SENATE JUDICIARY COMMITTEE
Senator Thomas Umberg, Chair
2021-2022 Regular Session

SB 310 (Rubio)
Version: March 25, 2021
Hearing Date: April 6, 2021
Fiscal: Yes
Urgency: No
AWM

SUBJECT

Unused medications: cancer medication recycling

DIGEST

This bill establishes a Cancer Medical Recycling Program overseen by the Medical Board of California (Board) to allow for the donation and redistribution of cancer drugs between patients and a participating physician.

EXECUTIVE SUMMARY

Current law permits California counties to establish medication repositories through which licensed health care facilities, pharmacies, and drug manufacturers may donate unopened surplus prescription medication to be donated to persons in need of financial assistance. The program does not permit repositories to accept medication from individuals. This bill would establish the Cancer Medication Recycling Act, which would allow licensed practitioners to accept unopened, intact cancer drug donations from their existing patients, under specified circumstances, and distribute the drugs to patients in need of financial assistance. The bill grants immunity to donors, participating physicians, and pharmaceutical manufacturing companies for injuries caused by, or injuries arising from, medication donated and dispensed through the program, except in cases of gross negligence, recklessness, or intentional conduct; to strengthen protections for patients, the author has agreed to amendments clarifying that the immunity does not extend to malpractice unrelated to the quality of the donated medication.

SB 310 is sponsored by the American Cancer Society, the Association of Northern California Oncologists, and the Medical Oncology Association of California. There is no known opposition. This bill passed out of the Senate Business, Professions, and Economic Development Committee with a 14-0 vote.

PROPOSED CHANGES TO THE LAW

Existing law:

1) Establishes limits and requirements for a prescriber to dispense drugs or dangerous devices, for the labeling of such devices, and for the recordkeeping and packaging of prescribed pharmaceuticals. (Bus. & Prof. Code, §§ 4170, 4176.)

2) 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. Under the program, each county may voluntarily establish a drug repository to accept and dispense surplus medications and establish procedures to ensure eligibility for participants receiving medication and proper safety and management of medications collected. (Health & Saf. Code, §§ 150200, 150204.)

3) Provides that a county repository may accept donated medication from a range of licensed medical facilities, including a licensed general acute care hospital, a licensed intermediate care facility, and a licensed psychiatric health facility. The licensed medical facility must have received the medication directly from the dispensing pharmacy or manufacturer, and must have stored it in a central location. Medication that originated from a patient or resident is not eligible for donation. A county repository may also accept medication from a wholesaler or drug manufacturer licensed under federal law. (Health & Saf. Code, §§ 150202-150203.)

4) Provides immunity from criminal or civil liability to prescription drug manufacturers, wholesalers, governmental entities, participating entities, pharmacists or physicians accepting or dispensing drugs, and licensed health care facilities and pharmacies for injury caused when donating, accepting, or dispensing prescription drugs under the program, except in cases of noncompliance with the program, bad faith, or gross negligence. (Health & Saf. Code, §§ 150205-150206.)

This bill:

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

2) Defines the following terms under the Cancer Medication Recycling Act:
    a) "Donor" is 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" are 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" is 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" is an individual who voluntarily receives donated prescription medications.
e) "Unused cancer medication" or "medication" is 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.

3) Requires the Board to regulate and enforce the program by:
    a) Accepting and approving applications from eligible practitioners to participate in the program.
    b) Creating a registry of participating practitioners.
    c) Developing a form for donors to execute when they donate medication under the program. The donor form must include certain personal information about the donor, information about the medication being donated, an acknowledgement by the donor that the medication was handled and stored in accordance with the physician's order and per the manufacturer's recommendation, and the signature of the practitioner who is accepting and inspecting the medication.
    d) Creating a form for recipients to execute when they receive medication under the program. The recipient form must include certain personal information about the recipient, information about the medication being received, an acknowledgement by the practitioner that the donor is known to the practitioner and the practitioner has no reason to believe the medication was improperly handled or stored, and acknowledgements by the recipient that (1) the recipient accepts any risk that accidentally mishandled medication could create, and (2) that the donor, practitioner, and manufacturer are released from certain forms of liability for injuries caused by the donated medication.

