

Date of Hearing: July 13, 2021

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
SB 310 (Rubio) – As Amended July 6, 2021

SENATE VOTE: 40-0

SUBJECT: Unused medications: cancer medication recycling.

SUMMARY: Establishes the Cancer Medication Recycling Program (program) which permits the donation and redistribution of an unused cancer medication by a participating practitioner. Requires a participating practitioner to register with a surplus medication collection and distribution intermediary (intermediary) to participate in the program. Specifically, **this bill:**

- 1) Defines the following terms:
 - a) Donor means an individual who donates unused prescription medications to a participating practitioner for the purpose of redistribution to established patients of that practitioner;
 - b) Ineligible drugs means drugs that are not able to be accepted for redistribution as part of the program. Including 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 means a person who is licensed to practice medicine by the Medical Board of California (MBC) and is board certified in medical oncology or hematology and is registered with an intermediary;
 - d) Recipient means an individual who voluntarily receives donated prescription medications; and,
 - e) Unused cancer medication” or “medication” means a medication or drug, including a “dangerous drug” that is prescribed as part of a cancer treatment plan and is in its original container or packaging, as specified.
- 2) Establishes the program which permits an unused cancer medication that is not an ineligible drug to be donated to a participating practitioner who may accept and redistribute the donated prescription drugs.
- 3) Requires a participating practitioner to comply with all of the following:
 - a) Be registered with an intermediary in order to participate in the program , as specified;
 - b) Only accept donated medications originally prescribed for use by established patients of that participating practitioner or practice;
 - c) Accept or redistribute a medication only if the expiration date listed on the packaging is more than six months after the date of acceptance or redistribution;
 - d) Refuse a medication that has previously been redistributed;
 - e) Store all donated medications separately from all other medication stock;
 - f) Store all donated medications in compliance with the manufacturer’s storage requirements per the drug monograph;

- g) Remove all confidential patient information, personal information, and any other information through which the prior patient could be identified from donated medications;
 - h) Require all donors to read and sign the donor form approved by the intermediary;
 - i) Keep all donor forms and recipient forms in the records, separately, for at least three years;
 - j) 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;
 - k) Require all recipients of a donated medication to read and sign the recipient form approved by the intermediary;
 - l) Dispose of any donated medications that were collected but not redistributed in accordance with all local, state, and federal requirements for the disposal of medications;
 - m) Monitor all FDA recalls, market withdrawals, and safety alerts and communicate with recipients if medications they received may be impacted by the FDA action;
 - n) Inspect all donated medications to determine that the drugs are unaltered, safe, and suitable for redistribution and meet all of the following conditions:
 - i) Tamper-resistant packaging is unopened and intact or, in the case of unit dose packaging, the tamper-resistant dose packaging is intact for each dose donated;
 - 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; and,
 - iv) The date of donation is less than six months from the date of the initial prescription or prescription refill.
 - o) Establish policies and procedures for the administration of the program, including, but not limited to, criteria for determining medication distribution to patients. Provide the intermediary with updated sections of their policy and procedures manual that indicate how the practitioner will accept, reuse, and keep records of donated medications.
- 4) Exempts a donor from any penalty under the Sherman Food, Drug, and Cosmetic Law (Sherman Law) for an injury caused when donating, accepting, or dispensing medication in compliance with this bill, unless an injury arising from the donated medication is caused by the gross negligence, recklessness, or intentional conduct of the donor, or in cases of noncompliance with this bill.
- 5) Exempts a participating practitioner that receives and redistributes a donated medication from any penalty under the Sherman 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, in cases of noncompliance with this division, or in cases of malpractice unrelated to the quality of the medication.
- 6) Specifies that the following persons and entities are not subject to criminal or civil liability or disciplinary actions taken by licensing and regulatory agencies for an injury caused when donating, accepting, or dispensing prescription drugs in compliance with this bill:
- a) A prescription drug manufacturer, wholesaler, or participating entity;
 - b) A participating practitioner who accepts or dispenses prescription drugs; and,
 - c) A donor

