



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 January 29, 2014.

a. LEGISLATION REPORT

The California Legislature reconvened on January 6, 2014.

1. Status of Board-Sponsored Provisions

Attachment 1

A. Issuance of a Public Reprimand for Violations That Would Not Warrant License Denial or Issuance of a Probationary License

In May 2012, the board voted to sponsor a statutory provision to authorize the board to issue a public reprimand for violations that may not warrant license denial or issuance of a probationary license. Any such reprimand issued with a license would constitute discipline, and would be reported to the National Practitioner Data Bank. Staff continues to work to secure an author to carry the proposal. A copy of the board-approved text is provided in Attachment 1.

B. Designated Representatives – Minimum Age Requirement

In 2012, the board voted to amend Business and Professions Code Section 4053 to amend requirements related to Designated Representatives. The board-sponsored provisions were included in the Senate Committee on Business, Professions and Consumer Protection's 2013 omnibus measure, SB 821. Following introduction of Senate Bill 821, the board voted to also require that a designated representative meet a minimum age requirement of 18 years of age. This amendment will be provided for inclusion in the 2014 omnibus committee bill. A copy of the approved language is provided in Attachment 1.

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

Attachment 2

A. AB 467 (Stone) Prescription Drug Collection and Distribution Program

Last Amend: January 7, 2014
Board Position: Support (1/10/14)
Status: Passed SEN Business, Professions and Economic Development (1/13); referred to SEN Appropriations

A copy of the bill and the board's support letter are provided in Attachment 2. As recently amended, AB 467 will require Prescription Drug Collection and Distribution Program "intermediaries" to be licensed with the board. Within the scope of that license, these intermediaries may facilitate the donation and distribution of donated medications to and from participating programs. The bill requires an intermediary to be licensed, and to renew the license yearly.

The fee for such an intermediary license and renewal is \$300 but provisions allow non-profit organizations, as defined, to be fee exempt. The bill has an "urgency clause" which means that upon signature by the Governor, the provisions would be effective.

Recommendation: Ratify the "Support" position taken by the Messrs. Weisser and Lippe taken January 10, 2014. A copy of the Support Letter is in Attachment 2.

B. SB 506 (Hill) Retail Sales of Ephedrine Products: Pilot Project

Introduced: February 21, 2013
Board Position: None
Status: 2-Year Bill

Under current law, pseudoephedrine and related products (PSE) are available without a prescription in limited quantities. These drugs must be kept behind the pharmacy counter, and pharmacies are required to maintain logs related to purchases. Retailers cannot sell in a single transaction more than three packages, or 9 grams of a product that he or she knows to contain PSE products. These limitations and requirements do not apply to the dispensing a PSE product pursuant to a valid prescription.

SB 506 would repeal existing statutory provisions for over-the-counter sales of PSE products and replace them with new sales limits consistent with federal law. The bill would impose restrictions on sales of PSE products, and require retailers to store them in a locked cabinet behind the counter.

SB 506 would authorize a pilot project (until 2019) to require the electronic recording of PSE sales (those not related to a prescription). The bill provides that

retailers would be required to immediately transmit specified information regarding PSE purchases to the National Precursor Log Exchange (NPLEx), a privately funded out-of-state data base. This information would include the individual's name, date of birth, address and the product sold, the quantity of packages, and the total gram amount of PSE products involved in the sale. This system would also provide retailers with a real-time alert if an individual attempts to purchase PSE products in excess of the sale limits. This pilot project would sunset on January 1, 2019.

The board does not have a position on SB 506. Staff continues to monitor this 2-year, a copy of which is in Attachment 2. As of January 16, the bill has not been set for hearing.

C. SB 727 (Jackson) Medical Waste: pharmaceutical product stewardship

Last Amend: April 3, 2013
Board Position: *None*
Status: 2-Year Bill

A copy of the most recent version of the bill is provided in Attachment 2. The author's office advised staff on January 15 that they are no longer moving the bill.

b. REGULATION REPORT

1. Discussion and Possible Initiation of a Rulemaking to Amend Title 16 California Code of Regulations Section 1707.5 Related to Patient-Centered Prescription Labels

Attachment 3

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 read as follows:

§ 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 those 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.

The language reflects the board's discussion 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 will discuss a recommendation from staff to initiate the rulemaking.

A copy of the draft proposed text showing these amendments is provided in Attachment 3.

2. Board-Approved – Undergoing Administrative Review (Information Only)

Attachment 4

A. 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. 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 submitted to Business, Consumer Services and Housing Agency on January 14, 2014. A copy of the Proposed Text to amend Section 1749 is provided in Attachment 4.

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

At the February 2013 Board Meeting, the board voted to modify the text of its proposal at Section 1762. This is the board’s combined rulemaking to Amend Sections 1745 and 1769, and to add Section 1762 to Title 16 of the California Code of Regulations. Staff prepared a notice of modified text that was issued for a 15-day public comment period.

The final rulemaking file was submitted to the Department of Consumer Affairs for review on October 10, 2013. In accordance with Business and Professions Code section 313.1, the Director of the Department of Consumer Affairs may request an extension for the one-year notice period review in the event that the one-year notice period lapses during the Director’s 30-day review period. Board staff was advised on October 17, 2013, that the Director of the Department of Consumer Affairs signed an extension letter for the review of rulemaking file as the one-year notice lapsed October 18, 2013, during the Director’s 30-day review period. On January 10, 2014, the rulemaking file was delivered to the Office of Administrative Law for review. A copy of the adopted text is provided in Attachment 4.

3. Board-Approved – Discussion and Possible Action

A. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Section 1732.2, 1732.5, and 1732.05 Related to Continuing Education

Attachment 5

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 recommends revisiting the three continuing education regulation proposals. The currently approved language is provided in Attachment 2.

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.

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.

4. Board-Approved – Awaiting Notice

Attachment 6

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 6.

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. 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 6.

Attachment 1

**Board of Pharmacy
Legislative Proposal
Issuing a License with a Letter of Reprimand**

1 Add Section 4210.5 to the Business and Professions Code, to read:

2

3 (a) Notwithstanding subdivision (c) Section 4300, the board may issue a license to an
4 applicant who has committed minor violations that the board deems, in its discretion, do
5 not merit the denial of a certificate or require probationary status under Section 4300, and
6 may concurrently issue a public letter of reprimand.

