



California State Board of Pharmacy

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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 will meet April 23, 2014.

a. LEGISLATION REPORT

1. Legislation Recently Enacted

ATTACHMENT 1

AB 467 (Stone) Prescription Drug Collection and Distribution Program

Assembly Bill 467 (Stone, Chapter 10, Statutes 2014) was signed by the Governor on April 9, 2014, and provides for the licensure of a “Surplus Medication Collection and Distribution Intermediary” to allow such an entity to perform specified duties related to the donation of drugs to a Surplus Medication Collection and Distribution program. AB 467 contained an “urgency clause” whereby upon filing with the Secretary of State, the provisions became operative. A copy of the chaptered bill is provided in Attachment 1.

2. Status of Board-Sponsored Provisions

ATTACHMENT 2

A. AB 2131 (Morrell) / SB 960 (Morrell) Pharmacy Licenses: Letters of Reprimand

Version: Amended April 7, 2014
Location: SEN Business Professions & Economic Development
Status: Hearing set for April 21, 2014

Senate Bill 960 contains the board’s sponsored provision to add section 4310.5 to the Business and Professions Code (BPC) to authorize the board to issue a public reprimand for violations that may not warrant license denial or issuance of a probationary license. The board’s proposal mirrors a tool utilized by the Medical Board of California.

The board’s provisions were previously contained in AB 2131. Senator Morrell moved the content into SB 960 after winning a Special Election (3/25/14) to fill the Senate seat formerly held by Senator Bill Emmerson. A staff analysis, author’s Fact Sheet and copy of the bill are provided in Attachment 2.

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

Version: Introduced March 25, 2014

Location: SEN Business Professions & Economic Development

Status: Hearing set for April 28, 2014

Senate Bill 1466, as introduced, contains one board-sponsored provision, and one other amendment to pharmacy law. Section 8 of the bill contains the board's sponsored provisions to amend section 4053 BPC to specify that a designated representative shall be at least 18 years of age.

SB 1466 also contains an amendment to section 4021.5 of the Business and Professions Code (BPC) to modify the definition of a "correctional pharmacy." The current definition applies to "state" correctional facilities – and the bill removes "state" – an amendment the board discussed and supported in concept in 2013. 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 those sections relevant to Pharmacy Law are provided in Attachment 2 (Sections 7 and 8).

C. Repeal of Pedigree Requirements

The Drug Quality and Security Act preempted California's pedigree requirements in 2013. In January 2014, the board voted to seek a legislative repeal California's e-pedigree provisions. The board also published a notice of preemption in the California Regulation Notice Registry on February 21, 2014. Staff is working with legislative staff to include the provisions in a bill sometime this session. A copy of the board-sponsored provisions are provided in Attachment 2, as is a copy of the California Regulatory Notice Register published in February 2014. Should bill language become available prior to or at the board meeting, staff will provide the board with the language for consideration of a position.

D. Licensure Requirements for Third Party Logistics Providers

The federal legislation enacted to eliminate California's e-pedigree requirements also contained provisions to establish national standards for wholesalers and 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. A copy of the board's proposal is provided in Attachment 2, and staff is working to secure an author to carry the board's provisions. Should bill language become available prior to or at the board meeting, staff will provide the board with the language for consideration of a position.

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

ATTACHMENT 3

A. AB 1535 (Bloom) Pharmacists: naloxone hydrochloride

Version: Amended April 1, 2014

Location: ASM Appropriations

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. A copy of AB 1535, the author's Fact Sheet, and a staff analysis are provided in Attachment 3.

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

Version: Introduced 2/14/14

Location: ASM Health

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 would prohibit a drug that can only be dispensed to a patient registered with a drug manufacturer in accordance with FDA requirements from being donated to a county repository and distribution program.

The bill is scheduled to be heard in Assembly Health on May 6. A copy of the bill, the author's Fact Sheet and a staff analysis are provided in Attachment 3.

C. AB 2165 (Patterson) Professions and vocations: licenses

Version: Amended April 10, 2014
Location: ASM Business, Professions and Consumer Protection
Status: Hearing – April 22, 2014

AB 2165 would require license applications to be reviewed, processed, and issued to applicants who have completed the necessary requirements within 45 days of the application filing date and also requires that each exam is offered a minimum of six times per year.

The board monitors its license processing activities through the Licensing Committee and through its strategic plan. Historical patterns would suggest that surges in applications, staff vacancies and other challenges have had an effect on the period of time a license is processed and issued. Staff is concerned that with the transition of the board's licensing systems to BreEze, it is unknown how the board's processing times will be impacted. As currently written, additional staff resources would be required to meet the 45 (calendar) day requirement.

A copy of the bill, the author's Fact Sheet, and a staff analysis is provided in Attachment 3.

D. AB 2605 (Bonilla) Pharmacy: sterile drug products

Version: Amended March 18, 2014
Location: ASM Business, Professions and Consumer Protection

AB 2605 appears to be a spot bill. Staff continues to monitor this bill, and maintains regular contact with the author's office regarding the bill. If the bill is amended prior to the board meeting, staff will provide the board with current bill language and provide a summary of any potential impact.

E. SB 981 (Huff) Regulations: review process

Version: Amended April 22, 2014
Location: SEN Governmental Organization
Status: Hearing – April 22, 2014

Senate Bill 981 amends California Rulemaking Law to require each agency to review every regulation adopted prior to January 1, 2014, and to develop and

submit to the Legislature on or before January 1, 2016, a report with specified information, and require a similar report every five years thereafter.

According to the author, SB 981 will reduce the state's regulatory burden on the private sector and California's job market by ensuring that all state agencies review and identify regulations that are the most burdensome and obsolete.

As a health care board subject to sunset review, the board actively monitors its regulatory efforts on an ongoing basis and includes summary information regarding its regulatory actions at each sunset review. SB 981 will have a fiscal impact on the board, as it does not have adequate staff resources to conduct the required reviews and reports required. A copy of the bill, the author's Fact Sheet and a staff analysis are provided in Attachment 3.

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

Version: Amended April 1, 2014 (*Amendments Expected*)
Location: SEN Business, Professions and Economic Development
Status: Hearing – April 21, 2014

Staff was advised on April 10 that amendments are expected which would codify California's (now inoperative) drug take-back model guidelines. The California Integrated Waste Management Board (now CalRecycle) developed the model guidelines through a working group with the Board of Pharmacy and others in 2008. A copy of the model guidelines is provided in Attachment 3. If amended language becomes available, staff will provide the board with a copy at the meeting.

G. SB 1039 (Hernandez) Pharmacies: furnishing drugs

Version: Amended April 10, 2014
Location: SEN Business, Professions and Economic Development
Status: Hearing – April 21, 2014

According to the author, Senate Bill 1039 will make more efficient use of pharmacy personnel in the acute care facility setting by expanding the type of tasks that pharmacy technicians and interns are permitted to perform, with the goal of freeing up pharmacists to focus on patient care. As outlined in the staff analysis, staff recommends that the board consider what tasks may be appropriate for a pharmacy technician, and what should be restricted to a pharmacist. A copy of SB 1039 as amended 4/10 is provided in Attachment 3, along with a copy of the author's Fact Sheet and a staff analysis.

H. SB 1258 (DeSaulnier) Controlled Substances: prescriptions: reporting

Version: Amended March 25, 2014
Location: SEN Business, Professions and Economic Development
Status: Hearing – April 21, 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.

According to the author, SB 1258 would permit 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. A copy of the bill, author's fact sheet, and a staff analysis with discussion points are provided in Attachment 3.

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

Version: Introduced February 21, 2014
Location: ASM Third Reading File

Pharmacy Law (BPC 4059.5) restricts the furnishing of a dangerous drug to be transferred, sold or delivered only to an entity licensed by the board, a manufacturer, or to an ultimate user or the ultimate user's agent.

Health and Safety Code sections 11350 and 11377 provide for penalties for the possession of controlled substances, as specified.

According to the author, AB 2603 would amend the Health and Safety Code to expressly authorize a person to possess another person's controlled substances if the prescription holder so authorizes the person to possess them. The author seeks to add clarity to the Health and Safety code to ensure that ill people who must rely on others to get their medications for them can do so without fear, i.e., "prescription defense." The author also states that the bill will address a conflict between the Health and Safety code (and Pharmacy law), to provide protections when a person's agent picks up their prescription

medications for them. A copy of the bill, and an author's fact sheet are provided in Attachment 3. A staff analysis will be provided as a handout at the board meeting.

4. Other Legislation Being Tracked by Board Staff

ATTACHMENT 4

A. AB 1437 (Mullin) Medically important antimicrobials: nontherapeutic use

Version: Introduced January 6, 2014

Location: In the Senate. (Passed out of ASM Health 3/26 Vote: 13-6)

AB 1437 is one of two bills that would impact access to and the administration of specific antibiotics (antimicrobials) to food animals. The FDA has issued Guidance for Industry (GFI #152, GFI #209 and GFI #213) that ranks antimicrobial drugs into three tiers. According to the author, AB 1437 will help protect the public health by placing a ban on the non-therapeutic use of antibiotics in livestock production; require a veterinarian to prescribe a medically important antimicrobial for specific animals for specific diagnosed conditions; and require the collection of and reporting of antibiotics used in food-animals. A copy of the bill, and the author's fact sheet are provided in Attachment 4. (Also see SB 835, Hill)

B. AB 1743 (Ting) Hypodermic needles and syringes

Version: Introduced February 14, 2014

Location: ASM Agriculture – Hearing set for April 30, 2014

AB 1743 would delete the limit on the number of syringes a pharmacist has the discretion to sell to an adult without a prescription and deletes the sunset date of January 1, 2015, that would end the statewide authorization to sell syringes without a prescription. Existing law allows a pharmacist or physician to furnish up to 30 hypodermic needles and syringes for human use, without a prescription or local government authorization, to a person 18 years of age or older, until January 1, 2015.

It appears there may be some technical issues in the bill regarding cross references to the Health and Safety Code, which staff has shared with the author's staff. Staff recommends the board support the bill, and that staff continue to work with the author's office regarding the cross references made to the Health & Safety Code. A copy of the bill and the author's fact sheet are provided in Attachment 4.

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

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 allow patients who run out of prescription eye medications because of accidental spillage or who use more than 70% of their eye drops to be eligible for an early refill.

The bill is sponsored by the California Pharmacists Association and the California Healthcare Institute. A copy of the bill and the author’s fact sheet are provided in Attachment 4.

D. SB 835 (Hill) Food animals: medically important antimicrobial drugs

Version: Amended March 26, 2014

Location: SEN Appropriations – Hearing set for April 28, 2014

Senate Bill 835 would codify the Food and Drug Administration’s Guidance for Industry #213 by requiring the California Department of Food and Agriculture to refuse to register a livestock drug administered in the feed or drinking water of food animals if the drug is a medically important antimicrobial drug. Currently, the CDFA registers over-the-counter livestock drugs and regulates their use. Retail sales of restricted livestock drugs require a license (issued by the CDFA), and each licensee is required to keep records of sales of these drugs, as specified.

The author states that the bill is necessary to preserve the efficacy of medically important antibiotics by putting into California law the voluntary FDA guidelines, which phase out the nontherapeutic use of medically important antibiotics in food-producing animals, and to require veterinary oversight of these drugs. “Nontherapeutic use” is considered as using antibiotics for purposes of growth promotion or feed efficiency.

A copy of the bill as amended March 25 and the author’s fact sheet are provided in Attachment 4, as is a copy of the FDA Guidance #213. Staff will continue to watch and monitor this bill, as well as AB 1437.

5. Other Legislation Impacting the Board or Its Regulatory Jurisdiction

b. REGULATION REPORT

1. Regulations Approved by the Office of Administrative Law

ATTACHMENT 5

Combined Rulemaking – Proposal to Amend Sections 1745 and 1769, and to add Section 1762 to Title 16 California Code of Regulations Related to Partial Fill of a Schedule II Prescription, Criteria for Rehabilitation, and to Define Unprofessional Conduct

On February 24, 2014, the Office of Administrative Law approved the board's rulemaking to amend Sections 1745 and 1769, and to add Section 1762 to Title 16 of the California Code of Regulations related to the Partial Fill of a Schedule II Prescription, Criteria for Rehabilitation, and to Define Unprofessional Conduct. The regulation went into effect April 1, 2014. A copy of the approved regulation (no mark-up) is provided in Attachment 5.

2. Board-Approved – Recently Noticed

ATTACHMENT 6

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. A copy of the proposed text is provided in Attachment 6.

3. Board-Approved – Undergoing Administrative Review

ATTACHMENT 7

Fee Schedule –Proposal to Amend Title 16 California Code of Regulations Section 1749

On April 24, 2013, the board approved a proposal to amend Title 16 California Code of Regulations Section 1749 to increase the board's fees to the statutory maximum. The rulemaking was initiated on June 14, 2013, and the 45-day public comment period concluded Monday, July 29, 2013. A regulation hearing was held at 1:00 p.m. on July 30, 2013.

At the July 2013 Board Meeting, the board approved the motion to 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 1749 as noticed on June 14, 2013.

The final rulemaking file was submitted to the Department of Consumer Affairs for review on October 21, 2013. The board was advised that the rulemaking file was approved by the Business, Consumer Services and Housing Agency and the Department of Finance. The final rulemaking file was filed with the Office of Administrative Law on March 13, 2014.

After the publication of the agenda, the board received notice the Office of Administrative Law approved the board's rulemaking to amend Section 1749 to Title 16 of the California Code of Regulations related to Fee Schedule on April 14, 2014. The effective date of the regulation will be July 1, 2014. A copy of the approved regulation (no mark-up) is provided in Attachment 7.

4. Board-Approved – Awaiting Notice

ATTACHMENT 8

A. 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 8.

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.

B. 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 8.

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.

C. 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 8.

Attachment 1

Assembly Bill No. 467

CHAPTER 10

An act to add Section 4046 to, and to add Article 11.5 (commencing with Section 4169.5) to Chapter 9 of Division 2 of, the Business and Professions Code, and to amend Sections 150201, 150202, and 150205 of, and to add Section 150208 to, the Health and Safety Code, relating to pharmaceuticals, making an appropriation therefor, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor April 9, 2014. Filed with
Secretary of State April 9, 2014.]

LEGISLATIVE COUNSEL'S DIGEST

AB 467, Stone. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish, by ordinance, a repository and distribution program under which specified pharmacies and primary care clinics may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Existing law authorizes specified health and care facilities, pharmacies, drug manufacturers, and pharmacy wholesalers to donate unused medications to the program. Existing law requires a county that has established a program to establish procedures to, among other things, ensure proper safety and management of any medications collected and maintained by a participating entity. Existing law exempts specified persons and entities, including prescription drug manufacturers and pharmacists and physicians who accept or dispense prescription drugs, from criminal and civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with these provisions.

Existing law, the Pharmacy Law, governs the scope and practice of pharmacy, including dispensing dangerous drugs and devices. Existing law establishes in the Department of Consumer Affairs the California State Board of Pharmacy to exercise licensing, regulatory, and disciplinary functions with respect to the practice of pharmacy. Existing law provides that fees collected on behalf of the board are credited to the Pharmacy Board Contingent Fund, a continuously appropriated fund. A violation of the Pharmacy Law is a crime.

This bill would require the California State Board of Pharmacy to license a surplus medication collection and distribution intermediary, as defined, established for the purpose of facilitating the donation of medications to or transfer of medications between participating entities under the unused medication repository and distribution program described above. Among other things, the bill would prohibit that intermediary from taking possession, custody, or control of dangerous drugs and devices, but would authorize

the intermediary to charge specified fees for the reasonable costs of the support and services provided. The bill would also require a surplus medication collection and distribution intermediary to keep and maintain for 3 years complete records for which the intermediary facilitated the donation of medications to or transfer of medications between participating entities. The bill would require that a surplus medication collection and distribution intermediary license be renewed annually, and would require the payment of a fee in the amount of \$300 to obtain or renew the license. The bill would provide that the fees collected would be deposited in the Pharmacy Board Contingent Fund. By providing a new source of funds for a continuously appropriated fund, the bill would make an appropriation. Because a violation of the provisions governing licensing and recordkeeping would be crimes, the bill would impose a state-mandated local program. The bill would exempt a surplus medication collection and distribution intermediary from criminal or civil liability for injury caused when facilitating the donation of medications to or transfer of medications in compliance with these provisions.

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.

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

Appropriation: yes.

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

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

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

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

Article 11.5. Surplus Medication Collection and Distribution
Intermediaries

4169.5. (a) A surplus medication collection and distribution intermediary established for the purpose of facilitating the donation of medications to or transfer of medications between participating entities under a program established pursuant to Division 116 (commencing with Section 150200)

of the Health and Safety Code shall be licensed by the board. The board shall enforce the requirements set forth in Section 150208 of the Health and Safety Code. The license shall be renewed annually.

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

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

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

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

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

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

(e) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and if 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 (b) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant’s entity. Upon request by the executive officer of the board, the applicant shall furnish the board with the information required by subdivision (b) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

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

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

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

(i) A surplus medication collection and distribution intermediary licensed pursuant to this section shall keep and maintain for three years complete records for which the intermediary facilitated the donation of medications to or transfer of medications between participating entities.

SEC. 3. Section 150201 of the Health and Safety Code is amended to read:

150201. For purposes of this division:

(a) “Donor organization” means an entity described in subdivision (a) of Section 150202.

(b) “Eligible entity” means all of the following:

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

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

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

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

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

SEC. 4. Section 150202 of the Health and Safety Code is amended to read:

150202. (a) Notwithstanding any other law, a donor organization is defined, for purposes of this division, to refer to one of the following health and care facilities that may donate centrally stored unused medications under a program established pursuant to this division:

(1) A licensed general acute care hospital, as defined in Section 1250.

(2) A licensed acute psychiatric hospital, as defined in Section 1250.

(3) A licensed skilled nursing facility, as defined in Section 1250, including a skilled nursing facility designated as an institution for mental disease.

(4) A licensed intermediate care facility, as defined in Section 1250.

(5) A licensed intermediate care facility/developmentally disabled-habilitative facility, as defined in Section 1250.

(6) A licensed intermediate care facility/developmentally disabled-nursing facility, as defined in Section 1250.

(7) A licensed correctional treatment center, as defined in Section 1250.

(8) A licensed psychiatric health facility, as defined in Section 1250.2.

(9) A licensed chemical dependency recovery hospital, as defined in Section 1250.3.

(10) A licensed residential care facility for the elderly, as defined in Section 1569.2, with 16 or more residents.

(11) An approved mental health rehabilitation center, as described in Section 5675 of the Welfare and Institutions Code.

(b) Medication donated by health and care facilities pursuant to subdivision (a) shall meet the requirements of subdivisions (c) and (d) of Section 150204 and shall be unexpired medication that would have otherwise been destroyed by the facility or another appropriate entity.

(c) Medication eligible for donation by the health and care facilities pursuant to subdivision (a) shall be directly delivered from the dispensing pharmacy, wholesaler or manufacturer, to the health or care facility and subsequently centrally stored. Centrally stored medication that originated from a patient or resident is not eligible for donation under this division.

SEC. 5. Section 150205 of the Health and Safety Code is amended to read:

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

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

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

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

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

SEC. 6. Section 150208 is added to the Health and Safety Code, to read:

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

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

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

(2) It shall ensure that notification is provided to participating entities that a package has been shipped when the surplus medication collection and

distribution intermediary has knowledge of the shipment and provided logistical support to facilitate a shipment directly from a donor organization, as defined in subdivision (a) of Section 150202, to a participating entity.

(3) It shall not select, or direct a donor organization, as defined in subdivision (a) of Section 150202, to select, a specific participating entity to receive surplus medications.

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

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

(2) Contract directly with a county to facilitate the donation of medications to or transfer of medications between participating entities and provide general support in a county's implementation of a program established pursuant to this division.

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

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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

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

Attachment 2



Bill Number:	SB 960
Introduced:	<i>As AB 2131 on 2/20/14</i>
Amendment Date:	4/7/2014
Author:	Morrell
Topic:	Pharmacy. Letter of Reprimand
Position:	<i>Support (4/2/14 Sponsor Letter)</i>

Affected Sections: Add Section 4310.5 to the Business and Professions Code

Status: In SEN Business Professions and Economic Development
Hearing set for April 21, 2014

SUMMARY:

Senate Bill 960 would authorize the board to issue a letter of reprimand, which would describe in detail the nature and facts of an individual's violations concurrent with a new license. SB 960 would provide the individual the right to contest the Letter of Reprimand, would specify the process and timeframe for the contesting of the letter, and would require that a letter of reprimand be purged three years from the date of issuance.

The Letter of Reprimand is a tool also utilized by the Medical Board of California. The board anticipates using a LOR a handful of times each year.

BACKGROUND:

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. It investigates all matters related to the issuance of the license that may affect the public welfare. This includes the 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. The board believes SB 960 would serve to protect the public by licensing an individual who may 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.

EXISTING LAW:

The Pharmacy Law issues individual licenses to pharmacists, intern pharmacists, pharmacy technicians, and designated representatives.

The board has two options when considering a new application for licensure: approve or deny.

THIS BILL WOULD:

- Add section 4310.5 to the Business and Professions Code to authorize the board to issue a letter of reprimand concurrently with a license
- Within 30 days of issuance, allow the individual to request an office conference to contest the letter of reprimand;
- Require an office conference to be held within 30 days of receipt of the request;
- Allow the board's executive officer, or his or her designee, to affirm, modify or withdraw the LOR;
- Provide for judicial review of the board's decision;
- Require a LOR to be purged three years from the date of issuance, so long as no LOR, citation, notice of correction, or disciplinary action is initiated by the board during the three-year period;
- Require the individual to disclose a LOR issued pursuant to the provisions to an inquiring member of the public; and
- Require the board to post the LOR on the board's website.

FISCAL IMPACT ON THE BOARD:

Staff estimates minor and absorbable costs to implement the provisions of Senate Bill 960.

HISTORY:

Date	Action
04/11/14	Set for hearing April 21.
04/10/14	Re-referred to Com. on B., P. & E.D.
04/07/14	From committee with author's amendments. Read second time and amended. Re-referred to Com. on RLS.
02/20/14	Referred to Com. on RLS.
02/07/14	From printer. May be acted upon on or after March 9.
02/06/14	Introduced. Read first time. To Com. on RLS. for assignment. To print.



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 2, 2014

The Honorable Mike Morrell
California State Assembly
State Capitol, Room 4144
Sacramento, CA 95814

RE: Assembly Bill 2131 - SUPPORT

Dear Assembly Member Morrell:

The Board of Pharmacy thanks you for authoring Assembly Bill 2131, which would authorize the board to issue a letter of reprimand with an initial license.

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. It investigates all matters related to the issuance of the license that may affect the public welfare. This includes the 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.

Assembly Bill 2131 would authorize the board to issue a letter of reprimand, which would describe in detail the nature and facts of an individual's violations. Assembly Bill 2131 would provide the individual the right to contest the Letter of Reprimand, would specify the process and timeframe for the contesting of the letter, and would require that a letter of reprimand be purged three years from the date of issuance.

The Board of Pharmacy believes that Assembly Bill 2131 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.

We look forward to working with your office on this proposal. Please do not hesitate to contact me at 574-7911 or Legislative Coordinator Carolyn Klein at 574-7913 whenever you need our assistance.

Sincerely,

A handwritten signature in cursive script that reads "Virginia Herold".

VIRGINIA HEROLD
Executive Officer

AMENDED IN SENATE APRIL 7, 2014

SENATE BILL

No. 960

Introduced by Senator ~~Berryhill~~ Morrell

February 6, 2014

An act to amend Section 19801 of the Business and Professions Code, relating to gambling add Section 4310.5 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 960, as amended, ~~Berryhill~~ Morrell. ~~Gambling~~. Pharmacy.

Existing law, the Pharmacy Law, provides for the regulation and licensure of pharmacists by the California State Pharmacy Board. Existing law authorizes the board to refuse to license an applicant guilty of unprofessional conduct or to issue, at its sole discretion, a probationary license to an applicant who has met all other licensure requirements.

This bill would authorize the board to issue a license to an applicant who has committed minor violations that the board deems, in its discretion, do not merit the denial of a license or require probationary status, and to concurrently issue a public letter of reprimand, as specified. The bill would require the letter of reprimand to, among other things, describe in detail the nature and facts of the violation and inform the licensee that he or she may accept the letter of reprimand without challenge or, within 30 days of service of the letter, submit a written request for an office conference to contest the letter of reprimand. The bill would require the executive director of the board, or his or her designee, to hold an office conference with the licensee and his or her legal counsel or authorized representative, if any, within 30 days of receipt of the request, as specified. The bill would authorize the

executive officer, or his or her designee, to affirm, modify, or withdraw the letter of reprimand and would require the executive officer, or his or her designee, to provide the licensee with a written decision within 14 calendar days from the date of the office conference. The bill would require a letter of reprimand issued concurrently with a board license to be purged 3 years from the date of issuance, as specified. The bill would require a letter of reprimand to be disclosed to an inquiring member of the public and posted on the board’s Internet Web site.

~~The Gambling Control Act provides for the licensure and regulation of various legalized gambling activities and establishments by the California Gambling Control Commission and the investigation and enforcement of those activities and establishments by the Department of Justice. Existing law makes related findings and declarations.~~

~~This bill would make technical, nonsubstantive changes to these provisions.~~

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

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

- 1 *SECTION 1. Section 4310.5 is added to the Business and*
- 2 *Professions Code, to read:*
- 3 *4310.5. (a) Notwithstanding subdivision (c) of Section 4300,*
- 4 *the board may issue a license to an applicant who has committed*
- 5 *minor violations that the board deems, in its discretion, do not*
- 6 *merit the denial of a license or require probationary status under*
- 7 *Section 4300, and may concurrently issue a public letter of*
- 8 *reprimand.*
- 9 *(b) The letter of reprimand shall be in writing and shall describe*
- 10 *in detail the nature and facts of the violation, including a reference*
- 11 *to the statutes or regulations violated.*
- 12 *(c) The letter of reprimand shall inform the licensee that within*
- 13 *30 days of service of the letter of reprimand the licensee may do*
- 14 *either of the following:*
- 15 *(1) Submit a written request for an office conference to the*
- 16 *executive officer of the board to contest the letter of reprimand.*
- 17 *(A) Within 30 days of receipt of the request, the executive*
- 18 *officer, or his or her designee, shall hold an office conference with*
- 19 *the licensee and the licensee’s legal counsel or authorized*
- 20 *representative, if any. Unless authorized by the executive officer,*

1 or his or her designee, no individual other than the legal counsel
2 or authorized representative of the licensee may accompany the
3 licensee to the office conference.

4 (B) Prior to or at the office conference, the licensee may submit
5 to the executive officer, or his or her designee, declarations and
6 documents pertinent to the subject matter of the letter of reprimand.

7 (C) The office conference is intended to be an informal
8 proceeding and shall not be subject to the provisions of the
9 Administrative Procedure Act (Chapter 3.5 (commencing with
10 Section 11340), Chapter 4 (commencing with Section 11370),
11 Chapter 4.5 (commencing with Section 11400), and Chapter 5
12 (commencing with Section 11500) of Part 1 of Division 3 of Title
13 2 of the Government Code).

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

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

28 (2) The licensee may accept the letter of reprimand without
29 challenge. The board shall inform the licensee that the letter of
30 reprimand shall be purged after three years if no letter of
31 admonishment, citation, notice of correction, or disciplinary action
32 is initiated by the board within those three years.

33 (d) The letter of reprimand shall be served upon the licensee
34 personally or by certified mail at the applicant's address of record
35 with the board. If the applicant is served by certified mail, service
36 shall be effective upon deposit in the United States mail.

37 (e) A public letter of reprimand issued concurrently with a board
38 license shall be purged three years from the date of issuance if no
39 letter of admonishment, citation, notice of correction, or

1 *disciplinary action is initiated by the board during the three-year*
2 *period.*

3 *(f) A public letter of reprimand issued pursuant to this section*
4 *shall be disclosed to an inquiring member of the public and shall*
5 *be posted on the board’s Internet Web site.*

6 *(g) Nothing in this section shall be construed to affect the*
7 *board’s authority to issue an unrestricted license.*

8 SECTION 1. Section 19801 of the Business and Professions
9 Code is amended to read:

10 19801. The Legislature hereby finds and declares all of the
11 following:

12 ~~(a) State law prohibits commercially operated lotteries, banked~~
13 ~~or percentage games, and gambling machines, and strictly regulates~~
14 ~~parimutuel wagering on horse racing. To the extent that state law~~
15 ~~categorically prohibits certain forms of gambling and prohibits~~
16 ~~gambling devices, nothing herein shall be construed, in any manner,~~
17 ~~to reflect a legislative intent to relax those prohibitions.~~

18 ~~(b) The State of California has permitted the operation of~~
19 ~~gambling establishments for more than 100 years. Gambling~~
20 ~~establishments were first regulated by the State of California~~
21 ~~pursuant to legislation that was enacted in 1984. Gambling~~
22 ~~establishments currently employ more than 20,000 people in the~~
23 ~~State of California, and contribute more than one hundred million~~
24 ~~dollars (\$100,000,000) in taxes and fees to California’s~~
25 ~~government. Gambling establishments are lawful enterprises in~~
26 ~~the State of California and are entitled to full protection of the laws~~
27 ~~of this state.~~

28 ~~(c) Gambling can become addictive and is not an activity to be~~
29 ~~promoted or legitimized as entertainment for children and families.~~

30 ~~(d) Unregulated gambling enterprises are inimical to the public~~
31 ~~health, safety, welfare, and good order. Accordingly, no person in~~
32 ~~this state has a right to operate a gambling enterprise except as~~
33 ~~may be expressly permitted by the laws of this state and by the~~
34 ~~ordinances of local governmental bodies.~~

35 ~~(e) It is the policy of this state that gambling activities that are~~
36 ~~not expressly prohibited or regulated by state law may be prohibited~~
37 ~~or regulated by local government. Moreover, it is the policy of this~~
38 ~~state that no new gambling establishment may be opened in a city,~~
39 ~~county, or city and county in which a gambling establishment was~~
40 ~~not operating on and before January 1, 1984, except upon the~~

1 affirmative vote of the electors of that city, county, or city and
2 county.

3 (f) It is not the purpose of this chapter to expand opportunities
4 for gambling, or to create any right to operate a gambling enterprise
5 in this state or to have a financial interest in any gambling
6 enterprise. Rather, it is the purpose of this chapter to regulate
7 businesses that offer otherwise lawful forms of gambling games.

8 (g) Public trust that permissible gambling will not endanger
9 public health, safety, or welfare requires that comprehensive
10 measures be enacted to ensure that gambling is free from criminal
11 and corruptive elements, that it is conducted honestly and
12 competitively, and that it is conducted in suitable locations.

13 (h) Public trust and confidence can only be maintained by strict
14 and comprehensive regulation of all persons, locations, practices,
15 associations, and activities related to the operation of lawful
16 gambling establishments and the manufacture and distribution of
17 permissible gambling equipment.

18 (i) All gambling operations, all persons having a significant
19 involvement in gambling operations, all establishments where
20 gambling is conducted, and all manufacturers, sellers, and
21 distributors of gambling equipment must be licensed and regulated
22 to protect the public health, safety, and general welfare of the
23 residents of this state as an exercise of the police powers of the
24 state.

25 (j) To ensure that gambling is conducted honestly, competitively,
26 and free from criminal and corruptive elements, all licensed
27 gambling establishments in this state must remain open to the
28 general public, and the access of the general public to licensed
29 gambling activities must not be restricted in any manner, except
30 as provided by the Legislature. However, subject to state and
31 federal prohibitions against discrimination, nothing in this chapter
32 shall be construed to preclude exclusion of unsuitable persons from
33 licensed gambling establishments in the exercise of reasonable
34 business judgment.

35 (k) In order to effectuate state policy as declared in this section,
36 it is necessary that gambling establishments, activities, and
37 equipment be licensed, that persons participating in those activities
38 be licensed or registered, that certain transactions, events, and
39 processes involving gambling establishments and owners of
40 gambling establishments be subject to prior approval or permission,

1 that unsuitable persons not be permitted to associate with gambling
2 activities or gambling establishments, and that gambling activities
3 take place only in suitable locations. Any license or permit issued,
4 or other approval granted pursuant to this chapter, is declared to
5 be a revocable privilege, and no holder acquires any vested right
6 in that license, permit, or other approval or under this chapter.

7 ~~(l) The location of lawful gambling premises, the hours of~~
8 ~~operation of those premises, the number of tables permitted in~~
9 ~~those premises, and wagering limits in permissible games~~
10 ~~conducted in those premises are proper subjects for regulation by~~
11 ~~local governmental bodies. However, consideration of those same~~
12 ~~subjects by a state regulatory agency, as specified in this chapter,~~
13 ~~is warranted when local governmental regulation respecting those~~
14 ~~subjects is inadequate or the regulation fails to safeguard the~~
15 ~~legitimate interests of residents in other governmental jurisdictions.~~

16 ~~(m) The exclusion or ejection of certain persons from gambling~~
17 ~~establishments is necessary to effectuate the policies of this chapter~~
18 ~~and to maintain effectively the strict regulation of licensed~~
19 ~~gambling.~~

20 ~~(n) Records and reports of cash and credit transactions involving~~
21 ~~gambling establishments may have a high degree of usefulness in~~
22 ~~criminal and regulatory investigations and, therefore, licensed~~
23 ~~gambling operators may be required to keep records and make~~
24 ~~reports concerning significant cash and credit transactions.~~

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

March 25, 2014

An act to amend Sections 27, 2089.5, 2240, 2530.5, 2532.2, 2532.7, 4021.5, 4053, 4980, 4980.36, 4980.37, 4980.399, 4980.41, 4980.43, 4980.55, 4980.72, 4980.78, 4987.5, 4992.09, 4996.23, 4998, 4999.55, 4999.58, 4999.59, 4999.60, and 4999.123 of, and to amend the heading of Chapter 13 (commencing with Section 4980) of Division 2 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 introduced, Committee on Business, Professions and Economic Development. Health care professionals.

(1) 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.

(2) 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.

(3) 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 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.

(4) Existing law requires an applicant for a license as marriage and family therapist, social worker, or professional clinical counselor, to participate in and obtain a passing score on a board-administered California law and ethics examination in order to qualify for a license or renewal of a license.

This bill would permit an applicant who holds a registration eligible for renewal, and who applies for renewal of that registration between January 1, 2016, and June 30, 2016, if eligible, to renew the registration without first participating in the California law and ethics examination.

1 SEC. 7. Section 4021.5 of the Business and Professions Code
2 is amended to read:

3 4021.5. "Correctional pharmacy" means a pharmacy, licensed
4 by the board, located within a ~~state~~ correctional facility for the
5 purpose of providing pharmaceutical care to inmates of the ~~state~~
6 correctional facility.

7 SEC. 8. Section 4053 of the Business and Professions Code is
8 amended to read:

9 4053. (a) Notwithstanding Section 4051, the board may issue
10 a license as a designated representative to provide sufficient and
11 qualified supervision in a wholesaler or veterinary food-animal
12 drug retailer. The designated representative shall protect the public
13 health and safety in the handling, storage, and shipment of
14 dangerous drugs and dangerous devices in the wholesaler or
15 veterinary food-animal drug retailer.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 SEC. 9. The heading of Chapter 13 (commencing with Section
17 4980) of Division 2 of the Business and Professions Code is
18 amended to read:

19

20 CHAPTER 13. *LICENSED MARRIAGE AND FAMILY THERAPISTS*

21

22 SEC. 10. Section 4980 of the Business and Professions Code
23 is amended to read:

24 4980. (a) (1) Many California families and many individual
25 Californians are experiencing difficulty and distress, and are in
26 need of wise, competent, caring, compassionate, and effective
27 counseling in order to enable them to improve and maintain healthy
28 family relationships.

29 *Healthy*

30 (2) *Healthy* individuals and healthy families and healthy
31 relationships are inherently beneficial and crucial to a healthy
32 society, and are our most precious and valuable natural resource.
33 ~~Marriage~~ *Licensed marriage* and family therapists provide a crucial
34 support for the well-being of the people and the State of California.