- 7) States that the immunities in 6) above do not apply in cases of noncompliance with this bill, gross negligence, recklessness, intentional conduct, or in cases of malpractice unrelated to the quality of the medication.
- 8) States that this bill does not affect disciplinary actions taken by licensing and regulatory agencies.
- 9) Requires a participating practitioner in the collection and distribution of unused cancer medications under this bill to be registered with an intermediary. Requires the registration to be renewed annually.
- 10) Requires an application for registration with an intermediary to be made on a form furnished by the intermediary, and to state the name, address, usual occupation, and professional qualifications, if any, of the applicant.
- 11) Requires the intermediary, upon the approval of an application, and payment of a fee in an amount not to exceed three hundred dollars (\$300) to intermediary for processing the application and issuing or renewing the registration, to issue or renew a registration certificate to operate as a participating practitioner, if the practitioner has complied with all of the provisions of this bill.
- 12) Requires an intermediary to do all of the following:
 - a) Create a registry, not to exceed 50 participating practitioners;
 - b) Develop a donor form that may be in an electronic format and that includes all of the following information:
 - i) The date the medication was donated;
 - ii) The name, address, and telephone number of the donor;
 - iii) The name, strength, and quantity of the medication;
 - iv) The manufacturer and lot number of the medication;
 - v) The name and dated signature of the practitioner who is accepting and inspecting the donated medication; and,
 - vi) An acknowledgment that the medication was handled and stored in accordance with the physician's order and per the manufacturer's recommendation.
 - c) Develop a recipient form, which includes all of the following:
 - i) The date the recipient received the medication;
 - ii) The name, address, and telephone number of the recipient;
 - iii) The name, strength, and quantity of the medication;
 - iv) The manufacturer and the lot number of the medication;
 - v) The name and dated signature of the practitioner who is accepting and inspecting the donated medication;
 - vi) 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;
 - vii) An acknowledgment that by accepting the donated prescription medication, the recipient accepts any risks that an accidental mishandling could create;
 - viii) An acknowledgment that the donor and the participating practitioner are released from liability arising from their participation in the program; and,

- ix) An acknowledgment that the pharmaceutical manufacturer is released from liability of any claims or injury arising from the transfer of any prescription medication pursuant to this this bill.
 - d) Exempts a participating practitioner from licensure as a wholesaler.
- 13) Requires a participating practitioner to keep and maintain for three years records created by the participating practitioner for purposes of this bill.

EXISTING LAW:

- 1) Establishes the Sherman Law, administered by the Department of Public Health (DPH), which regulates the packaging, labeling, and advertising of drugs and devices, including dietary supplements.
- 2) Establishes the Surplus Medication Collection and Distribution program which establishes a voluntary drug repository and distribution program to distribute surplus medications to persons in need of financial assistance.
- 3) Establishes the California Pharmacy Act, administered by the California Board of Pharmacy (BOP), which regulates the practice of pharmacy in the state.

FISCAL EFFECT: According to the Senate Appropriations Committee, this bill will result in unknown fiscal impact to MBC, 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. The Senate Appropriations Committee notes that it will also result in unknown, potential increase in fee revenue from physicians participating which may offset, to some extent, administrative and enforcement costs. The Senate Appropriations Committee notes that revenue will likely not be substantial enough to cover MBC's total costs to operate the program.

COMMENTS:

- 1) **PURPOSE OF THIS BILL.** According to the author, the news of a cancer diagnosis is probably one of the most mind shocking, life-altering experiences anyone could have. This bill expands critical access to life-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. Currently 14 states have successfully implemented anti-cancer specific medication donation programs. The author concludes these recycling programs reduce initial costs, ensure timely access, and prevent unused medications from going to waste.
- 2) **BACKGROUND.**
 - a) **Cancer.** Cancer is a group of diseases characterized by the uncontrolled growth and spread of abnormal cells. If the spread is not controlled, it can result in death. Although the cause for many cancers, particularly those that occur during childhood, remains unknown, established cancer causes include lifestyle (external) factors, such as tobacco use and excess body weight, and nonmodifiable (internal) factors, such as inherited genetic mutations, hormones and immune conditions.

In 1988, the California Cancer Registry (CCR), California's statewide population-based cancer surveillance system, was fully implemented and collects information about all cancers diagnosed in California (except basal and squamous cell carcinoma of the skin and carcinoma in situ of the cervix). The CCR is now recognized as one of the leading cancer registries in the world. Due to the size and diversity of the California population, more is now known about the occurrence of cancer in diverse populations than ever before. The CCR has proven to be the cornerstone of a substantial amount of cancer research in the California population.

According to the 2017 Cancer Facts and Figures (CFF), the most recent data published by DPH, cancer is the second-leading cause of death in California, exceeded only by heart disease. Cancer accounts for nearly one in every four deaths in California. According to the American Cancer Society, the estimated new cases in 2021 is 187,140 with an estimated deaths of 61,860. According to the CCR, cancer incidence rates in California declined by 15% from 1988-2014, and the mortality rate also declined by 30% during the same time period. Over the past three decades, the five-year survival rate for all cancers combined increased 20% among whites and 24% among Blacks, yet still substantially lower for Blacks (68% vs. 61% respectively). Improvements in survival reflect improvements in treatment, and earlier diagnosis for some cancers. Survival varies greatly by cancer type and state of diagnosis. The CFF points out that in 2009-13, the overall cancer incidence rate in the state was lower compared to the rest of the nation. California incidence rates for African Americans, Asians/Pacific Islanders, and non-Hispanic whites were between 3% and 4% lower than the rest of the country. Hispanics in California had a nearly 11% lower incidence rate than other Hispanics in the nation.

The risk of developing cancer varies considerably by race or ethnicity. African American men have the highest overall cancer rate, followed by non-Hispanic white men. Among women, non-Hispanic white women are the most likely to be diagnosed with cancer, but African American women are more likely to die of the disease. Cancer rates are considerably lower among persons of Asian/Pacific Islander origin and of Hispanic ethnicity than those of other Californians. However, both groups have substantially higher rates of certain cancers, such as liver and stomach. Hispanic women are more likely to develop and die from cervical cancer. Research indicates that cancer rates in populations immigrating to the U.S. tend to increase over time.

