

AMENDED IN ASSEMBLY SEPTEMBER 1, 2005

AMENDED IN ASSEMBLY JUNE 21, 2005

AMENDED IN SENATE MAY 10, 2005

AMENDED IN SENATE MARCH 29, 2005

SENATE BILL

No. 798

Introduced by Senator Simitian

February 22, 2005

An act to add Division ~~H5 116~~ (commencing with Section ~~150000~~) 150200) to the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 798, as amended, Simitian. Prescription drugs: collection and distribution program.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to dispense a medication on prescription in a container that meets the requirements of state and federal law and is correctly labeled.

This bill would authorize a county to establish, by ~~local~~ ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. The bill would *limit the program to pharmacies owned by or contracting with the county*. It would require a county that elects to establish a repository and distribution program to establish procedures for, at a minimum, (1) establishing eligibility for medically indigent patients who may participate in the program, (2) ensuring that eligible patients are not charged for any medications provided under the program, (3)

developing a formulary of appropriate medications for the program,
 (4) ensuring proper safety and management of any medications collected by and maintained under the authority of a licensed pharmacist pharmacy, and ~~(4)~~ (5) ensuring the privacy of individuals for whom the medication was originally prescribed. The bill would authorize any drug manufacturer legally authorized under federal law to manufacture or sell pharmaceutical drugs, or a licensed health facility, pharmacy wholesaler, or pharmacy to donate medications pursuant to these provisions. Except in cases of bad faith or gross negligence, the bill would prohibit 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 bill's 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. Division ~~H5116~~ (commencing with Section
 2 ~~150000~~150200) is added to the Health and Safety Code, to read:

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DIVISION ~~H5~~ 116. SURPLUS MEDICATION
 COLLECTION AND DISTRIBUTION

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~~150000.~~

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150200. It is the intent of the Legislature in enacting this
 9 division to authorize the establishment of a voluntary drug
 10 repository and distribution program for the purpose of
 11 distributing surplus medications to persons in need of financial
 12 assistance to ensure access to necessary pharmaceutical
 13 therapies.

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~~150002. A health facility licensed under Chapter 2
 (commencing with Section 1250) of Division 2, a pharmacy
 wholesaler licensed pursuant to Article 11 (commencing with
 Section 4160) of Chapter 9 of Division 2 of the Business and
 Professions Code, a pharmacy licensed pursuant to Chapter 9
 (commencing with Section 4000) of Division 2 of the Business
 and Professions Code, and a drug manufacturer that is legally
 authorized under federal law to manufacture and sell
 pharmaceutical drugs, may donate excess or surplus unused~~

1 prescribed medications under a program established by a county
2 pursuant to this division.

3 150004. (a) A county may establish, by local ordinance, a
4 repository and distribution program for purposes of this division.

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

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

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

12 (3) Ensuring proper safety and management of any
13 medications collected by and maintained under the authority of a
14 licensed pharmacist by ensuring, at a minimum, all of the
15 following:

16 (A) That only those drugs that are received and maintained in
17 their unopened, tamper-evident packaging are dispensed.

18 (B) That any drugs received have not been adulterated,
19 misbranded, or stored under conditions contrary to standards set
20 by the United States Pharmacopocia or the product manufacturer.

21 (C) That any drugs received are dispensed prior to their
22 expiration date.

23 (D) That reasonable methods have been established to ensure
24 that drugs received have not been in the possession of any
25 individual member of the public.

26 (E) That a pharmacist may use his or her discretion and best
27 judgment in deciding whether or not to accept any donated drug.

28 (F) That records are kept for at least three years from the date
29 that any drug is received or dispensed, whichever is later,
30 pursuant to this division.

31 (G) That pharmacists adhere to standard pharmacy practices as
32 required by state and federal law when dispensing all prescription
33 drugs, including narcotics and other controlled substances.

34 (H) That donated drug stock is stored separately from a
35 pharmacy's general supply for inventory, accounting, and
36 inspection purposes.

37 (I) That any county that elects to dispense narcotics and other
38 controlled substances is required to receive public comment from
39 local law enforcement prior to establishing local protocols for

1 ~~packaging, transporting, storing, and distributing narcotics and~~
2 ~~other controlled substances.~~

3 ~~(J) That local protocols established pursuant to this act adhere~~
4 ~~to any applicable requirements established by the California State~~
5 ~~Board of Pharmacy regarding packaging, transporting, storing,~~
6 ~~and dispensing all prescription drugs, including narcotics and~~
7 ~~controlled substances.~~

8 ~~(K) That county protocols established for packaging,~~
9 ~~transporting, storing, and dispensing medications that require~~
10 ~~refrigeration, including, but not limited to, any biological product~~
11 ~~as defined in Section 351 of the Public Health and Service Act~~
12 ~~(42 U.S.C. Sec. 262), an intravenously injected drug, or an~~
13 ~~infused drug, include specific procedures to ensure that these~~
14 ~~medications are packaged, transported, stored, and dispensed at~~
15 ~~their appropriate temperatures and according to any applicable~~
16 ~~standards established by the California State Board of Pharmacy.~~

17 ~~(L) That, notwithstanding any other provision of law,~~
18 ~~participating pharmacies adhere to the same procedural drug~~
19 ~~pedigree requirements for donated drugs as they would for drugs~~
20 ~~purchased from a wholesaler or directly from a drug~~
21 ~~manufacturer.~~

22 ~~(4) Ensuring the privacy of individuals for whom the~~
23 ~~medication was originally prescribed.~~

