SB-310 Unused medications: cancer medication recycling. (2021-2022)

Date Published: 10/06/2021 09:00 PM

Senate Bill No. 310

CHAPTER 541

An act to add Article 11.7 (commencing with Section 4169.7) to Chapter 9 of Division 2 of the Business and Professions Code, and to add Division 117 (commencing with Section 150400) to the Health and Safety Code, relating to public health.

[Approved by Governor October 05, 2021. Filed with Secretary of State October 05, 2021.]

LEGISLATIVE COUNSEL'S DIGEST

SB 310, Rubio. Unused medications: cancer medication recycling.

Existing law, the Pharmacy Law, establishes the California State Board of Pharmacy in the Department of Consumer Affairs. Existing law authorizes a county to establish a voluntary drug repository and distribution program for the purpose of distributing surplus medications through a surplus medication collection and distribution intermediary that is licensed by the board. Existing law authorizes the board to charge a fee in the amount of $300 to issue or renew a license to operate as a surplus medication collection and distribution intermediary. Existing law makes a violation of the Pharmacy Law a crime.

This bill would establish, until January 1, 2027, a program for the collection and distribution of eligible unused cancer medications, to be known as the Cancer Medication Recycling Act. The bill would require each participating practitioner, as defined, in the collection and distribution of those medications to be registered with a surplus medication collection and distribution intermediary, as specified, and would require a surplus medication collection and distribution intermediary to create a registry for up to 50 participating practitioners, including developing both a donor and a recipient form containing specified information. The bill would authorize a surplus medication collection and distribution intermediary to charge a fee, not to exceed $300, as specified, to issue or renew the registration certificate of a participating practitioner under the program. The bill would require participating practitioners to meet specified requirements, including establishing criteria for determining medication distribution to patients.

This bill would exempt a participating practitioner from licensure as a wholesaler and would require the practitioner to keep and maintain for 3 years records created by the participating practitioner for purposes of the program. The bill would also exempt a donor and other specified persons and entities from criminal or civil liability for an injury caused when participating in the program, including, but not limited to, donating, accepting, or dispensing medication in compliance with the requirements of the act, unless the person or entity acted with gross negligence, recklessness, intentional conduct, or in cases of malpractice unrelated to the quality of the medication. The bill would also exempt a participating practitioner that receives a donated medication and redistributes it from a specified penalty resulting from the condition of the donated medication, except as specified. The bill would authorize the board to prohibit a participating practitioner from participating in the program if the participating practitioner does not comply with the requirements of the bill.

Because a violation of the requirements of the bill contained in the Pharmacy Law would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.
Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

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

SECTION 1. Article 11.7 (commencing with Section 4169.7) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 11.7 Cancer Medication Collection and Distribution: Registry of Participating Practitioners

4169.7. (a) A participating practitioner in the collection and distribution of unused cancer medications pursuant to the program established pursuant to Division 117 (commencing with Section 150400) of the Health and Safety Code shall be registered with a surplus medication collection and distribution intermediary, as defined in Section 150401 of the Health and Safety Code, in accordance with this section. The registration shall be renewed annually.

(b) An application for registration with a surplus medication collection and distribution intermediary shall be made on a form, which may be in an electronic format, furnished by the surplus medication collection and distribution intermediary, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant.

(c) Upon the approval of an application by a surplus medication collection and distribution intermediary, and payment of a fee in an amount not to exceed three hundred dollars ($300) to the surplus medication collection and distribution intermediary for processing the application and issuing or renewing the registration, the surplus medication collection and distribution intermediary shall issue or renew a registration certificate to operate as a participating practitioner, if the practitioner has complied with all of the provisions of this chapter.

(d) A surplus medication collection and distribution intermediary shall do all of the following:

(1) Create a registry, not to exceed 50 participating practitioners.

(2) Develop a donor form that may be in an electronic format and that shall include all of the following information:

(A) The date the medication was donated.

(B) The name, address, and telephone number of the donor.

(C) The name, strength, and quantity of the medication.

(D) The manufacturer and lot number, if applicable, of the medication.

(E) The name and dated signature of the practitioner who is accepting and inspecting the donated medication.

(F) An acknowledgment that the medication was handled and stored in accordance with the physician’s order and per the manufacturer’s recommendation.

(3) Develop a recipient form, which may be in an electronic format, and which shall include all of the following:

(A) The date the recipient received the medication.

