

AMENDED IN ASSEMBLY AUGUST 13, 2012

AMENDED IN ASSEMBLY JUNE 26, 2012

AMENDED IN SENATE MAY 14, 2012

AMENDED IN SENATE MARCH 29, 2012

**SENATE BILL**

**No. 1329**

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**Introduced by Senator Simitian**  
(Coauthor: Assembly Member Galgiani)

February 23, 2012

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An act to amend Sections *150200*, *150201*, *150202*, *150204*, and *150205* of, *and to add Section 150202.5 to*, the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 1329, as amended, Simitian. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish, by ordinance, a repository and distribution program under which a pharmacy that is owned by or contracts with the county may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. 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 pharmacy. Existing law authorizes a skilled nursing facility, specified drug manufacturer, or pharmacy wholesaler to donate medications to the program. Existing law requires medication under the program to be dispensed to an eligible patient, destroyed, or returned to a reverse distributor, as specified. Except in cases of noncompliance, bad faith,

or gross negligence, existing law prohibits certain people and entities from being subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the program's provisions.

This bill would authorize a county to establish the program by action of the county board of supervisors or by action of a public health officer of the county, as prescribed. This bill would also authorize specified primary care clinics and pharmacies to participate in the program. This bill would require a pharmacy or clinic seeking to participate in the program to inform the county health department in writing of its intent and prohibit the pharmacy or clinic from participating until the county health department has confirmed that it has received this notice. This bill would require participating pharmacies and clinics to disclose specified information to the county health department and require the county board of supervisors or public health officer to make this information available upon request to the California State Board of Pharmacy. This bill would authorize the county board of supervisors, public health officer, and California State Board of Pharmacy to prohibit a pharmacy or clinic from participating in the program, under certain circumstances, and require written notice to be provided to prohibited pharmacies or clinics. This bill would authorize *certain* licensed health and care facilities *and certain pharmacies*, as specified, to donate unused medications to the program, *in accordance with prescribed conditions*. This bill would also make other conforming changes to those provisions.

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

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

1     SECTION 1. Section 150200 of the Health and Safety Code is  
2     amended to read:  
3     150200. It is the intent of the Legislature in enacting this  
4     division to authorize the establishment of a voluntary drug  
5     repository and distribution program for the purpose of distributing  
6     surplus medications to persons in need of financial assistance to  
7     ensure access to necessary pharmaceutical therapies. *It is also the*  
8     *intent of the Legislature that the health and safety of Californians*  
9     *are protected and promoted through this program, while reducing*  
10    *unnecessary waste at licensed health and care facilities, by*  
11    *allowing those facilities to donate unused and unexpired*

1 *medications that were never in the hands of a patient or resident*  
2 *and for which no credit or refund to the patient or resident could*  
3 *be received.*

4 ~~SECTION 1.~~

5 *SEC. 2.* Section 150201 of the Health and Safety Code is  
6 amended to read:

7 150201. For purposes of this division:

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

9 (1) A licensed pharmacy, as defined in subdivision (a) of Section  
10 4037 of the Business and Professions Code, that is county owned  
11 or that contracts with the county pursuant to this division and is  
12 not on probation with the California State Board of Pharmacy.

13 (2) A licensed pharmacy, as defined in subdivision (a) of Section  
14 4037 of the Business and Professions Code, that is owned and  
15 operated by a ~~licensed~~ primary care clinic, as defined in Section  
16 1204, *that is licensed by the State Department of Public Health*  
17 and is not on probation with the California State Board of  
18 Pharmacy.

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

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

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

32 ~~SEC. 2.~~

33 *SEC. 3.* Section 150202 of the Health and Safety Code is  
34 amended to read:

35 150202. (a) Notwithstanding any other provision of law, the  
36 following health and care facilities may donate *centrally stored*  
37 unused medications under a program established pursuant to this  
38 division:

39 (a)