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

9 (c) The letter of reprimand shall inform the licensee that within 30 days of service of the
10 letter of reprimand the licensee may do either of the following:

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

13 (A) Upon a timely request, the executive officer, or his or her designee, shall hold an office
14 conference with the licensee or the licensee's legal counsel or authorized representative.
15 Unless so authorized by the executive officer, or his or her designee, no individual other
16 than the legal counsel or authorized representative of the licensee may accompany the
17 licensee to the office conference.

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

20 (C) The office conference is intended to be an informal proceeding and shall not be subject
21 to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with
22 Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing
23 with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division
24 3 of Title 2 of the Government Code).

25 (D) The executive officer, or his or her designee, may affirm, modify, or withdraw the
26 letter of reprimand. Within 14 calendar days from the date of the office conference, the
27 executive officer, or his or her designee, shall personally serve or send by certified mail to

28 the licensee's address of record with the board a written decision. This decision shall be
29 deemed the final administrative decision concerning the letter of reprimand.

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

35 (2) Accept the letter of reprimand. The board shall inform the licensee that the letter of
36 reprimand shall be purged after three years if no letter of admonishment, citation, notice of
37 correction, or disciplinary action is initiated by the board.

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

41 (e) A public letter of reprimand issued concurrently with a board license shall be purged
42 three years from the date of issuance if no letter of admonishment, citation, notice of
43 correction, or disciplinary action is initiated by the board during the three-year period.

44 (f) A public letter of reprimand issued pursuant to this section shall be disclosed to an
45 inquiring member of the public and shall be posted on the board's Internet Web site.

46 (g) Nothing in this section shall be construed to affect the board's authority to issue an
47 unrestricted license.

1 **Business and Professions Code 4053.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Attachment 2

AMENDED IN SENATE JANUARY 7, 2014
AMENDED IN SENATE SEPTEMBER 6, 2013
AMENDED IN SENATE AUGUST 19, 2013
AMENDED IN SENATE AUGUST 12, 2013
AMENDED IN ASSEMBLY APRIL 11, 2013
AMENDED IN ASSEMBLY MARCH 19, 2013
CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL

No. 467

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

February 19, 2013

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 ~~Section~~ *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.

LEGISLATIVE COUNSEL'S DIGEST

AB 467, as amended, 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 ~~connection of eligible and~~ *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 be licensed by the board, as specified, *would require that the 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 ~~provision~~ *provisions* governing licensing *and record-keeping* would be a ~~crime~~, *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 ~~prescription drugs~~ *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.

Vote: $\frac{2}{3}$. Appropriation: yes. Fiscal committee: yes.
State-mandated local program: yes.

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

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

3 4046. “Surplus medication collection and distribution
4 intermediary” means a firm, association, partnership, corporation,
5 limited liability company, state governmental agency, or political
6 subdivision that performs the functions specified in Section 4169.5
7 for the purpose of a program established pursuant to Division 116
8 (commencing with Section 150200) of the Health and Safety Code.

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

12
13 Article 11.5. Surplus Medication Collection and Distribution
14 Intermediaries
15

16 4169.5. (a) A surplus medication collection and distribution
17 intermediary established for the purpose of facilitating the
18 ~~connection of eligible and~~ *donation of medications to or transfer*
19 *of medications between* participating entities under a program
20 established pursuant to Division 116 (commencing with Section
21 150200) of the Health and Safety Code shall be licensed by the
22 board. The board shall enforce the requirements set forth in Section

1 150208 of the Health and Safety Code. *The license shall be*
2 *renewed annually.*

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

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

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

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

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

19 (d) ~~In any case where~~ *If* the applicant is a charitable organization
20 described in Section 501(c)(3) of the Internal Revenue Code, the
21 applicant shall furnish the board with ~~organizations~~ *the*
22 *organization's* articles of incorporation. The applicant shall also
23 furnish the board with the names of the controlling members.

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

36 (f) The application shall contain a statement to the effect that
37 the applicant or persons beneficially interested have not been
38 convicted of a felony and have not violated any of the provisions
39 of this chapter. If the applicant cannot make this statement, the
40 application shall contain a statement of the violation, if any, or

1 reasons which will prevent the applicant from being able to comply
2 with the requirements with respect to the statement.

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

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

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

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

24 150201. For purposes of this division:

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

27 (~~a~~)

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

29 (1) A licensed pharmacy, as defined in subdivision (a) of Section
30 4037 of the Business and Professions Code, that is county owned
31 or that contracts with the county pursuant to this division and is
32 not on probation with the California State Board of Pharmacy.

33 (2) A licensed pharmacy, as defined in subdivision (a) of Section
34 4037 of the Business and Professions Code, that is owned and
35 operated by a primary care clinic, as defined in Section 1204, that
36 is licensed by the State Department of Public Health and is not on
37 probation with the California State Board of Pharmacy.

38 (3) A primary care clinic, as defined in Section 1204, that is
39 licensed by the State Department of Public Health and licensed to
40 administer and dispense drugs pursuant to subparagraph (A) of

1 paragraph (1) of subdivision (a) of Section 4180 of the Business
2 and Professions Code and is not on probation with the California
3 State Board of Pharmacy.

4 (b)

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

7 (e)

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

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

15 150202. (a) Notwithstanding any other ~~provision of~~ law, a
16 donor organization is defined, for purposes of this division, to
17 refer to one of the following health and care facilities that may
18 donate centrally stored unused medications under a program
19 established pursuant to this division:

20 (1) A licensed general acute care hospital, as defined in Section
21 1250.

22 (2) A licensed acute psychiatric hospital, as defined in Section
23 1250.

24 (3) A licensed skilled nursing facility, as defined in Section
25 1250, including a skilled nursing facility designated as an
26 institution for mental disease.

27 (4) A licensed intermediate care facility, as defined in Section
28 1250.

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

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

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

35 (8) A licensed psychiatric health facility, as defined in Section
36 1250.2.

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

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

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

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

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

14 ~~SEC. 3.~~

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

17 150205. (a) The following persons and entities shall not be
18 subject to criminal or civil liability for injury caused when
19 donating, accepting, or dispensing prescription drugs in compliance
20 with this division:

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

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

25 (3) A licensed health or care facility, as described in Section
26 150202, or a pharmacy, as described in Section 150202.5.