4) Requires a participating practitioner to comply with all the following requirements for, and limits, on the acceptance and donation of unused cancer medication to and from patients:
    a) The practitioner must register with the Board under a specific registry established for this program.
    b) The practitioner may accept donated medications only when (1) they were prescribed for use by an established patient in the practitioner's practice, (2)

the date of the expiration date on the package is more than six months after the date of the acceptance, and (3) the medication has not previously been redistributed.

c) The practitioner must store all donated medications separately from other medication stock, and in compliance with the manufacturer's storage requirements.
d) The practitioner must remove all confidential patient and personal information from donated medication.
e) The practitioner must require all donors and recipients to read and sign a donor form approved by the Board, and keep all donor and recipient forms separately for at least three years.
f) The practitioner must dispose of any donated medications that were collected but not redistributed in accordance with all federal, state, and local laws regarding medication disposal.
g) The practitioner must monitor all United States Food and Drug Administration (FDA) product recalls, market withdrawals, and safety alerts and communicate with recipients if they may be affected by the FDA action.
h) The practitioner must inspect all donated medications to determine that the drugs are unaltered, safe, and suitable for redistribution, and meet all of the following conditions:
    i. The tamper-resistant packaging is unopened, intact, and does not have breaks, cracks, or holes in the packaging.
    ii. Tablets or capsules have a uniformity of color, shape, imprint or markings, texture, and odor.
    iii. Liquids have a uniformity of color, thickness, particulates, transparency, and odor.
    iv. The date of donation is less than six months from the date of the initial prescription.
i) The practitioner must provide the board with updated sections of their policy and procedures manual that indicate how the practitioner will accept, reuse, and keep records of donated medications.

5) Provides that a donor is not subject to a penalty under 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.

6) Provides that a participating practitioner is not subject to a penalty under 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 participating practitioner.

7) Provides that a prescription drug manufacturer, wholesaler, participating entity, participating practitioner, or donor is not subject to civil or criminal liability for an injury caused when donating, accepting, or dispensing prescription drugs in compliance with this division, except in cases of noncompliance with the Cancer Medication Recycling Act, bad faith, or gross negligence.

8) Provides that the immunities above in parts 5)-7) shall not apply in licensing and regulatory agency disciplinary actions.

COMMENTS

1. Author's comment

According to the author:

> SB 310 will expand cancer medication access to patients in dire need, will reduce improper drug waste, and has the potential to save lives. Cancer patients spend thousands of dollars on life-saving medications every year. Cancer drugs represent a growing cost in the health care system; and that trend is expected to continue. The last 10 cancer drugs approved by the FDA in 2015 had an average annual price of $190,217. Because they are specialty drugs, cancer drugs tend to be more expensive than traditional drugs. These high costs are prohibitive and unrealistic for many patients and often times leave them to treatment non-compliance, delays, or treatment abandonment. These actions may result in serious negative health outcomes including extensive hospitalizations, and even death. Cancer medication is most effective when treatment begins on-time and is consistent; it is of utmost importance that patients do not experience delays and begin treatment when recommended to by their physician.
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> Cancer patients may have anti-cancer medications they will not use for a variety of reasons, including, but not limited to, a lack of tolerance for the medication due to the side effects. Physicians and patients can discover after a trial period if the original medications need to be stopped and other medications need to be prescribed. This leaves cancer patients with unused, unneeded, expensive, high-cost and high-quality medications.
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> There are also concerning reports about the amount of drug waste from individuals and health care facilities discarding usable drugs. In 2015, the Environmental Protection Agency estimated that about 740 tons of drugs were wasted. While this does not reflect cancer medication specifically, it does shed light to the larger problem. Often times, individuals wrongly flush drugs down the toilet, resulting in chemicals infiltrating and contaminating our water systems.

According to the National Council on State Legislatures, as of 2018, 21 states have active drug donation and reuse programs and 14 states have successfully implemented anti-cancer-specific medication donation programs. 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.

