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SB-1346 Surplus medication collection and distribution. (2021-2022)

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Senate Bill No. 1346

CHAPTER 886

An act to amend Sections 150202, 150202.5, and 150205 of, to add Section 150204.5 to, and to add and repeal Section 150204.6 of, the Health and Safety Code, relating to surplus medication.

[Approved by Governor September 30, 2022. Filed with Secretary of State September 30, 2022.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1346, Becker. Surplus medication collection and distribution.

Existing law authorizes a county to establish a repository and distribution program for the donation of surplus medication and redistribution to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.

This bill would, until January 1, 2030, authorize a regional pilot program in the Counties of Santa Clara and San Mateo and the City and County of San Francisco for the purpose of implementing and maintaining a repository and distribution program, as specified. The bill would require participating pharmacies in the regional pilot program to be owned or operated by one of the 3 counties and not on probation with the California State Board of Pharmacy. The bill would exempt the regional pilot program from a specified provision that generally applies to donation of surplus medication redistribution programs.

Specifically for the regional pilot program, this bill would authorize donated medication to be transferred more than once, but only within a county, and would allow donated medication from multiple facilities to be commingled by the participating entity. The bill would require participants to maintain a system of recording and logging donated medication to allow the tracking, as specified, and to disclose to the Board of Pharmacy any medication errors, as defined, within 30 days of discovery of the error by the participating entity.

This bill would, on January 1, 2028, require the Board of Pharmacy to submit to the Legislature an evaluation of the regional pilot program and the pilot program participants' compliance to program requirements.

Existing law defines a donor organization to refer to specified health and care facilities that may donate centrally stored, unused medications.

This bill would expand the list of entities that may act as a donor organization to include a facility licensed by the State Department of Social Services, the State Department of Public Health, the State Department of Health Care Services, the Department of Corrections and Rehabilitation, Division of Juvenile Justice, and other specified licensed facilities.

Existing law authorizes a pharmacy, licensed in California and not on probation with the California State Board of Pharmacy, whose primary or sole type of pharmacy practice type is limited to a skilled nursing facility, home health care, board and care, or mail order, to donate unused, unexpired medication, as specified.

This bill would authorize any pharmacy, licensed in California and not on probation with the California State Board of Pharmacy, to donate unused, unexpired medication, as specified.

This bill would exempt specified persons and entities, including a prescription drug manufacturer, a participating entity, and a pharmacist or physician, from criminal or civil liability for an injury caused when any entity or person donates, accepts, or dispenses prescription drugs in compliance with specified provisions. The bill would also include a surplus medication collection and distribution intermediary in this exemption, as specified.

This bill would make legislative findings and declarations as to the necessity of a special statute for these 3 counties.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 150202 of the Health and Safety Code is amended to read:

150202. (a) Notwithstanding any other law, a donor organization is defined, for purposes of this division, to refer to the following facilities, hospitals, and entities that legally possess centrally stored, unused medication:

- (1) A licensed general acute care hospital, as defined in Section 1250.
- (2) A licensed acute psychiatric hospital, as defined in Section 1250.
- (3) A licensed skilled nursing facility, as defined in Section 1250, including a skilled nursing facility designated as an institution for mental disease.
- (4) A licensed intermediate care facility, as defined in Section 1250.
- (5) A licensed intermediate care facility/developmentally disabled-habilitative facility, as defined in Section 1250.
- (6) A licensed intermediate care facility/developmentally disabled-nursing facility, as defined in Section 1250.
- (7) A licensed correctional treatment center, as defined in Section 1250.
- (8) A licensed psychiatric health facility, as defined in Section 1250.2.
- (9) A licensed chemical dependency recovery hospital, as defined in Section 1250.3.
- (10) A licensed residential care facility for the elderly, as defined in Section 1569.2, with 16 or more residents.
- (11) An approved mental health rehabilitation center, as described in Section 5675 of the Welfare and Institutions Code.
- (12) An eligible entity, as defined in subdivision (b) of Section 150201.
- (13) A juvenile facility, as described in Section 208.3 of the Welfare and Institutions Code.
- (14) A local detention facility, as described in Section 6031.4 of the Penal Code.
- (15) A facility that is any of the following:
 - (A) Licensed by the State Department of Social Services.
 - (B) Licensed by the State Department of Public Health.
 - (C) Licensed by the State Department of Health Care Services.
 - (D) Licensed by or under the jurisdiction of the Department of Corrections and Rehabilitation.
 - (E) Licensed by or under the jurisdiction of the Division of Juvenile Justice.
- (16) A licensed home health agency, as defined in Section 1725.
- (17) A licensed hospice agency, as defined in Section 1745.
- (18) A licensed hospice facility, as defined in subdivision (n) of Section 1250.

(b) Medication donated by facilities pursuant to subdivision (a) shall meet the requirements of subdivisions (c) and (d) of Section 150204 and shall be unexpired medication that would have otherwise been destroyed by the facility or another appropriate entity.

(c) Medication eligible for donation by facilities pursuant to subdivision (a) shall be directly delivered from the dispensing pharmacy, wholesaler or manufacturer, to the facility and subsequently centrally stored. Centrally stored medication that originated from a patient or resident is not eligible for donation under this division.

SEC. 2. Section 150202.5 of the Health and Safety Code is amended to read:

150202.5. Notwithstanding any other law, a pharmacy, licensed in California and not on probation with the California State Board of Pharmacy may donate unused, unexpired medication that meets the requirements of subdivisions (c) and (d) of Section 150204, under a program established pursuant to this division and that meets either of the following requirements:

(a) The medication was received directly from a manufacturer or wholesaler.