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

32 ~~SEC. 4.~~

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

35 150208. (a) A surplus medication collection and distribution
36 intermediary that is licensed pursuant to Section 4169.5 of the
37 Business and Professions Code, established for the purpose of
38 facilitating the ~~connection of eligible and~~ *donation of medications*
39 *to or transfer of medications between* participating entities under

1 a program established pursuant to this division is authorized to
2 operate under this section.

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

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

7 (2) It shall ensure that notification is provided to participating
8 entities that a package has been shipped when the surplus
9 medication collection and distribution intermediary has knowledge
10 of the shipment ~~or~~ *and* provided logistical support to facilitate a
11 shipment directly from ~~an eligible entity~~ *a donor organization, as*
12 *defined in subdivision (a) of Section 150202*, to a participating
13 entity.

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

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

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

22 ~~(2)~~
23 (1) Charge membership, administrative, or overhead fees
24 sufficient to cover the reasonable costs of the *support and* services
25 provided.

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

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

33 ~~SEC. 5.~~

34 *SEC. 7.* 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.

3 ~~SEC. 6.~~

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

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

O



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

January 10, 2014

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

RE: Assembly Bill 467 as Amended 1/7/2014 – Support

Dear Assemblymember Stone:

The Board of Pharmacy (board) supports your Assembly Bill 467 related to the Surplus Medication Collection and Distribution Program.

In October 2013, the board took a position of Support if Amended. Since that time, our office has worked with your staff and other stakeholders to provide appropriate oversight and licensure for the intermediaries that facilitate the donation and distribution of donated medications to and from these programs. As amended on January 7, 2014, AB 467 contains the board's requested amendments to define the term of licensure for intermediaries, and the board has changed its position to one of Support.

The board remains committed to ensuring that drug distribution to indigent patients has necessary safeguards to prevent the diversion of drugs, and we thank you for working with our office to achieve this goal.

Sincerely,

A handwritten signature in black ink that reads "Virginia Herold". The signature is fluid and cursive, with a large initial "V" and a long, sweeping underline.

Virginia Herold
Executive Officer

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



California
LEGISLATIVE INFORMATION

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

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

SENATE BILL

No. 506

Introduced by Senator Hill

February 21, 2013

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

LEGISLATIVE COUNSEL'S DIGEST

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

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

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

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

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

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

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

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

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

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

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

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

(26) Ergonovine maleate.

(27) N-methylephedrine.

(28) N-ethylephedrine.

(29) N-methylpseudoephedrine.

(30) N-ethylpseudoephedrine.

(31) Chloroephedrine.

(32) Chloropseudoephedrine.

(33) Hydriodic acid.

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

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

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

(37) Iodine or tincture of iodine.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(4)~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(37) Iodine or tincture of iodine.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) The date and time of the transaction.

(ii) The identification number presented.

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

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

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

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

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

(A) The date and time of the transaction.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



IN BRIEF

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

THE ISSUE

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

BACKGROUND

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

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

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

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

THE SOLUTION

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

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

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

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

FOR MORE INFORMATION

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[Support on backside](#)

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National Association of Chain Drug Stores
Peace Officers Research Association of California
Reckitt Benckiser
Rite Aid
Shasta County Sheriff
Valley Industry & Commerce Association

Today's Law As Amended 4/3/13



California
LEGISLATIVE INFORMATION

SB-727 Medical waste: pharmaceutical product stewardship program. (2013-2014)

AMENDED IN SENATE APRIL 03, 2013

CALIFORNIA LEGISLATURE— 2013–2014 REGULAR SESSION

SENATE BILL

No. 727

Introduced by Senator Jackson
(Coauthor(s): *Senator Hancock*)

February 22, 2013

An act to add Section ~~117647 to, and to add Chapter 12 (commencing with Section 118365) to Part 14 of Division 104 of, the Health and Safety Code, relating to public health.~~ 117670.1 to the Health and Safety Code, and to add Article 3.4 (commencing with Section 47122) to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, relating to waste management.

LEGISLATIVE COUNSEL'S DIGEST

SB 727, as amended, Jackson. Medical waste: pharmaceutical product stewardship program.

The ~~existing~~ Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, including pharmaceutical waste, as defined. Existing law requires, among other things, that all medical waste be hauled by either a registered hazardous waste hauler or by a person with an approved limited-quantity exemption granted pursuant to specified provisions of law. ~~Under the law, an enforcement agency may bring an action to enjoin the violation or threatened violation of these provisions or issue a specified order to a person who is responsible for a violation or threatened violation. A violation of that order, and other provisions of law, is a crime.~~

Existing law requires a pharmaceutical manufacturer selling or distributing medication that is intended to be self-injected at home to submit, on an annual basis, to the Department of Resources Recycling and Recovery a plan supporting the safe collection and proper disposal of specified waste devices.

This bill would require a producer of a pharmaceutical sold in the state to, individually or through a stewardship organization, to submit a plan, on or before January 1, 2015, to the Department of Resources Recycling and Recovery. The bill would require the plan to provide for the development of a program to collect, transport, and process home-generated pharmaceutical drugs and to include specified aspects, including the minimum amount of collection sites, including by January 1, 2016, at least one collection service within 10 miles per person in the state.

The bill would require the department to post on its Internet Web site a list of the producers or stewardship organizations that have submitted a plan within 10 days of receipt of the plan. The bill would provide for the

review and approval of the plan by the department, within 90 days of receipt of the plan. The bill would require the department to post on its Internet Web site a list of producers for which the department has approved a plan and the bill would require the department to update this list no less than once every 6 months.

The bill would require a producer or stewardship organization, on or after April 1, 2016, and every year thereafter, to prepare and submit to the department an annual report describing the activities carried out pursuant to the plan during the previous calendar year.

The bill would require the producer or stewardship organization to pay the department an annual administrative fee in an amount that is sufficient to cover the department's costs of administering and enforcing these provisions. The bill would require the department to deposit the fees in the Drug Abuse Prevention and Safe Disposal Program Account, which the bill would establish in the Integrated Waste Management Fund, and the department would be authorized to expend the moneys in that account upon appropriation by the Legislature, to administer and enforce the bill's requirement.

The bill would require the department to enforce these provisions and would authorize the department to impose an administrative civil penalty on a person who violates the bill's requirements or impose a fine on a producer or stewardship organization if a stewardship plan is not submitted by January 1, 2015. The bill would require the department to deposit these fines and penalties into the Drug Abuse Prevention and Safe Disposal Program Penalty Account, which this bill would establish in the Integrated Waste Management Fund, and the department would be authorized to expend the moneys in that account upon appropriation by the Legislature, to enforce the bill's requirements.