California is lagging behind in creating a cancer medication reuse program. SB 310 will ensure cancer patients have timely access to life-saving medication and at the same time prevent improper drug waste.

2. Background: the crushing cost of cancer treatment

In 2020, the American Cancer Society (ACS) estimated that roughly 1.8 million new cases of cancer would be diagnosed in the U.S. that year, and that more than 16.9 million living Americans have a history of cancer.[1] For Americans afflicted with cancer and their families, treating the disease comes with a staggering price tag: in 2018, cancer patients in the United States paid $5.6 billion out-of-pocket for cancer treatments, including surgical procedures, radiation treatments, and drugs.[2] In 2018, the President's Cancer Panel reported that drug costs account for approximately 20 percent of cancer treatment, and out-of-pocket spending for patients can range from hundreds to thousands of dollars a month.[3]

For many individuals, the cost is too high. "[M]any people with cancer and those who have survived cancer experience financial hardship, including problems paying bills, depletion of savings, delaying or skipping needed medical care, and potential bankruptcy."[4] Cancer-treatment-related financial hardships are especially likely to hit people of color, people with less than a high school degree, and, bleakly, people at both low and middle-income levels.[5] Having health insurance is no guarantor that a patient and their family will avoid crushing treatment costs: deductibles, co-pays, out-of-pocket maximums, out-of-network charges, "balance billing," and other permissible charges can add up and overwhelm an insured patient.[6]

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[1] American Cancer Society Cancer Action Network, *The Costs of Cancer, 2020 Edition* (Oct. 2020) at p. 3, *available at* https://www.fightcancer.org/sites/default/files/National%20Documents/Costs-of-Cancer-2020-10222020.pdf [last visited Mar. 24, 2021] (*The Costs of Cancer*).
[2] *Ibid.*
[3] President's Cancer Panel, Report, *Promoting Value, Affordability, and Innovation in Cancer Drug Treatment* (Mar. 2018) *available at* https://prescancerpanel.cancer.gov/report/drugvalue/pdf/PresCancerPanel_DrugValue_Mar2018.pdf [last visited Mar. 24, 2021], at pp. 3-4
[4] *The Costs of Cancer*, *supra*, fn. 1, at p. 4.
[5] *Ibid.*
[6] *Id.* at pp. 5-6.

The inadequacy of health care is not unique to cancer. In the United States, approximately 530,000 families declare bankruptcy each year because of medical issues and bills, comprising 66.5 percent of all bankruptcies.[7] The system is broken.

This bill seeks to alleviate the financial toll of cancer treatment by establishing a cancer medication recycling program. Under the program, a physician can register as a participating physician with the Medical Board of California, and then may accept and redistribute cancer medication donated from an existing patient, subject to certain requirements set forth below. The idea that some Californians' best option for cancer treatment is medication donated from other patients is hard to swallow. But it is also reality: America, the richest nation in the world, cannot, or will not, ensure that its residents can survive cancer without being driven into bankruptcy. By implementing a cancer medication recycling program, this program would reduce cancer treatment costs for some Californians, which is a worthwhile goal in the face of the failure at the national level to implement systemic reforms.

3. Outline of the program

The cancer medication recycling program set forth in this bill is reasonably straightforward. Board-certified oncologists and hematologists wishing to participate must apply to the Board and be approved for participation. The Board is tasked with creating a registry for participating practitioners and creating forms to be signed by donors and recipients when they donate/receive drugs.

Once a practitioner is approved for participation, a participating practitioner may accept donated medication, subject to the following limitations:

- The donor must be an existing patient of the practitioner's practice.
- The medication must have been prescribed by the practitioner's practice.
- The expiration date listed on the package must be more than six months after the date of donation.
- The medication cannot be a controlled substance, including all opioids, compounded medications, injectable medications, or drugs that have that have an approved United States Food and Drug Administration Risk Evaluation and Mitigation Strategy (REMS) requirement.
- The medication cannot have been previously redistributed.
- The donor must sign a form with the donor's information, information about the donated medication, and an acknowledgement that the medication was handled and stored in accordance with the physician's order and per the manufacturer's recommendation.