35 (b) No person may engage in the practice of marriage and family
36 therapy as defined by Section 4980.02, unless he or she holds a
37 valid license as a marriage and family therapist, or unless he or
38 she is specifically exempted from that requirement, nor may any
39 person advertise himself or herself as performing the services of
40 a marriage, family, child, domestic, or marital consultant, or in

E-Pedigree – Inoperative Statutes
Board of Pharmacy Proposal to Repeal Inoperative Statutes
All References are to the California Business and Professions Code

4034. - REPEAL

4034. (a) ~~“Pedigree” means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, repackagers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.~~

~~(b) A pedigree shall include all of the following information:~~

~~(1) The source of the dangerous drug, including the name, the federal manufacturer’s registration number or a state license number as determined by the board, and principal address of the source.~~

~~(2) The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number or, if not immediately available, a customer-specific shipping reference number linked to the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.~~

~~(3) The business name, address, and the federal manufacturer’s registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.~~

~~(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.~~

~~(5) The unique identification number described in subdivision (i).~~

~~(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number. Dangerous drugs that are repackaged shall be serialized by the repackager and a pedigree shall be provided that references the pedigree of the original package or packages provided by the manufacturer.~~

~~(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler or repackager, and~~

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~~received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug. For purposes of this section, the “smallest package or immediate container” of a dangerous drug shall include any dangerous drug package or container made available to a repackager, wholesaler, pharmacy, or other entity for repackaging or redistribution, as well as the smallest unit made by the manufacturer for sale to the pharmacy or other person furnishing, administering, or dispensing the drug.~~

~~(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.~~

~~(f) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.~~

~~(g) The following transactions are exempt from the pedigree requirement created by this section:~~

~~(1) An intracompany sale or transfer of a dangerous drug. For purposes of this section, “intracompany sale or transfer” means any transaction for any valid business purpose between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of the same corporate or legal entity.~~

~~(2) Dangerous drugs received by the state or a local government entity from a department or agency of the federal government or an agent of the federal government specifically authorized to deliver dangerous drugs to the state or local government entity.~~

~~(3) The provision of samples of dangerous drugs by a manufacturer’s employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.~~

~~(4) (A) A sale, trade, or transfer of a radioactive drug, as defined in Section 1708.3 of Title 16 of the California Code of Regulations, between any two entities licensed by the Radiologic Health Branch of the State Department of Public Health, the federal Nuclear Regulatory Commission, or an Agreement state.~~

~~(B) The exemption in this paragraph shall remain in effect unless the board, no earlier than the date that is two years after the compliance date for manufacturers set forth in subdivision (k) of Section 4034 or Section 4163.5, determines after consultation with the Radiologic Health Branch of the State Department of Public Health that the risk of counterfeiting or diversion of a~~

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~~radioactive drug is sufficient to require a pedigree. Two years following the date of any such determination, this paragraph shall become inoperative.~~

~~(5) The sale, trade, or transfer of a dangerous drug that is labeled by the manufacturer as “for veterinary use only.”~~

~~(6) The sale, trade, or transfer of compressed medical gas. For purposes of this section, “compressed medical gas” means any substance in its gaseous or cryogenic liquid form that meets medical purity standards and has application in a medical or homecare environment, including, but not limited to, oxygen and nitrous oxide.~~

~~(7) The sale, trade, or transfer of solutions. For purposes of this section, “solutions” means any of the following:~~

~~(A) Those intravenous products that, by their formulation, are intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium, calories, such as dextrose and amino acids, or both.~~

~~(B) Those intravenous products used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.~~

~~(C) Products that are intended for irrigation or reconstitution, as well as sterile water, whether intended for those purposes or for injection.~~

~~(8) Dangerous drugs that are placed in a sealed package with a medical device or medical supplies at the point of first shipment into commerce by the manufacturer and the package remains sealed until the drug and device are used, provided that the package is only used for surgical purposes.~~

~~(9) A product that meets either of the following criteria:~~

~~(A) A product comprised of two or more regulated components, such as a drug/device, biologic/device, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity.~~

~~(B) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products or device and biological products.~~

~~(h) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining~~

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~~that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.~~

~~(i) “Interoperable electronic system” as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture and supplemented by a linked unique identification number in the event that drug is repackaged, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, repackagers, and pharmacies for the pedigree of a dangerous drug. No particular data carrier or other technology is mandated to accomplish the attachment of the unique identification number described in this subdivision.~~

~~(j) The application of the pedigree requirement shall be subject to review during the board’s evaluation pursuant to Section 473.4.~~

~~(k) This section shall become operative on January 1, 2015.~~

4034.1. –Repeal

(a) (1) Upon the effective date of federal legislation or adoption of a federal regulation addressing pedigree or serialization measures for dangerous drugs, Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative.

(2) Within 90 days of the enactment of federal legislation or adoption of a regulation addressing pedigree or serialization measures for dangerous drugs, the board shall publish a notice that Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 are inoperative.

(3) Within 90 days of the enactment of federal legislation or adoption of a regulation that is inconsistent with any provision of California law governing the application of any pedigree or serialization requirement or standard, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.

(b) (1) If the Food and Drug Administration (FDA) enacts any rule, standard, or takes any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, that provision of California law shall be inoperative.

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~~(2) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall publish a notice that the provision is inoperative.~~

~~(3) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.~~

~~(c) If the board fails to recognize the inoperation within 90 days pursuant to this section, nothing in this section shall preclude a party from filing an action in state or federal court for declaratory or injunctive relief as an alternative to filing a petition with the board.~~

4163. - **REPEAL**

~~(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 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.~~

~~(c) Except as otherwise provided in Section 4163.5, commencing on July 1, 2016, a wholesaler or repackager may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.~~

~~(d) Except as otherwise provided in Section 4163.5, commencing on July 1, 2016, a wholesaler or repackager may not acquire a dangerous drug without receiving a pedigree.~~

~~(e) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.~~

~~(f) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not acquire a dangerous drug without receiving a pedigree.~~

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~~(g) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy warehouse may not acquire a dangerous drug without receiving a pedigree. For purposes of this section and Section 4034, a “pharmacy warehouse” means a physical location licensed as a wholesaler for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of those drugs to a group of pharmacies under common ownership and control.~~

Add Section 4163 to the Business and Professions Code to read:

(a) A manufacturer, wholesaler, third-party logistics provider, 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 the person acquiring the dangerous drugs or dangerous devices is a wholesaler or third-party logistics provider, the obligation of the wholesaler or third-party logistics provider shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

4163.1. – REPEAL

~~It is the intent of the Legislature that commencing on January 1, 2007, and continuing through the full implementation of the pedigree requirements specified by Section 4163, manufacturers and wholesalers shall use best efforts to provide in the most readily accessible form possible, information regarding the manufacturer’s specific relationships in the distribution of dangerous drugs with wholesalers.~~

4163.1. – REPEAL

~~(a) For purposes of Sections 4034 and 4163, “drop shipment” means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:~~

~~(1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.~~

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~~(2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.~~

~~(3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.~~

~~(b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.~~

4163.2. – **REPEAL**

~~(a) (1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and 4163, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.~~

~~(2) The written declaration shall include the National Drug Code Directory lot number for each dangerous drug designated. The written declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.~~

~~(3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations. Information contained in these declarations shall be considered trade secrets and kept confidential by the board.~~

~~(b) Any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the pedigree requirements, if the transfer complies with the other requirements of this chapter.~~

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4163.3. – repeal

~~(a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, third party logistics providers or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.~~

~~(b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.~~

~~(c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.~~

~~(d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.~~

~~(e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.~~

4163.4. – REPEAL

~~(a) All units of dangerous drug in the possession of a wholesaler or pharmacy, for which the manufacturer does not hold legal title on the effective date of the pedigree requirement set forth in Section 4163.5, shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163. However, if any units of those drugs are subsequently returned to the manufacturer, they shall be subject to the pedigree requirements if the manufacturer distributes those units in California.~~

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~~(b) All units of dangerous drug manufactured in California but distributed outside the state for dispensing outside the state shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163 at either the time of initial distribution or in the event that any of those units are subsequently returned to the manufacturer.~~

4163.5. - REPEAL

~~(a) The Legislature hereby finds and declares that:~~

~~(1) The electronic pedigree system required by Sections 4034 and 4163 will provide tremendous benefits to the public and to all participants in the distribution chain. Those benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end, all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.~~

~~(2) At the same time, it is recognized that the process of implementing serialized electronic pedigree for all prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, repackagers, pharmacies, and other supply chain participants. The Legislature seeks to ensure continued availability of prescription drugs in California while participants implement these requirements.~~

~~(b) Before January 1, 2015, each manufacturer of a dangerous drug distributed in California shall designate those dangerous drugs representing a minimum of 50 percent of its drugs, generic or single source, distributed in California, for which it is listed as the manufacturer by the federal Food and Drug Administration, which shall be the subject of its initial phase of compliance with the January 1, 2015, deadline of the state's serialized electronic pedigree requirements set forth in Sections 4034 and 4163. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.~~

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~~(c) Before January 1, 2016, each manufacturer of a dangerous drug distributed in California shall designate the final 50 percent of its drugs, generic or single source, distributed in California for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the state’s serialized electronic pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state’s serialized electronic pedigree requirement by January 1, 2016. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.~~

~~(d) For purposes of designating drugs to be serialized as required by subdivisions (b) and (c), manufacturers shall select from any of the following measures:~~

~~(1) Unit volume.~~

~~(2) Product package (SKU) type.~~

~~(3) Drug product family.~~

~~(e) Drugs not subject to compliance with the pedigree requirements set forth in Sections 4034 and 4163 under this section shall not be subject to the provisions of subdivisions (c), (d), (e), and (f) of Section 4163.~~

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ARTICLE 2. Definitions [4015 - 4045]

Amend **4022.5** to read:

(a) “Designated representative” means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.

(b) “Designated representative-in-charge” means a designated representative or a pharmacist proposed by a ~~wholesaler~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the ~~wholesaler’s~~ wholesaler’s, third-party logistics provider’s or veterinary food-animal drug retailer’s compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

Amend **4040.5** to read:

“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 nonsalable dangerous drugs.

Amend **4043** to read:

(a) “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.

~~(b) This section shall become operative January 1, 2006.~~

Amend **4045** to read:

“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

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warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. For purposes of ~~Sections~~ Section 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third-party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may only accept decommissioned drugs from pharmacies or wholesalers.

Article 3. Scope of Practice and Exemptions. References to Wholesaler , designated rep, or pedigree:

Amend **4053**, to read:

(a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a ~~wholesaler~~ 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~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer.

(b) An individual that 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.

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- (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).

Amend 4060. to read:

No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to either Section 4052.1 or 4052.2. This section shall 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, when in stock in containers correctly labeled with the name and address of the supplier or producer. Nothing in this section authorizes 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.

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Article 5 – Authority of Inspectors (Sections 4080-4086)

Amend **4081** to read:

(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 or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-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 or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

Article 6. General Requirements (Sections 4100 – 4107)

Amend **4101** to read:

(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 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~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer upon application by the ~~wholesaler~~ wholesaler, third-party logistics

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provider or veterinary food-animal drug retailer and approval by the board. Any 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.

Amend **4105** to read:

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

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deny the extension request within two business days of the time the extension request was made directly to the board.

Article 7. Pharmacies (Sections 4110 – 4126.5)

Amend 4120. to read:

(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.

Amend 4126 to read:

(a) Notwithstanding any other provision of 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

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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.

Amend 4149 to read:

4149. License Required for Nonresident Distributor of Needles or Syringes

(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), no license shall be 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.

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Amend the Title of Article 11 to read:

ARTICLE 11. ~~Wholesalers and Manufacturers~~ Wholesalers, Third-Party Logistics Providers and Manufacturers [4160 - 4169]

(Article 11 added by Stats. 1996, Ch. 890, Sec. 3.)

Amend **4160** to read:

- (a) A person may 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~~ wholesaler or third-party logistics provider. Each license shall be renewed annually and shall not be transferable.
- (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 or third party logistics provider's compliance with state and federal laws governing ~~wholesalers.~~ wholesalers or 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 license or third party logistics provider license without identification of an approved designated representative-in-charge for the ~~wholesaler.~~ wholesaler or third-party logistics provider.
- (e) Every 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 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.

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(f) 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) 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.

*Amend **4161** to read: (Nonresident WLS or nonresident third-party logistics providers)*

(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. 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

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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, ~~or transferred~~ 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 may 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 and notifies the board in writing of the identity and license number of the designated representative-in-charge.
- (j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's or nonresident third-party logistics provider's compliance with state and federal laws governing wholesalers and 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 within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.

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(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.

Amend 4162. to read:

(a) (1) An applicant, that is not a government owned and operated third-party logistics provider or wholesaler, for the issuance or renewal of a third-party logistics provider or wholesaler license 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) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) 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) 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 third-party logistics provider or wholesaler, shall not be required to post a surety bond as provided in paragraph (1).

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(4) For licensees subject to paragraph (2) or (3), 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.

Amend 4162.5 to read

(a) (1) An applicant for the issuance or renewal of a nonresident third-party logistics provider or wholesaler 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) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the nonresident third-party logistics provider or wholesaler is ten million dollars (\$10,000,000) or less in which the surety bond shall be twenty-five thousand dollars (\$25,000).

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

(4) 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 third-party logistics provider or wholesaler, 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.

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(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.

Amend 4164. to read:

(a) A wholesaler licensed by the board that distributes controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales 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. Each wholesaler shall have the tracking system required by this subdivision in place no later than January 1, 2006.

(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.

~~(e) This section shall become operative on January 1, 2006.~~

Amend 4165. to read:

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.

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Amend 4166. to read:

(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~~ wholesaler, third-party logistics provider or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

Amend 4167. to read:

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 licensed by the board.

Amend 4168. to read:

A county or municipality may 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.

Amend 4169. to read:

- (a) A person or entity may 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~~ 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.

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(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 provision of law, a violation of this section or of ~~subdivision (c) or (d)~~ of Section 4163 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.

Article 16 – Applications (Sections 4200 – 4209)

Amend 4201, to read:

(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) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or

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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 provision of 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 provision of law, the wholesale 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 provision of 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 devices. The license shall be renewed annually and shall not be transferable.

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

~~(i)~~ (j) For licenses referred to in subdivisions (f), (g), (h) and ~~(h)~~, (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.

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~~(j) This section shall become operative on July 1, 2001.~~

Amend **4305.5** to read:

(a) A person who has obtained a license to conduct a ~~wholesaler~~ 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. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(b) A person who has obtained a license to conduct a ~~wholesaler~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer, who willfully fails to notify the board of the termination of employment of the designated representative-in-charge, and who continues to operate the licensee in the absence of the designated representative-in-charge for that location, shall be subject to summary suspension or revocation of his or her license to conduct a ~~wholesaler~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer.

(c) A designated representative-in-charge of a ~~wholesaler~~ wholesaler, third-party logistics provider or veterinary food-animal drug retailer, who terminates his or her employment at the licensee, 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.

~~(d) This section shall become operative on January 1, 2006.~~

Amend **4312** to read:

(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

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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) In the event that the license of a wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer is cancelled 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) In the event that 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

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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.

Article 20 – Prohibitions and Offenses (Sections 4320-4343)

Amend **4331**, to read:

(a) A person who is neither a pharmacist nor a designated representative and who takes charge of a third-party logistics provider, wholesaler or veterinary food-animal drug retailer or who coordinates the warehousing or distribution of dangerous drugs or devices, dispenses a prescription or furnishes dangerous devices except as otherwise provided in this chapter is guilty of a misdemeanor.

(b) A person who has obtained a license to conduct a veterinary food-animal drug retailer and who 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) A person who has obtained a license to conduct a wholesaler or third-party logistics provider and who 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.

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~~(d) This section shall become operative on January 1, 2006.~~

Article 23 – Revenue and Renewal

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Attachment 3



Bill Number:	AB 1535
Introduced	
Amendment Date:	4/1/2014
Author:	Bloom
Topic:	Pharmacists: naloxone hydrochloride

Affected Sections: Business and Professions Code

Status: Passed ASM Business Professions and Consumer Protection on April 8 (14-0)
Referred to ASM Appropriations

Staff Recommendation: SUPPORT AB 1535 as Amended 4/1/14

SUMMARY:

According to the author's office, "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 overdoses that, when administered by a family member or another witness, can prevent death or disability. Currently, [NH] 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 [MBC] and [BOP]."

EXISTING LAW:

The Board of Pharmacy administers and enforces provisions of the Pharmacy Law (commencing with section 4001 BPC). California pharmacists are currently authorized to furnish the following medications without a prescription after appropriate training and pursuant to specified conditions:

- Emergency contraception drug therapy and self-administered hormonal contraceptives;
- Nicotine replacement products
- Prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside of the United States
- Administer immunizations, and
- Initiate and administer epinephrine.

The Medical Board of California (MBC) administers and enforces the Medical Practice Act (commencing with section 2004 BPC).

Article 3 of the Business and Professions Code (sections 4050-4068) specifies the scope of practice for a pharmacist.

Civil Code section 1714.22 authorizes a licensed health care provider to prescribe and dispense naloxone hydrochloride (NH) to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist a person at risk of an opioid related overdose. Likewise, a licensed health care provider may issue standing orders for the administration of NH to a person at risk of an opioid-related overdose (or other person to assist them) . The person who is prescribed or possesses NH pursuant to a standing order to receive NH is required to received specified training. However, the person who receives a prescription for NH directly from a licensed health care provider is not required to receive the specified training.

THIS BILL WOULD:

- Permit a pharmacist to furnish naloxone hydrochloride pursuant to standardized procedures or protocols developed and approved by the Board of Pharmacy and the Medical Board of California.
- The procedures or protocols would be developed by the BOP and MBC in consultation with the California Society of Addiction Medicine, the California Pharmacists Association and other appropriate entities.
 - The bill specifies information required to be included in the standardized procedures or protocol;
 - Prohibits a pharmacist furnishing NH from allowing a person receiving NH to waive the drug consultation;
 - Requires a pharmacist to complete a training program on the use of opioid antagonists that consists of at least one hour of approved CE on the use of NH prior to furnishing NH in accordance with the procedures or protocol;
- Authorizes the board and the MBC to ensure compliance with the bill, and each board is charged with enforcing the provisions with its respective licensees; and
- States that the bill shall not be construed to expand the authority of a pharmacist to prescribe any drug.

FISCAL IMPACT ON THE BOARD:

The board would develop standardized procedures or a protocol with the MBC and others, as specified, which may result in the promulgation of regulations.

HISTORY:

Date	Action
04/08/14	From committee: Do pass and re-refer to Com. on APPR. with recommendation: to consent calendar. (Ayes 14. Noes 0.) (April 8). Re-referred to Com. on APPR.
04/02/14	Re-referred to Com. on B.,P. & C.P.
04/01/14	From committee chair, with author's amendments: Amend, and re-refer to Com. on B.,P. & C.P. Read second time and amended.
03/19/14	Re-referred to Com. on B.,P. & C.P.
03/18/14	From committee chair, with author's amendments: Amend, and re-refer to Com. on B.,P. & C.P. Read second time and amended.
01/30/14	Referred to Com. on B.,P. & C.P.
01/22/14	From printer. May be heard in committee February 21.
01/21/14	Read first time. To print.

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

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

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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 by the pharmacist and an authorized prescriber or 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 ~~consider~~ *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.

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 either of the following:
6 ~~(1) Standardized procedures or protocols developed by the~~
7 ~~pharmacist and an authorized prescriber who is acting within his~~
8 ~~or her scope of practice.~~
9 ~~(2) Standardized~~ *standardized* procedures or protocols developed
10 and approved by both the board and the Medical Board of
11 California, *in consultation with the California Society of Addiction*
12 *Medicine, the California Pharmacists Association, and other*
13 *appropriate entities*. In developing *those* standardized procedures
14 or protocols pursuant to this paragraph, *protocols*, the board and
15 the Medical Board of California shall ~~consider~~ *procedures include*
16 *the following*:

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

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

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

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

18 ~~(b)~~

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

23 ~~(e)~~

24 (d) *The board and the Medical Board of California are each*
25 *authorized to ensure compliance with this section. Each board is*
26 *specifically charged with enforcing this section with respect to its*
27 *respective licensees. This section ~~shall~~ *does not be construed to*
28 *expand the authority of a pharmacist to prescribe any other drug*
29 *prescription medication.**



Bill Number:	AB 1727
Introduced:	2/14/14
Author:	Rodriguez
Topic:	Prescription drugs: collection and distribution program
Position:	

Affected Sections: Amend 150204 of the Health & Safety Code

Status: In ASM Health
Hearing set for May 6, 2014

SUMMARY:

AB 1727 would prohibit a drug that can only be dispensed to a patient registered with a drug manufacturer in accordance with FDA requirements from being donated to a county repository and distribution program.

EXISTING LAW:

The Surplus Medication Collection and Distribution program (Health and Safety Code sections 150200-150207) sets forth provisions by which specified entities may donate unused medications to a county that has established a voluntary repository and distribution program.

Counties that operate a repository and distribution program are required to establish written procedures with minimum specified information, ensure medications are dispensed to eligible patients (as defined by each county), and meet other requirements.

Currently, medications that are donated to a repository and distribution program must meet all of the following criteria: (HSC 150204(c)(1)-(3))

- No controlled substances shall be donated
- The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer.
- The medication shall not have been in the possession of a patient, or any individual member of the public, as specified.

The FDA Amendments Act of 2007 provides the FDA with the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. In some cases the FDA has imposed restricted distribution programs for specified drugs, and some programs require drug manufacturers to

track each prescription from the doctor, through the pharmacy, to the patient. The process ensures that patients receive initial and ongoing education about the risks and necessary precautions associated with these drugs.

These risk management programs are an integral part of the FDA-approved product labeling. Complying with the FDA’s requirement of keeping track and maintaining records of REMS-classified medication becomes challenging once it reaches an unused drug repository program. According to the author, allowing pharmacies that participate in a repository program to receive and re-distribute these types of drugs undermines the safety precautions established by REMS programs.

The author states that other states, including Arizona, Colorado, Montana, Washington and Wisconsin, have incorporated similar language in their drug repository programs either through statute or regulation. Since 2007, all bills to either create such a program or expand an existing program have contained this type of protective language.

THIS BILL WOULD:

Amend Health and Safety Code section 150204 to prohibit the donation of a medication that can be dispensed only to a patient registered with the drug’s manufacturer in accordance with the requirements of the United States FDA.

FISCAL IMPACT ON THE BOARD:

No fiscal impact.

HISTORY:

Date	Action
02/27/14	Referred to Com. on HEALTH.
02/18/14	From printer. May be heard in committee March 20.
02/14/14	Read first time. To print.

AB 1727 (Rodriguez)

Prescription Drug Repository and Distribution Program Exemptions

(As introduced 02/14/14)

SUMMARY

AB 1727 is a technical fix to California's Drug Repository and Distribution Program that would ensure medications with strict U.S. Federal Food and Drug Administration (FDA) restrictions are not distributed in county surplus drug collection and distribution programs.

BACKGROUND

California's Drug Repository and Distribution Program was established by SB 798 (Simitian), Statutes of 2006 for medically indigent patients to receive donated prescription drugs free of charge. The bill allows counties, on a voluntary basis, to establish the program under which the following entities donate unused and unexpired medications to county-owned pharmacies, or pharmacies that contract with the county: skilled nursing facilities, skilled nursing facilities designated as an institution for mental disease, drug wholesalers, and drug manufacturers. The program was further modified by SB 1329 (Simitian), Chapter 709, Statutes of 2012 expanding the types of entities that can donate and dispense medication and allowing counties to establish the program through an action by the Board of Supervisors or through an action of the Public Health Officer of the county, instead of only through county ordinance under existing law. Santa Clara County is the only county currently in the process of implementing the program since the program was established.

The FDA Amendments Act of 2007 provided the FDA with the authority to

require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. In some cases the FDA has imposed restricted distribution programs for specified drugs, and some programs require drug manufacturers to track each prescription from the doctor, through the pharmacy, to the patient. The process ensures that patients receive initial and ongoing education about the risks and necessary precautions associated with these drugs. These risk management programs are an integral part of the FDA-approved product labeling. Complying with the FDA's requirement of keeping track and maintaining records of REMS-classified medication becomes challenging once it reaches an unused drug repository program. Allowing pharmacies that participate in a repository program to receive and re-distribute these types of drugs undermines the safety precautions established by REMS programs.

Other states, including Arizona, Colorado, Montana, Washington and Wisconsin, have incorporated similar language in their drug repository programs either through statute or regulation. Since 2007, all bills to either create such a program or expand an existing program have contained this type of protective language.

THIS BILL

AB 1727 specifically would:

- Prohibit drugs that can only be dispensed to a patient registered with the drug's manufacturer in accordance with FDA

requirements from being accepted or distributed by a pharmacy participating in a drug repository program.

SUPPORT

Celgene Corporation

OPPOSITION

None on File

FOR MORE INFORMATION

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ASSEMBLY BILL

No. 1727

Introduced by Assembly Member Rodriguez

February 14, 2014

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

LEGISLATIVE COUNSEL'S DIGEST

AB 1727, as introduced, 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 prescription drug that can be dispensed only to a patient registered with the drug's manufacturer in accordance with the requirements of the United States Food and Drug Administration.

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 150204 of the Health and Safety Code
2 is amended to read:
3 150204. (a) (1) A county may establish, by an action of the
4 county board of supervisors or by an action of the public health
5 officer of the county, as directed by the county board of
6 supervisors, a repository and distribution program for purposes of
7 this division. The county shall advise the California State Board
8 of Pharmacy within 30 days from the date it establishes a repository
9 and distribution program.
10 (2) Only an eligible entity, pursuant to subdivision (a) of Section
11 150201, may participate in this program to dispense medication
12 donated to the drug repository and distribution program.
13 (3) An eligible entity that seeks to participate in the program
14 shall inform the county health department and the California State
15 Board of Pharmacy in writing of its intent to participate in the
16 program. An eligible entity may not participate in the program
17 until it has received written or electronic documentation from the
18 county health department confirming that the department has
19 received its notice of intent.
20 (4) (A) A participating entity shall disclose to the county health
21 department on a quarterly basis the name and location of the source
22 of all donated medication it receives.
23 (B) A participating primary care clinic, as described in paragraph
24 (3) of subdivision (a) of Section 150201 shall disclose to the county
25 health department the name of the licensed physician who shall
26 be accountable to the California State Board of Pharmacy for the
27 clinic's program operations pursuant to this division. This physician
28 shall be the professional director, as defined in subdivision (c) of
29 Section 4182 of the Business and Professions Code.
30 (C) The county board of supervisors or public health officer of
31 the county shall, upon request, make available to the California
32 State Board of Pharmacy the information in this division.
33 (5) The county board of supervisors, the public health officer
34 of the county, and the California State Board of Pharmacy may
35 prohibit an eligible or participating entity from participating in the
36 program if the entity does not comply with the provisions of the
37 program, pursuant to this division. If the county board of
38 supervisors, the public health officer of the county, or the California

1 State Board of Pharmacy prohibits an eligible or participating
2 entity from participating in the program, it shall provide written
3 notice to the prohibited entity within 15 days of making this
4 determination. The county board of supervisors, the public health
5 officer of the county, and the California State Board of Pharmacy
6 shall ensure that this notice also is provided to one another.

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

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

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

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

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

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

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

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

26 (2) *The medication shall not be a prescription drug that can be*
27 *dispensed only to a patient registered with the drug's manufacturer*
28 *in accordance with the requirements of the United States Food*
29 *and Drug Administration.*

30 ~~(2)~~

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

34 ~~(3)~~

35 (4) The medication shall not have been in the possession of a
36 patient or any individual member of the public, and in the case of
37 medications donated by a health or care facility, as described in
38 Section 150202, shall have been under the control of a staff
39 member of the health or care facility who is licensed in California

1 as a health care professional or has completed, at a minimum, the
2 training requirements specified in Section 1569.69.

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

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

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

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

- 22 (1) Dispensed to an eligible patient.
- 23 (2) Destroyed.
- 24 (3) Returned to a reverse distributor or licensed waste hauler.
- 25 (4) (A) Transferred to another participating entity within the
26 county to be dispensed to eligible patients pursuant to this division.
27 Notwithstanding this paragraph, a participating county-owned
28 pharmacy may transfer eligible donated medication to a
29 participating county-owned pharmacy within another adjacent
30 county that has adopted a program pursuant to this division, if the
31 pharmacies transferring the medication have a written agreement
32 between the entities that outlines protocols and procedures for safe
33 and appropriate drug transfer that are consistent with this division.
34 (B) Medication donated under this division shall not be
35 transferred by any participating entity more than once, and after
36 it has been transferred, shall be dispensed to an eligible patient,
37 destroyed, or returned to a reverse distributor or licensed waste
38 hauler.
39 (C) Medication transferred pursuant to this paragraph shall be
40 transferred with documentation that identifies the drug name,

1 strength, and quantity of the medication, and the donation facility
2 from where the medication originated shall be identified on
3 medication packaging or in accompanying documentation. The
4 document shall include a statement that the medication may not
5 be transferred to another participating entity and must be handled
6 pursuant to subparagraph (B). A copy of this document shall be
7 kept by the participating entity transferring the medication and the
8 participating entity receiving the medication.

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

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

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

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

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

38 (m) County protocols established for packaging, transporting,
39 storing, and dispensing medications that require refrigeration,
40 including, but not limited to, any biological product as defined in

1 Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262),
2 an intravenously injected drug, or an infused drug, shall include
3 specific procedures to ensure that these medications are packaged,
4 transported, stored, and dispensed at appropriate temperatures and
5 in accordance with USP standards and the Pharmacy Law.

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

O



Bill Number:	AB 2165
Introduced:	2/20/14
Amended:	4/10/14
Author:	Patterson
Topic:	Professions and Vocations: Licenses
Position:	

Affected Sections: Add section 101.8 to the Business and Professions Code

Status: ASM Business Professions and Consumer Protection
Hearing set for April 22, 2014

Staff Recommend: Support if Amended to specify **45 working days** (not including state holidays)

SUMMARY:

AB 2165 would require license applications to be reviewed, processed, and issued to applicants who have completed the necessary requirements within 45 days of the application filing date and also requires that each exam is offered a minimum of six times per year.

The bill does not specify if the requirement is 45 calendar days, or 45 working days, nor does it specify what is to occur should the 45 days not be met. The board tracks its strategic plan goals (for individual licensees) in working days (not including holidays).

EXISTING LAW:

The board issues individual licenses to pharmacists, intern pharmacists, pharmacy technicians, and designated representatives.

The board prescribes its permit processing times at 16 CCR section 1706.1 (operative in 1991). The regulation specifies that the board shall identify any application that is deficient, and what is needed to correct the deficiency within 30 days for individual applicants. The regulation further specifies that the maximum time to notify an applicant of its licensing decision is 30 days after all deficient items have been received.

THIS BILL WOULD:

Require the board to review, process and issue a license within 45 days of the application filing date. In practice, AB 2165 requires the board to make a licensing *decision* and issue its final determination within the 45 calendar days.

Historical patterns would suggest that surges in applications, staff vacancies and other challenges have had an effect on the period of time a license is processed and issued.

FISCAL IMPACT ON THE BOARD:

The board will require additional staff resources to meet a 45 calendar day requirement, to ensure the board can make and act on a licensing decision on or before 45 days.

Based on current staffing levels and workload, the board would require position authority to add 4.0 positions, as well as initial and ongoing funding for these positions on a permanent basis.

HISTORY:

Date	Action
04/10/14	From committee chair, with author's amendments: Amend, and re-refer to Com. on B.,P. & C.P. Read second time and amended.
03/06/14	Referred to Com. on B.,P. & C.P.
02/21/14	From printer. May be heard in committee March 23.
02/20/14	Read first time. To print.

AB 2165 (Patterson)

Department of Consumer Affairs: Licensing

SUMMARY

The Department of Consumer Affairs (DCA) establishes minimum qualifications and levels of competency for licensure in more than 100 business and 200 professional categories including: nurses, contractors, cosmetologists, automotive repair facilities, dental hygienists, real estate brokers, insurance agents, and physical therapists.

AB 2165 would add Section 101.8 to the Business and Professions Code to require each board within the Department of Consumer Affairs to review completed applications and issue licenses within 45 days from the date of application. The bill also requires that each exam is offered a minimum of 6 times per year.

PROBLEM

Professional and vocational applicants are currently experiencing extraordinary delays with application processing times.

In addition, several professions do not allow for testing upon graduation from accredited schools. They first must process the application and then authorize the applicant to test—a process which can take up to 3 months before the applicant is even cleared for examination. Then they are faced with **additional** wait times for taking the exam, waiting for exam results, and waiting for the license to finally be issued upon passage of the examination. It is unacceptable for California's vital professionals and tradesman to be unemployed for up to six months while waiting for the application process to be completed.

This bill aims to ensure that applicants are presumed ready to test upon graduation from accredited schools or approved programs and that they will not be further delayed from employment by an unnecessarily burdensome application processing times.

EXISTING LAW

Existing law requires each board within the Department of Consumer Affairs to establish eligibility and application requirements—including examination requirements—to license, certify, or register each applicant who successfully satisfies their requirements.

THE SOLUTION

AB 2165 does not alter any of the qualifications established by each board under DCA's jurisdiction.

It does require that each board process and issue licenses or certificates within a much more reasonable time period—45 days from the date the complete application was filed, if the individual has met all the requirements of the application and testing within that 45-day period.

FISCAL EFFECT

Unknown at this time.

SPONSOR

Author

For more information:

Contact: Christina Nelson at
(916) 319-2023

AMENDED IN ASSEMBLY APRIL 10, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL

No. 2165

Introduced by Assembly Member Patterson

February 20, 2014

An act to add Section 101.8 to the Business and Professions Code, relating to ~~licensing~~ *professions and vocations*.

LEGISLATIVE COUNSEL'S DIGEST

AB 2165, as amended, Patterson. Professions and vocations: licenses.

Under existing law, boards within the Department of Consumer Affairs license and regulate persons practicing various healing arts, professions, vocations, and businesses. Existing law requires these boards to establish eligibility and application requirements, including examinations, to license, certificate, or register each applicant who successfully satisfies applicable requirements.

This bill would require each board, *as defined*, to complete within 45 days the application review process with respect to each person who has filed with the board an application for issuance of a license, and to issue, within ~~that~~ *those* 45 days, a license to an applicant who *has* successfully satisfied all licensure requirements, *as specified*. The bill ~~would also require~~ *require* each board to offer each examination the board provides for ~~the applicant's passage of which is required for~~ licensure, a minimum of 6 times per year, *unless the board uses a national examination*. The bill would also authorize a person who has satisfied the educational requirements of the licensing act of which he or she seeks licensure to immediately apply for and take the professional examination required for licensure regardless of whether his or her

application for licensure is then pending with the board for which he or she seeks licensure.

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 101.8 is added to the Business and
2 Professions Code, to read:

3 101.8. (a) Notwithstanding any other law, every board, as
4 defined in Section 22, within 45 days following the filing date of
5 an application with the board for issuance of a license, as defined
6 in Section 23.7, to engage in the business or profession regulated
7 by that board, the board shall do both of the following:

- 8 (1) Complete the application review process.
- 9 (2) If the applicant has satisfied all of the requirements for
10 licensure under the applicable licensing act, issue the applicant the
11 applicable license.

12 *(b) For purposes of paragraph (2) of subdivision (a), an*
13 *applicant has satisfied all of the requirements for licensure under*
14 *the applicable licensing act only if all of the documents required*
15 *by the licensing board for licensure have been submitted to the*
16 *board, regardless of whether those documents are to be submitted*
17 *by the applicant with his or her application or separately by any*
18 *other person or entity, such as for purposes of, among other things,*
19 *verification of completion of the applicant’s coursework, training,*
20 *or clinical experience, if required under the applicable licensing*
21 *act.*

22 ~~(b)~~
23 (c) Every board that offers an examination that an applicant is
24 required to complete successfully for licensure, shall offer that
25 examination a minimum of six times per year, *unless the board*
26 *uses a national examination.*

27 (d) *Notwithstanding any other law, a person who has satisfied*
28 *the educational requirements of the licensing act of which he or*
29 *she seeks licensure, such as graduation from a state-approved or*
30 *state-accredited school of which graduation is required by the*
31 *applicable licensing act, may immediately apply for and take the*
32 *professional examination required for licensure, regardless of*

- 1 *whether his or her application for licensure is then pending with*
- 2 *the board for which he or she seeks licensure.*

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Bill Number:	SB 981
Introduced:	2/11/14
Amended:	4/10/14
Author:	Huff (Coauthor: Senator Gaines) Coauthors: Assembly Members Hagman, Harkey, Jones, and Olsen)
Topic:	Regulations: Review Process

Affected Sections: Add Sections 11349.10 and 11349.11 to the Government Code

Status: In SEN Governmental Organization
Hearing set for April 22, 2014

Staff Recommendation:

Support if Amended to exempt Health Care boards subject to sunset review.

SUMMARY:

Senate Bill 981 would require the board to perform a comprehensive review of each regulation and submit to the Legislature reports that contain specified information regarding the board's regulations.

EXISTING LAW:

The Administrative Procedure Act governs the process by which agencies promulgate regulations. (Gov. Code 11340 et seq.)

A state agency that proposes to adopt, amend, or repeal any regulation also must assess the rule for any adverse economic impact on California businesses, which is designed to avoid the imposition of unnecessary or unreasonable regulations or reporting, recordkeeping or compliance requirements on business enterprises or individuals. (Gov. Code 11346.3)

The Board of Pharmacy has broad authority under which it may promulgate regulations, as well as specific mandates to specify requirements in regulation. The board's regulations are found in Title 16 of Division 17 of the California Code of Regulations. To date (not including repealed regulations) the board has approximately 124 regulations that apply to individuals and/or businesses under the board's jurisdiction.

THIS BILL WOULD:

Senate Bill 981 (Huff) would require each state agency to review each regulation adopted prior to January 1, 2014 and provide a report that includes the following:

- The date the regulation was approved
- The purpose of the regulation
- The statutory authority
- The identification of impacted sectors
- Whether the regulation is duplicative of other regulations
- Whether the regulation is still relevant, and
- Whether the regulation needs to be updated in order to become less burdensome or more effective

In addition, Section 11349.11 would require the board, on or before January 1, 2021 and at least every five years thereafter, to review each regulation that is at least 20 years old and has not been reviewed within the last 10 years, and develop a report to be submitted to the Legislature, to contain specified information (similar to that noted above).

FISCAL IMPACT ON THE BOARD:

The board is not able to absorb the workload that would be required by Senate Bill 981, and would require two Associate Governmental Program Analysts on a full time basis to perform the required review of existing, produce the required reports, and conduct on-going reviews of the board's regulations.

STAFF COMMENTS:

The board is subject to an in depth review by policy committees of the Legislature. (Section 4001(f) BPC). These reviews cover the activities of the board to include changes to the board since the last sunset review – to include all proposed regulations initiated since the board's last sunset review; fiscal issues, performance measures, summaries of licensing programs and processing times, the board's enforcement activities, policies, etc.

Should the board (and other boards subject to sunset review?) be exempt from the proposed requirements?

