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AMENDED IN SENATE AUGUST 1, 2016
AMENDED IN SENATE JULY 1, 2015
AMENDED IN ASSEMBLY MAY 6, 2015
AMENDED IN ASSEMBLY MARCH 26, 2015
CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 1069

Introduced by Assembly Member Gordon
(Coauthors: Assembly Members Chu, Low, and Mark Stone)
(Coauthors: Senators Beall and Wieckowski)

February 26, 2015

An act to amend Section 150204 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 1069, as amended, Gordon. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish a repository and distribution program under which a pharmacy, including 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. Under existing law, only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet the United States Pharmacopoeia standards, and that includes lot numbers and expiration dates, is eligible for donation to the program. Existing law prohibits

medication that does not meet the requirements for donation and distribution from being sold, dispensed, or otherwise transferred to any other entity. Existing law requires medication donated to the repository and distribution program to be maintained in the donated packaging units.

This bill would authorize a pharmacy that exists solely to operate the repository and distribution program to repackage a reasonable quantity of donated medicine in anticipation of dispensing the medicine to its patient population. The bill would require a pharmacy that repackages medication to have repackaging policies and procedures in place for identifying and recalling ~~medications~~ *medications, and to label the repackaged medicine with the earliest expiration date.*

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 150204 of the Health and Safety Code
- 2 is amended to read:
- 3 150204. (a) (1) A county may establish, by an action of the
- 4 county board of supervisors or by an action of the public health
- 5 officer of the county, as directed by the county board of
- 6 supervisors, a repository and distribution program for purposes of
- 7 this division. The county shall advise the California State Board
- 8 of Pharmacy within 30 days from the date it establishes a repository
- 9 and distribution program.
- 10 (2) Only an eligible entity, pursuant to Section 150201, may
- 11 participate in this program to dispense medication donated to the
- 12 drug repository and distribution program.
- 13 (3) An eligible entity that seeks to participate in the program
- 14 shall inform the county health department and the California State
- 15 Board of Pharmacy in writing of its intent to participate in the
- 16 program. An eligible entity may not participate in the program
- 17 until it has received written or electronic documentation from the
- 18 county health department confirming that the department has
- 19 received its notice of intent.
- 20 (4) (A) A participating entity shall disclose to the county health
- 21 department on a quarterly basis the name and location of the source
- 22 of all donated medication it receives.

1 (B) A participating primary care clinic, as described in Section
2 150201, shall disclose to the county health department the name
3 of the licensed physician who shall be accountable to the California
4 State Board of Pharmacy for the clinic's program operations
5 pursuant to this division. This physician shall be the professional
6 director, as defined in subdivision (c) of Section 4182 of the
7 Business and Professions Code.

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

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

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

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

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

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

32 (4) Ensuring proper safety and management of any medications
33 collected by and maintained under the authority of a participating
34 entity.

35 (5) Ensuring the privacy of individuals for whom the medication
36 was originally prescribed.

37 (c) Any medication donated to the repository and distribution
38 program shall comply with the requirements specified in this
39 division. Medication donated to the repository and distribution
40 program shall meet all of the following criteria:

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

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

5 (3) The medication shall not have been in the possession of a
6 patient or any individual member of the public, and in the case of
7 medications donated by a health or care facility, as described in
8 Section 150202, shall have been under the control of a staff
9 member of the health or care facility who is licensed in California
10 as a health care professional or has completed, at a minimum, the
11 training requirements specified in Section 1569.69.

12 (d) (1) Only medication that is donated in unopened,
13 tamper-evident packaging or modified unit dose containers that
14 meet USP standards is eligible for donation to the repository and
15 distribution program, provided lot numbers and expiration dates
16 are affixed. Medication donated in opened containers shall not be
17 dispensed by the repository and distribution program, and once
18 identified, shall be quarantined immediately and handled and
19 disposed of in accordance with the Medical Waste Management
20 Act (Part 14 (commencing with Section 117600) of Division 104).

21 (2) (A) A medication that is the subject of a United States Food
22 and Drug Administration managed risk evaluation and mitigation
23 strategy pursuant to Section 355-1 of Title 21 of the United States
24 Code shall not be donated if this inventory transfer is prohibited
25 by that strategy, or if the inventory transfer requires prior
26 authorization from the manufacturer of the medication.

27 (B) A medication that is the subject of a United States Food and
28 Drug Administration managed risk evaluation and mitigation
29 strategy pursuant to Section 355-1 of Title 21 of the United States
30 Code, the donation of which is not prohibited pursuant to
31 subparagraph (A), shall be managed and dispensed according to
32 the requirements of that strategy.

33 (e) A pharmacist or physician at a participating entity shall use
34 his or her professional judgment in determining whether donated
35 medication meets the standards of this division before accepting
36 or dispensing any medication under the repository and distribution
37 program.

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

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

3 (1) Dispensed to an eligible patient.

4 (2) Destroyed.

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

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

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

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

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

37 (i) (1) Except as provided in paragraph (2), medication donated
38 to the repository and distribution program shall be maintained in
39 the donated packaging units until dispensed to an eligible patient
40 under this program, who presents a valid prescription. When

1 dispensed to an eligible patient under this program, the medication
2 shall be in a new and properly labeled container, specific to the
3 eligible patient and ensuring the privacy of the individuals for
4 whom the medication was initially dispensed. Expired medication
5 shall not be dispensed.

6 (2) A pharmacy that exists solely to operate the repository and
7 distribution program may repackage a reasonable quantity of
8 donated medicine in anticipation of dispensing the medicine to its
9 patient population. The pharmacy shall have repackaging policies
10 and procedures in place for identifying and recalling medications.
11 *Medication that is repackaged shall be labeled with the earliest*
12 *expiration date.*

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

17 (k) A participating entity shall keep complete records of the
18 acquisition and disposition of medication donated to, and
19 transferred, dispensed, and destroyed under, the repository and
20 distribution program. These records shall be kept separate from
21 the participating entity's other acquisition and disposition records
22 and shall conform to the Pharmacy Law (Chapter 9 (commencing
23 with Section 4000) of Division 2 of the Business and Professions
24 Code), including being readily retrievable.

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

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

36 (n) Notwithstanding any other provision of law, a participating
37 entity shall follow the same procedural drug pedigree requirements

- 1 for donated drugs as it would follow for drugs purchased from a
- 2 wholesaler or directly from a drug manufacturer.

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