(B) The name, address, and telephone number of the recipient.

(C) The name, strength, and quantity of the medication.

(D) The manufacturer and the lot number, if applicable, of the medication.

(E) The name and dated signature of the practitioner who is accepting and inspecting the donated medication.

(F) An acknowledgment that the donor is known to the practitioner and is a patient of record, and that there is no reason to believe that the donated prescription medication was improperly handled or stored.

(G) An acknowledgment that by accepting the donated prescription medication, the recipient accepts any risks that an accidental mishandling could create.

(H) An acknowledgment that the donor, the participating practitioner, and the surplus medication collection and distribution intermediary are released from liability arising from their participation pursuant to this article and the program established

pursuant to Division 117 (commencing with Section 150400) of the Health and Safety Code.

(I) An acknowledgment that the pharmaceutical manufacturer is released from liability of any claims or injury arising from the transfer of any prescription medication pursuant to this article and the program established pursuant to Division 117 (commencing with Section 150400) of the Health and Safety Code.

(J) An acknowledgment that the recipient is receiving donated prescription medication and that the recipient is receiving the donated prescription medication at no cost.

(e) A participating practitioner is exempt from licensure as a wholesaler.

(f) A participating practitioner shall keep and maintain for three years records created by the participating practitioner for purposes of this article.

(g) The board may request records from the distribution intermediary and participating practitioner to confirm compliance with this section and Section 150400 of the Health and Safety Code.

(h) The board may prohibit a participating practitioner from participating in the program established pursuant to Division 117 (commencing with Section 150400) of the Health and Safety Code if the participating practitioner does not comply with the requirements of the program or this article. If the board prohibits a participating practitioner from participating in the program, it shall, within 15 days of making that determination, provide written notice to the participating practitioner and to the surplus medication collection and distribution intermediary that issued the participating practitioner a registration certificate to operate as a participating practitioner.

(i) For purposes of this section, the following definitions apply:

(1) “Donor” means an individual who donates unused prescription medications to a participating practitioner for the purpose of redistribution to established patients of that practitioner.

(2) “Ineligible drugs” means drugs that are not able to be accepted for redistribution as part of the program established pursuant to Division 117 (commencing with Section 150400) of the Health and Safety Code. “Ineligible drugs” include all controlled substances, including all opioids, all compounded medications, injectable medications, drugs that have an approved United States Food and Drug Administration Risk Evaluation and Mitigation Strategy (REMS) requirement, and all growth factor medications.

(3) “Participating practitioner” means a person who is licensed to practice medicine by the Medical Board of California and is board certified in medical oncology or hematology and is registered with a surplus medication collection and distribution intermediary.

(4) “Recipient” means an individual who voluntarily receives donated prescription medications.

(5) “Unused cancer medication” or “medication” means a medication or drug, including a “dangerous drug” as defined in Section 4022 or a “drug” as defined in Section 4025, that is prescribed as part of a cancer treatment plan and is in its original unopened, tamper-evident dose unit packaging that includes the drug’s lot number and expiration date. A cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit dose packaging is unopened.

4169.8. This article shall remain in effect only until January 1, 2027, and as of that date is repealed.

SEC. 2. Division 117 (commencing with Section 150400) is added to the Health and Safety Code, to read:

DIVISION 117. Cancer Medication Recycling Act

150400. This division shall be known, and may be cited, as the Cancer Medication Recycling Act.

150401. For purposes of this division, the following definitions apply:

(a) “Donor” means an individual who donates unused prescription drugs to a participating practitioner for the purpose of redistribution to established patients of that practitioner.

(b) “Ineligible drugs” means drugs that are not able to be accepted for redistribution as part of the program established pursuant to this division. “Ineligible drugs” include all controlled substances, including all opioids, all compounded medications, injectable medications, drugs that have an approved United States Food and Drug Administration Risk Evaluation and Mitigation Strategy (REMS) requirement, and all growth factor medications.

(c) “Participating practitioner” means a person who is licensed to practice medicine by the Medical Board of California and is board certified in medical oncology or hematology and is registered with a surplus medication collection and distribution intermediary.

(d) “Recipient” means an individual who voluntarily receives donated prescription medications.

(e) “Surplus medication collection and distribution intermediary” means an entity licensed pursuant to Section 4169.5 of the Business and Professions Code as a surplus medication collection and distribution intermediary, as described in Section 150208.

