

SENATE THIRD READING
SB 310 (Rubio)
As Amended August 30, 2021
Majority vote

SUMMARY

Establishes a registration program for the collection and distribution of specified unused cancer medications under the Cancer Medication Recycling Act.

Major Provisions

- 1) Establishes, 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.
- 2) Defines "donor" as an individual who donates unused prescription medications to a participating practitioner for the purpose of redistribution to established patients of that practitioner.
- 3) Defines "ineligible drugs" as drugs that are not able to be accepted for redistribution as part of the cancer donation program established under this bill, including 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.
- 4) Defines "participating practitioner" as a licensed physician and surgeon who is board certified in medical oncology or hematology and is registered with a licensed surplus medication collection and distribution intermediary under this bill, as specified.
- 5) Defines recipient" as an individual who voluntarily receives donated prescription medications.
- 6) Defines "unused cancer medication" or "medication" as a medication or drug, including a "dangerous drug" or a "drug" as defined under the Pharmacy Law, that is prescribed as part of a cancer treatment plan and is in its original container or packaging, as specified.
- 7) Requires a surplus medication collection and distribution intermediary licensed by the Board of Pharmacy to create a registry for up to 50 participating practitioners, including developing both a donor and a recipient form containing specified information, including that the recipient receives the donated prescription at no cost.
- 8) Authorizes a licensed 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.
- 9) Exempts a participating practitioner from licensure as a wholesaler and would require the practitioner to keep and maintain for three years records created by the participating practitioner for purposes of the program.
- 10) Exempts a donor and other specified persons and entities from criminal or civil liability for an injury caused when 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.

- 11) Exempts 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.

COMMENTS

Background. This bill establishes a drug recycling program that is specific to unused cancer medications. According to the sponsors, the existing drug donation and redistribution program is limited in geographic scope as well as the available drugs. As a result, this bill seeks to establish a separate program that is operated directly through participating physicians.

Existing Drug Donation Program. California's voluntary drug repository and distribution program was established in 2006 and 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.

At least three counties in California (Santa Clara, San Mateo, and San Francisco) have established a 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.

Similar Programs in Other States. According to the National Conference of State Legislatures (NCSL):

Thirty-nine states and Guam have enacted legislation regarding prescription drug donation, return and reuse. State legislation usually determines the type of medication accepted, the entities eligible to donate, the pharmacy protocols to ensure safety and the individuals eligible for redistribution. Most programs focus on providing expensive medications to those with limited resources. Programs also vary in their efficacy and operational status, as states range in their ability to fund them and provide access points to redistribute medication.

Return, reuse and donation protocols must follow states' board of pharmacy guidelines for the safe return and redistribution of all drugs to ensure that future recipients are issued safe and untampered medication. The National Association of Boards of Pharmacy, which oversees the state-level boards, supports drug reuse programs when they can demonstrate that the medication's integrity remains intact and is safe for patients.

According to the Author

"The news of a cancer diagnosis is probably one of the most mind shocking, life-altering experiences anyone could have. Under [this bill], we are expanding critical access to live-saving medication to patients in need. Studies show that delaying treatment during the approval process is detrimental to the overall care of the patient, on top of the billions of dollars wasted on drug disposal every year. Across the [United States] (U.S.), currently 14 states have successfully

implemented anti-cancer specific medication donation programs. These recycling programs reduce initial costs, ensure timely access, and prevent unused medications from going to waste."

Arguments in Support

The *American Cancer Society Cancer Action Network, Inc.* (co-sponsor) writes in support:

Cancer is one of the leading causes of death and disease in the U.S. The American Cancer Society (ACS) estimates that roughly 1.7 million new cases of cancer will be diagnosed in the U.S. in 2017 and more than 15 million Americans living today have a cancer history. Not only does cancer take an enormous toll on the health of patients and survivors—it also has a tremendous financial impact.

In 2014, U.S. Cancer patients paid nearly \$4 billion in out-of-pocket costs, and the disease cost the country \$87.8 billion in cancer-related health care spending. Even with insurance, cancer patients often face unpredictable or unmanageable costs including high co-insurance, high deductibles, having to seek out-of-network care, and needing a treatment that is not covered by their health plan. Even when cancer treatments are covered by their health plan, it is often difficult to afford their initial treatments and they are frequently forced to wait for treatments to begin due to health insurance approval delays. At the same time, it is not uncommon for some cancer patients to find out early in their treatment that their medication is not the correct treatment for them and they need to return the medication and begin a new treatment. This often leaves physicians with unused medication that could be used by another patient.

In 2005, the Legislature passed SB 798 (Simitian), Chapter 444 which allowed counties to establish programs to dispense donated, unused medications. This bill was limited to county-run or contracted pharmacies, but limitations have resulted in Santa Clara as the only county to establish such program. Furthermore, cancer medications have not been included in these programs. Currently, there are programs in 21 other states that have active drug donation programs that allow for redistribution of unused cancer medications. One medical practice in New Mexico saved patients more than \$300,000 in its first year of operations.

[This bill] would reduce waste of cancer medication, save money, and increase timely access to these needed medications for those patients who cannot afford their medication or whose health plans forces untimely approval times. For cancer patients, time is of the essence and, often, they must begin treatments immediately to be effective.