HISTORY:

Date	Action
03/19/14	Re-referred to Com. on B.,P. & C.P.
03/18/14	From committee chair, with author's amendments: Amend, and re-refer to Com. on B.,P. & C.P. Read second time and amended.
03/17/14	Referred to Com. on B.,P. & C.P.
02/24/14	Read first time.
02/23/14	From printer. May be heard in committee March 25.
02/21/14	Introduced. To print.

California State Senate

SENATOR
BOB HUFF

SENATE REPUBLICAN LEADER

TWENTY-NINTH SENATE DISTRICT



SB 981 – REGULATORY REFORM

IN BRIEF

This bill will reduce the state's regulatory burden on the private sector and California's job market by ensuring that all state agencies review state regulations in order to identify those that are the most burdensome and obsolete. It will also reduce outdated or duplicative regulations by requiring departments to review all regulations that are at least 20 years old, every five years.

THE ISSUE

According to the 2013 Bureau of Labor Statistics, California ranks the 5th worst state in unemployment. Much of this is due to the impact of California's arduous and vast regulatory laws on businesses.

When Bing Energy, a high-tech alternative energy developer, announced plans to close its California-based operations and relocate to Florida, it cited California's corporate tax rate, coupled with stringent permitting rules and regulations that led to their decision to leave the Golden State. ***Bing Energy Chief Financial Officer Dean Minardi explained: "I just can't imagine any corporation in their right mind would decide to set up in California today."***

Generally, all regulations must follow the rulemaking procedures outlined in the Administrative Procedures Act (APA). The APA requires all rulemaking agencies to, among other things: (1) find that no alternative would be more effective or would be as effective and less burdensome to private persons than the adopted regulations; (2) describe the potential cost impact of a regulation; and (3) assess to what extent the regulation will create or eliminate jobs and businesses.

The Office of Administrative Law (OAL) reviews and approves all regulations. The OAL determines whether rulemaking agencies have properly complied with APA, but the OAL does not review the cost information to determine whether it is accurate.

Despite the procedures set forth under the APA, California's economy is struggling due to onerous and duplicative regulations. A Sacramento State University study found the total cost of regulation is approximately \$493 billion, or 3.8 million lost jobs – a tenth of the state's population.

Forbes Magazine ranks California as the most costly state to do business, while the Chief Executive Magazine finds California's business climate as the worst in the nation for 9 years in a row.

Today, there are well over 28,000 pages of regulations with hundreds of new agency laws added each year by unelected bureaucracies. All of these carry the same force of law as any legislation.

THE SOLUTION

Senate Bill 981 will require a system-wide review of state regulations to identify excessive or duplicative laws.

This legislation will provide policy makers with the objective information needed to identify job-killing regulations and allow the state to take appropriate action to reform or repeal these regulations.

Reducing duplicative and burdensome regulations is a key driver towards economic recovery. SB 981 is vital reform that welcomes new business and investments to California while reducing obvious barriers to our economic prosperity.

FOR MORE INFORMATION

Beth Hummel
Office of Senator Bob Huff
(916) 651-4029

AMENDED IN SENATE APRIL 10, 2014

SENATE BILL

No. 981

Introduced by Senator Huff

(Coauthor: Senator Gaines)

(Coauthors: Assembly Members Hagman, Harkey, Jones, and Olsen)

February 11, 2014

An act to add Section 11349.11 to, and to add and repeal Section 11349.10 of, the Government Code, relating to regulations.

LEGISLATIVE COUNSEL'S DIGEST

SB 981, as amended, Huff. Regulations: review process.

Existing law, the Administrative Procedure Act, governs the procedure for the adoption, amendment, or repeal of regulations by state agencies.

This bill would require each agency to review each regulation adopted prior to January 1, 2014, and to develop a report with prescribed information to be submitted to the Legislature on or before January 1, 2016. The bill would also require each agency, on or before January 1, 2021, and at least every 5 years thereafter, to conduct additional reviews of regulations that have been in effect for at least 20 years, as specified, and to submit an annual report to the Legislature that identifies the regulations reviewed during that year and the associated findings.

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 11349.10 is added to the Government
2 Code, to read:

1 11349.10. (a) Each agency shall review each regulation
2 adopted prior to January 1, 2014. The review shall be developed
3 into a report that includes, but is not limited to, the following
4 information for each regulation:

- 5 (1) The date that the office approved the regulation.
- 6 (2) The purpose.
- 7 (3) The statutory authority.
- 8 (4) The identification of impacted sectors.
- 9 (5) The direct costs by sector.
- 10 (6) Whether the regulation is duplicative of other regulations.
- 11 (7) Whether the regulation is still relevant.
- 12 (8) Whether the regulation needs to be updated in order to
13 become ~~more effective~~ or less burdensome *or more effective*.

14 (b) The agency shall consult with parties affected by the
15 regulation in developing the report.

16 (c) The agency shall submit the report to the Legislature pursuant
17 to Section 9795 on or before January 1, 2016.

18 (d) To the extent that an agency is a component member of
19 another agency, the member agency shall submit a copy of its
20 report to the highest ranking agency head prior to submitting the
21 report to the Legislature as required by this section. The agency
22 head shall review the reports for each component agency for the
23 purpose of identifying duplicative or conflicting regulations
24 between departments.

25 (e) This section shall remain in effect only until January 1, 2020,
26 and as of that date is repealed, unless a later enacted statute, that
27 is enacted before January 1, 2010, deletes or extends that date.

28 SEC. 2. Section 11349.11 is added to the Government Code,
29 to read:

30 11349.11. (a) On or before January 1, 2021, and at least every
31 five years thereafter, each agency shall review each regulation that
32 is at least 20 years old and has not been reviewed within the last
33 10 years. The review shall be developed into a report that shall be
34 submitted to the Legislature and includes, but is not limited to, the
35 following information for each regulation:

- 36 (1) The date that the office approved the regulation.
- 37 (2) The purpose.
- 38 (3) The statutory authority.
- 39 (4) The identification of impacted sectors.
- 40 (5) The direct costs by sector.

- 1 (6) Whether the regulation is duplicative of other regulations.
- 2 (7) Whether the regulation is still relevant.
- 3 (8) Whether the regulation needs to be updated in order to
- 4 become more effective or less burdensome.
- 5 (b) Each agency shall submit an annual report to the Legislature
- 6 pursuant to Section 9795 that identifies the regulations reviewed
- 7 during the previous year and the associated findings.

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Appendix D. Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs

Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) requires the California Integrated Waste Management Board (CIWMB now CalRecycle) to develop model programs for the collection from consumers and proper disposal of unused or expired home-generated pharmaceuticals¹. In developing model programs in California, the CIWMB is also required to evaluate programs used by other state, local, and other governmental entities. The CIWMB provided a survey to those entities that have collection programs and requested that they complete and return it to the CIWMB. The purpose of the survey was to acquire information on existing home-generated pharmaceutical waste collection programs in California. From the survey results, the Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs (Procedures) were developed that would help organizations or local governments create programs through which the public may return unused or expired home-generated pharmaceutical waste (typically a prescription drug dispensed to a consumer, or a non-prescription item, such as over the counter drugs, that are no longer wanted or needed by the consumer) and meet the following minimum criteria and goals of SB 966 and of the Pharmaceutical Working Group (staff from CIWMB, California Department of Public Health (CDPH), Board of Pharmacy, Department of Toxic Substances Control, and the State Water Resources Control Board).

The minimum criteria of SB 966 and of the Pharmaceutical Working Group for home-generated pharmaceutical waste collection model programs are as follows:

1. Requires, at no additional cost to the consumer, the safe and environmentally sound take back and disposal of unused or expired home-generated pharmaceuticals;
2. Ensures protection of the public's health and safety and the environment;
3. Ensures protection of the health and safety of consumers, and employees;
4. Report to the Board the amounts of home-generated pharmaceutical waste collected for purposes of program evaluation for safety, efficiency, effectiveness and funding sustainability, and incidents of diversion of drugs for use or sale;
5. Protects against the potential for the diversion of drug waste for unlawful use or sale;
6. Provides notices and informational materials about potential impacts of improper disposal of pharmaceutical waste and options for proper disposal;
7. Subjects persons or businesses to consequences for failure to comply with model programs per SB 966 and related state and federal pharmaceutical and waste management statutes at the point of transportation, deposition, and consolidation;
8. Requires that once home-generated pharmaceutical waste has been consolidated at a facility or place of business, the waste must be managed as medical or hazardous waste. This would include all statutory requirements for storage and handling as medical or hazardous waste, the use of registered medical or hazardous waste haulers and approved treatment technology for disposal; and
9. Requires collection locations to have written policies and procedures to document their operations and compliance with this home-generated pharmaceutical waste collection program.

Additional goals of SB 966 and the Pharmaceutical Working Group include:

1. Providing for the collection of home-generated pharmaceuticals that is convenient for consumers;

¹ Throughout this document, the terms "home-generated pharmaceuticals" or "home-generated pharmaceutical waste" are used. Although the term does not appear in the law establishing this program, it is the term commonly used by stakeholders to refer to unused or expired pharmaceuticals in the possession of consumers.

2. Maintaining privacy of all participants;
3. Preventing the illegal collection of controlled substances through displaying signage or legally manages them if they are collected;
4. Ensuring that medication information is legible, so that it can be identified in case of a poisoning;
5. Developing a sustainable funding source for collection and disposal of home-generated pharmaceuticals, such as grants, utility funding, or advanced disposal fees placed on home-generated pharmaceuticals and local general funds or via extended producer responsibility funding framework.
6. Striving to develop permanent collection programs rather than one-day events, so they will be more accessible to the public;
7. Providing recommendations for implementation of a statewide program; and
8. Recommending statutory changes to, for example, the Medical Waste Management Act.

The following Procedures have been extracted from both the Pharmaceutical Collection Programs Survey collection program information on the internet, and from the Pharmaceutical Working Group and are recommended for pharmaceutical collection programs. The Procedures are not only a tool to determine if a program meets the minimum criteria of model programs, but also can be used as a model to develop a collection and disposal program for unused/expired home-generated pharmaceuticals. The Procedures are broken down by (I) Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs, (II) One-Time or Periodic Events, and (III) Mail Back Programs.

I. Procedures for Model Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs

As mentioned in the previous section on goals, it is preferable that permanent home-generated pharmaceutical collection programs be developed to provide the public with consistently accessible and convenient venues to drop off unused or expired home-generated pharmaceuticals. The following procedures are basic steps to implement permanent collection programs at these types of facilities.

1. **Types of Collection Facilities** – Only the following may maintain permanent collection locations for home-generated pharmaceuticals: pharmacies with active unrestricted licenses from the California State Board of Pharmacy, police and sheriff's stations, public/environmental health agencies, physician and other licensed health care prescribers' offices, Household Hazardous Waste (HHW) facilities, and healthcare collection sites. Healthcare collection sites are physical locations licensed or operated by individuals or entities licensed by an agency within the Department of Consumer Affairs (DCA), with these locations electing to collect or take-back home-generated pharmaceutical waste and/or sharps, as applicable. Examples of healthcare collection sites include but are not limited to physicians and surgeons' offices, dentists, veterinary offices and pharmacies. If a DCA licensee has their license revoked, suspended, placed on probation or otherwise limited in any way, it shall not operate a healthcare collection site. If collection is at a police station, law enforcement must agree to and be able to collect the controlled substances and other home-generated pharmaceutical waste.

Participation by any entity is voluntary and must be done in accordance with these provisions in these procedures in order to be considered a model program. Jurisdictions such as the City of Los Angeles, San Mateo County, Ventura County, Santa Cruz County, Marin County, Santa Clara County, and nonprofit groups such as the Teleosis Institute are current examples of entities implementing permanent and ongoing programs utilizing these types of venues.

A list of those facilities that collect home-generated pharmaceutical waste shall be provided to the CIWMB by the governmental entity, organization, or business that is implementing these programs. The list of collection facilities shall include the name, address, contact, and telephone number of the facility collecting and disposing of the home-generated pharmaceutical waste.

- 2. Government Agency Authorization** – Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.
- 3. Medical/Hazardous Waste Hauler/Disposal Arrangements** – Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage at <http://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf>. A medical or hazardous waste transporter transporting medical waste shall have a copy of the transporter’s valid hazardous waste transporter registration certificate in the transporter’s possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.
- 4. What Can and Cannot Be Collected**
 - a. Home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste, may be accepted.
 - b. Sharps in containers approved by the local enforcement agency may be accepted at collection sites, but shall not be placed in the same containers as the home-generated pharmaceutical waste.
 - c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall not be accepted.

d. **Controlled Substances** - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to take custody of, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drugs and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines).

5. **Signage** – Signage must be provided regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.), as well as the hours during which collection is permitted. Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. Wastes commingled in this manner must be handled as medical or hazardous waste. If home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words “INCINERATION ONLY” or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. A stand alone sign may be provided by the consolidation point (facility) which further describes the container as a waste pharmaceutical consolidation container. This sign shall be located in close proximity to the container to direct consumers to the container location. During periods of non-operation this sign may be removed and the container shall be stored in a secure storage area to prevent theft.

Signage should include instructions on how to deposit pharmaceuticals into the secured container. Any signage should also advise consumers to remove personal information from the medicine containers but leave information as to the type of medication being deposited.

6. **How Home-Generated Pharmaceuticals Shall Be Collected** – Home-generated pharmaceuticals should be emptied from its original container into the secured container at the collection location. The emptied containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site other than pharmacies may assist consumers in placing home-generated pharmaceuticals in the bins if deemed necessary. The collection location must ensure that the home-generated pharmaceutical licensed waste hauler or handler transports the home-generated pharmaceutical for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered medical or hazardous waste hauler as specified in these procedures.

a. Packing Home-Generated Pharmaceutical Waste and Controlled Substances – Collection site staff may assist a consumer in opening a container but should not otherwise assist consumers in placing pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.

b. Storage – In accordance with Board of Pharmacy specifications, collection sites located in pharmacies shall not commingle pharmaceutical waste with expired, recalled or other quarantined drugs. Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste may be stored at an onsite location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH.

The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.

- c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in containers approved by the local enforcement agency cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in a container approved by the local enforcement agency and the collection site is willing to accept sharps, the consumer must place them in a container approved by the local enforcement agency. Employees should never touch the sharps or assist in this process.
- d. Chain of Custody- When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the generator of the pharmaceutical waste, which is medical waste, and is responsible for assuring that storage, removal and transportation of full containers and disposal are in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the medical or hazardous waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and registration number of the waste hauler taking the drugs.

For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

- 7. Staffing** - The following staff are recommended at collection programs to implement the specified tasks:
- a. Pharmacist (at pharmacies) – The pharmacist has the discretion to assist any consumer who brings in home-generated pharmaceutical waste or review each consumer's deposit into the collection bin. The consumer shall deposit the items into the secured locked container. If a pharmacist chooses to assist consumers with the identification of pharmaceuticals, the pharmacist should refer customers with pharmaceuticals that have been identified as controlled substances to an appropriate collection location for those items.
 - b. Law Enforcement – If a permanent home-generated pharmaceutical waste collection program decides to collect controlled substances, a police officer or other law enforcement officer is required to be present to monitor and collect the controlled substances.
 - c. Hazardous Waste Company Personnel (for collection at HHW facilities) - Hazardous waste personnel should provide drums/containers for collection of non-controlled substances, seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove home-generated pharmaceutical waste, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances at a licensed hazardous waste incinerator, provide a

certificate of destruction, and provide weight of materials collected. Do not allow home-generated pharmaceutical wastes that are hazardous waste (e.g. chemotherapy drugs) to be stored longer than 90 days at the facility as required for the management of hazardous waste.

- d. Medical Prescriber Staff - No physician, dentist, veterinarian or other prescriber or the staff in these offices may accept home-generated pharmaceutical waste directly from consumers. It is the consumer's responsibility to deposit the items into the secured locked container. A prescriber may assist consumers with the identification of drugs.

8. **Container Security** – It is the responsibility of the entity overseeing the collection location to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to prevent diversion and theft opportunities and not allow staff or the entity overseeing the program from having access to the contents. Containers at permanent locations shall be locked and stored in an area that is either locked or under direct supervision or surveillance. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.

Bins located at pharmacies shall have a two key security system--one in the possession of the collection site's designated responsible person and the other in the possession of the licensed hauler who will pick up the contents for appropriate destruction. Containers may be stored in the following manner: a lockable cage on the container, lockable collection bins or kiosks, or lockable closets. Intermediate storage areas shall be marked with the international biohazardous symbol. These warning signs shall be readily legible from a distance of five feet.

Every collection site that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. Once a collection device becomes full, no more pharmaceutical waste can be accepted from consumers by the collection site until a waste hauler has removed the pharmaceutical waste, and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported within 24 hours to the local police department, CDPH, California State Board of Pharmacy, and other agencies that have authorized the collection program.

9. Essential Equipment and Supplies

- a. Pharmacies, Physicians, Veterinarians and Other Prescribers' Offices and Police Stations – The following are examples of the types of equipment and supplies that should be provided: caged, lockable secure containers, lockable kiosks, lockable steel bins, refurbished lockable mail boxes with an internal container. These types of collection containers shall be located near a building entrance or in a lobby that allows people to drop off home-generated pharmaceuticals and not be able to retrieve them, in order to prevent theft. Other supplies include black markers to obscure personal data, signage informing the public about what can and shall not be collected.

- b. Permanent HHW Collection Facility Equipment – The following are examples of equipment and supplies typically used at permanent HHW collection facilities: four container types (55 gallon lab packing containers, 30-gal cardboard with plastic liner, a 5-gal plastic container for inhalers, and a 5-gallon plastic container for mercury items), gloves, indelible markers, and sharps container and/or mail back sharps disposal kit.

10. Budget – In order to ensure that the program is properly run, a budget estimate should be developed so that the program is free for the public to dispose of unused and unwanted home-generated pharmaceuticals at the point of disposal. In doing so the facility will need to determine who will pay for the collection and disposal of home-generated pharmaceuticals and whether there are sufficient funds to pay for any large increases in rates or in amounts collected.

11. Education and Advertising - Collection locations operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. Educational materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceuticals. Operators shall develop and distribute materials advertising the availability of permanent collection programs. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating jurisdictions, movie theater advertisements, advertisements on buses and bus stops, print ads in recycling guides, or English and multi-lingual public service announcements. The advertisements should list who is responsible for operation of the collection location, including the name, address and phone number of the operator.

Collection location operators shall provide instructions and information for consumers prior to bringing items to the collection location. These instructions should include:

- a. A list of what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste).
- b. Instructions on type of personal information to render illegible and pharmaceutical information to retain for purposes of identification.

12. Data Collection - Data shall be kept on the total number of pounds collected, the number of residents utilizing the collection facility, and when possible, the types of materials collected for further study and analysis. Examples of collection forms can be accessed at www.teleosis.org/pdf/Medicine_Return_Form.pdf. Security and confidentiality measures must be taken when retaining this data.

13. Site Visits to Collection Sites – For programs developed and overseen by public entities, those public entities shall visit collection locations periodically to help assure that procedures are being adhered to. A collection site shall make its premises available for inspection by government agencies with jurisdiction in this area.

II. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs at Government-Sponsored One Time or Periodic Collection Events

Although permanent collection programs are the preferred method to collect and properly manage home-generated pharmaceuticals, some jurisdictions such as Tuolumne County, Fresno County, City and County of Santa

Cruz, and the City of Watsonville provide One-time or Periodic Collection Events. The following procedures are basic steps to implement One-time events:

1. **Collection Site** - Access to the location must be restricted to only consumers dropping off home-generated pharmaceuticals. The designated operator shall observe consumers dropping off home-generated pharmaceuticals and shall ensure that the home-generated pharmaceutical wastes are stored in such a manner as to prevent theft. If any theft is observed or suspected, the operator shall contact the appropriate law enforcement agency and the Local Enforcement Agency of CDPH. The collection site should include the following:
 - a. Pharmacist (if a one day event is at a facility other than a pharmacy) – It is recommended that a licensed pharmacist in good standing with the California State Board of Pharmacy be present at the event.
 - b. Dedicated Collection Area - If the collection site is at an HHW facility and the home-generated pharmaceutical waste is being segregated, the facility must provide room to account for secured storage of pharmaceutical collection containers.
 - c. Law Enforcement - Law enforcement may participate in a collection event to provide security for event personnel. This is optional and at the discretion of collection organizers. A law enforcement officer is only required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Per U.S. Drug Enforcement Agency (DEA) law, only a law enforcement officer may accept controlled substances from the consumer. If controlled substances will be accepted, the operator of the event shall ask the law enforcement agency that is providing the officer if the agency has any specific requirements that the event must adhere to. For example, the law enforcement agency may specify the type of packaging that the drugs must be contained in to be accepted into their evidence locker, or if the containers the collection event will provide, are adequate for the law enforcement agency purposes. For controlled substances only, law enforcement must be on site at all times and be able to see the collection and movement of the home-generated pharmaceutical wastes from the public to the collection location. Law enforcement must be able to see the transfer of home-generated pharmaceutical wastes from vehicles to the collection containers. The operator should coordinate with law enforcement to determine the appropriate position for law enforcement to be stationed.
2. **Government Agency Authorization** - Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.
3. **Medical/Hazardous Waste Hauler/Disposal Arrangements** - Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage at <http://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf>. A medical or hazardous

waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.

4. What Can and Cannot Be Collected

- a. These programs provide for the collection and disposal of home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste.
- b. Sharps in containers approved by the local enforcement agency may be accepted at collection sites.
- c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall not be accepted.
- d. Controlled Substances - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to properly collect, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drug and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines).

5. **Signage** – Signage must describe what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.). Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. Wastes commingled in this manner must be handled as medical or hazardous waste. If home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. This sign shall be located in close proximity to the container to direct consumers to container location. During periods of non-operation this sign may be removed and the container shall be stored in a secure intermediate storage area.

Signage should include instructions on how to deposit pharmaceuticals into the secured container. Any signage should also advise consumers to remove personal information from the medicine containers.

6. How Home-Generated Pharmaceuticals Shall Be Collected

Home-generated pharmaceuticals should be emptied from its original container into the secured container at the collection location. The emptied containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site other than pharmacies may assist consumers in depositing home-generated pharmaceuticals in the bins when needed. The collection location must ensure that the medical or hazardous waste hauler or handler transports the home-generated pharmaceutical waste for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered waste hauler as specified in these procedures.

- a. Packing Home-Generated Pharmaceutical Waste and Controlled Substances - Collection site staff may assist a consumer in opening a container but should not otherwise assist consumers in placing pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.
- b. Storage - Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste must be removed the same day from the location in which the one-day or periodic event was held but may be stored at a secure location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH. The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.
- c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in containers approved by the local enforcement agency cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in a container approved by the local enforcement agency and the collection site is willing to accept sharps, the consumer must place them in an approved sharps disposal container. Never have employees touch the sharps or assist in this process.
- d. Chain of Custody - When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the generator of the pharmaceutical waste, which is medical waste, and is responsible for assuring that storage, removal and transportation of full containers and disposal are in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the medical or hazardous waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and registration number of the waste hauler taking the drugs.

For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

7. Staffing

Event organizers are encouraged to have the following staff at collection sites to implement the specified tasks:

- a. Greeter - direct people to the collection location and answer questions. Greeters can also screen incoming people and wastes for problems. If the event is large enough, radios are useful.
- b. Law Enforcement Staff - to provide security, take possession of controlled substances if it has been determined that a controlled substance has been brought in by a consumer, transport controlled substances to evidence storage locker, document the collection of controlled substances, and arrange for and ensure U.S. DEA authorized witnessed destruction of controlled substances. Law enforcement staff can also provide crowd control and watch for problem people. A law enforcement officer is required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Only a law enforcement officer may accept controlled substances, not collection event personnel. If controlled substances will be accepted, confirm with the law enforcement agency providing an officer for the event, whether they have requirements for the type of packaging the drugs must be contained in to be accepted into their evidence locker, or if containers the collection event will provide are adequate for the law enforcement agency purposes. Law enforcement may participate in a collection event to provide security for event personnel. This is optional at the discretion of collection organizers and not required for all events.
- c. Pharmacist - to determine if a medication is a controlled substance, identify non-labeled home-generated pharmaceutical waste, inventory controlled substances (if applicable), witness, and sign the inventory.
- d. Hazardous Waste Personnel - Provide drums/containers for collection of non-controlled substances. Seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove pharmaceutical waste on the same day as the event, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances in licensed hazardous waste incinerator, provide certificate of destruction, provide weight of materials collected, and complete data entry.

8. Container Security – It is the responsibility of the entity overseeing the collection event to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to prevent diversion and theft opportunities and not allow staff or the entity overseeing the event from having access to the contents. The collection device must be within the physical plant of a pharmacy, prescriber’s office, police department, or government agency operating the device so that it can only be accessed during operating hours.

Every collection event that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. Once a collection device becomes full, no more pharmaceutical waste can be accepted from consumers by the collection site until a waste hauler has removed the pharmaceutical waste, and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported with 24 hours to the local police department, CDPH, California State Board of Pharmacy, and other agencies that have authorized the collection program.

9. Recommended Equipment and Supplies

- a. Tools for counting home-generated pharmaceutical waste (pharmacist should provide this);
- b. Hazardous waste containers;
- c. Gloves (Disposable latex or non-latex);
- d. Sealable plastic bags (One-gallon and snack size, with external slide mechanism);
- e. Extension cords, grounded;
- f. Survey forms (examples can be found at www.teleosis.org/pdf/Medicine_Return_Form.pdf);
- g. Indelible markers;
- h. Packing tape;
- i. Containers- Check with your contracted medical or hazardous waste hauler for appropriate containers;
- j. Sharps disposal container - Provide sharps containers approved by the local enforcement agency to collect sharps if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point; and.
- k. Personal protective equipment – All staff must wear gloves (latex or non-latex) at all times when handling pharmaceutical waste. This is important as the containers may be powdery, sticky, and dirty. Accidental ingestion (even through skin or breathing) must be avoided. The use of facemasks should be considered, especially for the pharmacist who may be conducting the physical examination of the home-generated pharmaceutical waste.

10. Budget - An estimate of the budget should be developed and the program must be free to the public to dispose of unused and unwanted home-generated pharmaceuticals.

11. Education and Advertising – Collection event operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. These materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceutical waste. Event operators shall develop and distribute materials advertising for the collection event. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating cities, movie theatre advertisements, advertisements on buses and at bus stops, print ads in recycling guides or English and multi-lingual public service announcements. The advertisements should list who is responsible for operation of the collection location, including the name, address and phone number of the operator.

Collection event operators shall provide instructions and information for consumers to use as they prepare to bring items to the collection event:

- a. Date, Time, Location, operating hours, and contact information for the collection event.
- b. A list of what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste).
- c. Instructions on type of personal information to render illegible and pharmaceutical information to retain for purposes of identification.

12. Data Collection - Determine amounts of home-generated pharmaceuticals collected along with the number of donors. If time allows, determine the types and amounts of home-generated pharmaceuticals collected. This information could be used for further studies and policy recommendations. Security and confidentiality measures should be taken when retaining this data.

Each collection event must have a log specific to that collection event. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection event (b) the address, phone number and location number where the event was located; (c) the date the collection event took place; (d) the names of at least one person from the event who witnessed the pickup by the licensed waste hauler (e) the name of the waste hauler's staff person who picked up the collected waste; (f) the weight of home-generated pharmaceutical waste removed from collection event; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals. The log should indicate the name, address and hauler number of waste hauler taking the drugs. These records shall be kept for 3 years after the life of the collection event by the host agency.

- 13. Site Visits to Collection Sites** – The event organizer shall inspect the location to ensure compliance with all requirements. The CIWMB may request a report summarizing the activities of each collection location including amounts of home-generated pharmaceutical waste collected and the number of days in operation as a collection location for home-generated pharmaceuticals.

III. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs Through a Mail Back Program

In some jurisdictions mailing back used and unused home-generated pharmaceuticals may be the only or most convenient option for the proper management of these items. An example is the State of Maine, which uses pre-paid mailing envelopes available at pharmacies, doctors' offices, and post offices to collect home-generated pharmaceuticals that may include controlled substances. In addition, some pharmaceutical companies, such as Celgene, will take back their own home-generated pharmaceuticals via mail. Celgene allows patients to return unused drugs such as thalidomide purchased from the company, via UPS at no shipping cost to the patient. The following are some guidelines to look at when undertaking such a program:

Locations for Mail-Back Programs shall only be allowed if the following requirements are met:

1. Each entity overseeing either a Mail-Back Location or Mail-Back Program shall ensure that the home-generated pharmaceutical waste is destroyed in accordance with applicable regulations. CIWMB may request that each Mail-Back Location or Program provide information on the amounts of home-generated pharmaceuticals received and destroyed.
2. Determine locations where home-generated pharmaceuticals can be mailed for proper management and destruction. These facilities must be DEA-approved and able to accept controlled substances for destruction if controlled substances are mailed directly to the facility. In addition, these facilities must be able to provide data on the amounts of home-generated pharmaceuticals received and destroyed.
3. Operators of mail-back programs shall obtain self-sealing pre-addressed and pre-stamped envelopes that are approved by the U.S. Postal Service for containment and transportation of home-generated pharmaceutical waste. The envelopes shall also include an instruction sheet on how to package and send the home-generated pharmaceuticals.
4. Operators of mail back programs may provide postage-paid envelopes to pharmacies, one-time collection events, hospice care providers, doctors' offices, and post offices to be utilized by consumers for the mailing and destruction of unused and expired home-generated pharmaceuticals.

5. Envelopes shall be tracked to assure that all envelopes are used for their intended purposes and that all of the home-generated pharmaceuticals get to the destruction facility.
6. Operators may advertise its mail back program at pharmacies, convalescent homes, and retirement homes in order to inform potential users of the program of its availability and requirements for participation.
7. The operator shall review data on the amounts of home-generated pharmaceuticals collected to assure that the amounts are increasing and shall make changes to the program as needed to the program to assure continued growth.

Appendix I-Definitions

1. **Controlled Substance**-any substance listed in Chapter 2 (commencing with Section 11053) of Davison 10 of the CA Health & Safety Code.
2. **Event** – Include programs and one- time events for the collection of home-generated pharmaceutical waste to assure appropriate disposal of these items.
3. **Collection Programs** – include permanent collection programs, temporary collection programs, and mail back collection programs
4. **Model Program** - CIWMB a[p[proved program through which the public may return unused or expired home-generated that meets statutory criteria.
5. **Over the Counter Drug** - a non-prescription drug a defined per CA Business & Professions Code Section 4025.1 which states “non-prescription drugs” means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the laws and rules of this state and the federal government.
6. **Collection Facility** - any entity CIWMB finds appropriate to implement or evaluate a model home-generated pharmaceutical waste program. The participant must agree to participate as a model program. Entities that may qualify to participate:
 - a. Governmental entities (includes police and sheriff’s stations, public/environmental health agencies and HHW facilities);
 - b. Pharmacies with active unrestricted licenses from the California State Board of Pharmacy;
 - c. Other Physician and other licensed health care prescribers’ offices; and
 - d. Healthcare Collection Sites that are licensed by the Department of Consumer Affairs
7. **Pharmaceutical Waste** - In this document it is considered to be a prescription drug dispensed to a consumer or a non-prescription item, no longer wanted or need by the consumer and includes home-generated pharmaceuticals in many delivery systems, such as pills, liquids, and inhalers.
8. **Prescription Drug** - is a dangerous drug as defined per California Business and Professions Code Section 4022 which means any drug unsafe for self-use in humans or animals, without the oversight of a licensed prescriber 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 other drug that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to CA Business & Professions Code Section 4006.



Bill Number:	SB 1039
Introduced	2/18/14
Last Amend:	4/10/14
Author:	Senator Hernandez
Topic:	Hospital Pharmacies
Sponsor:	California Society of Health System Pharmacists (CSHP)

Current Bill Status: **4/21/14** Hearing - SEN Business, Professions & Economic Development
(The bill has been double-referred to SEN BP&ED and SEN Health)

Affected Sections: Amend Sections 4052.6, 4115, BPC
Add Sections 4119.6 and 4119.7 BPC
Amend sections 11150 and 11210 HSC

SUMMARY:

According to the author, Senate Bill 1039 will make more efficient use of pharmacy personnel in the acute care facility setting by expanding the type of nondiscretionary tasks that pharmacy technicians are permitted to perform, which would free up pharmacists to focus on patient care. The bill would also allow a pharmacist to order patient assessments.

EXISTING LAW:

Re: Advanced Practice Pharmacist

Article 3 of the Business and Professions Code (BPC) (commencing with Section 4050) provides for the scope of practice, and exemptions, for a pharmacist licensed by the board.

In 2013, ¹legislation was passed to create a new license/recognition of an Advanced Practice Pharmacist" (APP) and to specify the minimum requirements and fee for licensure. License requirements are found at sections 4210 and 4233 BCP. The board supported SB 493 which enacted these provisions.

¹ Senate Bill 493 (Hernandez), Chapter 469 Statutes 2013, effective January 1, 2014.

²An Advanced Practice Pharmacist licensed by the board is authorized to:

- (1) Perform patient assessments.
- (2) Order and interpret drug therapy-related tests.
- (3) Refer patients to other health care providers.
- (4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health providers, and
- (5) Initiate, adjust or discontinue drug therapy, as specified, to allow a pharmacist, recognized as an advanced practice pharmacist (APP) to order patient assessments.

Dispensing of Drugs

A pharmacist is authorized to ³dispense a dangerous drug or device upon a ⁴prescription from an authorized ⁵prescriber.

Drug Distribution in Hospitals

The board issues licenses to inpatient hospital pharmacies (HPS) as well as to hospital outpatient pharmacies (PHYs). Every pharmacy licensed by the board is required to have a pharmacist-in-charge (PIC) (section 4113 BPC), who is responsible for the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

The California Department of Public Health (DPH) licenses acute care ⁶hospitals, and DPH ⁷regulations specify requirements for the hospital's drug distribution services. Under existing regulations (in part),

- a pharmacist shall seal an emergency drug supply (22 CCR 70263(f)(2))
- a pharmacist shall inspect portable emergency drug containers at least every 30 days (22 CCR 70263(f)(3))
- a pharmacist shall inspect drugs maintained throughout the hospital at least monthly, and irregularities shall be reported in accordance with hospital policy. (22 CCR 70263(q)(10))
- a pharmacist must be consulted on the proper methods for repackaging and labeling bulk cleaning agents, solvents, chemicals and poisons used throughout the hospital. (22 CCR 70263(s))

² Business and Professions Code section 4052.6

³ Business and Professions Code section 4024

⁴ Requirements for patient-specific prescriptions are defined at B&PC 4040

⁵ Physicians and other practitioners are defined at B&PC 4039

⁶ Health and Safety Code section 1250(a)

⁷ Title 22 California Code of Regulations

Pharmacist Scope of Practice / Duties

Article 3 of the B&PC specifies the scope of practice for a pharmacist (sections 4050-4068).

Board regulation further specifies the duties of a pharmacist, or an intern acting under the supervision of a pharmacist, to include the supervision of the packaging of drugs as well as all functions which require professional judgment. (16 CCR 1793.1)

Intern Pharmacists

The board issues licenses to intern pharmacists that meet specified minimum requirements as defined in section 4208 BPC. Pharmacists are responsible for all professional activities performed by an intern under his or her supervision. (16 CCR 1726)

Ancillary Personnel

Section 4115 BPC specifies those tasks that may be performed by a pharmacy technician while under the direct supervision and control of a pharmacist.

A “pharmacy technician” is defined as an individual who, under the direct supervision and control of a pharmacist, performs packaging, manipulative, and repetitive or other nondiscretionary tasks, but who does not perform duties restricted to a pharmacist, as specified. (16 CCR 1793)

“Nondiscretionary tasks” include: (16 CCR 1793.2, last amended in 2004)

- (a) removing the drug or drugs from stock
- (b) counting, pouring, or mixing pharmaceuticals
- (c) placing the product into a container
- (d) affixing a label or labels to a container, and
- (e) packaging and repackaging.

In an acute care hospital that has an ongoing clinical pharmacy program, a pharmacy technician is authorized to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital. (i.e., “tech-check-tech”). Board regulation authorizes a technician to fill unit dose distribution systems, and floor and ward stocks, only with those compounded or repackaged products that have been previously checked by a pharmacist. The overall responsibility for and supervision of these technicians are the responsibility of the pharmacist-in-charge. (16 CCR 1793.8)

THIS BILL WILL:

Advanced Practice Pharmacist

Amend section 4052.6 BPC to authorize an APP to also *order* patient assessments.

Amend sections 11150 and 11210 HSC to make non-substantive technical changes to incorporate references to the APP.

Drug Distribution in Hospitals

Amend section 4115 to specify additional tasks that may be performed by a pharmacy technician, to include emergency supply packaging and sealing in or for hospitals, hospital unit inspections and other tasks. The sponsors of the bill (CSHP) have stated the intent is to limit these additional tasks to pharmacy technicians that are employed by and work in an acute care hospital.

Add section 4119.6 to specify that a pharmacy may furnish a dangerous drug or device to a hospital's emergency medical services system (i.e., emergency drug supplies, replenish emergency drugs to an ambulance, etc.) and that a pharmacy technician or intern pharmacist may stock, replenish, and inspect the hospital's emergency pharmaceutical supplies container, to include controlled substances. The section specifies the period of time records are to be maintained. The sponsors state the intent of the language is to allow only an acute care hospital pharmacies to furnish the drugs to its emergency pharmaceutical supplies container.

Add section 4119.7 to

Authorize a pharmacy to furnish a dangerous drug or device, pursuant to preprinted or electronic standing orders, order sets, and protocols established under hospital policies and procedures, as specified.