~~This bill would, effective January 1, 2015, prohibit a producer of a pharmaceutical that is a cover drug, as defined, from selling or distributing that pharmaceutical in the state unless it is included in a product stewardship plan that is approved by the department. This bill would require each producer to operate, individually or jointly with other producers, an approved product stewardship program or to enter into an agreement with a stewardship organization, as defined, to operate that program on the producer's behalf. This bill would require a producer, group of producers, or stewardship organization, if applicable, to pay all associated costs with its product stewardship program, as specified, including the costs incurred by the state for administration and enforcement of the program. The bill would prohibit the producer from charging specified fees to recover the costs of its program.~~

~~This bill would require a producer, individually or jointly with other producers, in consultation with specified entities, to develop a product stewardship plan that includes, among other things, certification that the product stewardship program will accept all unwanted products, except as specified, contact information for the individual or entity submitting the plan and for each producer participating in the program, and a description of the methods by which unwanted products will be collected in the state. This bill would require the producer, group of producers, or stewardship organization operating the program to prepare and submit a written report to the department, as prescribed. This bill would require the department to administer any penalties under those provisions. By expanding the definition of a crime, this bill would impose a state-mandated local program.~~

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

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

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

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

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

(a) The stockpiling of unused and unwanted pharmaceuticals has increased rapidly in recent years, creating access to potentially dangerous drugs to children and adults alike. Accidental poisoning from ingestion of drugs among children often occurs in homes where medicine is easily accessible. The Partnership for a Drug-Free America released a report in February 2010 indicating that over 60 percent of teenagers are able to obtain prescription painkillers free of charge from family and friends.

(b) Poisoning is the fastest rising cause of accidental death among older adults, particularly from overdoses of prescription drugs and over-the-counter medications. Unintentional poisoning of adults over 60 years of age resulting in hospitalization increased by 43 percent in the County of Alameda from 1998 to 2006.

(c) Pharmaceutical residues have been accumulating in groundwater and drinking water. Drugs enter the environment through multiple sources, including flushing toilets or through leaks in landfills. Even the most advanced wastewater treatment plants are not currently able to account for these chemicals. The cost of developing this waste treatment for wastewater is extremely high. Thus, many drugs will continue to pass through wastewater treatment systems and contaminate receiving waters unless the source of the problem is addressed.

(d) Safe and convenient medical waste recovery programs are critical in reducing the negative social and environmental health impacts of improper or illegal disposal.

(e) Product stewardship programs in Canada and Europe for hazardous wastes, medical wastes, and hard-to-handle wastes, including electronic waste, packaging, beverage containers, batteries, mercury-containing lamps, and other mercury-containing products have demonstrated that shared producer responsibility results in significant improvements in safe end-of-life management and reductions in taxpayer and ratepayer costs.

SEC. 2. *Section 117670.1 is added to the Health and Safety Code, to read:*

117670.1. "Home-generated pharmaceutical waste" means a prescription or over-the-counter human or veterinary drug, including, but not limited to, a drug as defined in Section 109925 or in Section 321 (g)(1) of Title 21 of the United States Code, that is a waste, as defined in Section 25124, derived from a household, including, but not limited to, a multifamily residence or household. Home-generated pharmaceutical waste may be handled through a home-generated pharmaceutical waste stewardship plan pursuant to Article 3.4 (commencing with Section 47122) of the Public Resources Code.

SEC. 3. *Article 3.4 (commencing with Section 47122) is added to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, to read:*

Article 3.4. Drug Abuse Prevention and Safe Disposal Program

47122. The purpose of the Drug Abuse Prevention and Safe Disposal Program established pursuant to this article is to require the producers of pharmaceuticals to develop and implement a program to collect, transport, and process home-generated pharmaceutical drug waste to reduce the costs, public health risk, and environmental impacts of the illegal and unsafe disposal of this medical waste.

47123. For purposes of this article, the following terms have the following meanings:

(a) "Consumer" means a purchaser or owner of home-generated pharmaceuticals, including a person, business, corporation, limited partnership, nonprofit organization, or governmental entity.

(b) "Department" means the Department of Resources Recycling and Recovery.

(c) "Distributor" means a person that sells or provides for free pharmaceuticals to the general public, which may include, but is not limited to, retailers, hospitals, veterinarians, and health clinics.

(d) "Drug abuse prevention and safe disposal plan" or "plan" means a plan written by an individual producer, or stewardship organization, on behalf of one or more producers.

(e) "Home-generated pharmaceutical waste" means pharmaceutical waste as defined in Section 117670.1 of the Health and Safety Code.

(f) "Pharmaceutical" means a prescription or over-the-counter human or veterinary drug as defined in Section 117747 of the Health and Safety Code. For purposes of this article, "pharmaceutical" includes any pharmaceutical that is regulated pursuant to (1) the federal Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. Sec. 6901 et seq.), and (2) the Radiation Control Law (Chapter 8 (commencing with Section 114960) of Part 9). For purposes of this article, "pharmaceutical" does not include the following items:

(1) Vitamins or supplements.

(2) Herbal-based remedies and homeopathic drugs.

(3) Cosmetics, soap (with or without germicidal agents), laundry detergent, bleach, household cleaning products, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.).

(4) Drugs for which the producers provide a take-back program as part of a federal Food and Drug Administration managed risk evaluation and mitigation strategy (21 U.S.C. Sec. 355-1).

(5) Drugs that are biological products as defined by Section 600-3(h) of Title 21 of the Code of Federal Regulations as it exists on January 1, 2014 if the producer already provides a take-back program.

(6) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other delivery systems.

(g) "Prescription drug" means any drug that by federal or state law may be dispensed lawfully only on prescription.

(h) (1) "Producer" shall be determined with regard to a pharmaceutical that is sold, offered for sale, or distributed in California as meaning one of the following:

(A) The person that manufactures a pharmaceutical and that sells, offers for sale, or distributes that pharmaceutical in California under that person's own name or brand.

(B) If there is no person who sells, offers for sale, or distributes the pharmaceutical in California under the person's own name or brand, the producer of the pharmaceutical is the owner or licensee of a trademark or brand under which the pharmaceutical is sold or distributed in California, whether or not the trademark is registered.

(C) If there is no person who is a producer of the pharmaceutical for purposes of subparagraphs (A) and (B), the producer of that pharmaceutical is the person who brings the pharmaceutical into California for sale or distribution.

