Date of Hearing: June 22, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
SB 310 (Rubio) – As Amended June 21, 2021

SENATE VOTE: 40-0

SUBJECT: Unused medications: cancer medication recycling

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

EXISTING LAW:

1) Regulates and licenses the practice of pharmacy under the Pharmacy Law and establishes the California State Board of Pharmacy to administer and enforce the Pharmacy Law. (Business and Professions Code (BPC) §§ 4000-4427.8)

2) Makes it unlawful for a person to practice pharmacy, which means to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription of a prescriber unless the person is a pharmacist licensed under the Pharmacy Law. (BPC § 4051(a))

3) Establishes a voluntary drug repository and distribution program for the purpose of distributing surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies and allowing licensed health and care facilities to donate unused and unexpired medications that were never in the hands of a patient or resident and for which no credit or refund to the patient or resident could be received. (Health and Safety Code §§ 150200-150208)

4) Requires a surplus medication collection and distribution intermediary established for the purpose of facilitating the donation of medications to or transfer of medications between participating entities under a voluntary drug repository and distribution program to be licensed by the Board of Pharmacy and requires the board to enforce the requirements relating to the voluntary drug repository and distribution programs. (BPC § 4169.5)

THIS BILL:

1) Establishes 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.

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.

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.

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 3 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.

FISCAL EFFECT: According to the Senate Committee on Appropriations analysis of the May 20, 2021, version of this bill, which would have placed the program under the Medical Board of California rather than the licensed intermediaries:

- Unknown fiscal impact to the Medical Board of California, likely ranging in the low hundreds of thousands of dollars, to implement the program. Initial startup costs would include workload related to developing forms and information technology changes. Ongoing costs would include workload related to reviewing applications and conducting other enforcement activities.

- Unknown, potential increase in fee revenue from physicians participating in the program, to be deposited in the Medical Board Contingent Fund. While fee revenue may offset, to some extent, administrative and enforcement costs, revenue will likely not be substantial enough to cover the Board's total costs to operate the program.

COMMENTS:

Purpose. This bill is co-sponsored by the *American Cancer Society Cancer Action Network, Inc.*, and the *Association of Northern California Oncologists*. 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 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."

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.[1]

Prior Related Legislation. SB 983 (Rubio) of 2020 was substantially similar to this bill, establishing the Cancer Medication Recycling Act but would have placed the program under the Medical Board of California. SB 983 was pulled by the author due to COVID-19-related bill restrictions in the Senate Business, Professions, and Economic Development Committee.

SB 650 (Rubio) of 2019, which was held under submission in the Assembly Committee on Appropriations, would have required the California State Board of Pharmacy to establish the Cancer Medication Advisory Committee for the purpose of identifying 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.

AB 1069 (Gordon), Chapter 316, Statutes of 2016 authorized a pharmacy that exists solely to operate the Program to repackage a reasonable quantity of donated medicine in anticipation of dispensing the medicine to its patient population. Requires the pharmacy to have repackaging policies and procedures in place for identifying and recalling medications; and requires the medication that is repackaged to be labeled with the earliest expiration date.

AB 467 (Stone), Chapter 10, Statutes of 2014 established a licensure category for a surplus medication collection and distribution intermediary established for the purpose of facilitating the donation of medications to, or transfer of medications between, participating entities under a county's unused medication repository and distribution program.

SB 1329 (Simitian), Chapter 709, Statutes of 2012 revised and recast provisions authorizing a county to establish a drug repository and distribution program, to authorize a program to be established by an action of the county board of supervisors, or by the county public health officer, as specified and expanded the types of entities that are eligible to participate in a program.

SB 798 (Simitian), Chapter 444, Statutes of 2005 authorized the establishment of a voluntary prescription drug collection and distribution program for the purpose of distributing surplus prescription drugs to medically indigent patients free of charge.

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.

---

[1] Kristina Berg and Richard Cauchi, "States Look to Drug Donations to Improve Access to Medication," NCSL LegisBrief, Vol . 26, No. 43, November 2018, https://www.ncsl.org/research/health/states-look-to-drug-donations-to-improve-access-to-medication636772027.aspx.

> 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), which allows patients to take medication without 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 Medical Board of California was opposed to the May 20, 2021, version of this bill, which would have placed the program under the board:

> While the Board agrees that this program could benefit consumers who may be unable to access necessary cancer medications, this program is not related to the Board's existing licensing or enforcement programs and it is unclear why the Board is the appropriate entity to administer this program. In addition, the types of activities required by participating physicians to verify that a donated drug is safe for redistribution may be better suited to pharmacists.
>
> Further, the Board's fund is significantly challenged and it is facing insolvency. Despite the recent amendment limiting the number of participating physicians to 50, the fee revenue from this bill is not anticipated to cover all Board expenses. The fee is only authorized to address initial application and renewal costs, but does not include enforcement costs that the Board may face related to a consumer complaint and related investigation that may stem from this new program.
>
> We appreciate the dialogue that your staff and sponsors have had with Board staff on the bill and the sponsor's willingness to consider an alternate administering agency.

IMPLEMENTATION ISSUES:

1) *Registration Mandate and Enforcement*. This bill would require all licensed intermediaries to establish a cancer medication registration program. While the sponsors note that there is currently only one licensed intermediary who has expressed a willingness to operate a registry under this bill, there may be additional intermediaries who seek licensure in the future who may only want to participate in the existing voluntary donation program or the cancer program under this bill. In addition, the existing law relating to licensed intermediaries only cross-references the existing voluntary drug repository and distribution program for purposes of enforcement by the Board of Pharmacy.

   If this bill passes this committee, the author may wish to work with the sponsors and stakeholders to determine whether the registration requirement should be amended into an authorization and add a cross-reference to the new program under BPC § 4169.5(a).

2) *50 Participant Cap*. This bill currently caps the number of participating physicians and surgeons to 50 per program. According to the author, this was a cost-saving provision to address concerns by the Medical Board. If this bill passes this committee, the author may wish to remove the cap given that the current version of the bill no longer involves the Medical Board.

3) *Selection Criteria*. This bill does not currently specify how participating providers choose which patients receive donated medication under the program. The sponsors assume that, in practice, the medication would be given according to time of diagnosis and need. For example, if two patients are diagnosed and both need the same medication then the physician may weigh place in line, inability to pay, or stage in diagnosis. Still, there is nothing that currently prevents a physician from favoring one patient over another because of a personal relationship or personal preference. If this bill passes this committee, the author may wish to amend the bill to include selection criteria.

REGISTERED SUPPORT:

American Cancer Society Cancer Action Network, Inc. (co-sponsor)
Association of Northern California Oncologists (co-sponsor)

REGISTERED OPPOSITION:

Medical Board of California (unless amended)

Analysis Prepared by: Vincent Chee / B. & P. / (916) 319-3301