AMENDED IN ASSEMBLY JUNE 26, 2012

AMENDED IN SENATE MAY 14, 2012

AMENDED IN SENATE MARCH 29, 2012

SENATE BILL No. 1329

Introduced by Senator Simitian
(Coauthor: Assembly Member Galgiani)

February 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 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 licensed health and care facilities, as specified, to donate unused medications to the program. 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:

SECTION 1. Section 150201 of the Health and Safety Code is amended to read:

150201. For purposes of this division:

(a) "Eligible entity" means all of the following:

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

(2) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is owned and operated by a licensed primary care clinic, as defined in Section 1204*, and is not on probation with the California State Board of Pharmacy*.

(3) A licensed primary care clinic, as defined in Section 1204, that is licensed to administer and dispense drugs pursuant to subparagraph (A) of paragraph (1) of subdivision (a) of Section 4180 of the Business and Professions Code *and is not on probation with the California State Board of Pharmacy*.

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

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

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

150202. Notwithstanding any other provision of law, the following health and care facilities may donate unused medications under a program established pursuant to this division:

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

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

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

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

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

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

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

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

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

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

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

(*l*) An approved mental health rehabilitation center, as described in Section 5675 of the Welfare and Institutions Code.

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

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

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

(3) An eligible entity that seeks to participate in the program shall inform the county health department, *and the California State Board of Pharmacy,* in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4) (A) A participating entity shall disclose to the county health department the name and location of the source of all donated medication it receives.

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

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

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. *If the county board of supervisors, the public health officer of the county, or the*

California State Board of Pharmacy prohibits an eligible or participating entity from participating in the program, it shall provide written notice to the prohibited entity within 15 days of making this determination. The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy shall ensure that this notice also is provided to one another.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor.

(4) Transferred to another participating entity to be dispensed to eligible patients pursuant to this division.

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

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

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

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

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

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

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

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

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

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

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

(c) A health or care facility, as described in Section 150202.

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