SENATE COMMITTEE ON
BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT
Senator Richard Roth, Chair
2021 - 2022 Regular

Bill No:	SB 310	**Hearing Date:**	March 8, 2021
Author:	Rubio		
Version:	February 4, 2021		
Urgency:	No	**Fiscal:**	Yes
Consultant:	Sarah Mason		

Subject: Unused medications: cancer medication recycling

SUMMARY: Establishes a Cancer Medical Recycling Program overseen by the Medical Board of California (MBC) to allow for the donation and redistribution of cancer drugs between patients of a participating physician.

Existing law:

1) Establishes certain requirements for a prescriber to dispense drugs or dangerous devices to patients in his or her office or place of practice which are necessary in the treatment of the condition for which the prescriber is attending the patient. Prohibits a prescriber from keeping a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons. Subjects prescribers to the labeling requirements imposed upon pharmacists, the recordkeeping requirements in Pharmacy Law, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers. (Business and Professions Code (BPC) § 4170)

2) Establishes a voluntary drug repository and distribution program (Program) to distribute surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Expresses the intent of the Legislature in establishing this program that the health and safety of Californians are protected and promoted through this program, while reducing unnecessary waste at licensed health and care facilities, by allowing those 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 (HSC) § 150200)

3) Authorizes a county to establish a Program. (HSC § 150204 (a))

4) Requires a county that establishes a Program to establish written procedures for, at a minimum, all of the following:

   a) Establishing eligibility for medically indigent patients who may participate in the program.

   b) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

c) Developing a formulary of medications appropriate for the repository and distribution program.

d) Ensuring proper safety and management of any medications collected by and maintained under the authority of a participating entity.

e) Ensuring the privacy of individuals for whom the medication was originally prescribed. (HSC § 150204 (b))

5) Establishes the following criteria for any medication donated to the Program:

a) The medication shall not be a controlled substance.

b) 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.

c) 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 health or care facility, 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, specified training requirements.

d) 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 Program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the Program, and once identified, shall be quarantined immediately and handled and disposed of.

e) A medication that is the subject of a United States Food and Drug Administration (FDA) managed risk evaluation and mitigation strategy (REMS):

i) 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;

ii) Shall be managed and dispensed according to the requirements of that strategy.

f) A pharmacist or physician at a participating entity shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the Program.

g) A pharmacist or physician shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

6) Defines the following licensed entities as eligible to donate drugs: a general acute care hospital; pharmacy; acute psychiatric hospital; skilled nursing facility, including a skilled nursing facility designated as an institution for mental disease; intermediate care facility; intermediate care facility/developmentally disabled habilitative facility; intermediate care facility/developmentally disabled-nursing facility; correctional

treatment center; psychiatric health facility; chemical dependency recovery hospital; residential care facility for the elderly with 16 or more residents; and an approved mental health rehabilitation center. (HSC § 150202)

This bill:

1) Establishes the Cancer Medication Recycling Act and requires MBC to establish a program to oversee the collection and distribution of unused cancer medications (Cancer Medication Program).

2) Defines the following terms for purposes of the Cancer Medication Program:

   a) Donor" as 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" as 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 (FDA) Risk Evaluation and Mitigation Strategy (REMS) requirement, and all growth factor medications.

   c) "Participating practitioner" as a person who is registered with the board, is board certified in medical oncology or hematology, and is subject to rules promulgated by the board to participate in the collection of donated medications, prescribed for use by established patients of that practitioner and donated for the purpose of redistribution to established patients of that practitioner.

   d) "Recipient" as an individual who voluntarily receives donated prescription medications.

   e) "Unused cancer medication" or "medication" as a medication or drug that is prescribed as part of a cancer treatment plan and is in its original container or packaging.

3) Requires MBC to create a registry for participating practitioners and develop donor and recipient forms that include specific information about the donor and recipient, about the medication, and for the recipient form:

   a) 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.

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

   c) An acknowledgment that the donor and the participating practitioner are released from liability arising from their participation in the Cancer Medication Program.

d) An acknowledgment that the pharmaceutical manufacturer is released from liability of any claims or injury arising from the transfer of any prescription medication pursuant the Cancer Medication Program.

4) Specifies that a participating practitioner is exempt from licensure as a wholesaler and subject to certain record keeping requirements.

5) Requires a participating practitioner to register with MBC and pay a fee up to $300, or an amount sufficient to cover the reasonable costs to the board for processing the application and issuing or renewing the registration, whichever is less.

6) Specifies that a participating practitioner can only accept donated medications originally prescribed for use by established patients of that participating practitioner or practice. Specifies that a participating practitioner can accept or redistribute a medication only if the expiration date listed on the packaging is not more than six months after the date the medication was accepted. Requires a participating practitioner to refuse a medication that has previously been redistributed. Specifies that a participating physician must store all donated medications separately from all other medication stock and in compliance with the manufacturer's storage requirements. Requires confidential patient and personal information to be removed from donated medications. Requires participating practitioners to 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. Require participating practitioners to monitor all FDA recalls, market withdrawals, and safety alerts and communicate with recipients if medications they received may be impacted by the FDA action. Specifies requirements for donated medications to ensure that the drugs are unaltered, safe, and suitable for redistribution.

7) States that a donor acting in good faith is not subject to criminal or civil liability, and is not subject to a penalty pursuant to the Sherman Food, Drug, and Cosmetic Law, for an injury caused when donating, accepting, or dispensing medication in compliance with this division.

8) States that a participating practitioner acting in good faith that receives and redistributes a donated medication is not subject to a penalty pursuant to the Sherman Food, Drug, and Cosmetic Law 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.