24 ~~150005. The following persons and entities shall not be~~
25 ~~subject to criminal or civil liability for injury caused when~~
26 ~~donating, accepting, or dispensing prescription drugs in~~
27 ~~compliance with this division:~~

28 ~~(a) A prescription drug manufacturer, pharmacy wholesaler,~~
29 ~~governmental entity, or health facility.~~

30 ~~(b) A pharmacist or health care professional who accepts or~~
31 ~~dispenses prescription drugs.~~

32 ~~(c) A pharmacy or health facility that employs a health care~~
33 ~~professional who accepts or can legally dispense prescription~~
34 ~~drugs.~~

35 *150202. Notwithstanding any other provision of law, a*
36 *licensed skilled nursing facility, as defined in Section 1250,*
37 *including a skilled nursing facility designated as an institution*
38 *for mental disease, may donate unused medications under a*
39 *program established pursuant to this division.*

1 150203. Notwithstanding any other provision of law, a
2 wholesaler licensed pursuant to Article 11 (commencing with
3 Section 4160) of Chapter 9 of Division 2 of the Business and
4 Professions Code and a drug manufacturer that is legally
5 authorized under federal law to manufacture and sell
6 pharmaceutical drugs may donate unused medications under the
7 voluntary drug repository and distribution program established
8 by a county pursuant to this division.

9 150204. (a) A county may establish, by ordinance, a
10 repository and distribution program for purposes of this division.
11 Only pharmacies that are county-owned or that contract with the
12 county pursuant to this division may participate in this program
13 to dispense medication donated to the drug repository and
14 distribution program.

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

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

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

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

24 (4) Ensuring proper safety and management of any
25 medications collected by and maintained under the authority of a
26 county-owned or county-contracted, licensed pharmacy.

27 (5) Ensuring the privacy of individuals for whom the
28 medication was originally prescribed.

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

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

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

38 (3) In the case of medications donated by a skilled nursing
39 facility, the medication shall not have been in the possession of a

1 *patient or any individual member of the public, but instead shall*
2 *have been under the control of staff of the skilled nursing facility.*

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

9 *(e) A pharmacist shall use his or her professional judgment in*
10 *determining whether donated medication meets the standards of*
11 *this division before accepting or dispensing any medication*
12 *under the repository and distribution program.*

13 *(f) Medication that is donated to the repository and*
14 *distribution program shall be handled in any of the following*
15 *ways:*

16 *(1) Dispensed to an eligible patient.*

17 *(2) Destroyed.*

18 *(3) Returned to a reverse distributor.*

19 *(g) Medication that is donated to the repository and*
20 *distribution program that does not meet the requirements of this*
21 *division shall not be distributed under this program and shall be*
22 *either destroyed or returned to a reverse distributor. This*
23 *medication shall not be sold, dispensed, or otherwise transferred*
24 *to any other entity.*

25 *(h) Medication donated to the repository and distribution*
26 *program shall be maintained in the donated packaging units until*
27 *dispensed to an eligible patient under this program, who presents*
28 *a valid prescription. When dispensed to an eligible patient under*
29 *this program, the medication shall be in a new and properly*
30 *labeled container, specific to the eligible patient and ensuring*
31 *the privacy of the individuals for whom the medication was*
32 *initially dispensed. Expired medication shall not be dispensed.*

33 *(i) Medication donated to the repository and distribution*
34 *program shall be segregated from the pharmacy's other drug*
35 *stock by physical means.*

36 *(j) The pharmacy shall keep complete records of the*
37 *acquisition and disposition of medication donated to and*
38 *dispensed under the repository and distribution program. These*
39 *records shall be kept separate from the pharmacy's other*
40 *acquisition and disposition records and shall conform to the*

1 *Pharmacy Law (Chapter 9 (commencing with Section 4000), of*
2 *Division 2 of the Business and Professions Code), including*
3 *being readily retrievable.*

4 *(k) Local and county protocols established pursuant to this act*
5 *shall conform to the Pharmacy Law regarding packaging,*
6 *transporting, storing, and dispensing all prescription drugs.*

7 *(l) County protocols established for packaging, transporting,*
8 *storing, and dispensing medications that require refrigeration,*
9 *including, but not limited to, any biological product as defined in*
10 *Section 351 of the Public Health and Service Act (42 U.S.C. Sec.*
11 *262), an intravenously injected drug, or an infused drug, include*
12 *specific procedures to ensure that these medications are*
13 *packaged, transported, stored, and dispensed at their*
14 *appropriate temperatures and in accordance with USP standards*
15 *and the Pharmacy Law.*

16 *(m) Notwithstanding any other provision of law, a*
17 *participating county-owned or county-contracted pharmacy shall*
18 *follow the same procedural drug pedigree requirements for*
19 *donated drugs as it would follow for drugs purchased from a*
20 *wholesaler or directly from a drug manufacturer.*

21 *150205. The following persons and entities shall not be*
22 *subject to criminal or civil liability for injury caused when*
23 *donating, accepting, or dispensing prescription drugs in*
24 *compliance with this division:*

25 *(a) A prescription drug manufacturer, wholesaler,*
26 *governmental entity, county-owned or county-contracted licensed*
27 *pharmacy, or skilled nursing facility.*

28 *(b) A pharmacist or health care professional who accepts or*
29 *dispenses prescription drugs.*

30 ~~150006.~~

31 *150206. The immunities provided in Section ~~150005~~ 150205*
32 *shall not apply in cases of bad faith or gross negligence.*

33 ~~150007.~~

34 *150207. Nothing in this division shall affect disciplinary*
35 *actions taken by licensing and regulatory agencies.*