Specify that a hospital shall store and maintain drugs in accordance with national standards, and otherwise pursuant to the manufacturer's guidelines, and

Permit a pharmacist, pharmacy technician or intern pharmacist to inspect the drugs maintained in the hospital at least once per month, in accordance with hospital policy and procedures. Any irregularities identified shall be reported in accordance with hospital policy; and

Require a hospital to adopt policies and procedures regarding the responsibility for ensuring proper methods for repackaging and labeling of bulk cleaning agents, solvents, chemicals, and nondrug hazardous substances used throughout the hospital.

STAFF COMMENTS:

Amendments to HSC 11150 and 11150 – to incorporate reference to the advanced practice pharmacist statutes – appear to be technical and nonsubstantive.

Section 1 of the bill (amends 4052.6) would expand the scope of the advanced practice pharmacist to also “order” patient assessments.

Section 2 of the bill amends BPC 4115 to specify that a pharmacy technician may perform packaging, including emergency supply packaging and sealing in or for hospitals, hospital unit inspections, and other tasks, as specified. The sponsors state the intent is to limit these tasks to technicians that work in an acute care hospital; however, the language may be more broad.

Section 3 of the bill (adds section 4119.6) specifies the stocking of an “emergency medical services system” in accordance with the hospital’s policies and procedures. The sponsors state the intent of this section is to allow a hospital pharmacy to furnish or restock emergency supply drugs used in the hospital’s emergency medical services system (i.e., crash carts, replenishing ambulance drugs, and other emergency supplies). This section would also allow a pharmacy technician or intern pharmacist to stock, replenish and inspect these emergency drug supplies in accordance with the hospital’s policies and procedures. These provisions appear to be inconsistent with existing Title 22 regulations (22 CCR 70263), which require a pharmacist to perform these duties.

In Section 4 of the bill (adds section 4119.7) would allow a pharmacy to furnish a dangerous drug or device to a licensed general acute care hospital pursuant to preprinted or electronic standing orders, order sets, and protocols established by the hospital, as specified. The section further requires hospitals to store and maintain these drugs in accordance with national standards regarding the storage area and refrigerator or freezer temperature, and otherwise pursuant to the manufacturer’s guidelines.” In some cases – such as the storage of sterile compounded drug products – the board has specific storage requirements, and California may have standards that are more restrictive than USP (for example). It is unclear if this language is intended to incorporate specific national standards, or to specify minimum standards that would supersede any board regulations or requirements.

Also in Section 4 of the bill, SB 1039 would require a hospital to adopt policies and procedures regarding the proper methods for repackaging and labeling of bulk cleaning agents, solvents, chemicals, and nondrug hazardous substances used throughout the hospital, as specified. These provisions do not appear to have anything to do with a hospital pharmacy, or the role of a pharmacist, intern pharmacist, ancillary personnel – or the drug distribution in a hospital. The board would have no legitimate need to enforce provisions as to how a hospital stores, packs, or labels cleaning agents, etc. Staff suggests these provisions may be better suited for the Health and Safety Code or Title 22.

POLICY CONSIDERATIONS:

Does the board feel the scope of an advanced practice pharmacist should be expanded to allow the APP to also “order patient assessments”? When the advanced practice pharmacist provisions were originally being considered by the Legislature in 2013, the California Medical Association opposed language that would authorize a pharmacist to “order” patient assessments.

Is it appropriate for the board to oversee a hospital’s packaging and labeling of the hospital’s bulk cleaning agents, solvents, etc.? This does not appear to be consistent with the board’s licensing, regulatory and enforcement oversight of its licensees.

Is it appropriate for a pharmacy technician to conduct inspections of and replenish a hospital's emergency drug supplies (including controlled substances), to include floor stocks, crash carts, restocking of ambulance emergency drugs, etc.? Title 22 regulations currently restrict this activity to a pharmacist.

Should provisions in the bill that require a hospital to store and maintain drugs in accordance with national standards, specify that where California standards are more stringent than a national standard, that California requirements shall prevail?

FISCAL IMPACT ON THE BOARD:

SB 1039 may result in a fiscal impact to the board, as yet to be defined, to

Promulgate and/or amend regulations related to appropriate tasks of a pharmacy technician and/or intern pharmacist (i.e., inspection and stocking of hospital emergency drug supplies);

Result in additional enforcement activities related to the compromise or diversion a hospital's emergency drug supply stocks by ancillary staff.

Determine if national standards related to drug storage in hospitals is inconsistent with existing board regulations.

History

Date	Action
04/02/14	Set for hearing April 21.
04/01/14	Set, first hearing. Hearing canceled at the request of author.
03/28/14	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
03/20/14	Set for hearing April 7.
02/27/14	Referred to Coms. on B., P. & E.D. and HEALTH.
02/19/14	From printer. May be acted upon on or after March 21.
02/18/14	Introduced. Read first time. To Com. on RLS. for assignment. To print

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SENATE HEALTH COMMITTEE
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BUSINESS, PROFESSIONS AND
ECONOMIC DEVELOPMENT
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GOVERNMENTAL
ORGANIZATION

SB 1039 (Hernandez)

Efficient use of health facility pharmacy personnel

Purpose

This bill makes more efficient use of pharmacy personnel in the facility setting expanding the types of nondiscretionary tasks that pharmacy technicians are permitted to perform, freeing up pharmacists to focus on patient care.

Primary Care Physician Workforce Shortage

According to a report commissioned by the California Health Care Foundation, the number of primary care physicians actively practicing in California is at or below the very bottom range of, or below, the state's need based on Council on Graduate Medical Education estimates. The distribution of these physicians is also poor. In 2008, there were 69,460 actively practicing physicians in California (this includes Doctors of Medicine and Doctors of Osteopathic Medicine), and only 35 percent of these physicians reported practicing primary care. This equates to 63 active primary care physicians in patient care per 100,000 persons. According to the Council on Graduate Medical Education, a range of 60 to 80 primary care physicians are needed per 100,000 in order to adequately meet the needs of the population. When the same metric is applied regionally, only 16 of California's 58 counties fall within the needed supply range for primary care physicians. In other words, less than one third of Californians live in a community where they have access to the health care services they need.

The ACA

As a result of implementation of the ACA, about 4.7 million more Californians will be eligible for health insurance starting in 2014. The newly insured will increase demand for health care on an already strained system. Furthermore, the ACA aims to change how care is delivered. It will provide incentives for expanded and improved primary care, which may affect demand for some health care professionals more than others, and create team-based models of service delivery. Research indicates that health care reform will place higher skill demands on all members of the healthcare workforce as systems try to improve quality while limiting costs. The scale of change with health care reform is unlike anything that the state has previously faced. Many newly insured Californians will have a pent-up demand for services and will create even more pressure on the already strained health care system, particularly in medically underserved areas.

SB 493 (Hernandez)

In response to the primary care shortage in California, SB 493 (Hernandez), Chapter 469, Statutes of 2013, was enacted. SB 493 gives healthcare facilities greater flexibility to focus their pharmacist workforce on providing patient-centered services as part of a multi-disciplinary team. This is especially important given that previously uninsured patients entering the healthcare system under the Affordable Care Act will likely suffer disproportionately from multiple comorbidities and have low health literacy rates.

However, this flexibility is in conflict with existing regulatory requirements on pharmacists that have been in place for decades and that have long been outdated. Removing the burden of simple nondiscretionary activities unrelated to professional judgment of pharmacists, such as checking expiration dates for drug stock or repackaging or labeling cleaning agents, will help redirect pharmacy resources where they are needed most – the patient.

This bill makes more efficient use of pharmacy personnel in the facility setting by:

- Permitting pharmacy technicians, under the direct supervision of a pharmacist to fill and seal emergency drugs into trays;
- Permitting pharmacy staff to furnish a dangerous drug or dangerous device pursuant preprinted or electronic standing orders, order sets and protocols established under the policies and procedures of a health care facility;
- Permitting pharmacy technicians and intern pharmacists, under the direct supervision of a pharmacist and as specified, to inspect drugs maintained throughout the hospital; and,
- Requiring hospitals to adopt policies and procedures regarding the responsibility for assuring proper methods for repackaging and labeling of bulk cleaning agents, solvents, chemicals and non-drug hazardous substances used throughout the hospital.

Contact

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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, ~~4059~~, ~~4059.5~~, and 4115, and ~~4142~~ of, and to add Sections 4119.6 and 4119.7 to, the Business and Professions Code, and to amend Sections 11150 and 11210 of the Health and Safety Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

SB 1039, as amended, Hernandez. Pharmacies: furnishing drugs.

(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, including emergency supply packaging and sealing in or for hospitals, hospital unit inspections, and other physical, manipulative, repetitive, or other nondiscretionary tasks under supervision of a pharmacist, as specified.

(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 a pharmacy to furnish a dangerous drug or dangerous device to the emergency medical services system of a licensed general acute care hospital, as defined, for storage in a secured emergency pharmaceutical supplies container maintained within the hospital in accordance with the hospital's policies and procedures. The bill would require both the hospital and the dispensing pharmacy to maintain records pertaining to the dangerous drugs or dangerous devices furnished to the hospital's emergency medical services system for at least 3 years. The bill would also authorize a pharmacy to furnish a dangerous drug or dangerous device to a licensed general acute care hospital pursuant to preprinted or electronic standing orders, order sets, and protocols established under the policies and procedures of a licensed general acute care hospital under specified conditions. The bill would require a pharmacist, ~~or a pharmacy technician, or an intern pharmacist,~~ under the direct supervision and control of a pharmacist, to inspect the drugs maintained in the hospital at least once per month, and to report any irregularities, as specified. The bill would also require a hospital to adopt policies and procedures for ensuring proper methods for repackaging and labeling of specified substances.

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.

This bill would also authorize a pharmacist recognized by the board as an advanced practice pharmacist to order patient assessments.

(4) Existing law authorizes a pharmacist to initiate or adjust the drug regimen of a patient under specified circumstances. ~~Existing law authorizes specified practitioners to order a dangerous drug or device and prohibits a person from furnishing a dangerous drug or device, except upon the prescription of those practitioners. 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 ~~and would make related conforming changes.~~

(5) 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:

- 5 (1) Order and perform patient assessments.
- 6 (2) Order and interpret drug therapy-related tests.
- 7 (3) Refer patients to other health care providers.
- 8 (4) Participate in the evaluation and management of diseases
9 and health conditions in collaboration with other health care
10 providers.

11 (5) Initiate, adjust, or discontinue drug therapy in the manner
12 specified in paragraph (4) of subdivision (a) of Section 4052.2.

13 (b) A pharmacist who adjusts or discontinues drug therapy shall
14 promptly transmit written notification to the patient's diagnosing
15 prescriber or enter the appropriate information in a patient record
16 system shared with the prescriber, as permitted by that prescriber.
17 A pharmacist who initiates drug therapy shall promptly transmit
18 written notification to, or enter the appropriate information into,
19 a patient record system shared with the patient's primary care
20 provider or diagnosing provider, as permitted by that provider.

21 (c) This section shall not interfere with a physician's order to
22 dispense a prescription drug as written, or other order of similar
23 meaning.

24 (d) Prior to initiating or adjusting a controlled substance therapy
25 pursuant to this section, a pharmacist shall personally register with
26 the federal Drug Enforcement Administration.

1 (e) A pharmacist who orders and interprets tests pursuant to
2 paragraph (2) of subdivision (a) shall ensure that the ordering of
3 those tests is done in coordination with the patient's primary care
4 provider or diagnosing prescriber, as appropriate, including
5 promptly transmitting written notification to the patient's
6 diagnosing prescriber or entering the appropriate information in a
7 patient record system shared with the prescriber, when available
8 and as permitted by that prescriber.

9 ~~SEC. 2. Section 4059 of the Business and Professions Code is~~
10 ~~amended to read:~~

11 ~~4059. (a) A person shall not furnish a dangerous drug, except~~
12 ~~upon the prescription of a physician, dentist, podiatrist, optometrist,~~
13 ~~veterinarian, naturopathic doctor pursuant to Section 3640.7, or~~
14 ~~pharmacist pursuant to Section 4052.1, 4052.2, or 4052.6. A person~~
15 ~~shall not furnish a dangerous device, except upon the prescription~~
16 ~~of a physician, dentist, podiatrist, optometrist, veterinarian,~~
17 ~~naturopathic doctor pursuant to Section 3640.7, or pharmacist~~
18 ~~pursuant to Section 4052.1, 4052.2, or 4052.6.~~

19 ~~(b) This section does not apply to the furnishing of a dangerous~~
20 ~~drug or dangerous device by a manufacturer, wholesaler, or~~
21 ~~pharmacy to each other or to a physician, dentist, podiatrist,~~
22 ~~optometrist, veterinarian, or naturopathic doctor pursuant to Section~~
23 ~~3640.7, or to a laboratory under sales and purchase records that~~
24 ~~correctly give the date, the names and addresses of the supplier~~
25 ~~and the buyer, the drug or device, and its quantity. This section~~
26 ~~does not apply to the furnishing of a dangerous device by a~~
27 ~~manufacturer, wholesaler, or pharmacy to a physical therapist~~
28 ~~acting within the scope of his or her license under sales and~~
29 ~~purchase records that correctly provide the date the device is~~
30 ~~provided, the names and addresses of the supplier and the buyer,~~
31 ~~a description of the device, and the quantity supplied.~~

32 ~~(c) A pharmacist, or a person exempted pursuant to Section~~
33 ~~4054, may distribute dangerous drugs and dangerous devices~~
34 ~~directly to dialysis patients pursuant to regulations adopted by the~~
35 ~~board. The board shall adopt any regulations as are necessary to~~
36 ~~ensure the safe distribution of these drugs and devices to dialysis~~
37 ~~patients without interruption thereof. A person who violates a~~
38 ~~regulation adopted pursuant to this subdivision shall be liable upon~~
39 ~~order of the board to surrender his or her personal license. These~~
40 ~~penalties shall be in addition to penalties that may be imposed~~

1 pursuant to Section 4301. If the board finds any dialysis drugs or
2 devices distributed pursuant to this subdivision to be ineffective
3 or unsafe for the intended use, the board may institute immediate
4 recall of any or all of the drugs or devices distributed to individual
5 patients.

6 ~~(d) Home dialysis patients who receive any drugs or devices~~
7 ~~pursuant to subdivision (c) shall have completed a full course of~~
8 ~~home training given by a dialysis center licensed by the State~~
9 ~~Department of Public Health. The physician prescribing the dialysis~~
10 ~~products shall submit proof satisfactory to the manufacturer or~~
11 ~~wholesaler that the patient has completed the program.~~

12 ~~(e) A pharmacist may furnish a dangerous drug authorized for~~
13 ~~use pursuant to Section 2620.3 to a physical therapist. A record~~
14 ~~containing the date, name and address of the buyer, and name and~~
15 ~~quantity of the drug shall be maintained. This subdivision shall~~
16 ~~not be construed to authorize the furnishing of a controlled~~
17 ~~substance.~~

18 ~~(f) A pharmacist may furnish electroneuromyographic needle~~
19 ~~electrodes or hypodermic needles used for the purpose of placing~~
20 ~~wire electrodes for kinesiological electromyographic testing to~~
21 ~~physical therapists who are certified by the Physical Therapy Board~~
22 ~~of California to perform tissue penetration in accordance with~~
23 ~~Section 2620.5.~~

24 ~~(g) Nothing in this section shall be construed as permitting a~~
25 ~~licensed physical therapist to dispense or furnish a dangerous~~
26 ~~device without a prescription of a physician, dentist, podiatrist,~~
27 ~~optometrist, or veterinarian, or a pharmacist acting within the scope~~
28 ~~of his or her practice.~~

29 ~~(h) A veterinary food-animal drug retailer shall dispense, furnish,~~
30 ~~transfer, or sell veterinary food-animal drugs only to another~~
31 ~~veterinary food-animal drug retailer, a pharmacy, a veterinarian,~~
32 ~~or to a veterinarian's client pursuant to a prescription from the~~
33 ~~veterinarian for food-producing animals.~~

34 ~~SEC. 3. Section 4059.5 of the Business and Professions Code~~
35 ~~is amended to read:~~

36 ~~4059.5. (a) Except as otherwise provided in this chapter,~~
37 ~~dangerous drugs or dangerous devices may only be ordered by an~~
38 ~~entity licensed by the board and shall be delivered to the licensed~~
39 ~~premises and signed for and received by a pharmacist. When a~~

1 licensee is permitted to operate through a designated representative,
2 the designated representative shall sign for and receive the delivery.

3 ~~(b) A dangerous drug or dangerous device transferred, sold, or~~
4 ~~delivered to a person within this state shall be transferred, sold, or~~
5 ~~delivered only to an entity licensed by the board, to a manufacturer,~~
6 ~~or to an ultimate user or the ultimate user's agent.~~

7 ~~(c) Notwithstanding subdivisions (a) and (b), deliveries to a~~
8 ~~hospital pharmacy may be made to a central receiving location~~
9 ~~within the hospital. However, the dangerous drugs or dangerous~~
10 ~~devices shall be delivered to the licensed pharmacy premises within~~
11 ~~one working day following receipt by the hospital, and the~~
12 ~~pharmacist on duty at that time shall immediately inventory the~~
13 ~~dangerous drugs or dangerous devices.~~

14 ~~(d) Notwithstanding any other law, a dangerous drug or~~
15 ~~dangerous device may be ordered by and provided to a~~
16 ~~manufacturer, physician, dentist, podiatrist, optometrist,~~
17 ~~veterinarian, naturopathic doctor pursuant to Section 3640.7,~~
18 ~~pharmacist pursuant to Section 4052.1, 4052.2, or 4052.6, or~~
19 ~~laboratory, or a physical therapist acting within the scope of his~~
20 ~~or her license. A person or entity receiving delivery of a dangerous~~
21 ~~drug or dangerous device, or a duly authorized representative of~~
22 ~~the person or entity, shall sign for the receipt of the dangerous drug~~
23 ~~or dangerous device.~~

24 ~~(e) A dangerous drug or dangerous device shall not be~~
25 ~~transferred, sold, or delivered to a person outside this state, whether~~
26 ~~foreign or domestic, unless the transferor, seller, or deliverer does~~
27 ~~so in compliance with the laws of this state and of the United States~~
28 ~~and of the state or country to which the dangerous drugs or~~
29 ~~dangerous devices are to be transferred, sold, or delivered.~~
30 ~~Compliance with the laws of this state and the United States and~~
31 ~~of the state or country to which the dangerous drugs or dangerous~~
32 ~~devices are to be delivered shall include, but not be limited to,~~
33 ~~determining that the recipient of the dangerous drugs or dangerous~~
34 ~~devices is authorized by law to receive the dangerous drugs or~~
35 ~~dangerous devices.~~

36 ~~(f) Notwithstanding subdivision (a), a pharmacy may take~~
37 ~~delivery of dangerous drugs and dangerous devices when the~~
38 ~~pharmacy is closed and no pharmacist is on duty if all of the~~
39 ~~following requirements are met:~~

1 ~~(1) The drugs are placed in a secure storage facility in the same~~
2 ~~building as the pharmacy.~~

3 ~~(2) Only the pharmacist-in-charge or a pharmacist designated~~
4 ~~by the pharmacist-in-charge has access to the secure storage facility~~
5 ~~after dangerous drugs or dangerous devices have been delivered.~~

6 ~~(3) The secure storage facility has a means of indicating whether~~
7 ~~it has been entered after dangerous drugs or dangerous devices~~
8 ~~have been delivered.~~

9 ~~(4) The pharmacy maintains written policies and procedures for~~
10 ~~the delivery of dangerous drugs and dangerous devices to a secure~~
11 ~~storage facility.~~

12 ~~(5) The agent delivering dangerous drugs and dangerous devices~~
13 ~~pursuant to this subdivision leaves documents indicating the name~~
14 ~~and amount of each dangerous drug or dangerous device delivered~~
15 ~~in the secure storage facility.~~

16 ~~The pharmacy shall be responsible for the dangerous drugs and~~
17 ~~dangerous devices delivered to the secure storage facility. The~~
18 ~~pharmacy shall also be responsible for obtaining and maintaining~~
19 ~~records relating to the delivery of dangerous drugs and dangerous~~
20 ~~devices to a secure storage facility.~~

21 ~~SEC. 4.~~

22 ~~SEC. 2.~~ Section 4115 of the Business and Professions Code is
23 amended to read:

24 4115. (a) A pharmacy technician may perform packaging,
25 including emergency supply packaging and sealing in or for
26 hospitals, hospital unit inspections, and other physical,
27 manipulative, repetitive, or other nondiscretionary tasks, only while
28 assisting, and while under the direct supervision and control of a
29 pharmacist.

30 (b) This section does not authorize the performance of any tasks
31 specified in subdivision (a) by a pharmacy technician without a
32 pharmacist on duty.

33 (c) This section does not authorize a pharmacy technician to
34 perform any act requiring the exercise of professional judgment
35 by a pharmacist.

36 (d) The board shall adopt regulations to specify tasks pursuant
37 to subdivision (a) that a pharmacy technician may perform under
38 the supervision of a pharmacist. Any pharmacy that employs a
39 pharmacy technician shall do so in conformity with the regulations
40 adopted by the board.

1 (e) No person shall act as a pharmacy technician without first
2 being licensed by the board as a pharmacy technician.

3 (f) (1) A pharmacy with only one pharmacist shall have no
4 more than one pharmacy technician performing the tasks specified
5 in subdivision (a). The ratio of pharmacy technicians performing
6 the tasks specified in subdivision (a) to any additional pharmacist
7 shall not exceed 2:1, except that this ratio shall not apply to
8 personnel performing clerical functions pursuant to Section 4116
9 or 4117. This ratio is applicable to all practice settings, except for
10 an inpatient of a licensed health facility, a patient of a licensed
11 home health agency, as specified in paragraph (2), an inmate of a
12 correctional facility of the Department of Corrections and
13 Rehabilitation, and for a person receiving treatment in a facility
14 operated by the State Department of State Hospitals, the State
15 Department of Developmental Services, or the Department of
16 Veterans Affairs.

17 (2) The board may adopt regulations establishing the ratio of
18 pharmacy technicians performing the tasks specified in subdivision
19 (a) to pharmacists applicable to the filling of prescriptions of an
20 inpatient of a licensed health facility and for a patient of a licensed
21 home health agency. Any ratio established by the board pursuant
22 to this subdivision shall allow, at a minimum, at least one pharmacy
23 technician for a single pharmacist in a pharmacy and two pharmacy
24 technicians for each additional pharmacist, except that this ratio
25 shall not apply to personnel performing clerical functions pursuant
26 to Section 4116 or 4117.

27 (3) A pharmacist scheduled to supervise a second pharmacy
28 technician may refuse to supervise a second pharmacy technician
29 if the pharmacist determines, in the exercise of his or her
30 professional judgment, that permitting the second pharmacy
31 technician to be on duty would interfere with the effective
32 performance of the pharmacist's responsibilities under this chapter.
33 A pharmacist assigned to supervise a second pharmacy technician
34 shall notify the pharmacist in charge in writing of his or her
35 determination, specifying the circumstances of concern with respect
36 to the pharmacy or the pharmacy technician that have led to the
37 determination, within a reasonable period, but not to exceed 24
38 hours, after the posting of the relevant schedule. No entity
39 employing a pharmacist may discharge, discipline, or otherwise
40 discriminate against any pharmacist in the terms and conditions

1 of employment for exercising or attempting to exercise in good
2 faith the right established pursuant to this paragraph.

3 (g) Notwithstanding subdivisions (a) and (b), the board shall
4 by regulation establish conditions to permit the temporary absence
5 of a pharmacist for breaks and lunch periods pursuant to Section
6 512 of the Labor Code and the orders of the Industrial Welfare
7 Commission without closing the pharmacy. During these temporary
8 absences, a pharmacy technician may, at the discretion of the
9 pharmacist, remain in the pharmacy but may only perform
10 nondiscretionary tasks. The pharmacist shall be responsible for a
11 pharmacy technician and shall review any task performed by a
12 pharmacy technician during the pharmacist's temporary absence.
13 Nothing in this subdivision shall be construed to authorize a
14 pharmacist to supervise pharmacy technicians in greater ratios
15 than those described in subdivision (f).

16 (h) The pharmacist on duty shall be directly responsible for the
17 conduct of a pharmacy technician supervised by that pharmacist.

18 ~~SEC. 5.~~

19 *SEC. 3.* Section 4119.6 is added to the Business and Professions
20 Code, to read:

21 4119.6. (a) Notwithstanding any other law, a pharmacy may
22 furnish a dangerous drug or dangerous device to the emergency
23 medical services system of a licensed general acute care hospital,
24 as defined in subdivision (a) of Section 1250 of the Health and
25 Safety Code, for storage in a secured emergency pharmaceutical
26 supplies container maintained within the hospital in accordance
27 with the hospital's policies and procedures. A pharmacy technician
28 or intern pharmacist under the direct supervision and control, as
29 defined in Section 4023.5, of a pharmacist may stock, replenish,
30 and inspect the hospital's emergency pharmaceutical supplies
31 container.

32 (b) Both the hospital and the dispensing pharmacy acting under
33 this section shall maintain records of each request by, and
34 dangerous drugs or dangerous devices furnished to, the hospital's
35 emergency medical services system, for at least three years.

36 (c) Controlled substances shall be furnished to the hospital's
37 emergency medical services system under this section in
38 accordance with the California Uniform Controlled Substances
39 Act (Division 10 (commencing with Section 11000) of the Health
40 and Safety Code).

1 ~~SEC. 6.~~

2 *SEC. 4.* Section 4119.7 is added to the Business and Professions
3 Code, to read:

4 4119.7. (a) Notwithstanding any other law, a pharmacy may
5 furnish a dangerous drug or dangerous device to a licensed general
6 acute care hospital, as defined in subdivision (a) of Section 1250
7 of the Health and Safety Code, pursuant to preprinted or electronic
8 standing orders, order sets, and protocols established under the
9 policies and procedures of the hospital, as approved according to
10 the policies of the hospital's governing body, if the order is
11 promptly dated, timed, and authenticated in the medical record of
12 the patient to whom the dangerous drug or dangerous device is
13 dispensed by the ordering practitioner or another practitioner
14 responsible for the care of that patient and authorized by the
15 hospital's policies and procedures to write orders.

16 (b) The hospital shall store and maintain drugs in accordance
17 with national standards regarding the storage area and refrigerator
18 or freezer temperature, and otherwise pursuant to the
19 manufacturer's guidelines.

20 (c) (1) A pharmacist, pharmacy technician, or an intern
21 pharmacist under the direct supervision and control, as defined in
22 Section 4023.5, of a pharmacist, shall inspect the drugs maintained
23 in the hospital at least once per month. The hospital shall establish
24 specific written policies and procedures for inspections pursuant
25 to this paragraph.

26 (2) The person conducting the inspection pursuant to paragraph
27 (1) shall report any irregularities to the director or chief executive
28 officer of the hospital, or other person holding an equivalent
29 position, and in accordance with the hospital's policy.

30 (d) The hospital shall adopt policies and procedures regarding
31 the responsibility for ensuring proper methods for repackaging
32 and labeling of bulk cleaning agents, solvents, chemicals, and
33 nondrug hazardous substances used throughout the hospital
34 according to state and federal law and standards.

35 ~~SEC. 7.~~ Section 4142 of the Business and Professions Code is
36 amended to read:

37 4142. Except as otherwise provided by this article, no
38 hypodermic needle or syringe shall be sold at retail except upon
39 the prescription of a physician, dentist, veterinarian, podiatrist,

1 ~~naturopathic doctor pursuant to Section 3640.7, or pharmacist~~
2 ~~pursuant to Section 4052.1, 4052.2, or 4052.6.~~

3 ~~SEC. 8.~~

4 *SEC. 5.* Section 11150 of the Health and Safety Code is
5 amended to read:

6 11150. No person other than a physician, dentist, podiatrist,
7 or veterinarian, or naturopathic doctor acting pursuant to Section
8 3640.7 of the Business and Professions Code, or pharmacist acting
9 within the scope of a project authorized under Article 1
10 (commencing with Section 128125) of Chapter 3 of Part 3 of
11 Division 107 or within the scope of Section 4052.1, 4052.2, or
12 4052.6 of the Business and Professions Code, a registered nurse
13 acting within the scope of a project authorized under Article 1
14 (commencing with Section 128125) of Chapter 3 of Part 3 of
15 Division 107, a certified nurse-midwife acting within the scope of
16 Section 2746.51 of the Business and Professions Code, a nurse
17 practitioner acting within the scope of Section 2836.1 of the
18 Business and Professions Code, a physician assistant acting within
19 the scope of a project authorized under Article 1 (commencing
20 with Section 128125) of Chapter 3 of Part 3 of Division 107 or
21 Section 3502.1 of the Business and Professions Code, a
22 naturopathic doctor acting within the scope of Section 3640.5 of
23 the Business and Professions Code, or an optometrist acting within
24 the scope of Section 3041 of the Business and Professions Code,
25 or an out-of-state prescriber acting pursuant to Section 4005 of the
26 Business and Professions Code shall write or issue a prescription.

27 ~~SEC. 9.~~

28 *SEC. 6.* Section 11210 of the Health and Safety Code is
29 amended to read:

30 11210. A physician, surgeon, dentist, veterinarian, naturopathic
31 doctor acting pursuant to Section 3640.7 of the Business and
32 Professions Code, or podiatrist, or pharmacist acting within the
33 scope of a project authorized under Article 1 (commencing with
34 Section 128125) of Chapter 3 of Part 3 of Division 107 or within
35 the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and
36 Professions Code, or registered nurse acting within the scope of a
37 project authorized under Article 1 (commencing with Section
38 128125) of Chapter 3 of Part 3 of Division 107, or physician
39 assistant acting within the scope of a project authorized under
40 Article 1 (commencing with Section 128125) of Chapter 3 of Part

1 3 of Division 107, or naturopathic doctor acting within the scope
2 of Section 3640.5 of the Business and Professions Code, or an
3 optometrist acting within the scope of Section 3041 of the Business
4 and Professions Code may prescribe for, furnish to, or administer
5 controlled substances to his or her patient when the patient is
6 suffering from a disease, ailment, injury, or infirmities attendant
7 upon old age, other than addiction to a controlled substance.

8 The physician, surgeon, dentist, veterinarian, naturopathic doctor
9 acting pursuant to Section 3640.7 of the Business and Professions
10 Code, or podiatrist, or pharmacist acting within the scope of a
11 project authorized under Article 1 (commencing with Section
12 128125) of Chapter 3 of Part 3 of Division 107 or within the scope
13 of Section 4052.1, 4052.2, or 4052.6 of the Business and
14 Professions Code, or registered nurse acting within the scope of a
15 project authorized under Article 1 (commencing with Section
16 128125) of Chapter 3 of Part 3 of Division 107, or physician
17 assistant acting within the scope of a project authorized under
18 Article 1 (commencing with Section 128125) of Chapter 3 of Part
19 3 of Division 107, or naturopathic doctor acting within the scope
20 of Section 3640.5 of the Business and Professions Code, or an
21 optometrist acting within the scope of Section 3041 of the Business
22 and Professions Code shall prescribe, furnish, or administer
23 controlled substances only when in good faith he or she believes
24 the disease, ailment, injury, or infirmity requires the treatment.

25 The physician, surgeon, dentist, veterinarian, or naturopathic
26 doctor acting pursuant to Section 3640.7 of the Business and
27 Professions Code, or podiatrist, or pharmacist acting within the
28 scope of a project authorized under Article 1 (commencing with
29 Section 128125) of Chapter 3 of Part 3 of Division 107 or within
30 the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and
31 Professions Code, or registered nurse acting within the scope of a
32 project authorized under Article 1 (commencing with Section
33 128125) of Chapter 3 of Part 3 of Division 107, or physician
34 assistant acting within the scope of a project authorized under
35 Article 1 (commencing with Section 128125) of Chapter 3 of Part
36 3 of Division 107, or a naturopathic doctor acting within the scope
37 of Section 3640.5 of the Business and Professions Code, or an
38 optometrist acting within the scope of Section 3041 of the Business
39 and Professions Code shall prescribe, furnish, or administer

1 controlled substances only in the quantity and for the length of
2 time as are reasonably necessary.

3 ~~SEC. 10.~~

4 *SEC. 7.* No reimbursement is required by this act pursuant to
5 Section 6 of Article XIII B of the California Constitution because
6 the only costs that may be incurred by a local agency or school
7 district will be incurred because this act creates a new crime or
8 infraction, eliminates a crime or infraction, or changes the penalty
9 for a crime or infraction, within the meaning of Section 17556 of
10 the Government Code, or changes the definition of a crime within
11 the meaning of Section 6 of Article XIII B of the California
12 Constitution.

O

Title 22. Social Security

Division 5. Licensing and Certification of Health Facilities, Home Health Agencies, Clinics, and Referral Agencies

Chapter 1. General Acute Care Hospitals

Article 3. Basic Services ([Refs & Annos](#))

➡ § 70263. **Pharmaceutical Service General Requirements.**

(a) All hospitals having a licensed bed capacity of 100 or more beds shall have a pharmacy on the premises licensed by the California Board of Pharmacy. Those hospitals having fewer than 100 licensed beds shall have a pharmacy license issued by the Board of Pharmacy pursuant to Section 4029 or 4056 of the Business and Professions Code.

(b) The responsibility and the accountability of the pharmaceutical service to the medical staff and administration shall be defined.

(c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or his or her representative and the administrator or his or her representative.

(1) The committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.

(2) The committee shall be responsible for the development and maintenance of a formulary of drugs for use throughout the hospital.

(d) There shall be a system maintained whereby no person other than a pharmacist or an individual under the direct supervision of a pharmacist shall dispense medications for use beyond the immediate needs of the patients.

(e) There shall be a system assuring the availability of prescribed medications 24 hours a day.

(f) Supplies of drugs for use in medical emergencies only shall be immediately available at each nursing unit or service area as required.

(1) Written policies and procedures establishing the contents of the supply procedures for use, restocking and sealing of the emergency drug supply shall be developed.

(2) The emergency drug supply shall be stored in a clearly marked portable container which is **sealed by the pharmacist** in such a manner that a seal must be broken to gain access to the drugs. The contents of the container shall be listed on the outside cover and shall include the earliest expiration date of any drugs within.

(3) The supply **shall be inspected by a pharmacist** at periodic intervals specified in written policies. Such inspections shall occur **no less frequently than every 30 days**. Records of such inspections shall be kept for at least three years.

(g) No drugs shall be administered except by licensed personnel authorized to administer drugs and upon the order of a person lawfully authorized to prescribe or furnish. This shall not preclude the administration of aerosol drugs by respiratory care practitioners. The order shall include the name of the drug, the dosage and the frequency of administration, the route of administration, if other than oral, and the date, time and signature of the prescriber or furnisher. Orders for drugs should be written or transmitted by the prescriber or furnisher. Verbal orders for drugs shall be given only by a person lawfully authorized to prescribe or furnish and shall be recorded promptly in the patient's

medical record, noting the name of the person giving the verbal order and the signature of the individual receiving the order. The prescriber or furnisher shall countersign the order within 48 hours.

(1) Verbal orders for administration of medications shall be received and recorded only by those health care professionals whose scope of licensure authorizes them to receive orders for medication.

(2) Medications and treatments shall be administered as ordered.

(h) Standing orders for drugs may be used for specified patients when authorized by a person licensed to prescribe. A copy of standing orders for a specific patient shall be dated, promptly signed by the prescriber and included in the patient's medical record. These standing orders shall:

(1) Specify the circumstances under which the drug is to be administered.

(2) Specify the types of medical conditions of patients for whom the standing orders are intended.

(3) Be initially approved by the pharmacy and therapeutics committee or its equivalent and be reviewed at least annually by that committee.

(4) Be specific as to the drug, dosage, route and frequency of administration.

(i) An individual prescriber may notify the hospital in writing of his or her own standing orders, the use of which is subject to prior approval and periodic review by the pharmacy and therapeutics committee or its equivalent.

(j) The hospital shall develop policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. The limitations shall be established for classes of drugs and/or individual drug entities.

(k) If drugs are supplied through a pharmacy, orders for drugs shall be transmitted to the pharmacy either by written prescription of the prescriber, by an order form which produces a direct copy of the order or by an electronically reproduced facsimile. When drugs are not supplied through a pharmacy, such information shall be made available to the hospital pharmacist.

(l) Medications shall not be left at the patient's bedside unless the prescriber so orders. Such bedside medications shall be kept in a cabinet, drawer or in possession of the patient. Drugs shall not be left at the bedside which are listed in Schedules II, III and IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 as amended. If the hospital permits bedside storage of medications, written policies and procedures shall be established for the dispensing, storage and records of use, of such medications.

(m) Medications brought by or with the patient to the hospital shall not be administered to the patient unless all of the following conditions are met:

(1) The drugs have been ordered by a person lawfully authorized to give such an order and the order entered in the patient's medical record.

(2) The medication containers are clearly and properly labeled.

(3) The contents of the containers have been examined and positively identified, after arrival at the hospital, by the patient's physician or the hospital pharmacist.

(n) The hospital shall establish a supply of medications which is accessible without entering either the pharmacy or drug storage room during hours when the pharmacist is not available. Access to the supply shall be limited to designated registered nurses. Records of drugs taken from the supply shall be maintained and the pharmacist shall be notified of such use. The records shall include the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the

drug was administered and the signature of the registered nurse. The pharmacist shall be responsible for maintenance of the supply and assuring that all drugs are properly labeled and stored. The drug supply shall contain that type and quantity of drugs necessary to meet the immediate needs of patients as determined by the pharmacy and therapeutics committee.