After accepting medication, a practitioner must comply with the following:

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[7] Konish, *This is the real reason most Americans file for bankruptcy*, CNBC (Feb. 11, 2019), https://www.cnbc.com/2019/02/11/this-is-the-real-reason-most-americans-file-for-bankruptcy.html [last visited Mar. 27, 2021].

- The practitioner must remove all confidential patient information, personal information, and any information through which the prior patient could be identified.
- The practitioner must store donated medications separately from other medication stock, and in compliance with the manufacturer's storage requirements.
- The practitioner must examine and inspect the donated medication to determine the following:
    - That the medication has not been adulterated, misbranded, or improperly stored.
    - That the medication's tamper-resistant packaging is unopened and intact or, in the case of individual dose unit packaging, the tamper-resistant dose packaging must be intact for each dose unit donated.
    - That tablets or capsules have a uniformity of color, shape, imprint or markings, texture, and odor.
    - That liquids have a uniformity of color, thickness, particulates, transparency, and odor.
    - That the date of donation is less than six months from date of the initial prescription or refill.
- The practitioner must monitor all FDA recalls, market withdrawals, and safety alerts related to donated medication.

A participating practitioner may then redistribute donated medication to a patient, under the following circumstances:

- The expiration date of the medication must be more than six months from the date of redistribution.
- The donor must sign a form with the recipient's personal information, information about the medication being donated, and acknowledgements that:
    - There is no reason to believe the medication was mishandled, but by accepting the donated prescription medication, the recipient accepts any risks that an accidental handling could create.
    - That the donor, practitioner, and pharmaceutical manufacturer are partially released from liability, as explained further in Comment 4.

The participating practitioner is required to retain records created under the program for at least three years. If the practitioner learns of any FDA recalls, market withdrawals, or safety alerts related to medication that was redistributed to a patient, the practitioner must contact the patient who may be impacted by the FDA action.

4. <u>This bill grants limited immunity from liability for injuries arising from donated medication</u>

The cancer medication recycling program in this bill has two categories of immunities. First, donors and participating practitioners are exempt from penalties under

California's Sherman Food, Drug, and Cosmetic Law[8]—which governs drug labeling and additives—unless the injury is caused by the donor or practitioner's gross negligence, recklessness, intentional conduct, or noncompliance with the program. Second, prescription drug manufacturers, wholesalers, or related entities, participating practitioners, and donors are immune from criminal or civil liability for injuries arising from the donation or dispensation of drugs under the program, except in cases of noncompliance with the program, recklessness, gross negligence, or intentional conduct. The immunities provided by this section are similar to the immunities granted under California's existing surplus prescription medication program: under that program, donors, practitioners, and health facilities can be liable for injuries arising from the program when the injury is the result of noncompliance with the program, bad faith, or gross negligence.[9]

Other states with medication recycling programs have similar liability limitations. For example, under Wisconsin's drug recycling program, drug manufacturers are immune from liability except in cases of bad faith, and donors and practitioners are immune except in cases of reckless, wanton, or intentional misconduct.[10] Some states' programs have an even broader grant of immunity, such as Ohio, which provides immunity except in cases of "willful and wanton misconduct."[11] Other states, however, impose even narrower immunities, by providing that a person who exercises "reasonable care" in donating, accepting, or dispensing medication under the state's medication recycling program is immune from civil and criminal liability.[12]

It is vital that persons receiving donated medication do not become second-class legal citizens by virtue of their economic desperation. It is the intent of the author that the limited immunities provided will extend only to injuries caused by medication where the quality was affected in the course of the donation and redistribution, and should not limit patients' rights to recover for injuries unrelated to the donation itself, such as injuries arising from a drug that was defectively designed or the manufacturer was aware of undisclosed side effects. This Committee has received no objections to the scope of the immunities provided in this bill. Nevertheless, it appears that, as drafted, there is a risk that the immunities could foreclose meritorious medical malpractice claims involving donated medication, but where the fact that the medication was donated was not the cause of the injury—such as a situation where it was malpractice to prescribe the medication in the first place, donated or not. In order to ensure that these claims are preserved, the author has agreed to the amendments set forth below clarifying that this bill's immunities do not extend to malpractice claims not arising from the quality of the donated medication.

