

Introduced by Senator SimitianFebruary 23, 2012

An act to amend Sections 150201, 150202, 150204, and 150205 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 1329, as introduced, 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 authorize a primary care clinic dispensary, as defined, 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 require the county board of supervisors or public health officer to approve the pharmacy or clinic. 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 State Board of Pharmacy. This bill would authorize the county board of supervisors, public health officer, and State Board of Pharmacy to prohibit a pharmacy or clinic from participating in the program, under certain circumstances. This bill would authorize licensed health and care facilities, as specified, to donate unused medications to the program. This bill would authorize medication under the program to be transferred to another participating pharmacy or primary care clinic. 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 150201 of the Health and Safety Code
 2 is amended to read:

3 150201. (a) For purposes of this division, “medication” or
 4 “medications” means a dangerous drug, as defined in Section 4022
 5 of the Business and Professions Code.

6 (b) For purposes of this division, “primary care clinic
 7 dispensary” means a licensed primary care clinic, as defined in
 8 Section 1204, that is licensed to administer and dispense drugs
 9 pursuant to subparagraph (A) of paragraph (1) of subdivision (a)
 10 of Section 4180 of the Business and Professions Code.

11 SEC. 2. Section 150202 of the Health and Safety Code is
 12 amended to read:

13 150202. Notwithstanding any other provision of law, ~~a licensed~~
 14 ~~skilled nursing facility, as defined in Section 1250, including a~~
 15 ~~skilled nursing facility designated as an institution for mental~~
 16 ~~disease, the following health and care facilities may donate unused~~
 17 ~~medications under a program established pursuant to this division.~~
 18 *division:*

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

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

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

6 (d) A licensed intermediate care facility, as defined in Section
7 1250.

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

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

12 (g) A licensed correctional treatment center, as defined in
13 Section 1250.

14 (h) A licensed psychiatric health facility, as defined in Section
15 1250.2.

16 (i) A licensed chemical dependency recovery hospital, as defined
17 in Section 1250.3.

18 (j) A licensed residential care facility for the elderly, as defined
19 in Section 1569.2.

20 (k) A licensed residential care facility for persons with chronic,
21 life-threatening illness, as defined in Section 1568.01.

22 SEC. 3. Section 150204 of the Health and Safety Code is
23 amended to read:

24 150204. (a) (1) A county may establish, by ~~ordinance~~ *an*
25 *action of the county board of supervisors or by an action of the*
26 *public health officer of the county, as delegated by the county*
27 *board of supervisors, a repository and distribution program for*
28 *purposes of this division. ~~Only pharmacies~~*

29 (2) *Only a pharmacy that ~~are~~ is county-owned or that ~~contract~~*
30 *contracts with the county pursuant to this division ~~may~~, or a*
31 *primary care clinic dispensary, as defined in subdivision (b) of*
32 *Section 150201, is eligible to participate in this program to dispense*
33 *medication donated to the drug repository and distribution program.*

34 (3) *An eligible pharmacy or primary care clinic dispensary that*
35 *seeks to participate in the program shall inform the county health*
36 *department in writing of its intent to participate in the program.*
37 *An eligible pharmacy or primary care clinic dispensary may not*
38 *participate in the program unless it is approved by the county*
39 *board of supervisors or the public health officer of the county.*

1 (4) (A) A participating pharmacy or primary care clinic
2 dispensary shall disclose to the county health department the name
3 and location of the source of all donated medication it receives.

4 (B) A participating primary care clinic dispensary shall disclose
5 to the county health department the licensed physician to be
6 accountable to the State Board of Pharmacy for the clinic's
7 program operations pursuant to this division.

8 (C) The county board of supervisors or public health officer of
9 the county shall, upon request, make available to the State Board
10 of Pharmacy the information in this paragraph.

11 (5) The county board of supervisors, the public health officer
12 of the county, and the State Board of Pharmacy may prohibit a
13 pharmacy or primary care clinic dispensary from participating in
14 the program if the pharmacy or primary care clinic dispensary
15 does not comply with the provisions of the program, pursuant to
16 this division.

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

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

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

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

26 (4) Ensuring proper safety and management of any medications
27 collected by and maintained under the authority of a county-owned
28 or county-contracted, licensed pharmacy or primary care clinic
29 dispensary.

30 (5) Ensuring the privacy of individuals for whom the medication
31 was originally prescribed.

32 (c) Any medication donated to the repository and distribution
33 program shall comply with the requirements specified in this
34 division. Medication donated to the repository and distribution
35 program shall meet all of the following criteria:

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

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

1 (3) The medication shall not have been in the possession of a
2 patient or any individual member of the public, and in the case of
3 medications donated by a ~~skilled nursing facility~~ *health or care*
4 *facility, as described in Section 150202*, shall have been under the
5 control of staff of ~~the skilled nursing facility~~ *the health or care*
6 *facility, as described in Section 150202*.

7 (d) Only medication that is donated in unopened, tamper-evident
8 packaging or modified unit dose containers that meet USP
9 standards is eligible for donation to the repository and distribution
10 program, provided lot numbers and expiration dates are affixed.
11 Medication donated in opened containers shall not be dispensed
12 by the repository and distribution program.

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

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

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

22 (1) Dispensed to an eligible patient.

23 (2) Destroyed.

24 (3) Returned to a reverse distributor.

25 (4) *Transferred to another participating pharmacy or primary*
26 *care clinic dispensary to be dispensed to eligible patients pursuant*
27 *to this division*.

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

34 (i) Medication donated to the repository and distribution program
35 shall be maintained in the donated packaging units until dispensed
36 to an eligible patient under this program, who presents a valid
37 prescription. When dispensed to an eligible patient under this
38 program, the medication shall be in a new and properly labeled
39 container, specific to the eligible patient and ensuring the privacy

1 of the individuals for whom the medication was initially dispensed.
 2 Expired medication shall not be dispensed.

3 (j) Medication donated to the repository and distribution program
 4 shall be segregated from the pharmacy's *or primary care clinic*
 5 *dispensary's* other drug stock by physical means, for purposes
 6 including, but not limited to, inventory, accounting, and inspection.

7 (k) The pharmacy *or primary care clinic dispensary* shall keep
 8 complete records of the acquisition and disposition of medication
 9 donated ~~to~~ *to, transferred,* and dispensed under the repository and
 10 distribution program. These records shall be kept separate from
 11 the pharmacy's *or primary care clinic dispensary's* other
 12 acquisition and disposition records and shall conform to the
 13 Pharmacy Law (Chapter 9 (commencing with Section 4000) of
 14 Division 2 of the Business and Professions Code), including being
 15 readily retrievable.

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

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

28 (n) Notwithstanding any other provision of law, a participating
 29 county-owned or county-contracted pharmacy *or primary care*
 30 *clinic dispensary* shall follow the same procedural drug pedigree
 31 requirements for donated drugs as it would follow for drugs
 32 purchased from a wholesaler or directly from a drug manufacturer.

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

35 150205. The following persons and entities shall not be subject
 36 to criminal or civil liability for injury caused when donating,
 37 accepting, or dispensing prescription drugs in compliance with
 38 this division:

- 1 (a) A prescription drug manufacturer, wholesaler, governmental
- 2 entity, county-owned or county-contracted licensed pharmacy, or
- 3 ~~skilled nursing facility~~ *primary care clinic dispensary*.
- 4 (b) A pharmacist or health care professional who accepts or
- 5 dispenses prescription drugs.
- 6 (c) *A health or care facility, as described in Section 150202.*

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