According to the federal Centers for Disease Control and Prevention, each year in the U.S., more than 1.7 million people are diagnosed with cancer, and almost 600,000 die from it, making it the second leading cause of death. The cost of cancer care continues to rise and is expected to reach almost \$174 billion per year by 2020. According to the National Cancer Institute, some cancer patient may face out-of-pocket costs of nearly \$12,000 a year for one drug.

- b) Drug Donation Program.** SB 798 (Simitian), Chapter 444, Statutes of 2005, and SB 1329 (Simitian), Chapter 709, Statutes of 2012, established a voluntary, county-option drug repository and distribution program to distribute surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Entities that could participate in this program as donors include pharmacies, hospitals, acute psychiatric hospitals, skilled nursing facilities, intermediate care facilities and licensed pharmacies and primary care clinics. Supporting Initiatives to Redistribute

Unused Medicine (SIRUM), a nonprofit organization founded by students from Stanford University provides logistics and tools that allow for the safe donation of unused prescriptions, and serves as a major connection between donating facilities and recipient safety-net clinics.

Santa Clara County operates the only drug donation program in California. Life-saving medications like insulin, Epipens, and asthma inhalers were three-life saving medications that were provided at no cost, no co-payments to Santa Clara County residents. Additionally, Santa Clara County also opened the Better Health Pharmacy, the only dedicated drug donation pharmacy in California. In 2019, the County's Better Health Pharmacy dispensed 31,940 prescriptions, a significant increase over 24,123 prescriptions in 2018.

According to the National Conference of State Legislatures, as of fall 2018 there are 38 states and Guam with enacted laws for donation and reuse. Twelve states (Florida, Kentucky, Michigan, Minnesota, Montana, Nebraska, Nevada, Ohio, Pennsylvania, Utah, Washington, and Wisconsin) currently have cancer-related prescription drugs donation programs.

- 3) **SUPPORT.** The American Cancer Society Cancer Action Network and the Association of Northern California Oncologists are the sponsors and state in support that 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.
- 4) **OPPOSE UNLESS AMENDED.** The BOP has taken an oppose unless amended position and respectfully requests consideration of the following amendments:
 - a) Require the intermediary to employ an individual with expertise in the requirements of the United States Pharmacopeia and state and federal law related to prescription medications;
 - b) 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;
 - c) 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;
 - d) Include all drug recall information including recalls issued by drug manufacturers not just recalls issued by the FDA;
 - e) Establish authority for the intermediary to cancel a registration and prohibit further participation by a practitioner that violates the provisions of the program. Further, specify the oversight responsibilities of the SMCIDI including ensuring compliance with the provisions established;
 - f) 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; and,

- g) Provide the BOP with the authority to request records from the SMCDI and participating practitioners to confirm compliance with the provisions of the measure.
- 5) **RELATED LEGISLATION.** SCR 11 (Rubio) proclaims specified principles as the Cancer Patients' Bill of Rights. SCR 11 is pending a hearing in Assembly Health Committee.
- 6) **DOUBLE-REFERRAL.** This bill is double referred, it passed the Assembly Committee on Business and Professions with a vote of 19-0 on June 22, 2021.
- 7) **PREVIOUS LEGISLATION.** SB 650 (Rubio) of 2019 would have created an advisory committee charged with recommending to the Legislature and administration statutory changes to expand access to affordable or no-cost medications for cancer patients, based largely on an assessment of how currently authorized county-administered drug donation and redistribution programs could be improved. SB 650 was held in the Assembly Appropriations Committee suspense file.
- 8) **SUGGESTED AMENDMENTS.** To strengthen the patient protection provisions of this bill, the Committee recommends the following amendments.
- a) Consistent with the existing drug donation program, recipients who are beneficiaries of donated cancer drugs must receive these drugs at no-cost.
- b) Consistent with the issues raised by the BOP, include the following provisions in this bill:
- i) Only medications in sealed original manufacturer tamper-evidence packaging or in the case of unit dose packaging, with the secondary packaging component intact for each dose that is donated;
- ii) Require the participating practitioner to monitor manufacturer recalls;
- iii) Specify in the recipient acknowledgement form that the cancer medications are donated; and,
- iv) Permit the BOP to request records from the intermediary and participating practitioners to confirm compliance with the provisions of this measure.
- c) Five year sunset. Unlike the current drug donation program and other states where the medications are donated by pharmacies or specific facilities, the program created under this bill is under the oversight of the physician and surgeon for medications donated by their patients. In an effort to ensure successful implementation that protects consumers, a five year sunset is recommended.

REGISTERED SUPPORT / OPPOSITION:

Support

American Cancer Society Cancer Action Network Inc.
Association of Northern California Oncologists

Opposition

None on file.

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