(2) "Producer" does not include (A) a retailer that puts its store label on a pharmaceutical or (B) a pharmacist who dispenses prescription drugs to, or compounds a prescribed individual drug product for a consumer.

(i) "Retailer" means a person that sells a pharmaceutical in the state to a consumer. A sale includes, but is not limited to, transactions conducted through sales outlets, catalogs, or the Internet or any other similar electronic means.

(j) "Stewardship organization" means a nonprofit organization created by the producers, including at a minimum, four representatives one each from local government, a distributor, a waste hauler, and a consumer health organization, to implement the Drug Abuse Prevention and Safe Disposal Program stewardship program.

47124. A producer of any pharmaceutical sold in this state shall, individually or through a stewardship organization, submit a drug abuse prevention and safe disposal stewardship plan pursuant to Section 47125 to the department to develop and implement a recovery program to manage home-generated pharmaceutical waste in an environmentally sound and medically safe fashion, including collection, transportation, processing, and disposal.

47125. (a) (1) On or before January 1, 2015, a producer or the designated stewardship organization for producers of pharmaceuticals shall submit a stewardship plan to the department.

(2) The plan shall be posted on the producer or stewardship organization's Internet Web site.

(b) A producer, group of producers, or stewardship organization shall consult with stakeholders during the development of the stewardship plan, including soliciting stakeholder comments, and responding to stakeholder comments, and document the comments and responses in the plan prior to submitting the stewardship plan.

(c) A stewardship plan shall include, at a minimum, all of the following elements:

(1) Contact information for all participating producers.

(2) The number of collection services for the home-generated pharmaceuticals subject to the plan. A baseline of the number of home-generated pharmaceutical collection services shall be at least one collection service within 10 miles per person in the state.

(d) The minimum number of collection sites for each plan submitted to the department shall be as follows:

(1) On and after January 1, 2016, there shall be at least one collection service within 10 miles per person in the state.

(2) On and after January 1, 2017, the number of collection services shall increase 20 percent from the reported number of collection services in 2016.

(e) On January 1, 2018, and annually thereafter, the department shall consult with the producers and stewardship organizations, local government, haulers, health community, and all stakeholders on how the program is performing, and to set fair and reasonable collection services for each year forward toward the goal of ultimately achieving safe management of all home-generated pharmaceuticals. The producer shall demonstrate to the department that it has achieved maximum improvement in the collection services.

(f) A baseline of the number of home-generated pharmaceuticals collected by all producers, or stewardship organizations, subject to a plan, shall be calculated by weight based on the percentage of home-generated pharmaceuticals collected during the preceding three years.

(g) The plan shall address collecting both solid and liquid home-generated pharmaceuticals.

(h) The methods of collection must be consistent with the requirements of Section 47115.5. Collection shall involve the use of two-key system whereby two individuals are needed to unlock the disposal bin, or if a one-key system is used, whereby only one person is needed to unlock the bin, the bin system shall render the medication unusable.

(i) The plan shall demonstrate sufficient funding for the stewardship program as described in the plan, including a funding mechanism for securing and dispersing funds to cover administrative, operational, and capital costs.

(j) The plan shall address the coordination of the stewardship program with existing local medical waste collection programs as much as is reasonably feasible and is mutually agreeable between those programs.

(k) The plan shall include goals to reduce the number of home-generated pharmaceuticals that are improperly disposed, and to maximize the proper end-of-life management of home-generated pharmaceuticals, including collection of home-generated pharmaceuticals, as practical, based on current medical waste program information.

(l) The plan shall include consumer, medical community, and retailer education and outreach efforts to promote the collection of home-generated pharmaceuticals. This information may include, but is not limited to, developing, and updating as necessary, educational and other outreach materials aimed at all distributors of pharmaceuticals. These materials shall be made available to those parties. These materials may include, but are not limited to, one or more of the following:

(1) Signage that is prominently displayed and easily visible to the consumer.

(2) Written materials and templates of materials for reproduction by retailers to be provided to the consumer at the time of purchase or delivery, or both. Written materials shall include information on proper disposal of home-generated pharmaceuticals.

(3) Advertising or other promotional materials, or both, that include references to home-generated pharmaceuticals collection opportunities.

(m) Any retailer may participate, on a voluntary basis, at a home-generated pharmaceuticals collection point pursuant to the home-generated pharmaceuticals stewardship program.

47126. (a) The department shall post on its Internet web-site a list of the producers or stewardship organizations that have submitted a stewardship plan within 10 days of receipt of the plan.

(b) The department shall review the plan within 90 days of receipt, and make a determination whether or not to approve the plan. The department shall approve the plan if it provides for the establishment of a home-generated pharmaceuticals stewardship program that meets the requirements of Section 47125.

(c) (1) The approved plan shall be a public record, except that financial, production, or sales data reported to the department by a producer or the stewardship organization is not a public record under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code) and shall not be open to public inspection.

(2) Notwithstanding paragraph (1), the department may release a summary form of financial, production, or sales data if it does not disclose financial, production, or sales data of a producer or stewardship organization.

(d) Three months after a plan is approved, the producer or stewardship organization shall implement the home-generated pharmaceuticals stewardship program described in the approved plan.

(e) (1) Within five days of the department approving the plan, the department shall post on its Internet Web site a list of producers for which the department has approved a plan pursuant to subdivision (b). The department shall update this posting that includes a list of producers that are in compliance with this article no less than once every six months thereafter.

(2) A producer that is not listed on the department's Internet Web site pursuant to this section, but demonstrates to the satisfaction of the department that it is in compliance with this article before the next update of the list of compliant producers by the department, pursuant to paragraph (1), may request a certification letter from the department stating that the producer is in compliance. The producer who receives the letter shall be deemed to be in compliance with this article.

47127. (a) On or before April 1, 2016, and every year thereafter, a producer or stewardship organization implementing a stewardship plan shall prepare and submit to the department an annual report describing the activities carried out pursuant to the plan during the previous calendar year. The annual report shall include, but is not limited to, all of the following elements:

(1) The number of home-generated pharmaceuticals collected by the program in the prior year and the collection services achieved in the prior year.

(2) A report of the total sales data for pharmaceuticals sold to distributors in the state for the previous calendar year.

(3) A report on the feedback from a stakeholders' meeting, hosted by producers or the stewardship organization, that was made available by Web cast, prior to submittal of the annual report.