(o) Investigational drug use shall be in accordance with applicable state and federal laws and regulations and policies adopted by the hospital. Such drugs shall be used only under the direct supervision of the principal investigator, who shall be a member of the medical staff and be responsible for assuring that informed consent is secured from the patient. Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity of investigational drugs shall be available at the nursing station where such drugs are being administered and in the pharmacy. The pharmacist shall be responsible for the proper labeling, storage and distribution of such drugs pursuant to the written order of the investigator.

(p) No drugs supplied by the hospital shall be taken from the hospital unless a prescription or medical record order has been written for the medication and the medication has been properly labeled and prepared by the pharmacist in accordance with state and federal laws, for use outside of the hospital.

(q) Labeling and storage of drugs shall be accomplished to meet the following requirements:

(1) Individual patient medications, except those that have been left at the patient's bedside, may be returned to the pharmacy for appropriate disposition.

(2) All drug labels must be legible and in compliance with state and federal requirements.

(3) Drugs shall be labeled only by persons legally authorized to prescribe or dispense or under the supervision of a pharmacist.

(4) Test agents, germicides, disinfectants and other household substances shall be stored separately from drugs.

(5) External use drugs in liquid, tablet, capsule or powder form shall be segregated from drugs for internal use.

(6) Drugs shall be stored at appropriate temperatures. Refrigerator temperature shall be between 2.2°C (36°F) and 7.7°C (46°F) and room temperature shall be between 15°C (59°F) and 30°C (86°F).

(7) Drugs shall be stored in an orderly manner in well-lighted cabinets, shelves, drawers or carts of sufficient size to prevent crowding.

(8) Drugs shall be accessible only to responsible personnel designated by the hospital, or to the patient as provided in 70263(l) above.

(9) Drugs shall not be kept in stock after the expiration date on the label and no contaminated or deteriorated drugs shall be available for use.

(10) Drugs maintained on the nursing unit shall be inspected at least monthly by a pharmacist. Any irregularities shall be reported to the director of nursing service and as required by hospital policy.

(11) Discontinued individual patient's drugs not supplied by the hospital may be sent home with the patient. Those which remain in the hospital after discharge that are not identified by lot number shall be destroyed in the following manner:

(A) Drugs listed in Schedules II, III or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, shall be destroyed in the presence of two pharmacists or a pharmacist and a registered nurse employed by the hospital. The name of the patient, the name and strength of the drug, the prescription number, the amount destroyed, the date of destruction and the

signatures of the witnesses required above shall be recorded in the patient's medical record or in a separate log. Such log shall be retained for at least three years.

(B) Drugs not listed under Schedules II, III or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, shall be destroyed in the presence of a pharmacist.

(r) The pharmacist shall develop and implement written quality control procedures for all drugs which are prepackaged or compounded in the hospital including intravenous solution additives. He or she shall develop and conduct an in-service training program for the professional staff to assure compliance therewith.

(s) The pharmacist shall be consulted on proper methods for repackaging and labeling of bulk cleaning agents, solvents, chemicals and poisons used throughout the hospital.

(t) Periodically, the pharmacy and therapeutics committee, or its equivalent, shall evaluate the services provided and make appropriate recommendations to the executive committee of the medical staff and administration.

Note: Authority cited: Sections 1275 and 131200, Health and Safety Code. Reference: Sections 1276, 131050, 131051 and 131052, Health and Safety Code.

HISTORY

1. Amendment of subsection (m) filed 3-13-80; effective thirtieth day thereafter (Register 80, No. 11).
2. Amendment of subsection (g), new subsections (g)(1) and (g)(2), and amendment of Note filed 11-26-96; operative 12-26-96 (Register 96, No. 48).
3. Change without regulatory effect amending subsection (a) and Note filed 6-16-2000 pursuant to section 100, title 1, California Code of Regulations (Register 2000, No. 24).
4. Change without regulatory effect amending subsections (c), (g), (i), (q)(8) and (r) and amending Note filed 3-12-2013 pursuant to section 100, title 1, California Code of Regulations (Register 2013, No. 11).



Bill Number:	SB 1258
Introduced	2/21/14
Last Amend:	3/25/14
Author:	Senator DeSaulnier
Topic:	CURES; electronic prescriptions; Schedule V; CURES investigations
Position:	<i>None</i>

Current Bill Status: 4/21/14 Hearing - SEN Business, Professions & Economic Development

The bill has been double-referred to SEN BP&ED and SEN Health

Affected Sections: Amend sections 4071, 4072 Business and Professions Code
Amend Health and Safety Code sections 11151, 11158, 11164, 11164.1,
11164.5, 11165, 11165.1, 11165.5, 11166, and 11200

SUMMARY:

The author states that SB 1258 will improve prescription drug laws and patient safety protections, by amending the Health and Safety Code to:

1. Permit the oral and electronic transmission of controlled substance prescriptions.
2. Establish dispensing limits for controlled substances (30- or 90-day supplies as specified).
3. Add Schedule V controlled substances to be monitored by the CURES program.
4. Allow designated investigators at the DCA to access CURES data for the purpose of investigations.

EXISTING LAW:

Business and Professions Code

Section 4071 authorizes a prescriber to authorize his or her agent on his or her behalf to orally or electronically transmit a prescription to the furnisher, and that the furnisher shall make a reasonable effort to determine that the person who transmits the prescription is authorized to do so. The furnisher is required to record the name of the authorized agent who transmits the order. This section specifically excludes the oral or electronic transmission of a Schedule II controlled substance.

Section 4072 specifies requirements for the oral and electronic transmission of prescriptions by authorized persons in specified health care facilities. As with 4071, section 4072 requires the furnisher to take appropriate steps to determine that the person who transmits the prescription is authorized to do so and shall record the name of the person who transmits the order. Likewise,

this section specifically excludes the oral or electronic order for a Schedule II controlled substance.

CURES / Prescription Drug Monitoring Program (PDMP)

The Uniform Controlled Substances Act 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, every prescriber and pharmacist approved by the PDMP can access CURES information in real time at the point of care so that they can make informed decisions and detect patients who may be abusing controlled substances by obtaining multiple prescriptions from various practitioners.

STAFF COMMENTS:

The following information is provided to aid in the discussion of SB 1258.

Electronic Transmission of Prescriptions

Amendments to BPC 4071 and 4072 changes the terms “that” to “whether.”

- These could potentially be substantive changes. The term “that” would seem to require that you confirm that an agent is authorized. The revised language (“whether”) might only require you to make an *attempt* to verify authorization (i.e., not actually succeed in confirming). Staff is seeking clarification from the author’s office as to whether or not this amendment was intended.

Amendments to BPC 4072 changes the term “shall not” to “does not”

- The term “shall” typically ¹imposes a duty to act.

Amendments to HSC 11164 appear to require the electronic transmission of controlled substance prescriptions, to comply with DEA regulations – but that they also be produced in hard copy form, signed and dated by the pharmacist.

Oral Transmission of Controlled Substances

While the language of SB 1258 as amended appears to permit prescribers and prescribers agents to orally transmit prescriptions for **Schedule II**, III, IV and V controlled substances, Senator DeSaulnier’s staff has indicated that the intent is that California law conforms with existing federal requirements. Thus if federal law does not permit the oral transmission of a Schedule II controlled substance, they will look at making a correction in a future amendment.

- Is it a good idea to allow oral transmission of a Schedule II controlled substance?
- If so, is it a good idea to permit a prescriber’s agent to transmit an oral order for a Schedule II controlled substance?

¹ “Legal, Legislative, and Rule Drafting in Plain English,” Thompson/West, 2005 (ISBN 0-314-15301-2)

In section 4072, oral orders are NOT included – which could mean that pharmacists are not able to orally transmit Schedule II prescriptions (but prescribers/agents are). This Senator's office is looking to determine if a correction may be needed to also authorize pharmacists to orally transmit controlled substances prescriptions.

- Should a pharmacist also be authorized to orally transmit a Schedule II prescription?

Amendments to HSC 11164 provide that if a prescriber is permitted to make an oral order, an *agent* of that prescriber may orally transmit the prescription (Schedule II, III, IV or V) so long as the prescription record specifies the name of the authorized agent.

Requirements for Prescriptions of Controlled Substances

Amendments to HSC 11164 would

- Authorize oral orders for Schedule II, III, IV and V controlled substances if technological failure prevents the electronic transmission of such a prescription, or if the prescription will be filled by a pharmacist located outside of California.
- Allow (not require) a prescription for a Schedule II, III, IV or V controlled substance on a controlled substance prescription form.
- Require an agent of a prescriber that transmits an electronic prescription for a Schedule II, III, IV or V controlled substance to bear the name of the agent authorized to transmit the prescription.

Accessing CURES Data

Amendments to HSC 11165.1(a)(1)(A)(iii) could potentially place a limit on the proper basis for accessing or using CURES data (i.e., restricts using the system to allegations regarding substance abuse). The author's office indicated that the intent is to also allow specified investigators to use CURES for specified purposes; not to change the ability of the board to access the data.

Limits To Dispensing Controlled Substances

Amendments to HSC 112000 establish dispensing limits of controlled substances (30- or 90-day, as specified). The author's office indicates other states observe limits, in essence to limit supplies of drugs out there that may go unused.

FISCAL IMPACT ON THE BOARD:

Staff has not assessed SB 1258 for a fiscal impact.

History

Date	Action
04/04/14	Set for hearing April 21.
04/03/14	Re-referred to Coms. on B., P. & E.D. and PUB. S.
03/25/14	From committee with author's amendments. Read second time and amended. Re-referred to Com. on RLS.
03/06/14	Referred to Com. on RLS.
02/24/14	Read first time.
02/22/14	From printer. May be acted upon on or after March 24.
02/21/14	Introduced. To Com. on RLS. for assignment. To print.

**SB 1258 (DeSaulnier)
As Amended, March 25, 2014**

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

SUMMARY

SB 1258 improves the Controlled Substance Utilization Review and Evaluation System (CURES) to help prevent prescription drug abuse and increase patient safety. SB 1258 would require controlled substance prescriptions be made electronically, add schedule V controlled substances to the CURES database, establish dispensing limits, and allow designated investigators at the Department of Consumer Affairs access the CURES data for purposes of investigations.

BACKGROUND

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

The automated PDMP is a valuable investigative, preventative, and educational tool for healthcare providers, law enforcement, and regulatory boards. However, increased protections are needed to prevent prescription drug abuse and to make the PDMP a better tool to assist in this effort.

PREVIOUS LEGISLATION

SB 734 (Torlakson) Chapter 487, Statutes of 2005
AB 2548 (Block) of 2010 - Held Asm Appropriation
SB 1071 (DeSaulnier) of 2010 – Held Senate Health
SB 360 (DeSaulnier) of 2011 - Signed by Governor
SB 616 (DeSaulnier) of 2012 – Failed passage Asm.
Business & Professions
SB 809 (DeSaulnier) Chapter 400, Statutes of 2013

THIS BILL

SB 1258 improves prescription drug laws and patient safety protections. The bill seeks to accomplish these goals through a number of changes including the following:

1. Mandate that controlled substances be prescribed electronically;
2. Limit the amount of controlled substance prescription to a quantity not to exceed a 30-day supply;
3. Add schedule V controlled substances to be monitored by the CURES program;
4. Allow designated investigators at the Department of Consumer Affairs to access the CURES data for purposes of investigations.

STATUS

- Senate Rules Committee

SUPPORT

- None on File

OPPOSITION

- None on File

FOR MORE INFORMATION

Emlyn Struthers
Office of Senator Mark DeSaulnier
(916) 651-4007

AMENDED IN SENATE MARCH 25, 2014

SENATE BILL

No. 1258

Introduced by Senator DeSaulnier

February 21, 2014

An act to amend ~~Section 11165~~ Sections 4071 and 4072 of the Business and Professions Code, and to amend Sections 11151, 11158, 11164, 11164.1, 11164.5, 11165, 11165.1, 11165.5, 11166, and 11200 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 1258, as amended, DeSaulnier. Controlled substances: prescriptions: reporting.

(1) Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. Existing law requires specified information regarding prescriptions for Schedule II, Schedule III, and Schedule IV controlled substances, including the ultimate user of the prescribed controlled substance and the National Drug Control number of the controlled substance dispensed, to be reported to the Department of Justice.

This bill would additionally require the prescribing and dispensing of Schedule V controlled substances to be monitored in CURES and would require specified information regarding prescriptions for Schedule V controlled substances to be reported to the Department of Justice.

(2) Existing law requires licensed health care practitioners, as specified, and pharmacists to apply to the Department of Justice to obtain approval to access information contained in the CURES Prescription Drug Monitoring System (PDMP) regarding the controlled substance history of a patient under his or her care. Existing law requires the Department of Justice, upon approval of that application, to provide to that health care practitioner or pharmacist the history of controlled substances dispensed to an individual under his or her care.

This bill would also authorize an individual designated to investigate an applicant for, or a holder of, a professional license to apply to the Department of Justice to obtain approval to access information contained in the CURES PDMP regarding the controlled substance history of an applicant or a licensee for the purpose of investigating the alleged substance abuse of an applicant or a licensee. The bill would, upon approval of that application, require the department to provide to that individual the history of controlled substances dispensed to the applicant or licensee.

(3) Existing law generally requires, subject to specified exceptions, that a prescription for Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances be made on a certain controlled substance prescription form and meet several requirements, including that the prescription be signed and dated by the prescriber in ink. Existing law authorizes, as an exception to that requirement, a Schedule III, Schedule IV, or Schedule V controlled substance to be dispensed upon an oral or electronically transmitted prescription, which must be produced in hard copy form and signed and dated by the pharmacist filling the prescription or another authorized person.

This bill would instead require, subject to specified exceptions, that a prescription for a controlled substance be made by an electronically transmitted prescription that complies with regulations promulgated by the Drug Enforcement Agency, which, except as specified, must be produced in hard copy form and signed and dated by the pharmacist filling the prescription or another authorized person.

(4) Existing law prohibits a prescription for a Schedule II controlled substance from being refilled and prohibits a prescription for a Schedule III or IV controlled substance from being refilled more than 5 times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply.

This bill would prohibit, subject to specified exceptions, a person from prescribing a controlled substance, or filling, compounding, or

dispensing a prescription for a controlled substance, in a quantity exceeding a 30 day supply. The bill would also prohibit a person from issuing a prescription for a controlled substance, or from filling, compounding, or dispensing a prescription for a controlled substance, for an ultimate user for whom a previous prescription for a controlled substance was issued within the immediately preceding 30 days until the ultimate user has exhausted all but a 7-day supply of the controlled substance filled, compounded, or dispensed from the previous prescription.

~~Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. Existing law authorizes the Department of Justice to seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES and requires that the operation of CURES comply with all applicable federal and state privacy and security laws and regulations.~~

~~This bill would make technical, nonsubstantive changes to those provisions:~~

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

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

- 1 SECTION 1. Section 4071 of the Business and Professions
- 2 Code is amended to read:
- 3 4071. Notwithstanding any other provision of law, a prescriber
- 4 may authorize his or her agent on his or her behalf to orally or
- 5 electronically transmit a prescription to the furnisher. The furnisher
- 6 shall make a reasonable effort to determine ~~that~~ *whether* the person
- 7 who transmits the prescription is authorized to do so and shall
- 8 record the name of the authorized agent of the prescriber who
- 9 transmits the order.
- 10 ~~This section shall not apply to orders for Schedule II controlled~~
- 11 ~~substances.~~
- 12 SEC. 2. Section 4072 of the Business and Professions Code is
- 13 amended to read:

1 4072. (a) Notwithstanding any other ~~provision~~ of law, a
2 pharmacist, registered nurse, licensed vocational nurse, licensed
3 psychiatric technician, or other healing arts licentiate, if so
4 authorized by administrative regulation, who is employed by or
5 serves as a consultant for a licensed skilled nursing, intermediate
6 care, or other health care facility, may orally or electronically
7 transmit to the furnisher a prescription lawfully ordered by a person
8 authorized to prescribe drugs or devices pursuant to Sections 4040
9 and 4070. The furnisher shall take appropriate steps to determine
10 ~~that whether~~ the person who transmits the prescription is authorized
11 to do so and shall record the name of the person who transmits the
12 order. This section ~~shall~~ *does* not apply to *oral* orders for Schedule
13 II controlled substances.

14 (b) In enacting this section, the Legislature recognizes and
15 affirms the role of the State Department of Public Health in
16 regulating drug order processing requirements for licensed health
17 care facilities as set forth in Title 22 of the California Code of
18 Regulations as they may be amended from time to time.

19 *SEC. 3. Section 11151 of the Health and Safety Code is*
20 *amended to read:*

21 11151. A prescription ~~written~~ *issued* by an unlicensed person
22 lawfully practicing medicine pursuant to Section 2065 of the
23 Business and Professions Code, shall be filled only at a pharmacy
24 maintained in the hospital which employs such unlicensed person.

25 *SEC. 4. Section 11158 of the Health and Safety Code is*
26 *amended to read:*

27 11158. (a) Except as provided in Section ~~11159~~ *11159*,
28 *11159.1, 11159.2, 11167, or 11167.5*, or in subdivision (b) of this
29 section, ~~no~~ a controlled substance classified in Schedule II shall
30 *not* be dispensed without a prescription meeting the requirements
31 of this chapter. Except as provided in Section ~~11159~~ *11159*,
32 *11159.1, 11159.2, 11167, or 11167.5*, or when dispensed directly
33 to an ultimate user by a practitioner, other than a pharmacist or
34 pharmacy, ~~no~~ a controlled substance classified in Schedule III,
35 IV, or V ~~may~~ *shall not* be dispensed without a prescription meeting
36 the requirements of this chapter.

37 (b) A practitioner specified in Section 11150 may dispense
38 directly to an ultimate user a controlled substance classified in
39 Schedule II in an amount not to exceed a 72-hour supply for the
40 patient in accordance with directions for use given by the

1 dispensing practitioner only ~~where if~~ the patient is not expected to
2 require any additional amount of the controlled substance beyond
3 the 72 hours. ~~Practitioners dispensing drugs pursuant to this~~
4 ~~subdivision shall meet the requirements of subdivision (f) of~~
5 ~~Section 11164.~~

6 (c) Except as otherwise prohibited or limited by law, a
7 practitioner specified in Section 11150, may administer controlled
8 substances in the regular practice of his or her profession.

9 *SEC. 5. Section 11164 of the Health and Safety Code is*
10 *amended to read:*

11 11164. Except as provided in Section 11158, 11159, 11159.1,
12 11159.2, 11167, ~~no~~ or 11167.5, a person shall *not* prescribe a
13 controlled substance, nor shall any person fill, compound, or
14 dispense a prescription for a controlled substance, unless it
15 complies with the requirements of this section.

16 (a) ~~Each prescription for a controlled substance classified in~~
17 ~~Schedule II, III, IV, or V, except as authorized by subdivision (b),~~
18 ~~shall be made on a controlled substance prescription form as~~
19 ~~specified in Section 11162.1 and shall meet the following~~
20 ~~requirements:~~

21 (1) ~~The prescription shall be signed and dated by the prescriber~~
22 ~~in ink and shall contain the prescriber's address and telephone~~
23 ~~number; the name of the ultimate user or research subject, or~~
24 ~~contact information as determined by the Secretary of the United~~
25 ~~States Department of Health and Human Services; refill~~
26 ~~information, such as the number of refills ordered and whether the~~
27 ~~prescription is a first-time request or a refill; and the name,~~
28 ~~quantity, strength, and directions for use of the controlled substance~~
29 ~~prescribed.~~

30 (2) ~~The prescription shall also contain the address of the person~~
31 ~~for whom the controlled substance is prescribed. If the prescriber~~
32 ~~does not specify this address on the prescription, the pharmacist~~
33 ~~filling the prescription or an employee acting under the direction~~
34 ~~of the pharmacist shall write or type the address on the prescription~~
35 ~~or maintain this information in a readily retrievable form in the~~
36 ~~pharmacy.~~

37 (b)

38 (a) (1) ~~Notwithstanding paragraph (1) of subdivision (a) of~~
39 ~~Section 11162.1, any A prescription for a controlled substance~~
40 ~~classified in Schedule II, III, IV, or V be dispensed upon an oral~~

1 ~~or electronically transmitted prescription;~~ *shall be made by an*
2 *electronically transmitted prescription that complies with*
3 *regulations promulgated by the Drug Enforcement Agency, which*
4 *shall be produced in hard copy form and signed and dated by the*
5 *pharmacist filling the prescription or by any other person expressly*
6 *authorized by provisions of the Business and Professions Code.*
7 *Any person who transmits, maintains, or receives any electronically*
8 *transmitted prescription shall ensure the security, integrity,*
9 *authority, and confidentiality of the prescription.*

10 ~~(2) The date of issue of the prescription and all the information~~
11 ~~required for a written prescription by subdivision (a) shall be~~
12 ~~included in the written record of the prescription; the pharmacist~~
13 ~~need not include the address, telephone number, license~~
14 ~~classification, or federal registry number of the prescriber or the~~
15 ~~address of the patient on the hard copy, if that information is readily~~
16 ~~retrievable in the pharmacy.~~

17 *(2) A prescription issued pursuant to this subdivision shall meet*
18 *the following requirements:*

19 *(A) The prescription shall contain the prescriber's address and*
20 *telephone number; the name of the ultimate user or research*
21 *subject, or contact information as determined by the Secretary of*
22 *the United States Department of Health and Human Services; refill*
23 *information, such as the number of refills ordered and whether*
24 *the prescription is a first-time request or a refill; and the name,*
25 *quantity, strength, and directions for use of the controlled*
26 *substance prescribed.*

27 *(B) The prescription shall contain the address of the person for*
28 *whom the controlled substance is prescribed. If the prescriber*
29 *does not specify this address on the prescription, the pharmacist*
30 *filling the prescription or an employee acting under the direction*
31 *of the pharmacist shall include the address on the prescription or*
32 *maintain this information in a readily retrievable form in the*
33 *pharmacy.*

34 ~~(3) Pursuant to an authorization of the prescriber, any an agent~~
35 ~~of the prescriber on behalf of the prescriber may orally or~~
36 ~~electronically transmit a prescription for a controlled substance~~
37 ~~classified in Schedule II, III, IV, or V, if in these cases the written~~
38 ~~record of the prescription required by this subdivision specifies~~
39 ~~the name of the agent of the prescriber transmitting the prescription.~~

1 (b) (1) A prescription for a controlled substance classified in
2 Schedule II, III, IV, or V, may be written on a controlled substance
3 prescription form as specified in Section 11162.1, or for a
4 controlled substance classified in Schedule III, IV, or V, may be
5 made orally, if technological failure prevents the electronic
6 transmission of a prescription pursuant to subdivision (a) or if the
7 prescription will be filled by a pharmacist located outside of
8 California, provided that the order contains all information
9 required by subdivision (a) and, if the prescription is written on
10 a controlled substance prescription form, is signed and dated by
11 the prescriber in ink.

12 (2) If a prescriber is permitted to make an oral prescription
13 pursuant to this section, pursuant to an authorization of the
14 prescriber, an agent of the prescriber on behalf of the prescriber
15 may orally transmit a prescription for a controlled substance
16 classified in Schedule II, III, IV, or V, if the written record of the
17 prescription specifies the name of the agent of the prescriber
18 transmitting the prescription.

19 (c) The use of commonly used abbreviations shall not invalidate
20 an otherwise valid prescription.

21 (d) Notwithstanding any provision of subdivisions (a) and (b),
22 prescriptions for a controlled substance classified in Schedule V
23 may be for more than one person in the same family with the same
24 medical need.

25 ~~(e) This section shall become operative on January 1, 2005.~~

26 *SEC. 6. Section 11164.1 of the Health and Safety Code is*
27 *amended to read:*

28 11164.1. (a) (1) Notwithstanding any other ~~provision of law,~~
29 a prescription for a controlled substance issued by a prescriber in
30 another state for delivery to a patient in another state may be
31 dispensed by a California pharmacy, if the prescription conforms
32 with the requirements for controlled substance prescriptions in the
33 state in which the controlled substance was prescribed.

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

39 (b) Pharmacies may dispense prescriptions for Schedule III,
40 Schedule IV, and Schedule V controlled substances from

1 out-of-state prescribers pursuant to Section 4005 of the Business
2 and Professions Code and Section 1717 of Title 16 of the California
3 Code of Regulations.

4 *SEC. 7. Section 11164.5 of the Health and Safety Code is*
5 *amended to read:*

6 11164.5. (a) ~~Notwithstanding Section 11164, with the approval~~
7 ~~of the California State Board of Pharmacy and the Department of~~
8 ~~Justice, a~~ A pharmacy or hospital ~~may~~ shall receive electronic data
9 transmission prescriptions or computer entry prescriptions or orders
10 as specified in Section 4071.1 of the Business and Professions
11 Code, for controlled substances in Schedule II, III, IV, or V ~~if~~
12 ~~authorized by federal law and~~ in accordance with regulations
13 promulgated by the Drug Enforcement Administration. ~~The~~
14 ~~California State Board of Pharmacy shall maintain a list of all~~
15 ~~requests and approvals granted pursuant to this subdivision.~~

16 (b) ~~Notwithstanding paragraph (1) of subdivision (a) of Section~~
17 ~~11164, if approved pursuant to subdivision (a),~~ a pharmacy or
18 hospital receiving an electronic transmission prescription or a
19 computer entry prescription or order for a controlled substance
20 classified in Schedule II, III, IV, or V ~~shall~~ is not be required to
21 reduce that prescription or order to writing or to hard copy form,
22 if for three years from the last day of dispensing that prescription,
23 the pharmacy or hospital is able, upon request of the board or the
24 Department of Justice, to immediately produce a hard copy report
25 that includes for each date of dispensing of a controlled substance
26 in Schedules II, III, IV, and V pursuant to the prescription all of
27 the information described in subparagraphs (A) to (E), inclusive,
28 of paragraph (1) of subdivision (a) of Section 4040 of the Business
29 and Professions Code and the name or identifier of the pharmacist
30 who dispensed the controlled substance.

31 (c) ~~Notwithstanding Section 11164, if~~ *If* only recorded and
32 stored electronically, on magnetic media, or in any other
33 computerized form, the pharmacy's or hospital's computer system
34 shall not permit the received information or the controlled
35 substance dispensing information required by this section to be
36 changed, obliterated, destroyed, or disposed of, for the record
37 maintenance period required by law, once the information has been
38 received by the pharmacy or the hospital and once the controlled
39 substance has been dispensed, respectively. Once the controlled
40 substance has been dispensed, if the previously created record is

1 determined to be incorrect, a correcting addition may be made
2 only by or with the approval of a pharmacist. After a pharmacist
3 enters the change or enters his or her approval of the change into
4 the computer, the resulting record shall include the correcting
5 addition and the date it was made to the record, the identity of the
6 person or pharmacist making the correction, and the identity of
7 the pharmacist approving the correction.

8 (d) Nothing in this section shall be construed to exempt any
9 pharmacy or hospital dispensing Schedule II controlled substances
10 pursuant to electronic transmission prescriptions from existing
11 reporting requirements.

12 ~~SECTION 1.~~

13 *SEC. 8.* Section 11165 of the Health and Safety Code is
14 amended to read:

15 11165. (a) To assist health care practitioners in their efforts
16 to ensure appropriate prescribing, ordering, administering,
17 furnishing, and dispensing of controlled substances, law
18 enforcement and regulatory agencies in their efforts to control the
19 diversion and resultant abuse of Schedule II, Schedule III, ~~and~~
20 ~~Schedule IV~~ *IV, and Schedule V* controlled substances, and for
21 statistical analysis, education, and research, the Department of
22 Justice shall, contingent upon the availability of adequate funds
23 in the CURES Fund, maintain the Controlled Substance Utilization
24 Review and Evaluation System (CURES) for the electronic
25 monitoring of, and Internet access to information regarding, the
26 prescribing and dispensing of Schedule II, Schedule III, ~~and~~
27 ~~Schedule IV~~ *IV, and Schedule V* controlled substances by all
28 practitioners authorized to prescribe, order, administer, furnish, or
29 dispense these controlled substances.

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

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

38 (2) CURES shall operate under existing law to safeguard the
39 privacy and confidentiality of patients. Data obtained from CURES
40 shall only be provided to appropriate state, local, and federal public

1 agencies for disciplinary, civil, or criminal purposes and to other
2 agencies or entities, as determined by the Department of Justice,
3 for the purpose of educating practitioners and others in lieu of
4 disciplinary, civil, or criminal actions. Data may be provided to
5 public or private entities, as approved by the Department of Justice,
6 for educational, peer review, statistical, or research purposes,
7 provided that patient information, including any information that
8 may identify the patient, is not compromised. Further, data
9 disclosed to an individual or agency as described in this subdivision
10 shall not be disclosed, sold, or transferred to a third party. The
11 Department of Justice shall establish policies, procedures, and
12 regulations regarding the use, access, evaluation, management,
13 implementation, operation, storage, disclosure, and security of the
14 information within CURES, consistent with this subdivision.

15 (d) For each prescription for a Schedule II, Schedule III, ~~or~~
16 ~~Schedule IV~~ *IV, or Schedule V* controlled substance, as defined in
17 the controlled substances schedules in federal law and regulations,
18 specifically Sections 1308.12, 1308.13, ~~and~~ 1308.14, *and 1308.15*,
19 respectively, of Title 21 of the Code of Federal Regulations, the
20 dispensing pharmacy, clinic, or other dispenser shall report the
21 following information to the Department of Justice as soon as
22 reasonably possible, but not more than seven days after the date a
23 controlled substance is dispensed, in a format specified by the
24 Department of Justice:

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

30 (2) The prescriber's category of licensure, license number,
31 national provider identifier (NPI) number, if applicable, the federal
32 controlled substance registration number, and the state medical
33 license number of any prescriber using the federal controlled
34 substance registration number of a government-exempt facility.

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

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

39 (5) Quantity of the controlled substance dispensed.

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

3 (7) Number of refills ordered.

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

6 (9) Date of origin of the prescription.

7 (10) Date of dispensing of the prescription.

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

16 (f) The Department of Justice shall, prior to upgrading CURES,
17 consult with prescribers licensed by one of the boards or
18 committees identified in subdivision (d) of Section 208 of the
19 Business and Professions Code, one or more of the boards or
20 committees identified in subdivision (d) of Section 208 of the
21 Business and Professions Code, and any other stakeholder
22 identified by the department, for the purpose of identifying
23 desirable capabilities and upgrades to the CURES Prescription
24 Drug Monitoring Program (PDMP).

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

28 *SEC. 9. Section 11165.1 of the Health and Safety Code is*
29 *amended to read:*

30 11165.1. (a) (1) (A) (i) A health care practitioner authorized
31 to prescribe, order, administer, furnish, or dispense Schedule II,
32 Schedule III, ~~or~~ Schedule ~~IV~~ IV, *or Schedule V* controlled
33 substances pursuant to Section 11150 shall, before January 1, 2016,
34 or upon receipt of a federal Drug Enforcement Administration
35 (DEA) registration, whichever occurs later, submit an application
36 developed by the Department of Justice to obtain approval to access
37 information online regarding the controlled substance history of
38 a patient that is stored on the Internet and maintained within the
39 Department of Justice, and, upon approval, the department shall
40 release to that practitioner the electronic history of controlled

1 substances dispensed to an individual under his or her care based
2 on data contained in the CURES Prescription Drug Monitoring
3 Program (PDMP).

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

13 (iii) *An individual designated by a board, bureau, or program*
14 *within the Department of Consumer Affairs to investigate an*
15 *applicant for, or a holder of, a professional license may, for the*
16 *purpose of investigating the alleged substance abuse of an*
17 *applicant or a licensee, submit an application developed by the*
18 *Department of Justice to obtain approval to access information*
19 *online regarding the controlled substance history of an applicant*
20 *or a licensee that is stored on the Internet and maintained within*
21 *the Department of Justice, and, upon approval, the department*
22 *shall release to that individual the electronic history of controlled*
23 *substances dispensed to the applicant or licensee based on data*
24 *contained in the CURES PDMP.*

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

28 (i) Materially falsifying an application for a subscriber.

29 (ii) Failure to maintain effective controls for access to the patient
30 activity report.

31 (iii) Suspended or revoked federal DEA registration.

32 (iv) Any subscriber who is arrested for a violation of law
33 governing controlled substances or any other law for which the
34 possession or use of a controlled substance is an element of the
35 crime.

36 (v) Any subscriber accessing information for any other reason
37 than caring for his or her patients.

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

1 (2) A health care practitioner authorized to prescribe, order,
2 administer, furnish, or dispense Schedule II, Schedule III,~~or~~
3 ~~Schedule IV~~ *IV, or Schedule V* controlled substances pursuant to
4 Section 11150 or a pharmacist shall be deemed to have complied
5 with paragraph (1) if the licensed health care practitioner or
6 pharmacist has been approved to access the CURES database
7 through the process developed pursuant to subdivision (a) of
8 Section 209 of the Business and Professions Code.

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

12 (c) In order to prevent the inappropriate, improper, or illegal
13 use of Schedule II, Schedule III,~~or~~ ~~Schedule IV~~ *IV, or Schedule*
14 *V* controlled substances, the Department of Justice may initiate
15 the referral of the history of controlled substances dispensed to an
16 individual based on data contained in CURES to licensed health
17 care practitioners, pharmacists, or both, providing care or services
18 to the individual.

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

26 (e) Information concerning a patient's controlled substance
27 history provided to ~~a prescriber or pharmacist~~ *an authorized*
28 *subscriber* pursuant to this section shall include prescriptions for
29 controlled substances listed in Sections 1308.12, 1308.13,~~and~~
30 ~~1308.14~~ *1308.14, and 1308.15* of Title 21 of the Code of Federal
31 Regulations.

32 *SEC. 10. Section 11165.5 of the Health and Safety Code is*
33 *amended to read:*

34 11165.5. (a) The Department of Justice may seek voluntarily
35 contributed private funds from insurers, health care service plans,
36 qualified manufacturers, and other donors for the purpose of
37 supporting CURES. Insurers, health care service plans, qualified
38 manufacturers, and other donors may contribute by submitting
39 their payment to the Controller for deposit into the CURES Fund
40 established pursuant to subdivision (c) of Section 208 of the

1 Business and Professions Code. The department shall make
 2 information about the amount and the source of all private funds
 3 it receives for support of CURES available to the public.
 4 Contributions to the CURES Fund pursuant to this subdivision
 5 shall be nondeductible for state tax purposes.

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

7 (1) “Controlled substance” means a drug, substance, or
 8 immediate precursor listed in any schedule in Section 11055,
 9 11056, ~~or 11057~~ 11057, or 11058 of the Health and Safety Code.

10 (2) “Health care service plan” means an entity licensed pursuant
 11 to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter
 12 2.2 (commencing with Section 1340) of Division 2 of the Health
 13 and Safety Code).

14 (3) “Insurer” means an admitted insurer writing health insurance,
 15 as defined in Section 106 of the Insurance Code, and an admitted
 16 insurer writing workers’ compensation insurance, as defined in
 17 Section 109 of the Insurance Code.

18 (4) “Qualified manufacturer” means a manufacturer of a
 19 controlled substance, but does not mean a wholesaler or nonresident
 20 wholesaler of dangerous drugs, regulated pursuant to Article 11
 21 (commencing with Section 4160) of Chapter 9 of Division 2 of
 22 the Business and Professions Code, a veterinary food-animal drug
 23 retailer, regulated pursuant to Article 15 (commencing with Section
 24 4196) of Chapter 9 of Division 2 of the Business and Professions
 25 Code, or an individual regulated by the Medical Board of
 26 California, the Dental Board of California, the California State
 27 Board of Pharmacy, the Veterinary Medical Board, the Board of
 28 Registered Nursing, the Physician Assistant Committee of the
 29 Medical Board of California, the Osteopathic Medical Board of
 30 California, the State Board of Optometry, or the California Board
 31 of Podiatric Medicine.

32 *SEC. 11. Section 11166 of the Health and Safety Code is*
 33 *amended to read:*

34 11166. ~~No~~A person shall *not* fill a prescription for a controlled
 35 substance after six months has elapsed from the date ~~written on~~
 36 the prescription *was issued* by the prescriber. ~~No~~A person shall
 37 *not* knowingly fill a mutilated or forged or altered prescription for
 38 a controlled substance except for the addition of the address of the
 39 person for whom the controlled substance is prescribed as provided
 40 by paragraph ~~(3)~~ (2) of subdivision (b) of Section 11164.

1 SEC. 12. Section 11200 of the Health and Safety Code is
2 amended to read:

3 11200. (a) ~~No~~A person shall *not* dispense or refill a controlled
4 substance prescription more than six months after the date thereof.

5 (b) (1) *Except as provided in paragraph (2), a person shall not*
6 *prescribe a controlled substance, nor shall a person fill, compound,*
7 *or dispense a prescription for a controlled substance, in a quantity*
8 *exceeding a 30-day supply.*

9 (2) *A person may prescribe a controlled substance, and a person*
10 *may fill, compound, or dispense a prescription for a controlled*
11 *substance, in a quantity not exceeding a 90-day supply if the*
12 *prescription is issued in the treatment of one of the following:*

13 (A) *A panic disorder.*

14 (B) *Attention deficit disorder.*

15 (C) *A chronic debilitating neurologic condition characterized*
16 *as a movement disorder or exhibiting seizure, convulsive, or spasm*
17 *activity.*

18 (D) *Pain in patients with conditions or diseases known to be*
19 *chronic or incurable.*

20 (E) *Narcolepsy.*

21 ~~(b) No~~

22 (c) (1) *A prescription for a Schedule III or IV substance may*
23 *shall not* be refilled more than five times and in an amount, for all
24 refills of that prescription taken together, exceeding a 120-day
25 supply.

