

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

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**ASSEMBLY BILL**

**No. 467**

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

February 19, 2013

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An act to ~~amend Section 150201 of,~~ *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 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.*

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

*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 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 services provided. The bill would require that a surplus medication collection and distribution intermediary be licensed by the board, as specified, and would require the payment of a fee in the amount of \$300 to obtain 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 governing licensing would be a crime, 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.*

*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: ~~no~~-yes. Fiscal committee: ~~no~~-yes. State-mandated local program: ~~no~~-yes.

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

1     ~~SECTION 1. Section 150201 of the Health and Safety Code~~  
2     ~~is amended to read:~~  
3     ~~150201. For purposes of this division:~~  
4     ~~(a) "Eligible entity" means all of the following:~~  
5     ~~(1) A licensed pharmacy, as defined in subdivision (a) of Section~~  
6     ~~4037 of the Business and Professions Code, that is county owned~~  
7     ~~or that contracts with the county pursuant to this division and is~~  
8     ~~not on probation with the California State Board of Pharmacy.~~  
9     ~~(2) A licensed pharmacy, as defined in subdivision (a) of Section~~  
10    ~~4037 of the Business and Professions Code, that is owned and~~  
11    ~~operated by a primary care clinic, as defined in Section 1204, that~~  
12    ~~is licensed by the State Department of Public Health and is not on~~  
13    ~~probation with the California State Board of Pharmacy.~~  
14    ~~(3) A primary care clinic, as defined in Section 1204, that is~~  
15    ~~licensed by the State Department of Public Health and licensed to~~  
16    ~~administer and dispense drugs pursuant to subparagraph (A) of~~  
17    ~~paragraph (1) of subdivision (a) of Section 4180 of the Business~~  
18    ~~and Professions Code and is not on probation with the California~~  
19    ~~State Board of Pharmacy.~~  
20    ~~(b) "Medication" or "medications" means a dangerous drug, as~~  
21    ~~defined in Section 4022 of the Business and Professions Code.~~  
22    ~~(c) "Participating entity" means an eligible entity that has~~  
23    ~~received written or electronic documentation from the county~~  
24    ~~health department pursuant to paragraph (3) of subdivision (a) of~~

1 ~~Section 150204 and that operates a repository and distribution~~  
 2 ~~program pursuant to this division.~~

3 (d) ~~“Person” includes a firm, association, partnership,~~  
 4 ~~corporation, limited liability company, state governmental agency,~~  
 5 ~~or political subdivision.~~

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

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

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

17  
 18 *Article 11.5. Surplus Medication Collection and Distribution*  
 19 *Intermediaries*

20  
 21 *4169.5. (a) A surplus medication collection and distribution*  
 22 *intermediary established for the purpose of facilitating the*  
 23 *connection of eligible and participating entities under a program*  
 24 *established pursuant to Division 116 (commencing with Section*  
 25 *150200) of the Health and Safety Code shall be licensed by the*  
 26 *board. The board shall enforce the requirements set forth in Section*  
 27 *150208 of the Health and Safety Code.*

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

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

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

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

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

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

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

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

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

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

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

6 150205. (a) The following persons and entities shall not be  
7 subject to criminal or civil liability for injury caused when  
8 donating, accepting, or dispensing prescription drugs in compliance  
9 with this division:

10 (a)  
11 (1) A prescription drug manufacturer, wholesaler, governmental  
12 entity, or participating entity.

13 (b)  
14 (2) A pharmacist or physician who accepts or dispenses  
15 prescription drugs.

16 (c)  
17 (3) A licensed health or care facility, as described in Section  
18 150202, or a pharmacy, as described in Section 150202.5.

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

23 ~~SEC. 2.~~  
24 SEC. 4. Section 150208 is added to the Health and Safety Code,  
25 to read:

26 ~~150208. Activities relating to the donation or distribution of~~  
27 ~~medications, including, but not limited to, facilitating or negotiating~~  
28 ~~the donation or distribution of medications, pursuant to this division~~  
29 ~~shall not be deemed wholesaling activities. Any person that is not~~  
30 ~~otherwise a wholesaler, as defined in Section 4043 of the Business~~  
31 ~~and Professions Code, shall not be deemed a wholesaler or required~~  
32 ~~to be licensed as a wholesaler under the Pharmacy Law (Chapter~~  
33 ~~9 (commencing with Section 4000) of Division 2 of the Business~~  
34 ~~and Professions Code) when performing those activities pursuant~~  
35 ~~to this division.~~

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

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

3 *(b) A surplus medication collection and distribution*  
4 *intermediary 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 provided logistical support to facilitate a*  
11 *shipment directly from an eligible entity to a participating entity.*

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

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

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

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

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

25 *SEC. 5. No reimbursement is required by this act pursuant to*  
26 *Section 6 of Article XIII B of the California Constitution because*  
27 *the only costs that may be incurred by a local agency or school*  
28 *district will be incurred because this act creates a new crime or*  
29 *infraction, eliminates a crime or infraction, or changes the penalty*  
30 *for a crime or infraction, within the meaning of Section 17556 of*  
31 *the Government Code, or changes the definition of a crime within*  
32 *the meaning of Section 6 of Article XIII B of the California*  
33 *Constitution.*

34 ~~SEC. 3.~~

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

39 *To ensure that California's medication donation program is*  
40 *allowed to continue to operate to facilitate the distribution of*

- 1 medications to the indigent population which would not otherwise
- 2 have access to these medications, it is necessary that this act take
- 3 effect immediately.

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