(4) Independently audited financial statements that detail the financing method selected to sustainably fund the implementation of the plan to achieve the identified collection services described in the plan, pursuant to Section 47125.

(5) A description of methods used to collect, transport, and process home-generated pharmaceuticals in this state.

(6) A description of how solid and liquid home-generated pharmaceuticals are collected.

(7) A description of how pharmaceuticals regulated pursuant to the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. Sec. 6901 et seq.), and the Radiation Control Law (Chapter 8 (commencing with Section 114960) of Part 9 of the Health and Safety Code) are collected.

(8) Locations, hours, and contact information for all California collection points set up by the producers covered by the plan.

(9) Examples and descriptions of educational materials distributed to various stakeholders aimed to increase collection.

(10) An evaluation of the effectiveness of the program specific to collection, public awareness, convenience, and reduced improper disposal by both legal and illegal drug use.

(11) Any programmatic changes the producer, the stewardship organization, or both recommend based on new data provided in the annual report.

(b) The department shall review an annual report by doing all of the following:

(1) For the reports submitted for the 2016 calendar year, and each year thereafter, producers and stewardship organizations shall certify the accuracy of the collection points listed in the annual report and that they are located in every county in the state and established at a minimum of one site per 5,000 people.

(2) Reviewing sales data and collection numbers provided for the state to verify collection services.

(3) If a collection service pursuant to Section 47125 is not achieved, the department shall direct the producer or the stewardship organization to determine the most effective way to improve collection services.

(4) Verifying that all annual report elements specified in subdivision (a) have been addressed in the report.

(c) If the department does not act on a report within 45 days of receipt, the report shall be approved.

(d) The department shall make all reports submitted pursuant to this section available to the public on the department's Internet Web site.

(e) If the collection service for the home-generated pharmaceuticals subject to the plan meets the collection service, specified in Section 47125, or if the producer or stewardship organization demonstrates compliance with this article that is consistently and significantly above mandated performance levels, the department may reduce the frequency of reporting pursuant to this section.

(f) The department shall review the annual report required pursuant to this section and, within 90 days of receipt, shall adopt a finding of compliance or noncompliance with this article.

47128. (a) The department shall enforce this chapter.

(b) (1) The producer or stewardship organization shall pay the department an annual administrative fee pursuant to paragraph (2).

(2) The department shall impose fees in an amount that is sufficient to cover the department's full costs of administering and enforcing this chapter, including any program development costs or regulatory costs incurred by the department prior to the submittal of the stewardship plans. Fee revenues collected pursuant to this section shall only be used to administer and enforce this article. The total fee revenue collected shall not exceed \$500,000 per year.

(3) The department shall deposit all fees collected pursuant to this subdivision into the Drug Abuse Prevention and Safe Disposal Program Account, which is hereby created in the Integrated Waste Management Fund. Upon appropriation by the Legislature, moneys deposited into the account may be expended by the department to administer and enforce this article.

(c) (1) A civil penalty may be administratively imposed by the department on any person who violates this article in an amount of up to one thousand dollars (\$1,000) per violation per day.

(2) A person who intentionally, knowingly, or negligently violates this article may be assessed a civil penalty by the department of up to ten thousand dollars (\$10,000) per violation per day.

(A) In assessing any fine and penalty, the department shall consider any exigent circumstance that contributed to the stewardship organization or individual producer not meeting the required recovery targets.

(B) The department may require the producer or stewardship organization to increase expenditure on program compliance in lieu of part of any fine or penalty to be imposed for not meeting the required recovery targets.

(d) (1) The department shall impose a fine on a producer or stewardship organization if a stewardship plan required pursuant to Section 47125 is not submitted by January 1, 2015.

(2) The fine in paragraph (1) shall be effective on the 120th day after the list described in Section 47126 is posted on the department's Internet Web site, and shall apply to any producer that is not listed on the department's Internet Web site, and shall remain in effect until the producer is listed on the department's Internet Web site or can demonstrate compliance with the requirements of Section 47125. A two-thousand-five-hundred-dollar (\$2,500) fine will be imposed on the first day, and will increase by 50 percent with interest each day thereafter until a plan is submitted.

(e) The department shall deposit all fines and penalties collected pursuant to subdivisions (c) and (d) into the Drug Abuse Prevention and Safe Disposal Program Penalty Account, which is hereby created in the Integrated Waste Management Fund. Upon appropriation by the Legislature, moneys deposited into the account may be expended by the department to enforce this article.

47129. (a) Except as provided in subdivision (c), an action solely to increase the collection of home-generated pharmaceuticals by a producer, stewardship organization, or retailer that affects the types or quantities being recycled, or the cost and structure of any return program, is not a violation of the statutes specified in subdivision (b).

(b) The following statutes are not violated by an action specified in subdivision (a):

(1) The Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code).

(2) The Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code).

(c) Subdivision (a) shall not apply to any agreement establishing or affecting the price of home-generated pharmaceuticals, except for the home-generated pharmaceuticals stewardship assessment, or the output or production of home-generated pharmaceuticals, or any agreement restricting the geographic area or customers to which home-generated pharmaceuticals will be sold.

~~SECTION 1. Section 117647 is added to the Health and Safety Code, to read: 117647.~~

~~(a) "Covered drugs" means all drugs as defined in Section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 321(g)(1)), and covered under Section 503 of the act (21 U.S.C. Section 353(b)(1)), including both brand name and generic drugs.~~

~~(b) Covered drugs do not include any of the following:~~

~~(1) Vitamins or supplements.~~

~~(2) Herbal-based remedies, or homeopathic drugs, products, or remedies.~~

~~(3) Cosmetics, soap, with or without germicidal agents, laundry detergent, bleach, household cleaning products, shampoo, sunscreen, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the FFDCA.~~

~~(4) Drugs for which a producer provides a take-back program as part of an FFDCA managed risk evaluation and mitigation strategy.~~

~~(5) Drugs that are biological products, as defined in Section 262(i) of Title 42 of the United States Code, if the producer already provides a take-back program.~~

~~(6) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other delivery systems.~~

~~(7) Nonprescription drugs.~~

~~SEC. 2. Chapter 12 (commencing with Section 118365) is added to Part 14 of Division 104 of the Health and Safety Code, to read: 12. Pharmaceutical Product Stewardship Program 118365.~~

~~For purposes of this chapter, "stewardship organization" means a nonprofit organization created by a producer to implement the pharmaceutical product stewardship program described in Section 118365.1.~~