(f) “Unused cancer medication” or “medication” means a medication or drug, including a “dangerous drug” as defined in Section 4022 of the Business and Professions Code or a “drug” as defined in Section 4025 of the Business and Professions Code, that is prescribed as part of a cancer treatment plan and is in its original container or packaging.

150402. An unused cancer medication that is not an ineligible drug as defined in subdivision (b) of Section 150401 may be donated to a participating practitioner, and a participating practitioner may accept and redistribute the donated prescription drugs.

150403. (a) A participating practitioner shall comply with all of the following:

(1) Be registered with a surplus medication collection and distribution intermediary in order to participate in the program established pursuant to this division and Article 11.7 (commencing with Section 4169.7) of Chapter 9 of Division 2 of the Business and Professions Code.

(2) Only accept donated medications originally prescribed for use by established patients of that participating practitioner or practice.

(3) Distribute a medication only if it will not expire before the proper use by the recipient based on the participating practitioner’s directions for use.

(4) Refuse a medication that has previously been redistributed.

(5) Store all donated medications separately from all other medication stock.

(6) Store all donated medications in compliance with the manufacturer’s storage requirements per the drug monograph.

(7) Remove or redact all confidential patient information, personal information, and any other information through which the prior patient could be identified from donated medications.

(8) Require all donors to read and sign the donor form approved by the surplus medication collection and distribution intermediary.

(9) Keep all donor forms and recipient forms in the records for at least three years.

(10) Examine the donated drug to determine that it has not been adulterated or misbranded and certify that the medication has been stored in compliance with the requirements of the product.

(11) Require all recipients of a donated medication to read and sign the recipient form approved by the surplus medication collection and distribution intermediary.

(12) Dispose of any donated medications that were collected but not redistributed in accordance with all local, state, and federal requirements for the disposal of medications.

(13) Monitor all United States Food and Drug Administration (FDA) or manufacturer recalls, market withdrawals, and safety alerts and communicate with recipients if medications they received may be impacted by the FDA action.

(14) Inspect all donated medications to determine that the drugs are unaltered, safe, and suitable for redistribution and meet all of the following conditions:

(A) Tamper-resistant packaging is unopened and intact or, in the case of unit dose packaging, the tamper-resistant dose packaging is intact for each dose donated.

(B) Tablets or capsules have a uniformity of color, shape, imprint or markings, texture, and odor.

(C) Liquids have a uniformity of color, thickness, particulates, transparency, and odor.

(D) The date of donation is less than six months from the date of the initial prescription or prescription refill.

(15) Establish policies and procedures for the administration of the cancer medication recycling program, including, but not limited to, criteria for determining medication distribution to patients. Provide the surplus medication collection and distribution intermediary with updated sections of their policy and procedures manual that indicate how the practitioner will accept, reuse, and keep records of donated medications, if requested.

(b) A donor is not subject to a penalty pursuant to the Sherman Food, Drug, and Cosmetic Law, as set forth in Part 5 (commencing with Section 109875) of Division 104, for an injury caused when donating, accepting, or dispensing medication in compliance with this division, unless an injury arising from the donated medication is caused by the gross negligence, recklessness, or intentional conduct of the donor, or in cases of noncompliance with this division.

(c) A participating practitioner that receives and redistributes a donated medication is not subject to a penalty pursuant to the Sherman Food, Drug, and Cosmetic Law, as set forth in Part 5 (commencing with Section 109875) of Division 104, resulting from the condition of the donated medication unless an injury arising from the donated medication is caused by the gross negligence, recklessness, or intentional conduct of the participating practitioner, in cases of noncompliance with this division, or in cases of malpractice unrelated to the quality of the medication.

(d) The following persons and entities are not subject to criminal or civil liability for an injury caused when participating in the program established pursuant to this division, including, but not limited to, donating, accepting, or dispensing prescription drugs in compliance with this division:

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

(2) A participating practitioner who accepts or dispenses prescription drugs.

(3) A donor, as defined in Section 150401.

(4) A surplus medication collection and distribution intermediary.

(e) The immunities provided in subdivision (d) do not apply in cases of noncompliance with this division, gross negligence, recklessness, intentional conduct, or in cases of malpractice unrelated to the quality of the medication.

(f) This division shall not affect disciplinary actions taken by licensing and regulatory agencies.

150404. This division shall remain in effect only until January 1, 2027, and as of that date is repealed.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.