26 ~~(e) No~~

27 (2) *A prescription for a Schedule II substance may shall not* be
28 refilled.

29 (d) *A person shall not issue a prescription for a controlled*
30 *substance, nor shall a person fill, compound, or dispense a*
31 *prescription for a controlled substance, for an ultimate user for*
32 *whom a previous prescription for a controlled substance was*
33 *issued within the immediately preceding 30 days until the ultimate*
34 *user has exhausted all but a seven-day supply of the controlled*
35 *substance filled, compounded, or dispensed from the previous*
36 *prescription.*

O



ISSUE

Current law permits a designated representative – such as a family member – to pick up a valid prescription on behalf of someone else. This is intended to protect individuals who pick up and transport prescriptions for infirm family members, friends, or those in their care. Unfortunately, a recent court ruling in *People v. Carboni* may now criminalize this activity.

BACKGROUND

In a recently release case from the California Court of Appeals, *People V. Carboni*, the court dealt with the issue of a person being charged with drug transportation for being in possession of the prescription drugs of a close friend he was trying to assist. Many of the controlled substance statutes in the Health and Safety Code criminalize possession or transportation of certain controlled substances absent a “prescription defense” – a written prescription by a physician, dentist, podiatrist, or veterinarian licensed to practice in California.

It is not uncommon for people to pick up and transport prescription medication for their infirm family and friends or in the case of an elderly person attended to by caretakers. This is particularly true in medically underserved areas where long distances must be traveled to reach the nearest pharmacy.

The court in *Carboni* held that a prescription defense does not extend to a person possessing or transporting prescription medications because it is for the Legislature, not the court, to remedy the issue. The court’s decision in restricting the prescription drug defense, in theory, criminalizes the possession and transportation of a prescribed controlled substance dispensed at a pharmacy to person intending merely to take the controlled substance to a patient confined at home.

Moreover, despite Pharmacy Law provisions that expressly allow a pharmacist to dispense prescribed controlled substances to a patient’s “agent” or “representative” (Bus. & Prof. Code 4059.5), the interpretation of Health and Safety Code law in the *Carboni* case may conflict with Pharmacy law.

SOLUTION

This bill would add clarity to Health and Safety Code sections 11350 and 11377 to allow for the possession and transportation of prescription medications by a

person authorized by and for the purposes of assisting the prescription holder.

SUPPORT

California Attorneys for Criminal Justice (Sponsor)
Congress of California Seniors
California Senior Legislature
California Advocates for Nursing Home Reform

OPPOSITION

None on File

FOR MORE INFORMATION

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ASSEMBLY BILL

No. 2603

Introduced by Assembly Member V. Manuel Pérez

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 introduced, 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 for a lawful purpose by anyone with the express authorization or direction of the prescription holder.

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 11350 of the Health and Safety Code is
- 2 amended to read:
- 3 11350. (a) Except as otherwise provided in this division, every
- 4 person who possesses (1) any controlled substance specified in
- 5 subdivision (b) or (c), or paragraph (1) of subdivision (f) of Section
- 6 11054, specified in paragraph (14), (15), or (20) of subdivision (d)

1 of Section 11054, or specified in subdivision (b) or (c) of Section
2 11055, or specified in subdivision (h) of Section 11056, or (2) any
3 controlled substance classified in Schedule III, IV, or V which is
4 a narcotic drug, unless upon the written prescription of a physician,
5 dentist, podiatrist, or veterinarian licensed to practice in this state,
6 shall be punished by imprisonment pursuant to subdivision (h) of
7 Section 1170 of the Penal Code.

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

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

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

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

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

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

35 (e) *This section does not apply to possession of a controlled*
36 *substance described in subdivision (a) for a lawful purpose by*
37 *anyone with the express authorization or direction of the*
38 *prescription holder.*

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

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

16 (b) (1) Any person who violates subdivision (a) by unlawfully
17 possessing a controlled substance specified in subdivision (f) of
18 Section 11056, and who has not previously been convicted of a
19 violation involving a controlled substance specified in subdivision
20 (f) of Section 11056, is guilty of a misdemeanor.

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

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

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

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

38 (d) *This section does not apply to possession of a controlled*
39 *substance described in subdivision (a) for a lawful purpose by*

- 1 *anyone with the express authorization or direction of the*
- 2 *prescription holder.*

O

Attachment 4



ASSEMBLY MEMBER

Kevin Mullin

DISTRICT 22



AB 1437: Medically Important Antimicrobials: Nontherapeutic Use

PURPOSE

This bill protects public health by combating the further spread of antibiotic-resistant bacteria, or “superbugs”. By banning the non-therapeutic use of medically important antimicrobials in the production of meat and poultry sold in California and requiring use reporting, this bill will help protect the effectiveness of these critical antibiotics for human medicine and help reduce the spread of antibiotic resistant bacteria in California.

BACKGROUND

A Centers for Disease Control and Prevention report released in September 2013 found that every year more than two million people in the United States contract infections that are resistant to antibiotics and at least 23,000 people die as a result.

Misuse and overuse of antibiotics in both medicine and livestock production contribute to the increase in antibiotic-resistant bacteria. However, according to the American Academy of Pediatrics, judicious use of antimicrobial agents in human medicine alone will address only part of the problem. California is a leader in encouraging the judicious use of antibiotics in humans and is the only state that mandates that general acute care hospitals monitor and evaluate the utilization of antibiotics. In order to effectively combat the threat of antibiotic-resistant bacteria and to reduce the spread of antibiotic-resistant bacteria in California, we must address the overuse of these critical medicines in livestock and poultry production.

Eighty percent of all antibiotics sold in the United States are for cattle, pigs, poultry, and other livestock, the vast majority to speed up growth and compensate for crowded, unsanitary conditions. Numerous studies have convincingly

demonstrated that the use of antibiotics in animals results in resistant bacteria in food animals, that these resistant bacteria can spread through the food supply and the environment and can be transmitted to humans, and, as a result, more and more humans are experiencing adverse health effects.

Since 1972, the U.S. Food and Drug Administration has recognized that the use of antibiotics in livestock poses health risks for people, but the Agency has yet to make more than a symbolic effort to address the issue.

THIS BILL

The bill has three main parts. First, it bans the non-therapeutic use of antibiotics in livestock production. Antibiotics could only be used if there is a clinical sign of disease, and in limited circumstances to control disease outbreaks, and never for growth promotion, feed efficiency, weight gain, or routine disease prevention. Food producers could no longer feed unnecessary antibiotics to livestock and poultry through food or water on a routine basis. Second, the bill requires a veterinarian to prescribe a medically important antimicrobial for specific animals for specific diagnosed medical conditions. Third, AB 1437 requires the collection of information about antibiotic administration to track progress. AB 1437 only bans the non-therapeutic use of medically important antimicrobials. This is a narrowly defined category. Food producers will still be able to use these antimicrobials for therapeutic reasons, including for treating an animal with a documented disease.

SUPPORT

Natural Resources Defense Council
Environmental Working Group
American Academy of Pediatrics, California
Black Women for Wellness
California State Grange
CALPIRG
Children's Advocacy Institute
Consumer Federation of California
Consumers Union
Endangered Habitats League
Infectious Disease Association of California
Keep Antibiotics Working
Physicians for Social Responsibility, Sacramento
Physicians for Social Responsibility, San Francisco-
Bay Area
Sustain LA
The Breast Cancer Fund
The Pew Charitable Trusts

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ASSEMBLY BILL

No. 1437

Introduced by Assembly Member Mullin

January 6, 2014

An act to amend Sections 14200, 14203, 14289, and 14381 of, to add Sections 14203.5, 14207.3, 14207.5, 14207.7, 14220, 14297, and 14366 to, and to add Article 5.5 (commencing with Section 14335) and Article 5.6 (commencing with Section 14340) to Chapter 4 of Division 7 of, the Food and Agriculture Code, relating to livestock drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 1437, as introduced, Mullin. Medically important antimicrobials: nontherapeutic use.

Existing law requires the manufacturer of a livestock drug, including a restricted drug, as defined, to register with the Director of Food and Agriculture and requires the director to refuse to register the drug if he or she makes specified findings. Under existing law it is unlawful, among other things, to use or administer any registered livestock drug, except in accordance with the label instructions, as specified, and makes an initial violation of these provisions subject to an infraction and, for subsequent violations, a misdemeanor.

This bill, as of January 1, 2017, would redefine “restricted drug” to also include a livestock drug that is recognized by either the Center for Disease Control and Prevention or the World Health Organization to increase the prevalence of antibiotic-resistant bacteria, as specified. The bill would prohibit registration of a restricted drug if the director finds that the restricted drug poses a risk to public health through the increased prevalence of antibiotic-resistant bacteria. The bill would also authorize the director to revoke the registration of a medically important

antimicrobial, as defined, for use in livestock if he or she finds that the drug threatens the public health by increasing the prevalence of antibiotic-resistant bacteria.

The bill would prohibit the administration of a medically important antimicrobial to a food-producing animal for nonroutine disease control unless certain conditions are met. By prohibiting the administration of a medically important antimicrobial, this bill would create a crime, thereby imposing a state-mandated local program. The bill would also require a livestock producer that does administer a medically important antimicrobial to a food-producing animal to annually report specified information to the director relating to the administration of the medically important antimicrobial and would make the failure to make that report an infraction subject to specified penalties. The bill would require the department post this information on an Internet Web site.

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 find and declare all of the
2 following:

3 (a) In 1977, the United States Food and Drug Administration
4 (FDA) concluded that feeding livestock low doses of antibiotics
5 that are used in human disease treatment could promote the
6 development of antibiotic-resistance in bacteria. The FDA,
7 however, did not act in response to these findings, despite laws
8 requiring the agency to do so.

9 (b) The FDA has promulgated voluntary regulations on the
10 nontherapeutic use of antibiotics, however these guidelines are
11 unlikely to significantly reduce the nontherapeutic use of antibiotics
12 in livestock.

13 (c) Not only do antibiotic-resistant bacteria affect the health of
14 our society, but they also have a monetary impact. In 1998, the
15 National Academy of Sciences noted that antibiotic-resistant

1 bacteria generate a minimum of four to five billion dollars in costs
2 to United States society and individuals every year.

3 (d) In April 1999, the United States Government Accountability
4 Office conducted a study concluding that three strains of
5 microorganisms that cause foodborne illnesses or disease in humans
6 are resistant to antibiotics and are linked to the use of antibiotics
7 in animals. These microorganisms are salmonella, Campylobacter,
8 and E. Coli.

9 (e) In 1999, 2011, and 2006, the United States Department of
10 Agriculture’s Animal and Plant Health Inspection Service
11 conducted large-scale, voluntary surveys that revealed all of the
12 following:

13 (1) Eighty-four percent of grower and finisher swine farms, 83
14 percent of cattle feedlots, and 84 percent of sheep farms administer
15 antimicrobials in feed or water for either health or growth
16 promotion reasons.

17 (2) Many of the antimicrobials that were identified were
18 identical or closely related to drugs used in human medicine,
19 including tetracyclines, macrolides, bacitracin, penicillins, and
20 sulfonamides.

21 (3) These drugs are used in people to treat serious diseases, such
22 as pneumonia, scarlet fever, rheumatic fever, sexually transmitted
23 infections, and skin infections; pandemics such as malaria and
24 plague; and bioterrorism agents such as anthrax.

25 (f) Overuse or misuse of antibiotics contributes to the spread of
26 antibiotic resistance, whether in human medicine or in agriculture.

27 (g) In June 2002, the peer-reviewed journal, “Clinical Infectious
28 Diseases,” published a report based on a two-year review, by
29 experts in human and veterinary medicine, public health,
30 microbiology, biostatistics, and risk analysis, of more than 500
31 scientific studies on the human health impacts of antimicrobial
32 use in agriculture. The report recommended that antimicrobial
33 agents should not be used in agriculture in the absence of disease
34 and should be limited to therapy for diseased individual animals
35 or prophylaxis when disease is documented in a herd or flock.

36 (h) In a March 2003 report, the National Academy of Sciences
37 stated that a decrease in antimicrobial use in human medicine alone
38 will have little effect on the rise in antibiotic-resistant bacteria and
39 that substantial efforts must be made to decrease the inappropriate
40 overuse of antimicrobials in animals and agriculture.

1 (i) In 2010, the peer-reviewed journal, “Molecular Cell,”
2 published a study demonstrating that a low-dosage use of
3 antibiotics causes a dramatic increase in genetic mutation, raising
4 new concerns about the agricultural practice of using low-dosage
5 antibiotics in order to stimulate growth promotion and routinely
6 prevent disease in unhealthy conditions.

7 (j) In 2010, the Danish Veterinary and Food Administration
8 testified that the Danish ban of the nontherapeutic use of antibiotics
9 in food animal production resulted in a marked reduction in
10 antimicrobial resistance in multiple bacterial species, including
11 *Campylobacter* and *Enterococci*.

12 (k) In 2011, the FDA found that in 2010:

13 (1) Thirteen million five hundred thousand kilograms of
14 antibacterial drugs were sold for use on food animals in the United
15 States.

16 (2) Three million three hundred thousand kilograms of
17 antibacterial drugs were used for human health.

18 (3) Eighty percent of antibacterial drugs disseminated in the
19 United States were sold for use on food-producing animals, rather
20 than being used for human health.

21 (l) In 2011, a review of all scientific studies on antimicrobial
22 use in farm animals, published in *Clinical Microbiology Reviews*,
23 found the following:

24 (1) The use of antibiotics in food-producing animals leads to
25 the development of reservoirs of antibiotic resistance.

26 (2) A ban on nontherapeutic antibiotic use in food-producing
27 animals would preserve the use of antibiotics for medicine.

28 (3) A Danish ban on nontherapeutic antibiotics in
29 food-producing animals resulted in little change in animal
30 morbidity and mortality, and only a modest increase in production
31 cost.

32 (m) The FDA’s National Antimicrobial Resistance Monitoring
33 System routinely finds that retail meat products are contaminated
34 with bacteria that are resistant to antibiotics that are important to
35 human medicine.

36 (n) According to the American Academy of Pediatrics, “[t]he
37 largest nonhuman use of antimicrobial agents is in food-producing
38 animal production, and most of this is in healthy animals to increase
39 growth or prevent diseases. Evidence now exists that these uses
40 of antimicrobial agents in food-producing animals have a direct

1 negative impact on human health and multiple impacts on the
2 selection and dissemination of resistance genes in animals and the
3 environment. Children are at increased risk of acquiring many of
4 these infections with resistant bacteria and are at great risk of
5 severe complications if they become infected.”

6 (o) Many scientific studies confirm that the nontherapeutic use
7 of antibiotics in food-producing animals contributes to the
8 development of antibiotic-resistant bacterial infections in people.

9 SEC. 2. Section 14200 of the Food and Agricultural Code is
10 amended to read:

11 14200. (a) The Legislature hereby declares that this chapter,
12 which prescribes the distribution and use of livestock drugs, is
13 intended to assure that ~~such~~ *the* drugs are available to livestock
14 producers for their use in protecting the health of the livestock
15 population of the state, and that ~~such~~ *the* use will in turn benefit
16 the general public by providing an abundant supply of wholesome
17 food and fiber.

18 ¶

19 (b) *It is further declared that nothing in this chapter is intended*
20 *to prevent a livestock producer from administering livestock drugs*
21 *safely and effectively when ~~such~~ *the* use is in accordance with the*
22 *labeling directions for the drug used and when the use protects*
23 *public health.*

24 SEC. 3. Section 14203 of the Food and Agricultural Code is
25 amended to read:

26 14203. (a) “Restricted drug” means ~~any livestock either of~~
27 ~~the following:~~

28 (1) *A livestock drug which is sold in ~~such~~ a form that it might*
29 *be administered to ~~humans and a person and, if so administered~~*
30 *administered, would be dangerous to the health of ~~such humans~~*
31 *or ~~any livestock~~ the person.*

32 (2) *A livestock drug ~~which that if improperly administered~~*
33 *administered, as defined in Section 14203.5, to livestock, is*
34 *dangerous to the health of ~~such~~ *the* livestock or to ~~humans~~ *persons**
35 *who consume products from ~~such~~ *the* livestock. ~~Restricted~~*

36 (3) *A livestock drug that is recognized by either the federal*
37 *Centers for Disease Control and Prevention or the World Health*
38 *Organization to increase the prevalence of antibiotic-resistant*
39 *bacteria.*

40 (b) *Restricted drugs include all of the following:*

- 1 (a)
2 (1) Arsenic compounds and preparations.
3 (b)
4 (2) Diethylstilbestrol and other substances which have a
5 hormonelike action.
6 (c)
7 (3) Sulfanilamide or substitute sulfanilamides.
8 (d)
9 (4) Antibiotic preparations.
10 (e)
11 (5) *A drug from an antimicrobial class that is listed as “highly*
12 *important,” “critically important,” or “important” by the World*
13 *Health Organization’s “Critically Important Antimicrobial for*
14 *Human Medicine,” as updated by the World Health Organization,*
15 *or its successor publication, unless the drug is used for therapeutic*
16 *use, as defined in Section 14220.*
17 ~~Such other~~
18 (6) *Other* drugs and their preparations ~~which~~ *that* the director
19 determines are hazardous to the health of livestock or the public
20 safety.
21 SEC. 4. Section 14203.5 is added to the Food and Agricultural
22 Code, to read:
23 14203.5. “Improperly administered” means either of the
24 following:
25 (a) Administration of a medically important antimicrobial to a
26 food-producing animal through either feed or water, or for purposes
27 of poultry hatcheries through any means, for purposes other than
28 therapeutic use, such as growth promotion, feed efficiency, weight
29 gain, disease prevention, or nonroutine disease control.
30 (b) A repeated or regular pattern of administration of a medically
31 important antimicrobial in food-producing animals for purposes
32 other than therapeutic use or nonroutine disease control.
33 SEC. 5. Section 14207.3 is added to the Food and Agricultural
34 Code, to read:
35 14207.3. “Medically important antimicrobial” means a drug
36 that is both of the following:
37 (a) Intended for use in food-producing animals.
38 (b) Composed wholly or partly of either of the following:
39 (1) Any kind of penicillin, tetracycline, macrolide, lincosamide,
40 streptogramin, aminoglycoside, sulfonamide, or cephalosporin.

1 (2) A drug from an antimicrobial class that is listed as either
2 “highly important,” “critically important,” or “important” by the
3 World Health Organization’s “Critically Important Antimicrobial
4 for Human Medicine,” as updated by the World Health
5 Organization, or its successor publication.

6 SEC. 6. Section 14207.5 is added to the Food and Agricultural
7 Code, to read:

8 14207.5. “Noncustomary situation” means a situation that does
9 not include normal or standard practices and conditions on the
10 premises that facilitate the transmission of disease.

11 SEC. 7. Section 14207.7 is added to the Food and Agricultural
12 Code, to read:

13 14207.7. “Nonroutine disease control” means the use of
14 antimicrobials in the feed or water of a food-producing animal that
15 is not sick, and where a particular disease or infection is, or is
16 likely to be, present on the premises because of a specific,
17 noncustomary situation.

18 SEC. 8. Section 14220 is added to the Food and Agricultural
19 Code, to read:

20 14220. “Therapeutic use,” with respect to a medically important
21 antimicrobial, means the use of the antimicrobial for the specific
22 purpose of treating an animal with a documented disease or
23 infection. Therapeutic use does not include the continued use of
24 the antimicrobial in the animal after the disease or infection has
25 been resolved.

26 SEC. 9. Section 14289 of the Food and Agricultural Code is
27 amended to read:

28 14289. If the livestock drug is a restricted drug, the director
29 shall also refuse registration if he *or she* finds that the instructions
30 for use do not contain adequate and satisfactory directions as to
31 the methods of handling, caring for, holding, or otherwise
32 managing the livestock to which the drug is administered so as to
33 eliminate any danger to the health of any person who might
34 consume food products ~~which~~ *that* are derived from ~~such~~ *that*
35 livestock *or if he or she finds that the restricted drug poses a risk*
36 *to public health by increasing the prevalence of antibiotic-resistant*
37 *bacteria.*

38 SEC. 10. Section 14297 is added to the Food and Agricultural
39 Code, to read:

1 14297. The director may revoke the registration of a medically
2 important antimicrobial for use in livestock if he or she finds that
3 the drug as used poses a risk to the public health by increasing the
4 prevalence of antibiotic-resistant bacteria.

5 SEC. 11. Article 5.5 (commencing with Section 14335) is
6 added to Chapter 4 of Division 7 of the Food and Agricultural
7 Code, to read:

8
9 Article 5.5. Use of Medically Important Antimicrobials

10
11 14335. (a) A person who administers or causes to be
12 administered a medically important antimicrobial to a
13 food-producing animal shall have a valid veterinarian-client-patient
14 relationship with a veterinarian to ensure that the medically
15 important antimicrobial is used in a manner that is consistent with
16 professionally accepted best practices.

17 (b) For purposes of this section, “veterinarian-client-patient
18 relationship” means a relationship in which all of the following
19 are met:

20 (1) The veterinarian has assumed the responsibility for making
21 medical judgments regarding the health of the animal-patient, and
22 the client has agreed to follow the veterinarian’s instructions.

23 (2) The veterinarian has sufficient knowledge of the
24 animal-patient to initiate at least a general or preliminary diagnosis
25 of the medical condition of the animal-patient.

26 (3) The veterinarian is readily available for follow-up evaluation,
27 or has arranged for veterinary emergency coverage, and continuing
28 care and treatment.

29 (4) The veterinarian provides oversight of treatment, compliance,
30 and outcome of the administration of the medically important
31 antimicrobial.

32 (5) Animal-patient records are maintained.

33 (c) For purposes of this section, “sufficient knowledge” means
34 the veterinarian is personally acquainted with the keeping and care
35 of the animal-patient by virtue of either of the following:

36 (1) A timely examination of the animal-patient by the
37 veterinarian.

38 (2) Medically appropriate and timely visits by the veterinarian
39 to the premises where the animal-patient is kept.

1 14336. (a) If a livestock producer administers or causes to be
2 administered a medically important antimicrobial to a
3 food-producing animal, the producer, or the contracted entity, shall
4 annually report to the director the following information on a
5 schedule and in a format specified by the director:

6 (1) The total number of food-producing animals given a
7 medically important antimicrobial in their feed.

8 (2) The type of medically important antimicrobial administered.

9 (3) The total amount of each medically important antimicrobial
10 used.

11 (4) The target food-producing animal species that were
12 administered the medically important antimicrobial.

13 (5) The length of time over which the medically important
14 antimicrobial was intended to be provided to the food-producing
15 animals and the dose of the active medically important
16 antimicrobial ingredient the food-producing animals were intended
17 to receive.

18 (6) The purpose for administering the medically important
19 antimicrobial to a food-producing animal. The purpose shall be
20 categorized in a manner determined by the director and shall
21 include, at a minimum, the following categories:

22 (A) Growth promotion.

23 (B) Disease prevention.

24 (C) Disease control.

25 (D) Disease treatment.

26 (7) The type of disease or infection to be treated by the medically
27 important antimicrobial, if applicable.

28 (8) The name of the processor, as defined in Section 20019,
29 where the livestock product will be processed.

30 (b) On or before December 31, 2017, the department shall
31 develop and make operational a consumer-friendly, publicly
32 accessible Internet Web site that creates a database of the
33 information collected pursuant to this section. The database shall
34 be searchable and able to accommodate a wide range of users,
35 including users with limited technical and scientific literacy. The
36 Internet Web site shall be designed to be easily navigable and to
37 enable users to compare and contrast livestock producers and the
38 reported usage of medically important antimicrobials.

1 SEC. 12. Article 5.6 (commencing with Section 14340) is
2 added to Chapter 4 of Division 7 of the Food and Agricultural
3 Code, to read:

4

5 Article 5.6. Nontherapeutic Use of Medically Important
6 Antimicrobials

7

8 14340. This article shall apply to the nontherapeutic use in a
9 food-producing animal of a drug that is a medically important
10 antimicrobial and is either of the following:

11 (a) A registered drug.

12 (b) A drug exempted under Article 3 (commencing with Section
13 14261).

14 14341. The registration or exemption of a drug subject to this
15 article shall be ineffective on and after January 1, 2017, unless the
16 director makes a final written determination that there is, with
17 reasonable certainty, no harm to human health due to the
18 development of antimicrobial resistance that is attributable in whole
19 or in part to the nontherapeutic use of the drug, based on one of
20 the following:

21 (a) The holder of the registration or exemption has demonstrated
22 this fact.

23 (b) A risk analysis of the drug, taking into consideration other
24 relevant information, conducted by the director.

25 SEC. 13. Section 14366 is added to the Food and Agricultural
26 Code, to read:

27 14366. It is unlawful to administer, including through means
28 of feed, a medically important antimicrobial to a food-producing
29 animal for nonroutine disease control, unless either of the following
30 apply:

31 (a) The director determines, with reasonable certainty, that there
32 is no harm to human health due to the development of
33 antibiotic-resistant bacteria that is attributable in whole or in part
34 to the use of the medically important antimicrobial and the use
35 does not threaten public health.

36 (b) All of the following conditions are met:

37 (1) There is a significant risk that a disease or infection that is
38 present on, or is likely to be present on, the premises will be
39 transmitted to the food-producing animal.

1 (2) The administration of the medically important antimicrobial
2 to the food-producing animal is necessary to prevent or reduce the
3 risk of transmission of the disease or infection.

4 (3) The medically important antimicrobial is administered to
5 the food-producing animal for the shortest duration possible to
6 prevent or reduce the risk of transmission of the disease or
7 infection.

8 (4) The medically important antimicrobial is administered to
9 the fewest food-producing animals possible in order to prevent or
10 reduce the risk of transmission of the disease or infection.

11 SEC. 14. Section 14381 of the Food and Agricultural Code is
12 amended to read:

13 14381. ~~A~~ (a) *Except as provided for in subdivision (b), a*
14 *violation of this chapter or of any regulation which that is adopted*
15 *by the director pursuant to this chapter is an infraction punishable*
16 *by a fine of not more than five hundred dollars (\$500) for the first*
17 *violation. A second or subsequent violation of this chapter is a*
18 *misdemeanor punishable by a fine of not less than one hundred*
19 *dollars (\$100) and not more than one thousand dollars (\$1,000).*

20 (b) *A violation of the reporting requirement in Section 14336*
21 *or of any regulation that is adopted by the director pursuant to*
22 *that section is an infraction punishable by a fine of one hundred*
23 *dollars (\$100) for the first violation. A second or subsequent*
24 *violation is an infraction punishable by a fine of not less than two*
25 *hundred dollars (\$200) and not more than one thousand dollars*
26 *(\$1,000).*

27 SEC. 15. This act shall become operative on January 1, 2017.

28 SEC. 16. No reimbursement is required by this act pursuant to
29 Section 6 of Article XIII B of the California Constitution because
30 the only costs that may be incurred by a local agency or school
31 district will be incurred because this act creates a new crime or
32 infraction, eliminates a crime or infraction, or changes the penalty
33 for a crime or infraction, within the meaning of Section 17556 of
34 the Government Code, or changes the definition of a crime within
35 the meaning of Section 6 of Article XIII B of the California
36 Constitution.

AB 1743 (Ting) – Safe Syringe Access Act

ASSEMBLYMEMBER
PHIL TING
19TH DISTRICT



SUMMARY

Current law provides pharmacists the discretion to sell up to 30 syringes to an adult without a prescription. This law will sunset on January 1, 2015, and without an extension of the law, pharmacists in only 15 counties and 4 cities will maintain the ability to sell syringes over the counter.

AB 1743 (Ting) will remove the number of syringes a pharmacist has the discretion to sell to an adult without a prescription and will remove the sunset date in current law, making over the counter syringe sales a permanent part of California's public health strategy.

BACKGROUND

Sharing used syringes remains the most common mode of transmission of hepatitis C, and the second most common cause of HIV and hepatitis B transmission. These diseases are costly and potentially deadly. The average lifetime cost to treat just one case of HIV can exceed \$600,000.

The California Department of Public Health and the Federal Centers for Disease Control & Prevention have found that allowing adults to purchase sterile syringes from pharmacists without prescriptions is a key component to the prevention and control of these diseases.

Studies consistently find that the transmission of disease is reduced in areas that allow adults to purchase syringes over the counter than areas that mandate prescriptions. According to a study published in the *Journal of the American Public Health Association*, in a national comparison of 60 cities that did not require a prescription for the sale of syringes and 36 that did require a prescription, there was no statistically significant difference in the prevalence of injection drug use between the two groups of cities. However, the rate of HIV among injection drug users was twice as high in the cities that prohibited sale of syringes (13.8% vs. 6.7%).

Additionally, from 2005-2010, 17 counties and a number of cities in California allowed pharmacists to provide syringes for personal use. Research subsequently conducted by the California Department of Public Health concluded there was no evidence of an increase in drug use or crime in the state of California as a whole or in areas that authorized sale of syringes without a prescription. It also found that the rate of syringe sharing in these communities was lower than areas where syringes were not available over the counter.

Providing discretion to pharmacists to sell syringes to adults without a prescription is an extremely effective public health tool that increases the health and safety of individuals and communities. Furthermore, this scientific and medically-backed approach is at no cost to the state. It is in the state's best interest to make this a permanent component of California's public health strategy.

THE BILL

AB 1743 would remove the cap of the number of syringes a pharmacist can provide to an adult without a prescription and make safe syringe access a permanent part of California's public health approach.

Under AB 1743, pharmacists would be required to meet specific requirements for the provision of information and materials, including letting purchasers know how to safely dispose of syringes, how to access drug treatment, and options for testing and treating HIV and hepatitis.

SUPPORT

Drug Policy Alliance (sponsor)
San Francisco AIDS Foundation (sponsor)

CONTACT

Office of Assemblymember Phil Ting
Evan Minton
(916) 319-2019

ASSEMBLY BILL

No. 1743

Introduced by Assembly Member Ting

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 of, and to repeal Section 11364 of, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1743, as introduced, 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 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.

This bill would delete that January 1, 2015, date of repeal and would 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 ~~4144. (a) A person may sell or obtain hypodermic needles and~~
4 ~~hypodermic syringes without a prescription or permit, for uses that~~
5 ~~the board determines are industrial, and that person shall not be~~
6 ~~required to comply with Section 4145 or 4146.~~

7 ~~(b) This section shall be inoperative until January 1, 2015.~~

8 SEC. 2. Section 4144.5 of the Business and Professions Code
9 is amended to read:

10 4144.5. ~~(a)~~—A person may sell or obtain hypodermic needles
11 and hypodermic syringes without a prescription or permit, for uses
12 that the board determines are industrial, and that person shall not
13 be required to comply with Section 4145.5 or 4146.

14 ~~(b) This section shall remain in effect only until January 1, 2015,~~
15 ~~and as of that date is repealed, unless a later enacted statute, that~~
16 ~~is enacted before January 1, 2015, deletes or extends that date.~~

17 SEC. 3. Section 4145 of the Business and Professions Code is
18 repealed.

19 ~~4145. (a) Notwithstanding any other provision of law, a~~
20 ~~pharmacist or physician may, without a prescription or a permit,~~
21 ~~furnish hypodermic needles and syringes for human use, and a~~
22 ~~person may, without a prescription or license, obtain hypodermic~~
23 ~~needles and syringes from a pharmacist or physician for human~~
24 ~~use, if one of the following requirements is met:~~

25 ~~(1) The person is known to the furnisher and the furnisher has~~
26 ~~previously been provided a prescription or other proof of a~~
27 ~~legitimate medical need requiring a hypodermic needle or syringe~~
28 ~~to administer a medicine or treatment.~~

29 ~~(2) Pursuant to authorization by a county, with respect to all of~~
30 ~~the territory within the county, or a city, with respect to the territory~~
31 ~~within the city, for the period commencing January 1, 2005, and~~
32 ~~ending December 31, 2018, a pharmacist may furnish or sell 10~~
33 ~~or fewer hypodermic needles or syringes at any one time to a~~
34 ~~person 18 years of age or older if the pharmacist works for a~~
35 ~~pharmacy that is registered with the Disease Prevention~~

1 ~~Demonstration Project pursuant to Chapter 13.5 (commencing~~
2 ~~with Section 121285) of Part 4 of Division 105 of the Health and~~
3 ~~Safety Code and the pharmacy complies with the provisions of~~
4 ~~that chapter.~~

5 (b) ~~Notwithstanding any other provision of law, a pharmacist,~~
6 ~~veterinarian, or person licensed pursuant to Section 4141 may,~~
7 ~~without a prescription or license, furnish hypodermic needles and~~
8 ~~syringes for use on animals, and a person may, without a~~
9 ~~prescription or license, obtain hypodermic needles and syringes~~
10 ~~from a pharmacist, veterinarian, or person licensed pursuant to~~
11 ~~Section 4141 for use on animals, providing that no needle or~~
12 ~~syringe shall be furnished to a person who is unknown to the~~
13 ~~furnisher and unable to properly establish his or her identity.~~

14 (c) ~~This section shall be inoperative until January 1, 2015.~~

15 SEC. 4. Section 4145.5 of the Business and Professions Code
16 is amended to read:

17 4145.5. (a) Notwithstanding any other provision of law, a
18 pharmacist or physician may, without a prescription or a permit,
19 furnish hypodermic needles and syringes for human use, and a
20 person may, without a prescription or license, obtain hypodermic
21 needles and syringes from a pharmacist or physician for human
22 use, if the person is known to the furnisher and the furnisher has
23 previously been provided a prescription or other proof of a
24 legitimate medical need requiring a hypodermic needle or syringe
25 to administer a medicine or treatment.

26 (b) Notwithstanding any other provision of law, as a public
27 health measure intended to prevent the transmission of HIV, viral
28 hepatitis, and other bloodborne diseases among persons who use
29 syringes and hypodermic needles, and to prevent subsequent
30 infection of sexual partners, newborn children, or other persons,
31 a physician or pharmacist may, without a prescription or a permit,
32 furnish ~~30 or fewer~~ hypodermic needles and syringes for human
33 use to a person 18 years of age or older, and a person 18 years of
34 age or older may, without a prescription or license, obtain ~~30 or~~
35 ~~fewer~~ hypodermic needles and syringes solely for personal use
36 from a physician or pharmacist.

37 (c) Notwithstanding any other provision of law, a pharmacist,
38 veterinarian, or person licensed pursuant to Section 4141 may,
39 without a prescription or license, furnish hypodermic needles and
40 syringes for use on animals, and a person may, without a

1 prescription or license, obtain hypodermic needles and syringes
2 from a pharmacist, veterinarian, or person licensed pursuant to
3 Section 4141 for use on animals, providing that no needle or
4 syringe shall be furnished to a person who is unknown to the
5 furnisher and unable to properly establish his or her identity.

6 (d) A pharmacy that furnishes nonprescription hypodermic
7 needles and syringes shall store hypodermic needles and syringes
8 in a manner that ensures that they are available only to authorized
9 personnel, and are not accessible to other persons.

10 (e) In order to provide for the safe disposal of hypodermic
11 needles and syringes, a pharmacy or hypodermic needle and syringe
12 exchange program that furnishes nonprescription hypodermic
13 needles and syringes shall provide consumers with one or more
14 of the following disposal options:

15 (1) It shall establish an onsite, safe, hypodermic needle and
16 syringe collection and disposal program that meets applicable state
17 and federal standards for collection and disposal of medical sharps
18 waste.

19 (2) It shall furnish, or make available, mail-back sharps
20 containers authorized by the United States Postal Service that meet
21 applicable state and federal requirements for the transport of
22 medical sharps waste, and shall provide tracking forms to verify
23 destruction at a certified disposal facility.

24 (3) It shall furnish, or make available, a sharps container that
25 meets applicable state and federal standards for collection and
26 disposal of medical sharps waste.

27 (f) A pharmacy that furnishes nonprescription syringes shall
28 provide written information or verbal counseling to consumers at
29 the time of furnishing or sale of nonprescription hypodermic
30 needles or syringes on how to do the following:

- 31 (1) Access drug treatment.
- 32 (2) Access testing and treatment for HIV and hepatitis C.
- 33 (3) Safely dispose of sharps waste.

34 ~~(g) This section shall remain in effect only until January 1, 2015,~~
35 ~~and as of that date is repealed, unless a later enacted statute, that~~
36 ~~is enacted before January 1, 2015, deletes or extends that date.~~

37 SEC. 5. Section 4148 of the Business and Professions Code is
38 repealed.

39 ~~4148. (a) All stocks of hypodermic needles or syringes shall~~
40 ~~be confiscated if found outside the licensed premises of any person~~

1 holding a permit under Section 4141 and found not in the
2 possession or under the control of a person entitled to an exemption
3 under Section 4143, 4144, or 4145.

4 ~~(b) This section shall be inoperative until January 1, 2015.~~

5 SEC. 6. Section 4148.5 of the Business and Professions Code
6 is amended to read:

7 4148.5. ~~(a)~~ All stocks of hypodermic needles or syringes shall
8 be confiscated if found outside the licensed premises of any person
9 holding a permit under Section 4141 and found not in the
10 possession or under the control of a person entitled to an exemption
11 under Section 4143, ~~4144, 4144.5,~~ or 4145.5, or under Section
12 11364.5, 121349, or 121349.1 of the Health and Safety Code.

