

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 115 (commencing with Section 150000) 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 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) ensuring proper safety and management of any medications collected by and maintained under the authority of a licensed pharmacist, and (4) 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 115 (commencing with Section
2 150000) is added to the Health and Safety Code, to read:

3

4 DIVISION 115. SURPLUS MEDICATION COLLECTION
5 AND DISTRIBUTION

6

7 150000. It is the intent of the Legislature in enacting this
8 division to authorize the establishment of a voluntary drug
9 repository and distribution program for the purpose of
10 distributing surplus medications to persons in need of financial
11 assistance to ensure access to necessary pharmaceutical
12 therapies.

13 150002. A health facility licensed under Chapter 2
14 (commencing with Section 1250) of Division 2, *a pharmacy*
15 *wholesaler licensed pursuant to Article 11 (commencing with*
16 *Section 4160) of Chapter 9 of Division 2 of the Business and*
17 *Professions Code*, a pharmacy licensed pursuant to Chapter 9
18 (commencing with Section 4000) of Division 2 of the Business
19 and Professions Code, and a drug manufacturer that is legally
20 authorized under federal law to manufacture and sell
21 pharmaceutical drugs, may donate excess or surplus unused
22 prescribed medications under a program established by a county
23 pursuant to this division.

24 150004. (a) A county may establish, by local ordinance, a
25 repository and distribution program for purposes of this division.

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

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

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

8 (3) Ensuring proper safety and management of any
9 medications collected by and maintained under the authority of a
10 licensed pharmacist by ensuring, at a minimum, all of the
11 following:

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

14 (B) That any drugs received have not been adulterated,
15 misbranded, or stored under conditions contrary to standards set
16 by the United States Pharmacopoeia or the product manufacturer.

17 (C) That any drugs received are dispensed prior to their
18 expiration date.

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

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

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

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

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

33 (I) That any county that elects to dispense narcotics and other
34 controlled substances is required to receive public comment from
35 local law enforcement prior to establishing local protocols for
36 packaging, transporting, storing, and distributing narcotics and
37 other controlled substances.

38 (J) That local protocols established pursuant to this act adhere
39 to any applicable requirements established by the California State
40 Board of Pharmacy regarding packaging, transporting, storing,

1 and dispensing all prescription drugs, including narcotics and
2 controlled substances.

3 (K) That county protocols established for packaging,
4 transporting, storing, and dispensing medications that require
5 refrigeration, including, but not limited to, any biological product
6 as defined in Section 351 of the Public Health and Service Act
7 (42 U.S.C. Sec. 262), an intravenously injected drug, or an
8 infused drug, include specific procedures to ensure that these
9 medications are packaged, transported, stored, and dispensed at
10 their appropriate temperatures and according to any applicable
11 standards established by the California State Board of Pharmacy.

12 (L) That, notwithstanding any other provision of law,
13 participating pharmacies adhere to the same procedural drug
14 pedigree requirements for donated drugs as they would for drugs
15 purchased from a wholesaler or directly from a drug
16 manufacturer.

17 (4) Ensuring the privacy of individuals for whom the
18 medication was originally prescribed.

19 *150005. The following persons and entities shall not be*
20 *subject to criminal or civil liability for injury caused when*
21 *donating, accepting, or dispensing prescription drugs in*
22 *compliance with this division:*

23 *(a) A prescription drug manufacturer, pharmacy wholesaler,*
24 *governmental entity, or health facility.*

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

27 *(c) A pharmacy or health facility that employs a health care*
28 *professional who accepts or can legally dispense prescription*
29 *drugs.*

30 *150006. The immunities provided in Section 150005 shall not*
31 *apply in cases of bad faith or gross negligence.*

32 *150007. Nothing in this division shall affect disciplinary*
33 *actions taken by licensing and regulatory agencies.*