Office of Senate Floor Analyses
(916) 651-1520 Fax: (916) 327-4478

UNFINISHED BUSINESS

Bill No: SB 310
Author: Rubio (D), et al.
Amended: 8/30/21
Vote: 21

SENATE BUS., PROF. & ECON. DEV. COMMITTEE: 14-0, 3/8/21
AYES: Roth, Melendez, Archuleta, Bates, Becker, Dodd, Eggman, Hurtado, Jones, Leyva, Min, Newman, Ochoa Bogh, Pan

SENATE JUDICIARY COMMITTEE: 11-0, 4/6/21
AYES: Umberg, Borgeas, Caballero, Durazo, Gonzalez, Hertzberg, Jones, Laird, Stern, Wieckowski, Wiener

SENATE APPROPRIATIONS COMMITTEE: 7-0, 5/20/21
AYES: Portantino, Bates, Bradford, Jones, Kamlager, Laird, Wieckowski

SENATE FLOOR: 40-0, 6/1/21
AYES: 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

ASSEMBLY FLOOR: 79-0, 9/8/21 - See last page for vote

SUBJECT: Unused medications: cancer medication recycling

SOURCE: American Cancer Society Cancer Action Network
Association of Northern California Oncologists
Medical Oncology Association of Southern California

DIGEST: This bill establishes the Cancer Medication Recycling Act (Cancer Medication Program) until January 1, 2027 to allow for the donation and redistribution of cancer drugs between patients of a participating physician.

Assembly Amendments (1) remove Cancer Medication Program oversight from the Medical Board of California (MBC) and instead require a participating practitioner to register with a Board of Pharmacy (Board) licensed surplus medication collection and distribution intermediary; (2) add a January 1, 2027 sunset date; (3) specify that only medication in unopened, tamper-evident dose unit packaging that includes the drug's lot number and expiration date or a cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit dose packaging is unopened; and (4) authorize the Board to prohibit a participating practitioner from participating if the practitioner does not comply with program requirements.

ANALYSIS:

Existing law:

1) 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)

2) Authorizes a county to establish a Program and requires a county to establish written procedures for Program administration to establish eligibility for medically indigent patients to participate, develop a formulary appropriate for the Program, ensure proper safety and management of medications, and other provisions. (HSC § 150204)

3) Specifies that medication donated to the Program shall not be a controlled substance; shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer and; 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. States that 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. Requires a pharmacist or physician at a

participating entity to use their professional judgment in determining whether donated medication meets the standards before accepting or dispensing any medication.

This bill:

1) Defines various terms for purposes of the Cancer Medication Program, including but not limited to "Donor" as an individual who donates unused prescription drugs to a participating practitioner for the purpose of redistribution to established patients of that practitioner; "Ineligible drugs" which 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 requirement, and all growth factor medications; "Participating practitioner" as a person licensed to practice medicine with MBC , is board certified in medical oncology or hematology, and is registered with a surplus medication collection and distribution intermediary; "Recipient" as an individual who voluntarily receives donated prescription medications and; "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, unopened, tamper-evident container or packaging that includes the drug's lot number and expiration date and; "Surplus medication collection and distribution intermediary" as an entity licensed by the Board for purposes of Program participation.

2) Requires a participating practitioner to annually register with a licensed surplus medication collection and distribution intermediary. Specifies, upon the approval of an application and payment of a fee in an amount not to exceed 300 to the surplus medication collection and distribution intermediary, that the surplus medication collection and distribution intermediary shall issue or renew a registration certificate to operate as a participating practitioner, if the practitioner has complied with all Cancer Medication Program requirements. Authorizes the Board to request records from the surplus medication collection and distribution intermediary and to prohibit a participating practitioner from participation if they do not comply with Cancer Medication Program requirements.

3) 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 distribute a medication only if it will not expire before the proper use by the recipient based on the participating practitioner's directions for use. 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.

4) 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 or in cases of malpractice unrelated to the quality of the medication. States that a participating practitioner 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 or in cases of malpractice unrelated to the quality of the medication. 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 immunities do not apply in cases of noncompliance with Cancer Medication Program requirements, gross negligence, recklessness, intentional conduct, or in cases of malpractice unrelated to the quality of the medication Specifies that this shall not affect disciplinary actions taken by licensing and regulatory agencies.

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 commonalities in most state drug donation programs, including no controlled substances, no adulterated or misbranded medication, 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, and liability protection for both donors and recipients usually is assured.

FISCAL EFFECT: Appropriation: No Fiscal Com.: Yes Local: Yes

According to the Assembly Appropriations Committee, costs for the Board are estimated to be approximately $95,000, costs for MBC are estimated to be minor and absorbable, and the bill will result in $1,000 in information technology costs for both boards.

SUPPORT: (Verified 9/8/21)

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

OPPOSITION: (Verified 9/8/21)

None received

ARGUMENTS IN SUPPORT: Supporters state that "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 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.

ASSEMBLY FLOOR: 79-0, 9/8/21
AYES: Aguiar-Curry, Arambula, Bauer-Kahan, Bennett, Berman, Bigelow, Bloom, Boerner Horvath, Mia Bonta, Bryan, Burke, Calderon, Carrillo, Cervantes, Chau, Chen, Chiu, Choi, Cooley, Cooper, Cunningham, Megan Dahle, Daly, Davies, Flora, Fong, Friedman, Gabriel, Gallagher, Cristina Garcia, Eduardo Garcia, Gipson, Lorena Gonzalez, Gray, Grayson, Holden, Irwin, Jones-Sawyer, Kalra, Kiley, Lackey, Lee, Levine, Low, Maienschein, Mathis, Mayes, McCarty, Medina, Mullin, Muratsuchi, Nazarian, Nguyen, O'Donnell, Patterson, Petrie-Norris, Quirk, Quirk-Silva, Ramos, Reyes, Luz Rivas, Robert Rivas, Rodriguez, Blanca Rubio, Salas, Santiago, Seyarto, Smith, Stone, Ting, Valladares, Villapudua, Voepel, Waldron, Ward, Akilah Weber, Wicks, Wood, Rendon
NO VOTE RECORDED: Frazier

Prepared by: Sarah Mason / B., P. & E.D. /
9/8/21 21:28:49

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