
Proposed Language

Proposal to Amend Section 1707.5 of Title 16 of the California Code of Regulations to read:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a ~~10-point sans serif typeface or, if requested by the consumer, at least a~~ 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

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

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

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and l [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, “appropriate dosage form” includes pill, caplet, capsule or tablet.

Note: Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076 and 4076.5, Business and Professions Code.

ATTACHMENT 5

Board-Approved Regulations

Awaiting Notice

Title 16. Board of Pharmacy
Proposed Language

To Amend Section 1702 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. Pharmacist Renewal Requirements
(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date ~~that occurs on or after December 7, 2010~~.
(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.
(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).
(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).
(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).
(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . ~~omitting t~~Traffic infractions under ~~$300~~ $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.
(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproval.
(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

To Add Section 1702.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:
1702. 1 Pharmacy Technician Renewal Requirements

(a) A pharmacy technician applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014.
(1) A pharmacy technician shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.
(2) A pharmacy technician applicant for renewal shall pay the actual cost of compliance with subdivision (a).
(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).
(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).
(b) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . Traffic infractions under $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.
(c) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.
(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 490, 4038, 4115, 4202, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

To Amend Section 1702.2 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:
1702. 2 Designated Representative Renewal Requirements

(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014.
(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her

fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.
(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).
(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).
(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).
(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . Traffic infractions under $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.
(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.
(c) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 490, 4022.5, 4053, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Title 16. Board of Pharmacy
Proposed Language

To Add Section 1702.5 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.5. Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy.

(a) As a condition of renewal, an applicant seeking renewal of a license as a nonresident wholesaler or as a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since the last renewal of the license. An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license. Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.

(b) For purposes of this section, "disciplinary action" means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation or public reprimand or reproval.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4112, 4161, 4300, 4301, Business and Professions Code

Title 16. Board of Pharmacy
Proposed Language

To Amend § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.05. Accreditation Agencies for Continuing Education.

(a) The following organizations are approved accreditation agencies:

(1) The Accreditation Council for Pharmacy Education.

(2) The ~~Pharmacy Foundation of California~~ California Pharmacists Association.

(b) Accreditation agencies shall:

(1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.

(2) Maintain a list of the name and address of the person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.

(3) Provide the board with the names, addresses and responsible party of each provider, upon request.

(4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.

(5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.

(6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board.

(7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

To Amend § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.2. Board Accredited Continuing Education

(a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six hours of continuing education for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six hours of continuing education per renewal period. The board shall designate on its public agenda which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician requesting continuing education pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded two hours of continuing education per renewal period. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(f) An individual may be awarded three hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

To Amend § 1732.5 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least six of the 30 units required for pharmacist license renewal shall be completed in one or more of the following subject areas:

1. Emergency/Disaster Response
2. Patient Consultation
3. Maintaining Control of a Pharmacy's Drug Inventory
4. Ethics
5. Substance Abuse

Pharmacists renewing their licenses which expire on or after July 1, 2015, shall be subject to the requirements of this subdivision.

~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

Draft Proposed Text

Amend Title 16 California Code of Regulations Section 1703

Related to Delegation of Certain Functions

§ 1703. Delegation of Certain Functions.

The power and discretion conferred by law upon the board to receive and file accusations; issue notices of hearing, statements to respondent and statements of issues; receive and file notices of defense; determine the time and place of hearings under Section 11508 of the Government Code; set and calendar cases for hearing and perform other functions necessary to the business-like dispatch of the business of the board in connection with proceedings under the provisions of Sections 11500 through 11528 of the Government Code, prior to the hearing of such proceedings; the certification and delivery or mailing of copies of decisions under Section 11518 of said code; ~~and~~ issue summary suspension orders or notices of suspension under Section 4311 of the Business and Professions Code; and make changes to its regulations without regulatory effect pursuant to Title 1, California Code of Regulations section 100 are hereby delegated to and conferred upon the executive officer, or, in his or her absence from the office of the board, the acting executive officer.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and 4311, Business and Professions Code.

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