- 1 (1) A licensed general acute care hospital, as defined in Section
- 2 1250.
- 3 ~~(b)~~
- 4 (2) A licensed acute psychiatric hospital, as defined in Section
- 5 1250.
- 6 ~~(c)~~
- 7 (3) A licensed skilled nursing facility, as defined in Section
- 8 1250, including a skilled nursing facility designated as an
- 9 institution for mental disease.
- 10 ~~(d)~~
- 11 (4) A licensed intermediate care facility, as defined in Section
- 12 1250.
- 13 ~~(e)~~
- 14 (5) A licensed intermediate care facility/developmentally
- 15 disabled-habilitative facility, as defined in Section 1250.
- 16 ~~(f)~~
- 17 (6) A licensed intermediate care facility/developmentally
- 18 disabled-nursing facility, as defined in Section 1250.
- 19 ~~(g)~~
- 20 (7) A licensed correctional treatment center, as defined in
- 21 Section 1250.
- 22 ~~(h)~~
- 23 (8) A licensed psychiatric health facility, as defined in Section
- 24 1250.2.
- 25 ~~(i)~~
- 26 (9) A licensed chemical dependency recovery hospital, as
- 27 defined in Section 1250.3.
- 28 ~~(j)~~
- 29 (10) A licensed residential care facility for the elderly, as defined
- 30 in Section 1569.2.
- 31 ~~(k) A licensed residential care facility for persons with chronic,~~
- 32 ~~life-threatening illness, as defined in Section 1568.01.~~
- 33 ~~(l)~~
- 34 (11) An approved mental health rehabilitation center, as
- 35 described in Section 5675 of the Welfare and Institutions Code.
- 36 (b) Medication donated by health and care facilities pursuant
- 37 to subdivision (a) shall meet the requirements of subdivisions (c)
- 38 and (d) of Section 150204 and shall be unexpired medication that
- 39 would have otherwise been destroyed by the facility or another
- 40 appropriate entity.

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

7 SEC. 4. Section 150202.5 is added to the Health and Safety  
8 Code, to read:

9 150202.5. Notwithstanding any other law, a pharmacy, licensed  
10 in California and not on probation with the California State Board  
11 of Pharmacy, whose primary or sole type of pharmacy practice  
12 type is limited to a skilled nursing facility, home health care, board  
13 and care, or mail order, may donate unused, unexpired medication  
14 that meets the requirements of subdivisions (c) and (d) of Section  
15 150204, under a program established pursuant to this division  
16 and that meets either of the following requirements:

17 (a) The medication was received directly from a manufacturer  
18 or wholesaler.

19 (b) The medication was returned from a health facility to the  
20 issuing pharmacy, in a manner consistent with state and federal  
21 law.

22 ~~SEC. 3.~~

23 SEC. 5. Section 150204 of the Health and Safety Code is  
24 amended to read:

25 150204. (a) (1) A county may establish, by an action of the  
26 county board of supervisors or by an action of the public health  
27 officer of the county, as directed by the county board of  
28 supervisors, a repository and distribution program for purposes of  
29 this division. The county shall advise the California State Board  
30 of Pharmacy within 30 days from the date it establishes a repository  
31 and distribution program.

32 (2) Only an eligible entity, pursuant to subdivision (a) of Section  
33 150201, may participate in this program to dispense medication  
34 donated to the drug repository and distribution program.

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

1 county health department confirming that the department has  
2 received its notice of intent.

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

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

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

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

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

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

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

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

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

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

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

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

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

11 (3) The medication shall not have been in the possession of a  
12 patient or any individual member of the public, and in the case of  
13 medications donated by a health or care facility, as described in  
14 Section 150202, shall have been under the control of *a* staff  
15 *member* of the health or care facility, ~~as described in Section~~  
16 ~~150202~~ *who is licensed in California as a health care professional*  
17 *or has completed, at a minimum, the training requirements*  
18 *specified in Section 1569.69.*

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

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

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

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

38 (1) Dispensed to an eligible patient.

39 (2) Destroyed.

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

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

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

16 (C) Medication transferred pursuant to this paragraph shall be  
17 transferred with documentation that identifies the drug name,  
18 strength, and quantity of the medication, and the donation facility  
19 from where the medication originated shall be identified on  
20 medication packaging or in accompanying documentation. The  
21 document shall include a statement that the medication may not  
22 be transferred to another participating entity and must be handled  
23 pursuant to subparagraph (B). A copy of this document shall be  
24 kept by the participating entity transferring the medication and  
25 the participating entity receiving the medication.

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

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

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

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

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

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

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

28 ~~SEC. 4.~~

29 *SEC. 6.* Section 150205 of the Health and Safety Code is  
30 amended to read:

31 150205. The following persons and entities shall not be subject  
32 to criminal or civil liability for injury caused when donating,  
33 accepting, or dispensing prescription drugs in compliance with  
34 this division:

35 (a) A prescription drug manufacturer, wholesaler, governmental  
36 entity, or participating entity.

37 (b) A pharmacist or ~~health care professional~~ *physician* who  
38 accepts or dispenses prescription drugs.

- 1 (c) A *licensed* health or care facility, as described in Section
- 2 150202, or a *pharmacy*, as described in Section 150202.5.

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