
SENATE COMMITTEE ON APPROPRIATIONS

Senator Anthony Portantino, Chair
2021 - 2022 Regular Session

SB 310 (Rubio) - Unused medications: cancer medication recycling

Version: April 8, 2021

Policy Vote: B., P. & E.D. 14 - 0, JUD. 11
- 0

Urgency: No

Mandate: Yes

Hearing Date: April 19, 2021

Consultant: Janelle Miyashiro

Bill Summary: SB 310 establishes the Cancer Medication Recycling Act for the collection and redistribution of unused cancer medications.

Fiscal Impact: The Medical Board of California anticipates costs of \$122,494 to implement the program. The Board also notes unknown, potentially significant enforcement costs related to the investigation of and subsequent hearings and formal discipline for violations of program requirements. Although enforcement costs are unquantifiable at this time, the Board estimates potential costs to range from \$50,000 to \$100,000 or more depending on the nature and severity of complaints.

The Office of Information Services within the Department of Consumer Affairs anticipates additional information technology costs of \$70,000 to create a new license type and online application for the program, which the Office reports can be absorbed through the redirection of existing maintenance resources.

Background: California's current voluntary drug repository and distribution program was established in 2006, which authorized California counties to adopt an ordinance under which certain licensed entities could donate unused medications to county-owned pharmacies, or pharmacies that contract with the county, for dispensing to medically indigent patients free of charge.

The voluntary drug repository and distribution program has since been revised three times in order to better effectuate its purposes: SB 1329 (Simitian, Chapter 709, Statutes of 2012) authorized a county public health officer to implement a voluntary drug repository and distribution program and added several categories of licensed health care facilities that may donate medications; AB 467 (Stone, Chapter 10, Statutes of 2014) established a licensure category to facilitate the transfer of donated medications; and AB 1069 (Gordon, Chapter 316, Statutes of 2016) authorized a voluntary drug repository and distribution program pharmacy to repackage a reasonable quantity of donated medicine in anticipation of dispensing to a specific patient.

At least three counties in California (Santa Clara, San Mateo, and San Francisco) have established a voluntary drug repository and distribution program, although the Santa Clara program is the only current operational program. As of April 2018, Santa Clara's Better Health Pharmacy has distributed more than 31,000 free prescriptions from 180 donors around California, saving residents more than \$2,000,000.

Proposed Law: Establishes the Cancer Medication Recycling Act.

- Requires participating practitioners in the collection and redistribution of unused cancer medications to register with the Board; requires registration to be renewed annually; and requires participating practitioner compliance with all of the following:
 - Accept only donated medications originally prescribed for use by established patients of that participating practitioner or practice.
 - Accept or redistribute a medication only if the expiration date listed on the packaging is more than six months after the date of the acceptance or redistribution.
 - Refuse a medication that has previously been redistributed.
 - Examine the donated drug to determine that it has not been adulterated or misbranded and certify the medication has been stored in compliance with the requirements of the product.
 - Inspect all donated medications to determine that the drugs are unaltered; safe and suitable for redistribution; that tamper resistant packaging is unopened and intact; tablets or capsules have uniform color, shape, imprint, markings, texture, and odor; liquids have a uniformity of color thickness, particulates, transparency, and odor; the date of donation is less than six months from the date of the initial prescription or prescription refill.
 - Monitor all FDA recalls, market withdrawals, and safety alerts and communicate with recipients if medications they received may be impacted by the FDA action.
 - Store all donated medication separately from all other medication stock and in compliance with the manufacturer's storage requirements.
 - Remove all confidential, personal, and identifying patient information.
 - Require all donors to read and sign a Board-approved donor form.
 - Require all recipients of a donated medication to read and sign a Board-approved recipient form.
 - Retain all donor and recipient records, separately, for at least three years.
 - Provide the Board with updated policy and procedures that indicate how the practitioner will accept, reuse, and keep records of donated medications.
- Requires the Board to create a registry of participating practitioners; oversee and establish procedures to implement the program; and develop a donor and recipient form.
 - Requires the donor form to include the date the medication was donated; name, address, and telephone number of the donor; name, strength, and quantity of the medication; the manufacturer and lot number of the

medication; name and dated signature of the participating practitioner; and an acknowledgement that the medication was handled and stored appropriately.

- Requires the recipient form to include the date the recipient received the medication; name, address, and telephone number of the recipient; name, strength, and quantity of the medication; the manufacturer and lot number of the medication; name and dated signature of the participating practitioner; and an acknowledgement that the donor is known to the practitioner, is a patient of record, and that there is no reason to believe that the donated drugs were improperly handled or stored; an acknowledgement by the recipient to accept any risks that an accidental mishandling could create; an acknowledgement that the donor and participating practitioner are released from liability arising from their participation; and an acknowledgement that the pharmaceutical manufacturer is released from liability of any claims or injury arising from the transfer of any donated drugs.
- Provides that a participating practitioner is exempt from licensure as a drug wholesaler.
- Provides that a donor or participating practitioner is not subject to penalties under the Sherman Food, Drug, and Cosmetic Law for an injury caused when donating, accepting, or dispensing medication unless the injury arising from the donation is caused by gross negligence, recklessness, noncompliance with program requirements, or intentional conduct.
- Provides that prescription drug manufacturers, wholesalers, participating entities, participating practitioners, or donors are not subject to criminal or civil liability for an injury caused when donating, accepting, or dispensing donated drugs except in cases of noncompliance with program requirements, gross negligence, recklessness, intentional conduct, or in cases of malpractice unrelated to the quality of the donated medication.
- Establishes definitions:
 - “Donor” means an individual who donates unused prescription medications to a participating practitioner for the purpose of redistribution to established patients of that practitioner.
 - “Ineligible drugs” means drugs that are not able to be accepted for redistribution as part of the program and includes all controlled substances, compounded medications, injectable medications, drugs that have an approved FDA Risk Evaluation and Mitigation Strategy requirement, and all growth factor medications.
 - “Participating practitioner” means a person who is registered with the Board, is Board certified in medical oncology or hematology, and is eligible for participation in the program.
 - “Recipient” means an individual who voluntarily receives donated prescription medications.

- “Unused cancer medication” means a medication or drug that is prescribed as part of a cancer treatment plan and is in its original container or packaging.

Related Legislation: SB 650 (Rubio, 2019) would have required the Board of Pharmacy to report to the Legislature on the best mechanism to enable the transfer of unused cancer medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. SB 650 was held on the Assembly Committee on Appropriations Suspense File.

Staff Comments: The Board is a special fund agency whose activities are funded through regulatory and license fees. The Board is currently experiencing a challenge with its reserve fund, which is expected to have less than a one-month spending reserve by the end of Fiscal Year 2021-22. Additionally, the Board is currently at or close to its statutory fee cap across all of its license types. Absent a statutory change, the Board would not be able to increase its fees.

While this bill may result in unknown, additional increased fee revenue to be deposited in the Medical Board Contingent Fund, the Board indicates that the increase in fee revenue would not be substantial enough to cover its anticipated increase in licensing, enforcement, or administrative costs.

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