~~118365.1. (a) Effective January 1, 2015, a producer of a pharmaceutical that is a covered drug shall not sell or distribute that pharmaceutical in the state unless it is included in a product stewardship plan approved by the department.~~

~~(b) Each producer shall do one of the following:~~

~~(1) Operate, individually or jointly with other producers, a product stewardship program approved by the department.~~

~~(2) Enter into an agreement with a stewardship organization to operate, on the producer's behalf, a product stewardship program approved by the department.~~

~~(c) (1) A producer, group of producers, or stewardship organization shall pay all administrative and operational fees associated with its product stewardship program, including the costs of collecting, transporting, and disposing of unwanted products collected from residential generators and the recycling or disposal, or both, of packaging collected with the unwanted product.~~

~~(2) A producer, group of producers, or stewardship organization shall pay for all fees associated with obtaining compliance with the California Environmental Quality Act (Division 13 (commencing with Section 21000) of the Public Resources Code), if required, for a product stewardship program and product stewardship plan.~~

~~(3) A person or producer shall not charge a specific point-of-sale fee to a consumer to recover the costs of its product stewardship program, and shall not charge a specific point-of-collection fee at the time the unwanted products are collected from residential generators or delivered for disposal.~~

~~(4) A producer, group of producers, or stewardship organization shall pay all costs incurred by the state, including, but not limited to, the department's costs, for the administration and enforcement of its pharmaceutical product stewardship program. Exclusive of any fines, the state shall only recover the actual~~

~~costs of administration and enforcement under this chapter, and shall not charge any amounts under this chapter in excess of the actual administrative and enforcement costs.~~

~~118365.2. In consultation with local governments, water districts, sanitation districts, pharmacies, waste haulers, environmental health officers, and all interested stakeholders, the producers, individually or jointly with other producers, shall develop a product stewardship plan.~~

~~(a) Each product stewardship plan required under Section 118365.1 shall contain all of the following:~~

~~(1) Certification that the product stewardship program will accept all unwanted products, regardless of who produced them under a joint plan, unless excused from this requirement by the department as part of its approval of the plan.~~

~~(2) Contact information for the individual and the entity submitting the plan and for each of the producers participating in the product stewardship program.~~

~~(3) A description of the methods by which unwanted products from residential generators will be collected in the state and an explanation of how the collection system will be convenient and adequate to serve the needs of all California residents.~~

~~(4) A description of how the product stewardship plan will provide collection services for unwanted products in all areas of California that are convenient to the public and adequate to meet the needs of the population in the area being served.~~

~~(5) If applicable, the location of each collection site and locations where envelopes for a mail-back program are available.~~

~~(6) A list containing the name, location, permit status, and record of any penalties, violations, or regulatory orders received in the previous five years by each person that will be involved in transporting unwanted products and each medical waste or hazardous disposal facility proposed to participate in the product stewardship program.~~

~~(7) A description of how the unwanted products will be safely and securely tracked and handled from collection through final disposal, and the policies and procedures to be followed to ensure security and adherence to highest management standards.~~

~~(8) A description of public education and outreach activities that are consistent with this chapter, and how the effectiveness of those programs and activities will be evaluated.~~

~~(9) A description of how the scope and extent of the product stewardship program is reasonably related to the amount of covered drugs that are sold in the state by the producer, or group of producers.~~

~~(10) A starting date for the collection of unwanted products.~~

~~(11) If applicable, a description of how support will be provided to any law enforcement agencies within the state that operate, or later agree to operate, a collection program for controlled substances, including the provision of a collection kiosk with appropriate accessories and signage, the ability to accept controlled substances and other covered drugs, and technical support, up to and including an appropriate person to provide on-site assistance with the sorting and separation of controlled substances at no cost to a participating law enforcement agency. Otherwise, controlled substances are expressly excluded from this chapter, notwithstanding any other provision.~~

~~(12) A description of how collection sites for unwanted products may be placed at appropriate retail stores in the state, including a description of the involvement of the retail store. Retailers are not required or mandated to host collection sites, and nothing in this chapter shall be interpreted as requiring that participation.~~

~~(13) If more than one producer will be involved in a proposed product stewardship program, the plan for that program shall include a fair and reasonable manner for allocating the costs of the program among the participants in that program, so that the portion of costs paid by each producer is reasonably related to the amount of covered drugs that producer sells in the state.~~

~~118365.3. On or before January 1, 2016, or at a later date as approved in writing by the department, and in each subsequent year, each producer, group of producers, or stewardship organization operating a product stewardship program shall prepare and submit to the department an annual written report describing the program's activities during the previous reporting period.~~

~~118365.4. The department shall administer the penalty provisions for this chapter.~~

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

Attachment 3

1 **Draft Proposed Text**

2 **Amend Title 16 California Code of Regulations Section 1707.5**

3 **Related to Patient-Centered Prescription Labels**

4
5 **§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.**

6 (a) Labels on drug containers dispensed to patients in California shall conform to the following format:

7
8 (1) Each of the following items, and only those four items, shall be clustered into one area of the label
9 that comprises at least 50 percent of the label. Each item shall be printed ~~in at least a 10-point sans~~
10 ~~serif typeface or, if requested by the consumer, at least a 12-point~~ sans serif typeface, and listed in
11 the following order:

12
13 (A) Name of the patient

14
15 (B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug"
16 means either the manufacturer's trade name of the drug, or the generic name and the name of the
17 manufacturer.

18
19 (C) The directions for the use of the drug.

20
21 (D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated
22 on the prescription.

23
24 (2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to
25 set off the items listed in subdivision (a)(1).

26
27 (3) The remaining required elements for the label specified in section 4076 of the Business and
28 Professions Code, as well as any other items of information appearing on the label or the container,
29 shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified
30 in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size
31 typeface.