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[8] Health & Saf. Code, div. 104, pt. 5 (§§ 109875 et seq.).
[9] *See* Health & Saf. Code, §§ 150205-150206.
[10] Wisc. Stat. § 255.056(6); *see also* Minn. Stat. § 151.555(12) (providing for pharmacist, health care facility, or donor liability in cases involving "reckless, wanton, or intentional misconduct, or malpractice unrelated to the quality of the drug or medical supply");
[11] Ohio Rev. Stat., §§ 3715.872.
[12] *E.g.*, Fla. Stat. § 499.029; Nev. Rev. Stat. § 453B.130.

5. Amendments

In order to ensure that the limited grant of immunity in this bill does not inadvertently foreclose legitimate medical malpractice claims in which the donated nature of the medication is not the cause of the injury, the author has agreed to the following amendments:

Amendment 1

On page 8, in line 15, strike out "or"

Amendment 2

On page 8, in line 16, strike out "division." and insert "division, or in cases of malpractice unrelated to the quality of the medication."

Amendment 3

On page 8, in line 27, strike out "or"

Amendment 4

On page 8, strike out line 28 and insert "conduct, or in cases of malpractice unrelated to the quality of the medication."

SUPPORT

American Cancer Society Action Network (co-sponsor)
Association of Northern California Oncologists (co-sponsor)
Medical Oncology Association of Southern California (co-sponsor)

OPPOSITION

None known

RELATED LEGISLATION

Pending Legislation:

SB 306 (Pan, 2021) permits certain medical professionals to dispense prescription drugs for certain sexually transmitted infections (STI) through the practice of "expedited partner therapy," in which a medical professional is permitted to provide STI medication to the partner(s) of a patient infected with an STI without the medical professional examining the partner(s), under specified circumstances. SB 306 is pending before the Senate Committee on Health.

AB 933 (Daly, 2021) requires an insured's defined cost sharing for a prescription drug to be calculated based on the cost of the drug at the point of sale as reduced by at least 90 percent of the available rebates received in connection with the drug. AB 933 is pending before the Assembly Health Committee.

AB 458 (Kamlager, 2021) creates the Affordable Prescription Drug Importation Program, which would, with federal approval, operate to import certain prescription medications from Canada. AB 458 is pending before the Assembly Health Committee.

Prior Legislation:

SB 983 (Rubio, 2020) was identical to this bill and would have established the same Cancer Medication Recycling Act contemplated here. SB 913 was voluntarily pulled by the author, in light of the COVID-19-related bill restrictions, before it was heard by the Senate Business, Professions, and Economic Development Committee.

SB 650 (Rubio, 2019) would have established the Cancer Medication Advisory Committee to identify the best mechanisms for the transfer of unused cancer medications to patients who cannot afford them. SB 650 was held in the Assembly Appropriations Committee.

AB 1668 (Calderon, Ch. 684, Stats. 2016), the Right to Try Act, permitted certain patients with immediately life-threatening diseases or conditions, in consultation with their physician and with informed consent, to undergo medical treatment that had successfully undergone at least one clinical trial approved by the USDA but had not yet received USDA approval.

AB 159 (Calderon, 2015) would have enacted the Right to Try Act passed in AB 1668 (Calderon, Ch. 684, Stats. 2016). AB 159 was vetoed by the governor.

SB 1329 (Simitian, Ch. 709, Stats. 2012) expanded the range of medical facilities that could donate medications to be distributed under a county-established drug distribution program, and expanded the range of entities eligible to distribute drugs under such a program.

SB 798 (Simitian, Ch. 444, Stats. 2005) authorized counties to establish a repository and distribution program for the distribution of unopened, unexpired prescription medication by county-owned or county-contracted pharmacies.

PRIOR VOTES:

Senate Business, Professions and Economic Development Committee (Ayes 14, Noes 0)

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