13 ~~(b) This section shall remain in effect only until January 1, 2015,~~
14 ~~and as of that date is repealed, unless a later enacted statute, that~~
15 ~~is enacted before January 1, 2015, deletes or extends that date.~~

16 SEC. 7. Section 4149.5 of the Business and Professions Code
17 is repealed.

18 ~~4149.5.—(a) Local authorizations related to Sections 4144,~~
19 ~~4145, and 4148 of this code and Sections 11364 and 121285 of~~
20 ~~the Health and Safety Code shall be inoperative until January 1,~~
21 ~~2015.~~

22 ~~(b) Local authorizations related to Sections 4144, 4145, and~~
23 ~~4148 of this code and Sections 11364 and 121285 of the Health~~
24 ~~and Safety Code shall again become operative on January 1, 2015,~~
25 ~~unless the city, county, or city and county acts to remove the~~
26 ~~authorization.~~

27 SEC. 8. Section 11364 of the Health and Safety Code is
28 repealed.

29 ~~11364.—(a) It is unlawful to possess an opium pipe or any~~
30 ~~device, contrivance, instrument, or paraphernalia used for~~
31 ~~unlawfully injecting or smoking (1) a controlled substance specified~~
32 ~~in subdivision (b), (c), or (e) or paragraph (1) of subdivision (f) of~~
33 ~~Section 11054, specified in paragraph (14), (15), or (20) of~~
34 ~~subdivision (d) of Section 11054, specified in subdivision (b) or~~
35 ~~(e) of Section 11055, or specified in paragraph (2) of subdivision~~
36 ~~(d) of Section 11055, or (2) a controlled substance which is a~~
37 ~~narcotic drug classified in Schedule III, IV, or V.~~

38 ~~(b) This section shall not apply to hypodermic needles or~~
39 ~~syringes that have been containerized for safe disposal in a~~

1 container that meets state and federal standards for disposal of
2 sharps waste.

3 ~~(e) Pursuant to authorization by a county, with respect to all of~~
4 ~~the territory within the county, or a city, with respect to the territory~~
5 ~~within the city, for the period commencing January 1, 2005, and~~
6 ~~ending December 31, 2018, subdivision (a) shall not apply to the~~
7 ~~possession solely for personal use of 10 or fewer hypodermic~~
8 ~~needles or syringes if acquired from an authorized source.~~

9 ~~(d) This section shall be inoperative until January 1, 2015.~~

10 SEC. 9. Section 11364.1 of the Health and Safety Code is
11 amended to read:

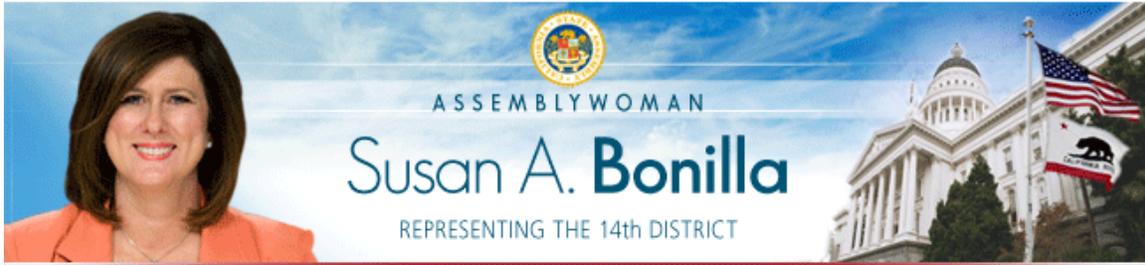
12 11364.1. (a) It is unlawful to possess an opium pipe or any
13 device, contrivance, instrument, or paraphernalia used for
14 unlawfully injecting or smoking (1) a controlled substance specified
15 in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f)
16 of Section 11054, specified in paragraph (14), (15), or (20) of
17 subdivision (d) of Section 11054, specified in subdivision (b) or
18 (c) of Section 11055, or specified in paragraph (2) of subdivision
19 (d) of Section 11055, or (2) a controlled substance which is a
20 narcotic drug classified in Schedule III, IV, or V.

21 (b) This section shall not apply to hypodermic needles or
22 syringes that have been containerized for safe disposal in a
23 container that meets state and federal standards for disposal of
24 sharps waste.

25 (c) As a public health measure intended to prevent the
26 transmission of HIV, viral hepatitis, and other bloodborne diseases
27 among persons who use syringes and hypodermic needles, and to
28 prevent subsequent infection of sexual partners, newborn children,
29 or other persons, this section shall not apply to the possession
30 solely for personal use of ~~30 or fewer~~ hypodermic needles or
31 syringes if acquired from a physician, pharmacist, hypodermic
32 needle and syringe exchange program, or any other source that is
33 authorized by law to provide sterile syringes or hypodermic needles
34 without a prescription.

35 ~~(d) This section shall remain in effect only until January 1, 2015,~~
36 ~~and as of that date is repealed, unless a later enacted statute, that~~
37 ~~is enacted before January 1, 2015, deletes or extends that date.~~

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AB 2418: Promoting Patient Medication Adherence

Summary:

Poor medication adherence is a major barrier to achieving better patient health outcomes. AB 2418 provides patients with a choice between picking up their medications at a local pharmacy or by having their medications delivered through mail order programs. In addition, this bill streamlines the medication refill process by making it more convenient for patients to pick up all their medications on one trip to the pharmacy and allows patients who run out of eye drops to obtain an early refill.

Background:

Approximately 50% of patient with chronic health conditions such as heart disease and diabetes do not take their medications as prescribed. Patients that do not take their medications regularly are at a greater risk of developing poor health outcomes and hospitalization. More importantly, 20-30% of patient medications are never filled.

By creating processes that support and improve patient access to medications; patients experience better health outcomes and improved quality of life. Patients who pick up their medications at their local pharmacy have the opportunity to talk with their pharmacist about how to properly take their medications and to understand the positive benefits of taking their medication.

This bill:

Specifically, this bill:

- Allows 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.
- Streamlines prescription medications by placing the patient's medications on the same refill schedule.
- Allows patients who run out of prescription eye medications because of accidental spillage or who use more than 70% of their eye drops to be eligible for an early refill.

Support:

California Healthcare Institute (Co-Sponsor)
California Pharmacists Association (Co-Sponsor)

Contact:

Norlyn Asprec
Office of Assemblywoman Susan A. Bonilla
(916) 319-2014
Norlyn.Asprec@asm.ca.gov

ASSEMBLY BILL

No. 2418

Introduced by Assembly Members Bonilla and Skinner

February 21, 2014

An act to add Section 1367.247 to the Health and Safety Code, and to add Section 10123.192 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2418, as introduced, Bonilla. Health care coverage: prescription drug 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, 2015, that provides prescription drug benefits and imposes a mandatory mail order restriction for all or some covered prescription drugs to establish a process allowing enrollees and insureds to opt out of the restriction, as specified. This bill would prohibit a health care service plan contract or a health insurance policy issued, amended, or renewed on or after January 1, 2015, that provides prescription drug benefits

from denying coverage for the refill of an otherwise covered drug when the refill is ordered for the purpose of placing all of the enrollee’s or insured’s medications on the same schedule for refill. The bill would also prohibit the contract or policy from denying coverage for the 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. Section 1367.247 is added to the Health and
2 Safety Code, to read:

3 1367.247. (a) (1) A health care service plan contract issued,
4 amended, or renewed on or after January 1, 2015, that provides
5 prescription drug benefits and that imposes a mandatory mail order
6 restriction for some or all covered prescription drugs shall establish
7 a process for enrollees to opt out of that restriction. The opt out
8 process shall comply with all of the following requirements:

9 (A) Not impose conditions or restrictions on an enrollee opting
10 out of the mandatory mail order restriction. For purposes of this
11 subparagraph, “conditions or restrictions” include, but are not
12 limited to, requiring prescriber approval or submission of
13 documentation by the enrollee or prescriber.

14 (B) Allow an enrollee to opt out of the mandatory mail order
15 restriction, and revoke his or her prior opt out of the restriction, at
16 any time.

17 (C) The choice by an enrollee to opt out shall be valid for as
18 long as the enrollee remains enrolled in the plan contract or elects
19 to revoke the opt out.

20 (D) A health care service plan shall provide an enrollee who
21 obtains a covered prescription drug that is subject to the mandatory
22 mail order restriction with a separate written notice of the

1 restriction no less than 30 days prior to the restriction taking effect
2 for each drug subject to the restriction. This written notice shall
3 be in addition to any information contained in the plan’s evidence
4 of coverage or evidence of benefits. The notice shall inform the
5 enrollee of the right to opt out of the mandatory mail order
6 restriction and instructions on how to do so, including designating
7 a mailing address, electronic mail address, and, if the plan chooses
8 to receive opt out elections by telephone or facsimile, a toll-free
9 telephone or facsimile number, to which the enrollee may deliver
10 his or her opt out election.

11 (2) This subdivision shall not apply to drugs that are not
12 available at an in-network community pharmacy due to a
13 manufacturer’s instructions or restrictions, or due to any risk
14 evaluation and management strategy approved by the federal Food
15 and Drug Administration.

16 (b) A health care service plan contract issued, amended, or
17 renewed on or after January 1, 2015, that provides prescription
18 drug benefits shall not deny coverage for the refill of an otherwise
19 covered drug when the refill is ordered for the purpose of placing
20 all of the enrollee’s medications on the same schedule for refill.

21 (c) A health care service plan contract issued, amended, or
22 renewed on or after January 1, 2015, that provides prescription
23 drug benefits shall not deny coverage for the refill of covered
24 topical ophthalmic products at 70 percent of the predicted days of
25 use.

26 (d) Nothing in this section shall be construed to establish a new
27 mandated benefit or to prevent the application of deductible or
28 copayment provisions in a plan contract.

29 SEC. 2. Section 10123.192 is added to the Insurance Code, to
30 read:

31 10123.192. (a) (1) A health insurance policy issued, amended,
32 or renewed on or after January 1, 2015, that provides prescription
33 drug benefits and that imposes a mandatory mail order restriction
34 for some or all covered prescription drugs shall establish a process
35 for insureds to opt out of that restriction. The opt out process shall
36 comply with all of the following requirements:

37 (A) Not impose conditions or restrictions on an insured opting
38 out of the mandatory mail order restriction. For purposes of this
39 subparagraph, “conditions or restrictions” include, but are not

1 limited to, requiring prescriber approval or submission of
2 documentation by the insured or prescriber.

3 (B) Allow an insured to opt out of the mandatory mail order
4 restriction, and revoke his or her prior opt out of the restriction, at
5 any time.

6 (C) The choice by an insured to opt out shall be valid for as
7 long as the insured remains covered under the policy or elects to
8 revoke the opt out.

9 (D) A health insurer shall provide an insured who obtains a
10 covered prescription drug that is subject to the mandatory mail
11 order restriction with a separate written notice of the restriction
12 no less than 30 days prior to the restriction taking effect for each
13 drug subject to the restriction. This written notice shall be in
14 addition to any information contained in the insurer's evidence of
15 coverage or evidence of benefits. The notice shall inform the
16 insured of the right to opt out of the mandatory mail order
17 restriction and instructions on how to do so, including designating
18 a mailing address, electronic mail address, and, if the insurer
19 chooses to receive opt out elections by telephone or facsimile, a
20 toll-free telephone or facsimile number, to which the insured may
21 deliver his or her opt out election.

22 (2) This subdivision shall not apply to drugs that are not
23 available at an in-network community pharmacy due to a
24 manufacturer's instructions or restrictions, or due to any risk
25 evaluation and management strategy approved by the federal Food
26 and Drug Administration.

27 (b) A health insurance policy issued, amended, or renewed on
28 or after January 1, 2015, that provides prescription drug benefits
29 shall not deny coverage for the refill of an otherwise covered drug
30 when the refill is ordered for the purpose of placing all of the
31 insured's medications on the same schedule for refill.

32 (c) A health insurance policy issued, amended, or renewed on
33 or after January 1, 2015, that provides prescription drug benefits
34 shall not deny coverage for the early refill of covered topical
35 ophthalmic products at 70 percent of the predicted days of use.

36 (d) Nothing in this section shall be construed to establish a new
37 mandated benefit or to prevent the application of deductible or
38 copayment provisions in a policy.

39 SEC. 3. No reimbursement is required by this act pursuant to
40 Section 6 of Article XIII B of the California Constitution because

1 the only costs that may be incurred by a local agency or school
2 district will be incurred because this act creates a new crime or
3 infraction, eliminates a crime or infraction, or changes the penalty
4 for a crime or infraction, within the meaning of Section 17556 of
5 the Government Code, or changes the definition of a crime within
6 the meaning of Section 6 of Article XIII B of the California
7 Constitution.

O



The Honorable Susan Bonilla
The Honorable Nancy Skinner
California State Assembly
State Capitol
Sacramento, CA 95814

April 4, 2014

Re: AB 2418 (Bonilla and Skinner) - SUPPORT

Dear Assembly Members Bonilla and Skinner:

The California Pharmacists Association (CPhA) and California Healthcare Institute (CHI) thank you for your commitment to increasing patient medication adherence by introducing AB 2418. As the co-sponsors of your legislation, our organizations strongly support your leadership in this important endeavor.

As you are well aware, a significant number of patients do not take their medications as prescribed. Between 50 percent and 75 percent of patients do not follow prescriber instructions or do not take their prescribed medications at all. This lack of medication adherence results in lost opportunities to effectively treat patients. As a consequence, patients experience preventable worsening of their health and utilize tens of millions of unnecessary hospitalizations and outpatient visits every year. Overall, poor medication adherence accounts for as much as \$290 billion per year in avoidable medical spending. Increasing medication adherence presents an opportunity to improve health while reducing health care costs.

Improving medication adherence requires a multifaceted approach. Many studies have explored possible solutions. AB 2418 focuses on key strategies that have been identified, increased interaction between patients and their health care providers and ensuring patients have access to their medications in the way that best works for them. Leading organizations studying the problem of medication adherence have specifically recommended refill synchronization, increased face-to-face communication with patients and improving the patient-provider relationship.

As the medication experts, pharmacists can play a key role in helping improve medication adherence. Pharmacists educate patients about their medications, including how and when to take them, what side effects to watch for, what to expect when taking the medication, foods and other drugs to avoid, and more. When pharmacists play a more active role with patients, health outcomes improve. Hundreds of clinical studies have shown improvements in medication adherence and benefits to patients' health outcomes when pharmacists work with other members of the care team on medication therapy.

The provisions in AB 2418 are designed to increase medication adherence by (1) protecting a patient's right to choose between obtaining their prescription medications from an in-network community pharmacy or via mail order delivery, (2) making it easier for pharmacists to synchronize the refill dates for patients with multiple prescriptions, and (3) ensuring that patients who run out of eye drops early can easily obtain a refill so they do not experience a gap in therapy. All three of these areas are

supported by ample evidence and are consistent with federal Centers for Medicare and Medicaid Services requirements and guidance for Medicare Part D Plans.

Mail order delivery of prescription medications has become a common feature of the prescription drug benefit for many health plans and insurers. We recognize many patients find mail order delivery a convenient option and AB 2418 would not prohibit mail order programs or health plan or insurer incentives for mail order. However, some patients prefer to obtain their prescription drugs in-person from a pharmacist who they know and trust. These patients find communication about health care issues easier and more effective in person. AB 2418 protects these patients' right to select the option that works best for them by providing a straightforward way to opt out. Patients who get to choose between mail order and community pharmacy have higher levels of medication adherence than patients in mandatory mail order programs.

AB 2418 would also streamline the process known as "refill synchronization," whereby pharmacists synchronize the refill dates for patients with multiple prescriptions. Now all prescriptions with the same days' supply can be refilled on the same day each month. This service significantly increases convenience for patients with numerous chronic medications by reducing the number of separate trips they have to make to the pharmacy. It also allows pharmacists to counsel patients on all of their prescriptions at the same time, which improves the comprehensiveness of the counseling and enhances the ability of pharmacists to catch medication errors. Refill synchronization programs have been shown to increase medication adherence rates by three to six times.

The final component of AB 2418 would ensure patients who run out of prescription eye drops can obtain an early refill. This is necessary due to mistakes in applying eye drops (e.g., spilling or missing the eye) and the imperfect method of dosing (e.g., inadvertently applying more than necessary). Overall, most patients are able to apply eye drops without a problem, but many patients do report problems with putting in their eye drops. When patients run out of eye drops early, they are often faced with either having to pay out-of-pocket for an additional refill or going without their medication. Due to the relatively low cost of most eye drops and the serious consequences of non-adherence, patients should be able to easily get an early fill if they run out close to their next refill date.

Improving medication adherence will result in better health outcomes for patients, reduce the number of preventable outpatient and inpatient services used, and reduce the overall cost of providing healthcare. AB 2418 promotes three strategies aimed at achieving this goal. We look forward to working with you on this important bill.

Sincerely,



Brian Warren
Vice President, Center for Advocacy
California Pharmacists Association



Eve Bukowski
Vice President, State Government Affairs
California Healthcare Institute



IN BRIEF

In order to preserve the efficacy of medically important antibiotics, SB 835 would put into California law the voluntary guidelines issued by the Food and Drug Administration (FDA) to phase out the nontherapeutic use of medically important antibiotics in food-producing animals and to require veterinary oversight for those drugs.

THE ISSUE

Current law does not prohibit the nontherapeutic use (i.e. for growth promotion) of medically important antibiotics in food-producing animals. Current law also does not require veterinary oversight or a prescription to administer medically important antibiotics to food-producing animals.

On December 11, 2013, the FDA announced finalized guidelines to phase out the nontherapeutic use of medically important antibiotics in food-producing animals and to require veterinarian oversight. However, the recommendations put forward in FDA Guidance for Industry document #213 are only voluntary – there is no obligation to comply.

BACKGROUND

The Centers for Disease Control and Prevention (CDC) estimates that each year at least 2 million people are infected with – and at least 23,000 people die from – antibiotic resistant infections. Each year, antibiotic resistant infections results in at least \$20 billion in direct health care costs and at least \$35 billion in lost productivity.¹

The CDC states, “antimicrobial resistance is one of our most serious health threats. Infections from resistant bacteria are now too common, and some pathogens have even become resistant to multiple types or classes of antibiotics (antimicrobials used to treat bacterial infections). The loss of effective antibiotics will undermine our ability to fight infectious diseases and manage the infectious complications common in vulnerable patients undergoing chemotherapy for cancer, dialysis for renal failure, and surgery, especially organ transplantation, for which the ability to treat secondary infections is crucial.”² The CDC has deemed antibiotic resistance its top public health threat for 2014.³

Antibiotic resistance means that bacterial infections can no longer be treated with antibiotics.⁴ Over what are often short periods of time, bacteria can evolve to resist antibiotics that would otherwise threaten their existence. As more antibiotics are used, resistance grows at a faster rate. The resistant bacteria can transfer from food animals to humans by entering the food supply or through the environment.

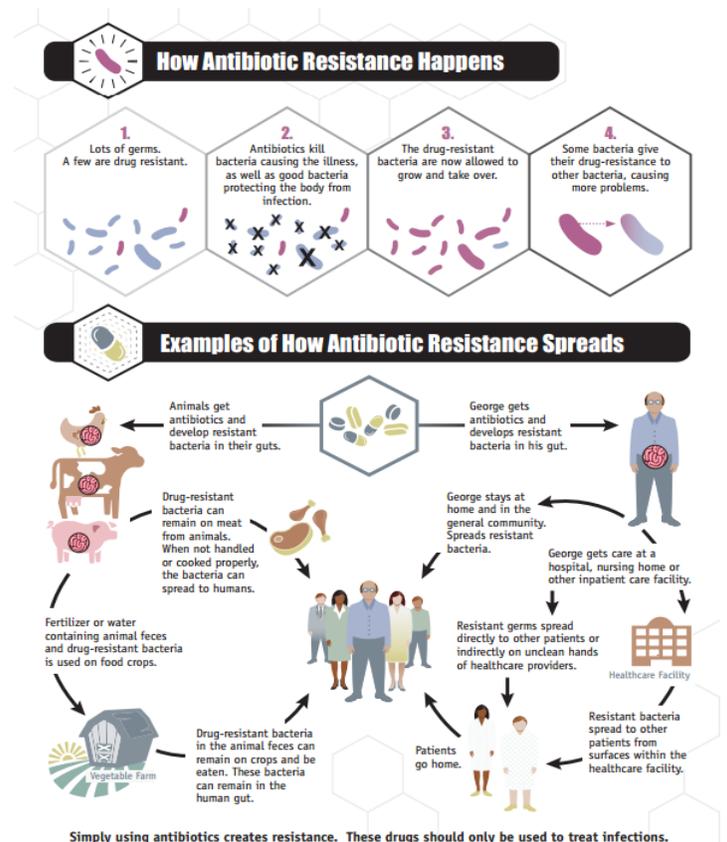


Image from the CDC's report: *Antibiotic Resistance Threats in the United States, 2013.*

According to FDA data published in 2011, a substantial majority of medically important antibiotics are used not in humans, but are actually used in food-producing animals.⁵ In fact, an independent analysis of the FDA data found that at least 70 percent of all medically important antibiotics are administered to food-producing animals.⁶

Some of the most common medically important antibiotics given to food-producing animals include tetracycline, macrolides and penicillin, all of which are used to treat common infections in humans.⁷

Medically important antibiotics do have legitimate uses in food-producing animals – to treat and prevent disease. But medically important antibiotics are more often used in food-producing animals for nontherapeutic purposes, such as growth promotion. Veterinary oversight is not required when administering a medically important antibiotic to food-producing animals. According to the FDA, it's poorly understood how these drugs promote growth.⁸ There is no scientific reason why medically important antibiotics should be used nontherapeutically in food-producing animals.

In December 2013 the FDA released the finalized version of Guidance for Industry document #213, which asks industry to voluntarily phase out the nontherapeutic use of medically important antibiotics in food-producing animals. According to the FDA press release, the agency is “*implementing a voluntary plan with the industry to phase out the use of certain antibiotics for enhanced food production*” because “*all uses of antimicrobial drugs, in both humans and animals, contribute to the development of antimicrobial resistance, [so] it is important to use these drugs only when necessary.*”⁹

The FDA guidance document is only voluntary – the industry does not have any obligation to comply. Some major drug companies, such as Zoetis (previously a part of Pfizer), have said they will comply. Some parts of the agricultural industry, such as the National Chicken Council, have also said they support the voluntary guidelines.

THE SOLUTION

SB 835 would put the FDA's voluntary Guidance for Industry (GFI) document #213 into California law to phase out the nontherapeutic use of medically important antibiotics and to require veterinarian oversight for the administration of those drugs. Specifically SB 835 would:

- Require the state Secretary of the Department of Food and Agriculture to refuse to register a medically important antibiotic for use in food-producing animals unless it complies with FDA GFI #213. This means, that in order to be eligible to register a drug for use in California, the drug manufacturer must meet all of, but not limited to, the following:

- The drug company must remove from the label of any medically important antimicrobial or animal combination drug, any mention or implication that growth enhancement or feed efficacy are approved uses of the substance.
- The drug company must revise the conditions for using medically important animal drugs and combination drug products so that they are no longer available over the counter (OTC) and require a veterinary prescription (Rx) in order to be purchased and used. This means sale and use of medicated feed products also would require a veterinary feed directive and no longer be available OTC. Sale and use of medicated drinking water products would require an Rx as well.
- The drug company must ensure that medically important antimicrobials are used only to treat, prevent, or control disease under the supervision of or by prescription from a licensed veterinarian.

- SB 835 would define a veterinarian-client-patient relationship as a relationship meeting the requirements of Section 2032.1 of Title 16 of the California Code of Regulations.
- SB 835 would provide manufacturers three years to make the necessary changes and reregister their drugs with the state Secretary of the Department of Food and Agriculture.
- SB 835 would stipulate that medically important antibiotics are any antimicrobial drugs listed in Appendix A of Guidance for Industry document #152 or its most updated version, and include all three tiers of medically important antimicrobials: those that are critically important, highly important and important. This includes penicillin, tetracyclines, cephalosporins and many others.¹⁰

SUPPORT

California State Grange

FOR MORE INFORMATION

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¹ Centers for Disease Control and Prevention, *Antibiotic Resistance Threats in the United States 2013*, <http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf>, pg. 11

² Centers for Disease Control and Prevention, *Antibiotic Resistance Threats in the United States 2013*, <http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf>, pg. 5.

³ CDC Works for You 24/7 Blog, *CDC's Top Ten: 5 Health Achievements in 2013 and 5 Health Threats in 2014*, <http://blogs.cdc.gov/cdcworksforyou24-7/2013/12/cdc%E2%80%99s-top-ten-5-health-achievements-in-2013-and-5-health-threats-in-2014/>.

⁴ Antibiotics are a class of medicines used to treat bacterial infections and are part of the broader class of antimicrobials, which include other drugs, like antivirals and antifungals, which are also used to kill microbes.

⁵ Food and Drug Administration, *2011 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*, <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM338170.pdf>, pg. 3.

⁶ PEW, *Human Health and Industrial Farming 101*, <http://www.pewhealth.org/reports-analysis/issue-briefs/human-health-and-industrial-farming-101-85899410551>.

⁷ Food and Drug Administration, *2011 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*, <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM338170.pdf>, pg. 3.

Tetracycline is used to treat common infections, such as pneumonia and other respiratory infections, as well as urinary tract infections, acne and stomach ulcers. Over 12 million pounds were administered to food-producing animals in 2011.

Macrolides are a family of broad spectrum antibiotics, such as erythromycin and azithromycin, used to treat staph infections, pneumonia and chlamydia. Over 1.2 million pounds were administered to food-producing animals in 2011.

Penicillin is used to treat many different infections such as syphilis and staph. Over 1.9 million pounds were administered to food-producing animals in 2011.

⁸ FDA Consumer Health Information, *Phasing Out Certain Antibiotic Use in Farm Animals*, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm378100.htm>.

FDA Consumer Health Information, *Phasing Out Certain Antibiotic Use in Farm Animals*, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm378100.htm>.

¹⁰ For the comprehensive list of medically important antibiotics, please see FDA Guidance for Industry document #152:

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf>.

AMENDED IN SENATE MARCH 26, 2014

SENATE BILL

No. 835

Introduced by Senator Hill

January 6, 2014

An act to amend Section 14288 of, and to add Article 4.5 (commencing with Section 18770) to Chapter 4 of Part 3 of Division 9 of, the Food and Agricultural Code, relating to food and agriculture.

LEGISLATIVE COUNSEL'S DIGEST

SB 835, as amended, Hill. ~~Food-producing~~ *Food* animals: medically important antimicrobial drugs.

Under existing law, the Secretary of Food and Agriculture has the responsibility of ensuring that food products are not adulterated and that they are capable for use as human food. A violation of the laws and regulations relating to the adulteration of livestock or poultry products is a crime, punishable as specified. Existing law regulates the sale of livestock drugs by the secretary, and requires livestock drugs to be registered.

This bill would prohibit the secretary from registering a medically important antimicrobial drug, as defined, ~~for use on a food-producing animal~~, *which is administered to food animals, as defined, through feed or drinking water*, unless prescribed requirements are met. The bill would, *except as specified*, provide that a medically important antimicrobial drug currently registered with the department that does not meet the prescribed requirements has until January 1, 2017, to meet the prescribed requirements and reregister with the secretary. The bill would require a veterinarian-client-patient relationship, as described, to exist prior to the use of a medically important antimicrobial drug.

Because a violation of the bill's 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.

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 14288 of the Food and Agricultural Code
2 is amended to read:

3 14288. The secretary shall refuse to register a livestock drug
4 if he or she finds any of the following is true of the drug:

5 (a) It is of little or no value for the purpose for which it is
6 intended to be used.

7 (b) It is dangerous to the health of livestock if used in accordance
8 with the instructions.

9 (c) The instructions for use do not contain adequate warnings
10 against use in those conditions, whether pathological or normal,
11 under which its use may be dangerous to the health of livestock
12 or humans who consume products from the livestock, or against
13 unsafe dosage, unsafe duration of use, or unsafe methods of
14 administration.

15 (d) If the application and the accompanying material, data, and
16 information do not comply with the requirements of this chapter
17 or are insufficient to permit the secretary to make the
18 determinations that are required by this section.

19 (e) It is a medically important antimicrobial drug, as defined in
20 Section 18770, ~~for use in food-producing animals, which is~~
21 *administered to food animals, as defined in Section 4825.1 of the*
22 *Business and Professions Code, through feed or drinking water,*
23 unless the drug complies with Section 18771.

24 SEC. 2. Article 4.5 (commencing with Section 18770) is added
25 to Chapter 4 of Part 3 of Division 9 of the Food and Agricultural
26 Code, to read:

1 Article 4.5. Medically Important Antimicrobial Drugs

2
3 18770. For purposes of this article, the following definitions
4 apply:

5 (a) “FDA” means the federal Food and Drug Administration.

6 (b) “*Food animal*” has the same meaning as defined in
7 subdivision (c) of Section 4825.1 of the Business and Professions
8 Code.

9 ~~(b)~~

10 (c) “Medically important antimicrobial drug” means an
11 antimicrobial drug listed in Appendix A of the FDA Guidance for
12 Industry #152, including a critically important, highly important,
13 and important antimicrobial drug. The secretary ~~may determine~~
14 ~~that shall have the discretion to consider any updates changes to~~
15 this list by the FDA ~~are also to determine whether a substance is~~
16 a medically important antimicrobial ~~drugs~~ drug.

17 (d) “*Veterinary feed directive*” is the directive described in
18 Section 354 of Title 21 of the United States Code.

19 18771. To comply with FDA Guidance for Industry #213,
20 dated December 2013, a medically important antimicrobial drug,
21 including a combination drug incorporating a medically important
22 ~~anti microbial~~ antimicrobial drug, shall meet all of the requirements
23 in the guidance document, including, but not limited to, the
24 following:

25 (a) To reflect the need for professional oversight by a licensed
26 veterinarian, the manufacturer shall remove from the approved
27 production uses on the label of the medically important
28 antimicrobial drug or combination drug the production indications,
29 including, but not limited to, “increased rate of weight gain” or
30 “improved feed efficiency.”

31 (b) The manufacturer shall revise the condition of the use of the
32 medically important antimicrobial drug or combination drug from
33 over the counter availability to a marketing status requiring
34 veterinary prescription, including, but not limited to, the following:

35 (1) For medicated feed products, a change from over the counter
36 to veterinary feed directive.

37 (2) For medicated drinking water products, a change from over
38 the counter to veterinary prescription.

39 ~~The~~ When administered through feed or drinking water the
40 medically important antimicrobial drug may only be used to treat,

1 prevent, or control disease under the supervision of, or by
2 prescription from, a licensed veterinarian.

3 18772. There shall be a veterinarian-client-patient relationship
4 to ensure that a medically important antimicrobial drug is used in
5 a manner that is consistent with professionally accepted best
6 practices. For the purposes of this section, a
7 “veterinarian-client-patient relationship” is a relationship meeting
8 the requirements of Section 2032.1 of Title 16 of the California
9 Code of Regulations.

10 18773. (a) (1) If a medically important antimicrobial drug,
11 or combination drug, for use in ~~food-producing~~ *food* animals is
12 registered with the department as of January 1, 2015, and the drug
13 does not comply with Section 18771, the manufacturer of the
14 medically important antimicrobial drug, or combination drug, shall
15 have until January 1, 2017, to reregister the drug with the secretary.
16 The secretary shall refuse to reregister the drug unless it complies
17 with Section 18771.

18 (2) *Notwithstanding paragraph (1), if a drug label reviewed by*
19 *the FDA under the Guidance for Industry #213 is delayed beyond*
20 *January 1, 2017, the secretary shall have the authority to continue*
21 *registering the drug during the FDA’s review period.*

22 (3) *If revision to the veterinary feed directive causes the FDA*
23 *to delay implementation of the Guidance for Industry #213, the*
24 *secretary shall have the authority to extend the time period by*
25 *which a manufacturer is required to reregister the drug pursuant*
26 *to paragraph (1) to be consistent with the delay in the*
27 *implementation of the guideline. If the secretary extends the time*
28 *period for reregistration, the extension shall not be later than the*
29 *federal implementation date of the guidance.*

30 (b) *If revisions to the veterinary feed directive causes the FDA*
31 *to revise the Guidance for Industry #213, the secretary shall have*
32 *the authority to promulgate regulations to ensure that California*
33 *law is consistent with the revisions to the guidance.*

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

1 the meaning of Section 6 of Article XIII B of the California
2 Constitution.

O

Guidance for Industry

New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209

Submit comments on this guidance at any time. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. All written comments should be identified with the Docket No. FDA-2011-D-0889.

For further information regarding this document, contact William T. Flynn, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9084. E-mail: william.flynn@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
December 2013**

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Guidance for Industry

New Animal Drugs and New Animal Drug Combination Products, Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the number listed on the previous page of this guidance.

I. Introduction

This guidance is intended for sponsors of approved applications for new animal drugs and new animal drug combination products containing medically important antimicrobial new animal drugs for use in or on medicated feed or water of food-producing animals. The guidance contains information for sponsors of such new animal drugs and combination products to facilitate voluntary changes to the conditions of use for such new animal drugs and combination products consistent with FDA's recommendations included in the guidance document entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (Judicious Use Guidance, GFI #209). In particular, the purpose of this guidance is to provide sponsors with specific recommendations on how to supplement their approved new animal drug applications to align with FDA's GFI #209.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in FDA's guidances means that something is suggested or recommended, but not required.

II. Background

On April 11, 2012, FDA finalized a guidance document entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (Judicious Use Guidance, GFI #209). That final guidance represents the Agency's current thinking regarding antimicrobial drugs that are medically important in human medicine and used in food-producing animals. Specifically, the final guidance discusses FDA's concerns regarding the development of antimicrobial resistance in human and animal bacterial pathogens when medically important antimicrobial drugs are used in food-producing animals in an injudicious manner. In addition,

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the Judicious Use Guidance provides two recommended principles regarding the appropriate or judicious use of medically important antimicrobial drugs:

- (1) Limit medically important antimicrobial drugs to uses in animals that are considered necessary for assuring animal health, and
- (2) Limit medically important antimicrobial drugs to uses in animals that include veterinary oversight or consultation.

As noted above, the purpose of this guidance is to provide sponsors with specific recommendations on how to voluntarily modify the use conditions of their medically important antimicrobial drug products to align with the above two principles. The voluntary process outlined in this guidance would help to phase out the use of medically important antimicrobial drugs for production purposes and phase in veterinary oversight of therapeutic uses of these drugs.

A. Therapeutic Uses that Help Assure the Health of Animals

As discussed in GFI #209, FDA believes that, in light of the risk that antimicrobial resistance poses to public health, the use of medically important antimicrobial drugs for production purposes in food-producing animals does not represent a judicious use of these drugs. Such uses are typically administered through the feed or water on a herd- or flock-wide basis and are currently approved for such uses as increasing rate of weight gain or improving feed efficiency.

Production uses are not directed at any specifically identified disease, but rather are expressly indicated and used for the purpose of enhancing the production of animal-derived products. FDA believes that production use indications such as “increased rate of weight gain” or “improved feed efficiency” are no longer appropriate for the approved conditions of use for medically important antimicrobial drugs. In contrast, FDA considers uses that are associated with the treatment, control, and prevention of specific diseases to be therapeutic uses that are necessary for assuring the health of food-producing animals.

B. Veterinary Oversight

New animal drugs and new animal drug combination products are approved with one of three types of marketing status: (1) over-the-counter (OTC), (2) veterinary prescription (Rx), or (3) veterinary feed directive (VFD). Products for which adequate directions for use can be written for use by lay persons are labeled for OTC marketing status. When adequate directions can not be written in a manner that enables a layperson to use a drug safely and for the purposes for which it is intended, the drug is restricted to use under veterinary oversight as an Rx or VFD product.

FDA believes it is important to include veterinary oversight in the use of antimicrobial new animal drugs to assure their appropriate and judicious use. Veterinarians play a critical role in the diagnosis of disease and in the decision-making process related to instituting measures to treat, control, or prevent disease. As discussed in more detail below, FDA believes that the

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judicious use of medically important antimicrobial new animal drugs in the feed or water of food-producing animals needs the scientific and clinical training of a licensed veterinarian.

III. Medically Important Antimicrobial Drugs

FDA uses the concepts set out in its Guidance for Industry (GFI) #152, “*Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern*,” in reviewing the human food safety component of new animal drug applications for medically important antimicrobial new animal drugs for use in food-producing animals. Guidance for Industry #152 includes an appendix that ranks antimicrobial drugs into three tiers, “critically important,” “highly important,” or “important,” in regard to their human medical importance. At this time, FDA considers all antimicrobial drugs listed in Appendix A to GFI #152 (Appendix A) to be “medically important” in the context of implementing the recommendations outlined in GFI #209 and further discussed in this guidance document (GFI #213). We believe that the policy in GFI #209 and GFI #213 applies to all three tiers of medically important antimicrobial drugs at this time because each tier (and thus all of the drugs listed in Appendix A) contains drugs that have been previously assessed through the public processes used to develop GFI#152 and determined to be important for treating bacterial infections in people.

FDA recognizes that the list of drugs in Appendix A is not static and should be periodically reassessed and updated as necessary. Such reassessment is necessary to take into consideration such factors as the development of new antimicrobials for human therapy, the emergence of diseases in humans, or changes in prescribing practices in the United States. FDA intends to update Appendix A, as necessary, through a separate process that will also be subject to public comment. However, because Appendix A identifies those antimicrobials that have been determined to be medically important to human medicine, FDA believes the existing Appendix A provides adequate clarity for purposes of moving forward with the recommendations outlined in GFI #209. Therefore, the current list of medically important antimicrobial drug classes that are the subject of this guidance includes: aminoglycosides, lincosamides, macrolides, penicillins, streptogramins, sulfonamides, and tetracyclines.

IV. Voluntary Adoption of Judicious Use Principles

As discussed in the following section, FDA intends to work with affected drug sponsors to help them to voluntarily implement the principles described above through modifications to the approved conditions of use of their new animal drug products. FDA believes a voluntary approach, conducted in a cooperative and timely manner, is the most effective approach to achieve the common goal of more judicious use of medically important antimicrobials in animal agriculture.

