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AMENDED IN SENATE SEPTEMBER 6, 2013
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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