The *Association of Northern California Oncologists* (co-sponsor) writes in support:

This bill to allow physicians the ability to redistribute unneeded medications gives patients and their doctors the best opportunity to properly treat cancer as quickly as possible and reduces the waste of high-quality medications. Our proposed legislation will ensure that more patients with cancer in California have access to important oral cancer therapies in a timely manner and reduces the amount of medications that are wasted.

We understand the only way this program works is if we can ensure patients who receive the medication receive the highest quality medication. To that end, the program will require [the safety provisions under this bill].

Per the National Council on State Legislatures, as of 2018, 21 states have active drug donation and reuse programs. The programs in these states have served thousands of patients, and saved tens of millions of dollars over the years. For example, Iowa's program has served 71,000 patients and redistributed \$17.7 million in free medications and supplies; and in Oklahoma, the program has filled 227,603 prescriptions, worth about \$22,518,462 through the end of May 2018.

We think it is important to note that in 2016, California adopted an investigational drug "right to try" policy AB 1668, (Calderon) [Chapter 684, Statutes of 2016] which allows patients to take medication without [United States Food and Drug Administration] (FDA) approval within certain parameters and with full informed consent. This Right to Try policy passed the Senate Business and Professions Committee with no "no" votes and far exceeds what we are trying to do here. We want to ensure patients have access to FDA-approved medication that our physicians know is appropriate to treat their life-threatening illness. With such broad California policy focused on removing barriers to potentially lifesaving drugs already enacted, this program is in keeping in line with that policy to ensure patients have access to cancer treatment that they need.

Arguments in Opposition

The Board of Pharmacy has an opposed unless amended position on the July 6, 2021, version of this bill, writing:

As proposed, the program would be overseen by an entity licensed by the Board of Pharmacy as a "surplus medication collection and distribution intermediary". Both state and federal laws related to prescription medications are intended to prevent the sale and distribution of pharmaceutical preparations and drugs that do not conform to the standards of the National Formulary or that violate the Sherman Food, Drug, and Cosmetic Act.

The board respectfully requests your consideration of amendments to address board concerns in the following areas:

- 1) Specify that the Surplus Medication Collection and Distribution Intermediary (SMCDI) must employ an individual with expertise in the requirements of the United States Pharmacopeia and state and federal law related to prescription medications.
- 2) Specify that only medications in sealed tamper-evidence packaging or in the case of unit dose packaging, with the secondary packaging component intact for each dose may be donated.
- 3) Specify as part of the definition of "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 Business and Profession Code that is prescribed as part of a cancer treatment plan and is in its

original manufacturer tamper-evident, sealed packaging or unit dose packaging and the tamper-resistant does packaging with the secondary packaging component intact for each dose donated.

- 4) Include all drug recalls including recalls issued by drug manufacturers not just recalls issued by the FDA.
- 5) Establish authority for the SMCDI to cancel a registration and prohibit further participation by a practitioner that violates the provisions. Further, specify the oversight responsibilities of the SMCDI including ensuring compliance with the provisions established.
- 6) In addition to the labeling requirements that must be met under existing law, specify that the label must also indicate that the medication was donated.
- 7) Provide the Board with the authority to request records from the SMCDI and participating practitioners to confirm compliance with the provisions of the measure.

FISCAL COMMENTS

According to the Assembly Appropriations Committee:

- 1) Costs for the Board of Pharmacy are estimated to be approximately \$95,000 (Pharmacy Board Contingent Fund).
- 2) Costs for the Medical Board of California are estimated to be minor and absorbable. The Department of Consumer Affairs Office of Information Costs (DCA/OIS) identified \$1,000 in information technology (IT) costs for the Medical Board (Medical Board Contingent Fund).
- 3) DCA/OIS identified \$1,000 in IT costs for the Osteopathic Medical Board of California (Osteopathic Medical Board Contingent Fund).

VOTES

SENATE FLOOR: 40-0-0

YES: Allen, Archuleta, Atkins, Bates, Becker, Borgeas, Bradford, Caballero, Cortese, Dahle, Dodd, Durazo, Eggman, Glazer, Gonzalez, Grove, Hertzberg, Hueso, Hurtado, Jones, Kamlager, Laird, Leyva, Limón, McGuire, Melendez, Min, Newman, Nielsen, Ochoa Bogh, Pan, Portantino, Roth, Rubio, Skinner, Stern, Umberg, Wieckowski, Wiener, Wilk

ASM BUSINESS AND PROFESSIONS: 19-0-0

YES: Low, Flora, Berman, Bloom, Chen, Chiu, Cunningham, Megan Dahle, Fong, Gipson, Grayson, Holden, Irwin, McCarty, Medina, Mullin, Salas, Ting, Akilah Weber

ASM HEALTH: 13-0-2

YES: Wood, Aguiar-Curry, Arambula, Burke, Carrillo, Flora, Maienschein, McCarty, Nazarian, Luz Rivas, Rodriguez, Santiago, Waldron

ABS, ABST OR NV: Mayes, Bigelow

ASM APPROPRIATIONS: 15-0-1

YES: Lorena Gonzalez, Bryan, Calderon, Carrillo, Chau, Megan Dahle, Davies, Fong, Gabriel, Eduardo Garcia, Levine, Quirk, Robert Rivas, Akilah Weber, Kalra

ABS, ABST OR NV: Bigelow

UPDATED

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FN: 0001201