FDA recognizes that it is equally important that the Agency also work with the veterinary and animal producer communities, the end users of these products, to ensure that their concerns are taken into consideration as these changes are implemented. One issue of concern is the

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ability of producers, particularly those with smaller operations in remote locations, to have adequate access to veterinary services. Therefore, as steps are taken to phase in the voluntary changes discussed in this document, FDA is working collaboratively with United States Department of Agriculture (USDA) to engage the veterinary community and other stakeholders to explore strategic approaches (e.g., new models, pilot programs) to address this issue.

A. Voluntarily Phasing out Production Uses

FDA is concerned about the risk that antimicrobial resistance poses to public health from the use of medically important antimicrobial drugs in food-producing animals for production purposes. As a consequence of this concern, FDA will be working with affected drug sponsors who wish to voluntarily withdraw approved production uses of their medically important antimicrobial new animal drugs and combination new animal drug products. This guidance is intended to facilitate the voluntary process by providing useful information for sponsors intending to revise their approved labeling through a supplemental new animal drug application. In addition, as discussed later in this guidance, FDA is asking affected sponsors to notify the Agency within 3 months from the date of publication of this final guidance to inform us of their intentions to make these voluntary changes.

B. Need for Veterinary Oversight of Medically Important Antimicrobial Drugs Used in the Feed or Water of Food-Producing Animals

Prior to 1993, most antimicrobial drugs were approved for over-the-counter use in food-producing animals and many of these were administered through medicated feed or drinking water. At that time, the methods used by FDA to assess the microbial food safety aspects of new animal drug applications for antimicrobials intended for use in food-producing animals were not as rigorous as those used today, in part because less scientific data about the public health ramifications of antimicrobial resistance existed at that time. In addition, FDA's recommended approach for conducting pre-approval microbial food safety assessments has evolved over time as the quantity and quality of epidemiologic and other data bearing on antimicrobial resistance has improved. As a result, all antimicrobial new animal drugs for use in food-producing animals approved by CVM since 1993 have been labeled with Rx or VFD marketing status, with the exception of approvals of generic copies of existing OTC products and approvals of combination medicated feeds using existing OTC antimicrobial Type A medicated articles¹. This shift to a marketing status requiring veterinary oversight was viewed as an important step to mitigate the microbial food safety risks of antimicrobial new animal drugs, particularly for those drugs considered to be medically important.

Based on the available scientific evidence concerning antimicrobial resistance, including information about resistance trends associated with the use of medically important antimicrobial drugs in food-producing animals, FDA believes that the judicious use of medically important antimicrobial drugs intended for use in food-producing animals should involve the scientific and

¹ A "Type A medicated article" is a concentrated new animal drug product used as a component in the manufacture of (1) another Type A medicated article, (2) an intermediate Type B medicated feed, or (3) a final formulation Type C medicated feed. See definition at 21 CFR 558.3(b)(2).

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clinical training of a licensed veterinarian. This is because judicious use involves accurately identifying bacterial disease that is present or likely to be present and selecting the suitable antimicrobial drug.

In the case of prevention, judicious use includes a consideration by the veterinarian of relevant factors for determining the risk of a specific bacterial disease and for determining whether the use of medically important antimicrobials for prevention purposes is appropriate in a particular situation. The decision by the veterinarian to use a specific approved drug or combination drug is based on factors such as the mode of antibacterial action, drug distribution in specific tissues, and the duration of effective drug levels at the site of infection. Other important factors veterinarians consider when determining the appropriateness of a preventive use include whether: (1) there is evidence of effectiveness, (2) such a preventive use is consistent with accepted veterinary practice, (3) the use is linked to a specific etiologic agent, (4) the use is appropriately targeted to animals at risk of developing a specific disease, and (5) no reasonable alternatives for intervention exist. Numerous risk factors have been documented to increase susceptibility to bacterial disease, including environmental factors (such as temperature extremes and inadequate ventilation), host factors (such as age, nutrition, genetics, immune status), and other factors (such as stress of animal transport). From FDA's standpoint, the administration of a drug to animals when a veterinarian determines that there is a risk of a specific disease, based on the presence of such risk factors, could be considered judicious prevention use. For example, if a veterinarian determines, based on the client's production practices and herd health history, that cattle being transported or otherwise stressed are more likely to develop a certain bacterial infection, preventively treating these cattle with an antimicrobial approved for prevention of that bacterial infection would be considered a judicious use. Another example would be the prevention of necrotic enteritis in broiler chickens. In this case, the preventive use of an antimicrobial approved for such use is important to manage this disease in certain flocks in the face of concurrent coccidiosis, a significant parasitic disease in chickens. On the other hand, FDA would not consider the administration of a drug to apparently healthy animals in the absence of any information that such animals were at risk of a specific disease to be judicious. FDA believes that veterinarians are uniquely qualified to determine which specific disease-causing microorganisms are likely to be present in a particular situation and to determine appropriately timed administration to prevent disease based on specific, known risk.

For these reasons, in FDA's 1999 proposed rule on veterinary feed directives (64 FR 35966; July 2, 1999), the Agency gave antimicrobial resistance as a key example of a reason it can be important for medicated feed to be administered under a veterinarian's supervision. FDA stated, "control of the usage of certain antimicrobials is critical to reducing unnecessary use of such drugs in animals and to slowing or preventing the development of bacterial resistance to antimicrobial drugs."

Accordingly, FDA recommends that affected drug sponsors voluntarily revise the conditions of use of their medically important antimicrobial new animal drugs and combination new animal drug products to reflect the need for the professional oversight of a licensed veterinarian. This would mean a change from OTC to VFD status for medicated feed products and from OTC to Rx status for medicated drinking water products. A proposed timeline for making such changes is discussed in more detail below. FDA acknowledges that in order to facilitate the OTC to VFD change in marketing status, existing requirements related to the

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distribution and use of VFD drugs must be updated and streamlined. Therefore, concurrent with the development of this guidance, FDA is actively pursuing revisions to the VFD regulations (in 21 CFR part 558) through the rulemaking process. Some of the key changes being considered include better alignment between the criteria for appropriate veterinary supervision or oversight and those established as part of veterinary licensing and practice requirements and streamlining administrative procedures. To facilitate the transition from OTC to VFD status, FDA believes it is critically important that changes such as these be implemented to minimize impacts on veterinarians, the animal feed industry, and animal producers.

While FDA believes that all medically important antimicrobial new animal drug products should be marketed with the appropriate professional oversight restriction, at this time FDA is most concerned with medically important antimicrobial new animal drugs and combination new animal drug products intended for use in or on the feed or water of food-producing animals. As discussed in GFI#209, FDA's current methodology for assessing antimicrobial risks associated with the use of antimicrobial new animal drugs in food-producing animals is premised on the concept that increasing the exposure of bacterial populations to antimicrobial drugs increases the risk of generating resistance to those antimicrobial drugs. Because feed or water use antimicrobial drugs are typically administered to entire herds or flocks of food-producing animals, such uses pose higher risk to public health than the administration of such drugs to individual animals or targeted groups of animals. For that reason, this guidance is focused on those medically important antimicrobial new animal drugs that are approved for use in the feed or water of food-producing animals.

C. Additional Considerations.

It is important to note that any extralabel use of medicated feed is not permitted by law (see sections 512(a)(2) and (a)(4)(A) of the FD&C Act). Neither veterinarians nor their clients may use, or direct the use of, a medicated feed in an extralabel manner. Therefore, when production claims for medically important antimicrobials are voluntarily removed from the approved labeling of these drugs, consistent with the judicious use principles of GFI #209, any further use of a drug without a production claim in medicated feed for production purposes will be considered an extralabel use and, thus, illegal.

V. Timeline for Voluntarily Implementing Changes

The Agency recognizes the significance of the proposed changes and the potential impacts such changes will have on the animal pharmaceutical industry, animal producers, the animal feed industry, and the veterinary profession. For this reason, FDA is currently pursuing a strategy for the voluntary adoption of these changes in an effort to minimize the impacts and provide for an orderly transition. FDA encourages all sponsors of affected new animal drugs and new animal drug combination products to contact the Agency and initiate steps to change product labeling and approved conditions of use through the process outlined in this guidance.

FDA also believes it is critical to see meaningful progress toward eliminating production uses of medically important antimicrobial drugs and bringing the remaining therapeutic uses of such drugs in or on the feed or water of food-producing animals under the oversight of

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veterinarians. In order to ensure progress under the cooperative framework outlined in this guidance, FDA will monitor progress to assess whether these changes are being adopted along the timelines discussed below. FDA is confident that the objective of phasing in these changes can be met through the cooperative process discussed in this guidance, which is why we are initially pursuing this voluntary approach. If, after the period of evaluation of the three year phase in, we determine that adequate progress has not been made, we will consider whether further action under the existing provisions of the FD&C Act may be appropriate. To assist FDA in effectively monitoring rates of adoption in the industry, we request that sponsors of affected products (i.e., those products containing antimicrobial new animal drugs of importance to human medicine that are administered in medicated feed or drinking water of food-producing animals) notify the Agency of their intentions to engage in the voluntary process to modify their product labeling within 3 months from the date of publication of this final guidance. FDA anticipates that sponsors of affected products should be able to complete implementation of the changes discussed in this final guidance within 3 years of the date of publication.

FDA intends to keep the public apprised of progress. First, FDA is making public on its website a listing of all antimicrobial products affected by the guidance. Second, FDA intends to notify affected drug sponsors and, following the 3-month notification period, FDA intends to publish summary information to provide an indicator of the level of engagement of affected drug sponsors in the voluntary process. In addition, the public will be notified of completed changes to affected products through publication of approval of supplemental new animal drug applications.

Upon issuance of this final guidance, the Agency will monitor the progress of its strategy for the voluntary adoption of the changes outlined, including the progress of measures intended to facilitate an orderly and minimally disruptive transition. Three years from the date of publication of this final guidance, FDA intends to evaluate the rate of adoption of the proposed changes across affected products. The Agency will then consider further action as warranted in accordance with existing provisions of the FD&C Act for addressing matters related to the safety of approved new animal drugs.

FDA recognizes that the proposed changes in the use of these antimicrobial drugs have significant practical implications for animal producers, veterinary practitioners, animal drug sponsors, and feed mills. In particular, as mentioned previously, implementing changes to streamline existing VFD requirements is pivotal to facilitating the transition to greater veterinary oversight (i.e., from OTC to VFD marketing status) for many of these products. Therefore, the 3-year timeframe for voluntary phase-in noted above is intended to provide sufficient time for the necessary changes to the existing VFD requirements to be developed and implemented through notice and comment rulemaking. Although FDA is committed to completing this rulemaking process within the 3-year timeframe for implementing the changes discussed in this guidance, FDA is prepared to extend the timeframe, as necessary, to ensure that it coincides with the implementation of the revised VFD requirements.

The 3-year timeframe for voluntary phase-in is also intended to provide time for animal drug sponsors to make these changes in an efficient and practical manner, and for other stakeholders to prepare for the resulting changes in management/business practices. When several approved products are involved (e.g., combination drug approvals containing the same

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active ingredients; same active ingredient in different dosage forms), sponsors are encouraged to coordinate implementation when practicable.

VI. Supplemental New Animal Drug Applications

A. Removing Production Uses/Changing Marketing Status

The procedures in this section (VI.A) apply to the situation where no new indications are being proposed. In the limited circumstances where a sponsor would be proposing that a new therapeutic indication be added, the procedures set forth at section VI.B below for submitting a supplemental application should be followed instead. As always, FDA encourages sponsors to consult with FDA prior to submitting supplemental applications to ensure that sponsors are targeting their submissions to answer questions that are relevant to the particular drug. The recommendations below, which, as guidance, establish no legally enforceable requirements, apply when sponsors who wish to voluntarily pursue judicious use changes are submitting supplemental new animal drug applications under 21 CFR 514.8.

1. Administrative Procedures

Sponsors who wish to voluntarily remove production use claims and change the marketing status for the remaining approved feed or water uses of affected products should indicate that their supplemental application is being submitted in accordance with GFI #213. Such supplemental applications do not need to include additional safety or effectiveness data. Sponsors of such applications would either (1) propose to change the marketing status to VFD or Rx and voluntarily withdraw the approval for all production uses or (2) for those applications without approved production uses, such sponsors would only propose a change in marketing status to VFD or Rx. No new indications would be proposed by the sponsors and in most cases the sponsors would only be required to submit revised labeling.

2. Applicable Supplemental New Animal Drug Application Technical Sections

Type A medicated articles and their associated medicated feeds should bear the VFD statement found in this Agency's regulations at 21 CFR 558.6(f) and medicated drinking water products (e.g., water soluble powders, concentrated solutions, etc.) should bear the Rx statement found in section 503(f)(4) of the FD&C Act (21 U.S.C. 353(f)(4)). The Type A medicated article and representative medicated feed labeling (Blue Bird) should be included in the supplemental application to verify: 1) the VFD statement found in this Agency's regulations at 21 CFR 558.6(f) has been appropriately added to all the labeling (Type A medicated article and Blue Bird feed labeling), and 2) the indications, mixing directions, feeding directions, etc., have been revised to reflect the voluntary withdrawal of the production use(s). Labeling for medicated drinking water products should be included in the supplemental application to verify: 1) the Rx statement found in section 503(f)(4) of the FD&C Act (21 U.S.C. 353(f)(4)) has been appropriately added to the labeling, and 2) the indications, directions for use, etc., have been revised to reflect the voluntary withdrawal of the production use(s).

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B. Adding New Therapeutic Indications

In some cases, it has been suggested that there could be a therapeutic benefit associated with the production use of a drug. In situations where this could be the case, concerns have been raised that removing production uses from approved conditions of use will have negative animal health impacts. In those cases, where scientific evidence demonstrates a therapeutic benefit associated with the use of the drug for treating, controlling, or preventing a particular disease, sponsors could wish to seek new therapeutic indications to fill the therapeutic needs of animals.

FDA stresses that such new indications must be based on scientific evidence that such drug is safe and effective for the intended therapeutic use. Such new therapeutic indications should be directed at specifically identified diseases and should involve dosage regimens that provide the desired therapeutic effect while minimizing overall extent of use.

1. Administrative Procedures

Sponsors who wish to seek new therapeutic indications for use of affected products should indicate that their supplemental application is being submitted in accordance with GFI #213. Because new therapeutic indications are being proposed, these supplemental applications require the inclusion of additional safety and effectiveness data. These supplemental applications would need to include specific information as follows:

2. Applicable Supplemental New Animal Drug Application Technical Sections

a. Labeling

Type A medicated articles and their associated medicated feeds should bear the VFD statement found in this Agency's regulations at 21 CFR 558.6(f) and medicated drinking water products (e.g., water soluble powders, concentrated solutions, etc.) should bear the Rx statement found in section 503(f)(4) of the FD&C Act (21 U.S.C. 353(f)(4)). The Type A medicated article and representative medicated feed labeling (Blue Bird) should be included in the supplemental application to verify: 1) the VFD statement found in this Agency's regulations at 21 CFR 558.6(f) has been appropriately added to all the labeling (Type A medicated article and Blue Bird feed labeling), and 2) the indications, mixing directions, feeding directions, etc., have been revised to reflect the voluntary withdrawal of the production use(s). Labeling for medicated drinking water products should be included in the supplemental application to verify: 1) the Rx statement found in section 503(f)(4) of the FD&C Act (21 U.S.C. 353(f)(4)) has been appropriately added to the labeling, and 2) the indications, directions for use, etc., have been revised to reflect the voluntary withdrawal of the production use(s). In both cases, the labeling would need to reflect the new therapeutic indications for use.

b. Chemistry, Manufacturing, and Controls

The recommendations in this section assume there is no change in the chemistry, manufacturing and controls (CMC) information for the Type A medicated article or medicated drinking water products, including the product formulation, raw materials, manufacturing process, controls and packaging. If there are changes to the CMC information for the Type A

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medicated article or medicated drinking water product associated with the new therapeutic indication, the sponsor should provide a description of such changes in the supplemental application, along with appropriate documentation and data to support the changes. See 21 CFR 514.8(b).

Medicated Drinking Water Product

If the new indication provides for use of the medicated drinking water product at the same concentration or concentration range as currently approved, no additional chemistry, manufacturing and controls (CMC) information is required. If the medicated drinking water product will be used to prepare medicated water at a different concentration than currently approved, the sponsor should address stability of the medicated drinking water at the new concentration (Ref. 1).

Type A Medicated Article

If the new indication is for a currently approved species and provides for a medicated feed inclusion rate currently approved for that species, no additional CMC information is required.

If the new indication is for a medicated feed inclusion rate outside of the currently approved inclusion rate or range (i.e., lower than the lowest currently approved inclusion rate or higher than the highest currently approved inclusion rate for that species), the sponsor should address homogeneity, non-segregation, and stability of the drug in representative medicated feeds at the higher/lower inclusion rate (Ref. 1). In addition, the sponsor should demonstrate that the approved medicated feed assay method is valid for assay of feeds manufactured at the higher/lower inclusion rate or provide a new method that is capable of assaying the feed (Refs. 2, 3, and 4).

If the new indication is for a species not currently approved, the sponsor should address homogeneity, non-segregation, stability, and medicated feed assay methodology in representative medicated feeds at the highest and lowest proposed medicated feed inclusion rates.

c. Human Food Safety

Toxicology/Residue Chemistry

Toxicology information associated with the original approval was considered for currently approved antimicrobial new animal drugs, and that information was the basis of the acceptable daily intake (ADI) that drove the residue chemistry conclusions (target tissue, tolerance, withdrawal times, etc.) for those approvals. The toxicological assessment is not expected to be reconsidered under proposed therapeutic indications with similar conditions of use to those corresponding to the production use (see Impact on Human Intestinal Flora below). If a new, proposed therapeutic indication has corresponding conditions of use (same species, with dose/duration/formulation/route of administration, etc.) that fit within existing residue chemistry parameters and are covered by previous residue chemistry evaluations, we do not anticipate that the sponsor will need to provide additional residue chemistry data or information. Sponsors are encouraged to contact CVM if they have any toxicological assessment questions.

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Microbial Food Safety

Antimicrobial Resistance

It should be noted that, at the time of the original approval of older antimicrobial new animal drug applications, microbial food safety was most likely not considered in the same way or to the same extent as is currently the case. The Agency is concerned, consistent with the general elements of judicious use discussed in section II above and GFI#152, that giving antimicrobial drugs to food-producing animals at low levels for long periods of time and in large numbers of animals may contribute to antibiotic resistance. We expect any new indication(s) to (1) have an explicitly defined duration of dosing, (2) specify a therapeutic dose level, and (3) be available only to those animals that need the drug for the new indication, rather than the entire flock or herd when such use is not necessary.

Generally, these changes are expected to remove injudicious use indications, and to result only in the therapeutic use of medically important antimicrobial drugs in or on the feed or water of food-producing animals. In addition, such indications for use should include risk mitigation measures intended to reduce antimicrobial resistance when these drugs are used in or on the feed or water of food-producing animals.

To assure these goals have been met, the approval of any new indications for use would also necessitate that microbial food safety concerns be addressed consistent with the objectives of GFI #152. Prior to submission of an application, sponsors should discuss with CVM the type of information needed for this purpose. This information may include, but is not limited to:

- (1) Basic information on the subject antimicrobial new animal drug, including information on mechanisms of action, spectrum of activity, resistance mechanisms, transfer of resistance, pharmacokinetics and/or pharmacodynamics if known, proposed conditions of use and how these could influence resistance development, and information on susceptibility among bacteria of human health concern;
- (2) Information on the use of the subject antimicrobial new animal drug in or on the feed or water of food-producing animals, focusing on numbers of animals treated, class, consumption rates for food products from treated animals, and rates of contamination by bacteria of human health importance.
- (3) Information on the use of the subject antimicrobial drug (or drugs similar to the subject drug) in human medicine. This information should address how loss of susceptibility of organisms of human health concern to the subject antimicrobial drug (or drugs similar to the subject drug) could impact human clinical medicine.
- (4) Information detailing how FDA's general elements of judicious use discussed in section II have been addressed. Specifically, all approved indications should be for treatment, control and/or preventive use only, require veterinary oversight, and restrict use to an explicitly defined duration of dosing. FDA considers these measures to be significant risk mitigations consistent with the goals of GFI #152.

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Upon review of this information, the Agency should be able to: 1) identify appropriate risk mitigations that would enable us to determine that the proposed use of the drug in food-producing animals is safe (i.e., a reasonable certainty of no harm to human health); and 2) advise on the types of additional information or data needed to address any existing data gaps associated with the new, proposed use of the subject antimicrobial new animal drug.

Impact of Antimicrobial Residues on Human Intestinal Flora

Based on the expected changes in use patterns for new indications described in the previous section, we do not anticipate that this issue will need to be addressed by sponsors. However, if changes in conditions of use (dose/duration/formulation/route of administration) are proposed that are expected to increase overall human exposure to residues of antimicrobial new animal drugs in animal-derived food products, then sponsors will be asked to address the safety of their proposed use with respect to impact of residues or metabolites of antimicrobial new animal drugs and compounds with antimicrobial activity on the intestinal flora of human consumers (Ref. 5).

d. Target Animal Safety

Regarding previously approved antimicrobial new animal drugs, target animal safety information associated with the original approval has already been considered. As long as any new, proposed therapeutic indication has conditions of use that are covered by previous target animal safety evaluations (same species, a dose within the approved dosage range, same or shorter duration, same route of administration, same formulation), we do not anticipate that the sponsor will need to provide additional data or information, unless the Agency becomes aware of human or animal health concerns that were not apparent at the time of the original target animal safety evaluation.

e. Evidence of Effectiveness

Sponsors seeking approval of a new therapeutic indication should provide substantial evidence in support of the effectiveness of the new animal drug for the proposed new therapeutic indication. As described in 21 CFR 514.4, the sponsor should provide information that will allow the Agency to determine that:

- parameters selected for measurement and the measured responses reliably reflect effectiveness;
- the results obtained are likely to be repeatable;
- valid inferences can be drawn from these sources to the use of the new animal drug in the target population; and
- the new animal drug is effective for the new therapeutic indication under the proposed conditions of use.

The type of information required to demonstrate effectiveness will need to be determined on a case-by-case basis and be consistent with substantial evidence as described in 21 CFR 514.4. The Center will consider data from a wide variety of sources including literature, data generated by food animal production facilities or universities, and other existing information for a substantial evidence package. Sponsors should not limit their consideration of potential useful

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data to only data that is prospectively generated. Previously approved therapeutic indications that are very similar or “related” to the new therapeutic indication could also provide inferential value in support of the new indication (e.g., a new “control of bovine respiratory disease” indication added to an application that has a previously approved “treatment of bovine respiratory disease” indication with a similar dosage regimen).

Sponsors are encouraged to discuss approaches to satisfying the requirements of substantial evidence of effectiveness with CVM.

f. Environmental Impact

By regulation (see 21 CFR 514.1(b)(14)), the Environmental Impact section must include either an environmental assessment (EA) (see 21 CFR 25.40), or a claim for categorical exclusion (see 21 CFR 25.30, 25.33). Under 21 CFR 25.15(a), a claim of categorical exclusion must include a statement of compliance with the categorical exclusion criteria and must state that to the sponsor’s knowledge, no extraordinary circumstances exist. “Environmental Impact Considerations” and directions for preparing an EA can be found in 21 CFR Part 25.

VII. Generic Drugs and Combinations

Revising the conditions of use in applications for a pioneer single ingredient new animal drug products may have an effect on abbreviated (generic) new animal drug applications and combination new animal drug applications that reference these single ingredient products. The effects that submission and approval of a supplement for the pioneer drug may have on these generic or combination drugs are discussed in this section. FDA intends to work expeditiously with the sponsors of affected generic and combination new animal drug applications to align their products with the revised conditions of use specified in the referenced (i.e., pioneer) applications for the single ingredient new animal drug products.

A. Generic Applications

If the approved conditions of use for a new animal drug application for a medically important antimicrobial new animal drug are revised under this guidance by voluntarily withdrawing a production use, the approved labeling for any currently approved generic application(s) that references the original new animal drug application must generally be revised in a similar fashion, as is now standard practice. FDA will contact affected generic drug sponsors when these revisions become necessary. Consistent with current practice, we expect that the generic sponsor will submit a supplemental application to come into compliance with the revised labeling of the reference listed new animal drug (RLNAD) within 60 days after FDA notifies the generic sponsor that the approved conditions of use for the RLNAD have been revised. In such cases, if the generic labeling is not revised accordingly, the generic application holder(s) faces the possibility of suspension of the generic application under section 512(c)(2)(G) of the FD&C Act (21 U.S.C. 360b(c)(2)(G)). With regard to suspension, FDA intends to follow the procedures outlined in its regulations at 21 CFR 314.153(b) relating to human generic drug

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suspensions until generic new animal drug regulations implementing section 512(c)(2)(G) of the FD&C Act (21 U.S.C. 360b(c)(2)(G)) are finalized.

In addition, any future generic sponsor that wants to use such a drug as its referenced listed new animal drug cannot include the production use that was voluntarily withdrawn from the pioneer application in its generic application because under section 512(n)(1)(F) of the FD&C Act (21 U.S.C. 360b(n)(1)(F)) the generic sponsor must submit labeling that is the same as the labeling approved for the referenced listed new animal drug with a few exceptions not relevant here. Furthermore, under section 512(c)(2)(A)(vii) of the FD&C Act (21 U.S.C. 360(c)(2)(A)(vii)), the Agency cannot approve an abbreviated new animal drug application unless the labeling proposed for the generic product is the same as the labeling approved for the referenced listed new animal drug with a few exceptions not relevant for purposes of this draft guidance.

B. Combination New Animal Drugs

The term *Combination new animal drug* is defined in the substantial evidence provisions of 21 CFR Part 514 to mean a new animal drug that contains more than one active ingredient or an animal drug that is applied or administered simultaneously in a single dosage form or simultaneously in or on animal feed or drinking water (See 21 CFR 514.4(c)(1)(i)). Although the term combination new animal drug applies both to products intended for use in or on animal feed and products intended for use in the drinking water of animals, the majority of approved combination new animal drug products are feed use combination drug products.

Most feed use combination new animal drugs are combinations of individual Type A medicated articles that have previously been separately approved. So, for example, a 3-way feed use combination actually involves four approved new animal drug applications, one for the combination and one for each of the three individual Type A medicated articles. The holder of an approved feed use combination new animal drug application is typically also the holder of an approved application for at least one of the individual Type A medicated articles in the combination.

1. Production Uses.

As discussed above, FDA is requesting affected sponsors to voluntarily withdraw production uses of their medically important antimicrobial new animal drugs and combination new animal drug products. In those instances where an approved combination new animal drug product with a production claim includes a medically important antimicrobial new animal drug and the sponsor of the individually approved new animal drug application for a medically important antimicrobial new animal drug has voluntarily withdrawn the production use claims, FDA expects the sponsor of the affected combination new animal drug product will voluntarily follow suit and similarly withdraw the production use claim from the combination new animal drug application. If sponsors of these affected combination new animal drug products do not voluntarily withdraw the production use claim from the combination new animal drug application, FDA intends to consider further action as warranted in accordance with existing provisions of the FD&C Act for addressing matters related to the safety of approved combination new animal drugs.

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2. Remaining Therapeutic Uses.

As discussed at section IV above, based on a number of factors FDA believes that the judicious use of medically important antimicrobial drugs intended for use in food-producing animals needs the scientific and clinical training of a licensed veterinarian. This belief applies not only to individual medically important antimicrobial new animal drugs but also to combination new animal drug products incorporating such drugs. However, as previously discussed, in recognition of the significant practical implications of revising the marketing status for these products, FDA has expressed its intent to pursue a strategy for voluntarily phasing in these changes over time in an effort to minimize the impacts and provide for an orderly transition. As explained more fully in section V, FDA is proposing clear timelines for sponsors of the affected products to make these changes in order to ensure effective progress under the cooperative framework outlined in this guidance.

However, once a sponsor of an individual Type A medicated article that is also part of a combination new animal drug submits a supplement to switch the marketing status of the individual product to VFD or Rx, FDA expects the sponsor of the affected combination new animal drug product to voluntarily follow suit. Indeed, for a combination new animal drug product containing individual Type A medicated articles intended for use in or on animal feed, this outcome is essentially compelled since a voluntary switch to VFD marketing status by one or more of the sponsors of the individual Type A medicated articles will automatically trigger the requirement for a VFD to be issued before the affected combination new animal drug product can be used in or on animal feed. This is the case because under section 504(a)(1) of the FD&C Act, “[a]ny animal feed bearing or containing a veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian’s professional practice.” (21 USC 354(a)(1)). Thus, the requirement for a VFD to be issued applies whenever a VFD drug will be used in feed, regardless of whether the VFD drug is being used by itself or in combination with other drugs. Because a voluntary switch to VFD marketing status by one or more of the Type A medicated articles contained in a combination new animal drug product results, by operation of law, in the requirement for a VFD to be issued before a feed containing the combination new animal drug product can be fed to animals, in effect, the combination new animal drug product takes on VFD status also.

Therefore, we believe that in such instances the combination new animal drug product sponsors should also submit their own supplements to formally change the marketing status of the affected combination new animal drug products to VFD in a timely manner.

This outcome is consistent with the Agency’s policy, as expressed in the substantial evidence notice of proposed rulemaking (62 FR 59835; Nov. 5, 1997) which provides that a combination new animal drug should generally bear VFD or Rx marketing status if one or more of the new animal drugs that make up the combination product were individually approved with VFD or Rx marketing status for any of the intended uses or conditions of use that are also applicable to the combination product.

VIII. References

1. FDA 2008. Guidance for Industry 5: Drug Stability Guidelines
2. FDA 2005. Guidance for Industry 135: Validation of Analytical Procedures for Type C Medicated Feeds
3. FDA 2007. Guidance for Industry #136: Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods
4. FDA 2007. Guidance for Industry #137: Analytical Methods Description for Type C Medicated Feeds
5. FDA 2013. Guidance for Industry #159: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI VICH GL36(R)
6. FDA 2012. Guidance for Industry #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals

Attachment 5

**Approved by the Office of Administrative Law
Filed with the Secretary of State
Effective Date 4/1/14**

§ 1745. Partial Filling of Schedule II Prescriptions.

(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code section 11055) may be partially filled, as defined in paragraph (b), if:

(1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code section 1250; or

(2) The prescription is for a terminally ill patient. "Terminally ill" as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.

(b) A "partially filled" prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.

(c) When partially filling a prescription pursuant to subsection (a), all of the following conditions must be met:

(1) The prescription must be tendered and at least partially filled within 60 days following the date of issue;

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

(3) No portion of the prescription is dispensed more than 60 days from the date of issuance of the prescription; and

(d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4301,

Business and Professions Code; and Sections 11055, 11153, 11154, 11166, 11200, Health and Safety Code.

§ 1762. Unprofessional Conduct Defined.

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(c) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Note: Authority: Section 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code.

§ 1769. Criteria for Rehabilitation

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

(b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

(1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.

(2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).

(4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) Evidence, if any, of rehabilitation submitted by the applicant.

(c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4200 and 4400, Business and Professions Code.

Attachment 6

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 1 [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 7

**Approved by the Office of Administrative Law
Filed with the Secretary of State
Effective Date 7/1/14**

To Amend § 1749 in Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1749. Fee Schedule.

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars (\$520). The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars (\$325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars (\$105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars (\$130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars (\$65).

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars (\$260).

(e) The fee for regrading an examination is one hundred fifteen dollars (\$115).

(f) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars (\$195).

(g) The fee for the biennial renewal of a pharmacist's license is one hundred ninety-five dollars (\$195). The penalty fee for failure to renew is ninety-seven dollars fifty cents (\$97.50).

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars (\$165). The penalty for failure to renew is eighty two dollars fifty cents (\$82.50).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars (\$195). The penalty for failure to renew is ninety seven dollars and fifty cents (\$97.50).

- (k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (l) The fee for an intern pharmacist license is one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars (\$30).
- (m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars (\$100).
- (n) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.
- (o) The fee for the issuance of a clinic license is five hundred twenty dollars (\$520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars (\$195). The penalty for failure to renew is ninety-seven dollars and fifty cents (\$97.50).
- (r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars (\$325). The fee for the issuance of a temporary license is two hundred and fifty dollars (\$250). The penalty for failure to renew is one hundred twenty-five dollars (\$125).
- (s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars (\$45).
- (t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be \$800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be \$800. The penalty for failure to renew is one hundred fifty dollars.

Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4400, 4401 and 4403, Business and Professions Code.

Attachment 8

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~~ ~~+~~ ~~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 reproof.

(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 reproof.

(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 reproof.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4112, 4161, 4300, 4301, Business and Professions Code

1 **Title 16. Board of Pharmacy**
2 **Proposed Language**
3

4 **To Amend § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to**
5 **read as follows:**

6 **§ 1732.05. Accreditation Agencies for Continuing Education.**

7 (a) The following organizations are approved accreditation agencies:

8 (1) The Accreditation Council for Pharmacy Education.

9 (2) The ~~Pharmacy Foundation of California~~ [California Pharmacists Association](#).

10 (b) Accreditation agencies shall:

11 (1) Evaluate each continuing education provider seeking accreditation in accordance with the
12 provider's ability to comply with the requirements of section 1732.1 of this Division.

13 (2) Maintain a list of the name and address of the person responsible for the provider's continuing
14 education program. The accreditation agency shall require that any change in the responsible person's
15 identity shall be reported to the accreditation agency within 15 days of the effective date of the
16 change.

17 (3) Provide the board with the names, addresses and responsible party of each provider, upon request.

18 (4) Respond to complaints from the board, providers or from pharmacists concerning activities of any
19 of its accredited providers or their coursework.

20 (5) Review at least one course per year offered by each provider accredited by the agency for
21 compliance with the agency's requirements and requirements of the board and, on request, report the
22 findings of such reviews to the board.

23 (6) Take such action as is necessary to assure that the continuing education coursework offered by its
24 providers meets the continuing education requirements of the board.

25 (7) Verify the completion of a specific continuing education course by an individual pharmacist upon
26 request of the board.

27 (c) Substantial failure of an approved accreditation agency to evaluate continuing education providers
28 as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation
29 agency by the board.

30
31 Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232,
32 Business and Professions Code.

34 **To Amend § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read**
35 **as follows:**

36 **§ 1732.2. Board Accredited Continuing Education**
37

38 (a) Individuals may petition the board to allow continuing education credit for specific coursework
39 which is not offered by a provider but meets the standards of Section 1732.3.

40 (b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance
41 to pharmacy practice and has been approved for continuing education by the Medical Board of
42 California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the
43 Dental Board of California shall, upon satisfactory completion, be considered approved continuing
44 education for pharmacists.

45 (c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing
46 the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to
47 section 4200.2 of the Business and Professions Code may annually be awarded up to six hours of
48 continuing education for conducting a review of exam test questions. A subcommittee member shall
49 not receive continuing education hours pursuant to this subdivision if that subcommittee member
50 requests reimbursement from the board for time spent conducting a review of exam test questions.

51 (d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six
52 hours of continuing education per renewal period. The board shall designate on its public agenda
53 which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician
54 requesting continuing education pursuant to this subdivision must sign in and out on an attendance
55 sheet at the board meeting that requires the individual to provide his or her first and last name, license
56 number, time of arrival and time of departure from the meeting.

57 (e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be
58 awarded two hours of continuing education per renewal period. A pharmacist or pharmacy technician
59 requesting continuing education hours pursuant to this subdivision must sign in and out on an
60 attendance sheet at the committee meeting that requires the individual to provide his or her first and
61 last name, license number, time of arrival and time of departure from the meeting.

62 (f) An individual may be awarded three hours of continuing education for successfully passing the
63 examination administered by the Commission for Certification in Geriatric Pharmacy.
64

65 Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232,
66 Business and Professions Code.

67 **To Amend § 1732.5 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read**
68 **as follows:**

69 **§ 1732.5. Renewal Requirements for Pharmacist.**

70

71 (a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this
72 Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the
73 board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

74 (b) At least six of the 30 units required for pharmacist license renewal shall be completed in one or
75 more of the following subject areas:

76 1. Emergency/Disaster Response

77 2. Patient Consultation

78 3. Maintaining Control of a Pharmacy's Drug Inventory

79 4. Ethics

80 5. Substance Abuse

81 Pharmacists renewing their licenses which expire on or after July 1, 2015, shall be subject to the
82 requirements of this subdivision.

83 ~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four years following completion
84 of a continuing education course.

85

86 Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and
87 4232, Business and Professions Code.

1 **Draft Proposed Text**

2 **Amend Title 16 California Code of Regulations Section 1703**

3 **Related to Delegation of Certain Functions**

4
5 **§ 1703. Delegation of Certain Functions.**

6 The power and discretion conferred by law upon the board to receive and file accusations; issue
7 notices of hearing, statements to respondent and statements of issues; receive and file notices of
8 defense; determine the time and place of hearings under Section 11508 of the Government Code; set
9 and calendar cases for hearing and perform other functions necessary to the business-like dispatch of
10 the business of the board in connection with proceedings under the provisions of Sections 11500
11 through 11528 of the Government Code, prior to the hearing of such proceedings; the certification and
12 delivery or mailing of copies of decisions under Section 11518 of said code; ~~and~~ issue summary
13 suspension orders or notices of suspension under Section 4311 of the Business and Professions Code;
14 and make changes to its regulations without regulatory effect pursuant to Title 1, California Code of
15 Regulations section 100 are hereby delegated to and conferred upon the executive officer, or, in his or
16 her absence from the office of the board, the acting executive officer.

17 Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and
18 4311, Business and Professions Code.