32
33 (4) When applicable, directions for use shall use one of the following phrases:

34
35 (A) Take 1 [insert appropriate dosage form] at bedtime

36
37 (B) Take 2 [insert appropriate dosage form] at bedtime

- 38
- 39 (C) Take 3 [insert appropriate dosage form] at bedtime
- 40
- 41 (D) Take 1 [insert appropriate dosage form] in the morning
- 42
- 43 (E) Take 2 [insert appropriate dosage form] in the morning
- 44
- 45 (F) Take 3 [insert appropriate dosage form] in the morning
- 46
- 47 (G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage
- 48 form] at bedtime
- 49
- 50 (H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage
- 51 form] at bedtime
- 52
- 53 (I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage
- 54 form] at bedtime
- 55
- 56 (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at
- 57 noon, and 1 [insert appropriate dosage form] in the evening
- 58
- 59 (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at
- 60 noon, and 2 [insert appropriate dosage form] in the evening
- 61
- 62 (L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at
- 63 noon, and 3 [insert appropriate dosage form] in the evening
- 64
- 65 (M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at
- 66 noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at
- 67 bedtime
- 68
- 69 (N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at
- 70 noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at
- 71 bedtime
- 72
- 73 (O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at
- 74 noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at
- 75 bedtime
- 76

77 (P) If you have pain, take ___ [insert appropriate dosage form] at a time. Wait at least ___ hours before
78 taking again. Do not take more than ___ [appropriate dosage form] in one day

79

80 (b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of
81 the directions for use listed in subdivision (a)(4) into at least five languages other than English, to
82 facilitate the use thereof by California pharmacies.

83

84 (c) The board shall collect and publish on its Web site examples of labels conforming to these
85 requirements, to aid pharmacies in label design and compliance.

86

87 (d) The pharmacy shall have policies and procedures in place to help patients with limited or no
88 English proficiency understand the information on the label as specified in subdivision (a) in the
89 patient's language. The pharmacy's policies and procedures shall be specified in writing and shall
90 include, at minimum, the selected means to identify the patient's language and to provide interpretive
91 services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in
92 the patient's language, if interpretive services in such language are available, during all hours that the
93 pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service
94 available by telephone at or adjacent to the pharmacy counter.

95

96 (e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal
97 conformance with Business and Professions Code section 4076.5.

98

99 (f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

100

101 Note: Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections
102 4005, 4076 and 4076.5, Business and Professions Code.

Attachment 4

Title 16. Board of Pharmacy Proposed Language

Proposal To Amend Section 1749 of 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) ~~four hundred dollars (\$400)~~. The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars (\$325) ~~two hundred fifty dollars (\$250)~~. The penalty for failure to renew is one hundred fifty dollars (\$150) ~~one hundred and twenty five dollars (\$125)~~.

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars (\$325) ~~two hundred fifty dollars (\$250)~~.

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars (\$105) ~~fifty dollars (\$50)~~. The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars (\$130) ~~fifty dollars (\$50)~~. The penalty for failure to renew a pharmacy technician license is sixty-five dollars (\$65) ~~twenty-five dollars (\$25)~~.

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars (\$260) ~~one hundred eighty-five dollars (\$185)~~.

(e) The fee for regrading an examination is one hundred fifteen dollars (\$115) ~~eighty-five dollars (\$85)~~.

(f) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars (\$195) ~~one hundred fifty dollars (\$150)~~.

(g) The fee for the biennial renewal of a pharmacist's license is one hundred ninety-five dollars (\$195) ~~one hundred fifty dollars (\$150)~~. The penalty fee for failure to renew is ninety-seven dollars fifty cents (\$97.50) ~~seventy-five dollars (\$75)~~.

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars (\$780) ~~six hundred dollars (\$600)~~. 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) ~~one hundred twenty five dollars (\$125)~~. The penalty for failure to renew is eighty two dollars fifty cents (\$82.50) ~~sixty-two dollars and fifty cents (\$62.50)~~.

(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) ~~two hundred fifty dollars (\$250)~~. If the applicant is not issued a license as a designated representative, the board shall refund one hundred ten dollars (\$110) of the fee. The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars (\$195) ~~one hundred fifty dollars~~

~~(\$150)~~. The penalty for failure to renew is ninety seven dollars and fifty cents (\$97.50) ~~seventy five dollars (\$75)~~.

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars (\$780) ~~six hundred dollars (\$600)~~. 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) ~~seventy five dollars (\$75)~~. The fee for transfer of intern hours or verification of licensure to another state is thirty dollars (\$30) ~~twenty dollars (\$20)~~.

(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) ~~four hundred dollars (\$400)~~. The fee for the annual renewal of a clinic license is three hundred twenty-five dollars (\$325) ~~two hundred fifty dollars (\$250)~~. The penalty for failure to renew is one hundred fifty dollars (\$150) ~~one hundred and twenty five dollars (\$125)~~.

(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) ~~six hundred dollars (\$600)~~. 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) ~~two hundred fifty dollars (\$250)~~. If the applicant is not issued a license as a designated representative, the board shall refund one hundred fifty dollars (\$150) of the fee. The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars (\$195) ~~one hundred ten dollars (\$110)~~. The penalty for failure to renew is ninety-seven dollars and fifty cents (\$97.50) ~~fifty five dollars (\$55)~~.

(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars (\$425) ~~four hundred dollars (\$400)~~. The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars (\$325) ~~two hundred and fifty dollars (\$250)~~. 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) ~~thirty dollars (\$30)~~.

(t) The fee for the issuance of a centralized hospital packaging pharmacy shall be \$800. The annual renewal fee for a centralized hospital packaging pharmacy 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, 4127.5, 4128.2, 4196, 4200, 4400, 4401 and 4403, Business and Professions Code.

**Order of Adoption
Board of Pharmacy
California Code of Regulations**

To Amend Section 1745 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 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 ~~and~~ 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

For the 15-Day Modified Text, Section 1762 (b) was stricken.

Added text is noted with double underline: thus, added text

Deleted text is noted with double strike-thru: thus, ~~deleted text~~

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.

To Add Section 1762 to Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 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 without lawful excuse to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later.~~

(b) ~~(e)~~ 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) ~~(d)~~ 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.

For the 15-Day Modified Text, Section 1762 (b) was stricken.

Added text is noted with double underline: thus, added text

Deleted text is noted with double strike-thru: thus, ~~deleted text~~

Authority: Section 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code.

To Amend Section 1769 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 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.

~~(a)~~ (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.

For the 15-Day Modified Text, Section 1762 (b) was stricken.

Added text is noted with double underline: thus, added text

Deleted text is noted with double strike-thru: thus, ~~deleted text~~

~~(b)~~ (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.

For the 15-Day Modified Text, Section 1762 (b) was stricken.

Added text is noted with double underline: thus, added text

Deleted text is noted with double strike-thru: thus, ~~deleted text~~

Attachment 5

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.

Attachment 6

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 **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.