9) States that a prescription drug manufacturer, wholesaler, participating entity, participating practitioner who accepts or dispenses prescription drugs, or a donor are not subject to criminal or civil liability for an injury caused when donating, accepting, or dispensing prescription drugs in compliance with the Cancer Medication Program. Specifies that this shall not affect disciplinary actions taken by licensing and regulatory agencies.

FISCAL EFFECT: Unknown. This bill is keyed fiscal by Legislative Counsel.

COMMENTS:

1. **Purpose.** The American Cancer Society Cancer Action Network, Association of Northern California Oncologists, and Medical Oncology Association of Southern California. According to the Author, this bill would allow cancer patients to donate their unused oral anti-cancer medications to patients in dire need of the medication, by coordinating with the prescribing physician. The Author notes that "the bill includes strict protections to ensure patients are not at undue risk."

2. **Background.**

   Costs. According to a 2018 report from The President's Cancer Panel, an independent panel established under the National Cancer Act of 1971 tasked with identifying high-priority issues that are impeding progress against cancer, from 1995 to 2014, there was a sharp increase in the launch price of new cancer drugs. Most cancer drugs launched between 2009 and 2014 were priced at more than $100,000 per patient for one year of treatment. The report found that the recent, dramatic rise in drug prices is straining patient, health system, and societal resources. Drugs account for about 20 percent of the total costs of cancer care in the United States, but cancer drug costs are accelerating faster than costs for other components of care. Launch prices of cancer drugs in the United States have risen so steeply over the past few decades that they have quickly outpaced growth in household incomes. U.S. patients and their insurers are paying more than ever for cancer drugs, $54,100 for a year of life in 1995 compared with $207,000 in 2013.

   According to the report, "the burden of high drug costs on patients, even those with health insurance, can be significant. Out-of-pocket spending on drugs can be hundreds, or even thousands, of dollars a month for patients in active treatment. Patients with higher out-of-pocket expenses are less likely to adhere to recommended treatment regimens, which may have a detrimental impact on outcomes."

   California's Existing Drug Donation Program. California's 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 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 Program and added several categories of licensed health care facilities that may donate medications; in 2013, 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 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 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), "[39] 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."

NCSL notes the following commonalities in most state drug donation programs:

- No "controlled substances" medication is allowed to be accepted or transferred.
- No adulterated or misbranded medication is allowed to be accepted or transferred.
- All pharmaceuticals must be checked by a pharmacist prior to being dispensed.
- All pharmaceuticals must not be expired at the time of receipt.
- All pharmaceuticals must be unopened and in sealed, tamper-evident packaging.
- Liability protection for both donors and recipients usually is assured.

3. **Drug Integrity.** The National Association of Boards of Pharmacy (NABP) is an independent and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. It developed a position paper in 2009, revised in 2012, on the issue of drug donation programs: "NABP endorses the return and reuse of medications that have been maintained in a closed system that ensures the integrity of the medication. A closed system is defined as the delivery to and/or the return of prescription medication from a health care or other institutional facility, which is maintained in a controlled environment under the control of a health care practitioner and not the patient. A closed distribution system enables the pharmacy to ensure that the integrity of the medications dispensed is intact, as they have not left the control of the pharmacy or institutional facility, and the control of the medication is under the direction of a health care practitioner.

   "NABP does not endorse the reuse of medications that have left the closed distribution system as there is an inability to ensure the integrity of such drugs, which may place the public at risk."

   The Food, Drug and Cosmetic Act (FDCA) was passed by Congress to ensure public confidence in the drug distribution system and to require that drugs are both safe and effective. The FDCA requires the FDA to regulate drug manufacturers and approve

drugs for sale and requires state governments to regulate the drug distribution system by licensing and regulating drug wholesalers. The NABP paper further notes that "FDA's Compliance Policy Guide on the Return of Unused Prescription Drugs to Pharmacy Stock directly states that '[a] pharmacist should not return drug products to his stock once they have been out of his possession" because of the inability to assure drug "strength, quality, purity or identity.'"

The program advocated by this bill would allow drugs that have left a pharmacists' possession to be re-dispensed to vulnerable cancer patients, in contrast to California's existing Program, which operates in a closed system.

4. **Previous Related Legislation.** SB 650 (Rubio) of 2019 would have originally established a Cancer Medication Program overseen by the Board of Pharmacy to allow the donation and redistribution of cancer drugs between patients of a physician and releases both donors and recipients from liability. The bill was amended to require 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. (Status: *The measure was held under submission in the Assembly Committee on Appropriations.*)

   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.

5. **Arguments in Support.** The American Cancer Society Cancer Action Network supports this bill, writing that "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." The organization would reduce waste of cancer medication and would 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.

According to the Association of Northern California Oncologists, "Patients with cancer can sometimes have anti-cancer medications that they will not be using for a variety of reasons, but most often the reason is a lack of tolerance due to side effects. Physicians and patients can quickly discover after a brief trial period that the original medications need to be stopped and other medications need to be prescribed. This common situation leaves many patients with a significant supply of unused, unneeded, expensive, high-quality medications. On the other hand, anti-cancer medications prescribed by the patient's physician can have a delayed approval process from health plans. In some cases, cancer drugs require a specific additional approval by the insurance company that can take weeks or even months for the physician and patient to receive. In cancer care, delaying treatment during the approval process can be the difference between life and death. Having a separate resource for effective therapy in this setting because of a separate pool of available medications can be lifesaving." The group believes that "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."

NOTE: ***Double-referral to Senate Committee on Judiciary, second.***

SUPPORT AND OPPOSITION:

Support:

American Cancer Society Cancer Action Network
Association of Northern California Oncologists

Opposition:

None received.

-- END --