(b) The medication was returned from a health facility to the issuing pharmacy, in a manner consistent with state and federal law.

SEC. 3. Section 150204.5 is added to the Health and Safety Code, to read:

150204.5. (a) (1) A regional pilot program may be established in the Counties of Santa Clara and San Mateo and the City and County of San Francisco to determine the feasibility and benefits of implementing and maintaining a repository and distribution program. The regional pilot program shall run until January 1, 2030.

(b) Participating pharmacies in the regional pilot program shall be owned or operated by the Counties of Santa Clara or San Mateo or the City and County of San Francisco, licensed in California, and not on probation with the California State Board of Pharmacy.

(c) (1) Participants in the regional pilot program shall develop and implement their programs in accordance with this division.

(2) While participating in the regional pilot program, participants shall continue to meet all other legal responsibilities and requirements relating to pharmacy services and comply with all relevant state and federal statutes when administering their programs.

(d) Section 150204 shall not apply to a pilot program established pursuant to this section and Section 150204.6

SEC. 4. Section 150204.6 is added to the Health and Safety Code, to read:

150204.6. (a) (1) A county specified in Section 150204.5 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 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 primary care clinic, as described in 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.

(B) 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 division.

(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 each ensure that this notice is also provided to the other two entities.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish written 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) Medication donated to the repository and distribution program or transferred between participating entities 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 hospital, facility, or entity, as described in Section 150202, shall have been under the control of a staff member of the health or care facility who is licensed in California as a health care professional or has completed, at a minimum, the training requirements specified in Section 1569.69.

(d) (1) 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, and once identified, shall be quarantined immediately and handled and disposed of in accordance with the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104).

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

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

(e) A pharmacist or physician at a participating entity shall use their professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing 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 or licensed waste hauler.
- (4) (A) Transferred to another participating entity within the county to be dispensed to eligible patients pursuant to this division. Notwithstanding this paragraph, a participating county-owned pharmacy may transfer eligible donated medication to a participating county-owned pharmacy within another adjacent county that has adopted a program pursuant to this division, if the pharmacies transferring the medication have a written agreement between the entities that outlines protocols and procedures for safe and appropriate drug transfer that are consistent with this division.

(B) Medication donated under this division may be transferred more than once only within the county and after the final transfer shall be dispensed to an eligible patient, destroyed, or returned to a reverse distributor or licensed waste hauler.

(C) Medication transferred pursuant to this paragraph shall be transferred with documentation that identifies the drug name, strength, and quantity of the medication, original manufacturer lot numbers, and current expiration date. The document shall include a statement that the medication shall be handled pursuant to subparagraph (B). A copy of this document shall be kept by the participating entity transferring the medication and the participating entity receiving the medication.

(D) Medication donated from multiple facilities under this division may be commingled by the participating entity. However, in the event of a recall, recalled medication shall be destroyed at the National Drug Code level.

(E) Participating facilities shall maintain a system for recording and logging donated medication which allows the tracking of medication in each repackaged container back to the facility or facilities that donated the medication.

(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. Donated medication that does not meet the requirements of this division shall not be sold, dispensed, or otherwise transferred to any other entity.

(i) (1) When dispensed to an eligible patient under this program, the donated medication shall be in a new, properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. However, medications donated in sealed manufacturer's packaging are not required to be placed into a new container, but shall otherwise be appropriately labeled. Expired medication shall not be dispensed.

(2) The pharmacy shall have repackaging policies and procedures in place for identifying and recalling medications. Medication that is repackaged shall be labeled with the earliest expiration date. Repackaged medication can only be dispensed to patients within the county.

(j) A participating entity shall keep complete records of the acquisition and disposition of medication donated to, and transferred, dispensed, and destroyed under, the repository and distribution program. Notwithstanding any other law, the acquisition record created by a participating entity may be used as the donation, destruction, or disposition record required of a donor organization for donated medication.

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

(l) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, a biological product as defined in Section 351 of the federal 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.

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

(n) On January 1, 2028, the Board of Pharmacy shall submit to the Legislature an evaluation of the regional pilot programs and pilot participants' compliance to program requirements as specified in this division. The report shall comply with Section 9795 of the Government Code.

(o) A participating entity shall disclose to the Board of Pharmacy any "medication errors," as that term is described in Section 1716 of Title 16 of the California Code of Regulations, arising out of a program under this division, within 30 days of a participating entity discovering the medication error.

(p) This section shall remain in effect only until January 1, 2030, and as of that date is repealed.

SEC. 5. Section 150205 of the Health and Safety Code is amended to read:

150205. (a) The following persons and entities shall not be subject to criminal or civil liability for injury caused when any entity or person donates, accepts, or dispenses prescription drugs in compliance with this division:

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

(2) A pharmacist or physician who accepts or dispenses prescription drugs.

(3) A licensed facility, as described in Section 150202, or a pharmacy, as described in Section 150202.5.

(b) A surplus medication collection and distribution intermediary, as described in Section 150208, shall not be subject to criminal or civil liability for injury caused when facilitating the donation of medications to or transfer of medications in compliance with this

division.

SEC. 6. The Legislature finds and declares that a special statute is necessary and that a general statute cannot be made applicable within the meaning of Section 16 of Article IV of the California Constitution because of the need for a pilot program to determine the benefits and possible expansion of the repository and distribution program.