

Date of Hearing: August 29, 2018

ASSEMBLY COMMITTEE ON APPROPRIATIONS
Lorena Gonzalez Fletcher, Chair
SB 212 (Jackson) – As Amended August 27, 2018

Policy Committee: Environmental Safety and Toxic Materials Vote: 5-0

Urgency: No State Mandated Local Program: Yes Reimbursable: No

SUMMARY:

This bill requires entities that sell drugs or medical sharps in the state to individually, or with other entities, develop and implement a statewide home-generated drug stewardship plan, or a home-generated sharps waste stewardship plan, or both for the collection and proper disposal of home-generated drug and sharps waste. This bill requires CalRecycle to oversee and enforce each stewardship plan (Plan). Among other provisions, this bill:

- 1) Provides various definitions specific to the bill.
- 2) Establishes a process where an organization can establish a stewardship program for covered drugs or for home-generated sharps waste, or for both.
- 3) Requires a stewardship program for covered drugs to have specific requirements of its program operator and to provide adequate funding for all administrative and operation costs to be borne by participating covered entities.
- 4) Requires a stewardship program for home-generated sharps waste to be a mail-back program, as specified, and to provide adequate funding for all administrative and operation costs to be borne by participating covered entities.
- 5) Requires a covered entity, no later than April 1, 2019, to provide a list of covered products, and a list and description of any covered products that it sells or offers for sale in the state to the Board of Pharmacy (Board). Requires the Board to verify the information as specified, make it available to CalRecycle, and authorizes the Board to gather information from entities selling or distributing drugs and sharps, as specified.
- 6) Authorizes the Board to adopt regulations to comply with the requirements of the bill.
- 7) Requires CalRecycle to adopt regulations to implement the bill with an effective date of no later than January 1, 2021.
- 8) Requires a stewardship program operator, at least 120 days before submitting a Plan to CalRecycle, to notify each potential authorized collector in the county or counties in which it operates of the opportunity to serve as an authorized collector.
- 9) Requires a program operator, within six months of adoption of regulations by CalRecycle, to submit a Plan for the establishment and implementation of a stewardship program to CalRecycle, for approval. Requires a program operator, at the time it submits a Plan to

CalRecycle, to submit an initial stewardship program budget for the first five calendar years of operation.

- 10) Requires CalRecycle to approve a Plan that meets the requirements of this bill.
- 11) Requires a program operator to initiate operation of an approved stewardship program no later than 270 days after CalRecycle approves the Plan.
- 12) Requires CalRecycle to make all Plans submitted to it available to the public, except for proprietary information.
- 13) Requires a program operator to conduct a comprehensive education and outreach program to promote participation in the stewardship program.
- 14) Requires a retail pharmacy to make a reasonable effort to serve as an authorized collector. Requires a retail pharmacy chain, if there are not at least five collection sites in a county, to require at least 15% of its store locations serve as authorized collectors.
- 15) Requires a program operator, on or before March 31, 2022, and each year thereafter, to prepare and submit to CalRecycle, a written report describing activities during the previous year and a written program budget for the upcoming calendar year.
- 16) Requires CalRecycle, on or before June 30, 2022, and at least annually thereafter, to post on its internet website, a list of covered entities, stewardship organizations, authorized collections sites, retail pharmacies, and retail pharmacy chains in compliance with the stewardship program.
- 20) Requires a Plan to include provisions to expand into local jurisdictions that currently have a local drug or home-generated sharps waste stewardship program, if that local jurisdiction repeals its local stewardship program.
- 21) Sets the amount of the administrative penalty CalRecycle may impose at up to \$10,000 per day for violations of the bill, except for violations that are intentional, knowing, or reckless, in which case the penalty may not exceed \$50,000 per day.
- 22) Provides this bill preempts local stewardship programs enacted by ordinances effective on or after April 18, 2018. Requires, if a local ordinance is repealed, covered drugs or home-generated sharps waste to be in compliance with this bill within 270 days after the date of repeal.

FISCAL EFFECT:

- 1) CalRecycle estimates increased annual costs of over \$3 million (25 PY) to implement the provisions of the bill.
- 2) Unknown costs for the Board of Pharmacy, likely between \$500,000 and \$750,000 annually, to review and verify specified information received from pharmacies and fulfill other requirements of the bill.

- 3) Unknown costs for other departments with areas of relevant authority, such as the Department of Toxic Substance Control, to assist CalRecycle with Plan reviews.

Initial start-up costs would have to be loaned from other funds, for example, the Integrated Waste Management Account for CalRecycle, and then would be reimbursed by the stewardship programs.

COMMENTS:

- 1) **Purpose.** According to the author:

For too long, our communities have dealt with the impacts from improperly disposed pharmaceutical drugs and medical sharps. The cost of inaction has been enormous to our public health, environment, water quality, and public safety. This bill establishes an industry-run and funded program, overseen by the state, that will ensure we provide convenient locations for Californians to safely dispose of their unused prescriptions and other medical waste. This is an important step to finally getting unused and discarded medical products out of our public spaces, municipal waste systems, and our environment.

- 2) **Background.** The Medical Waste Management Act (MWMA) was created to comprise a single, integrated, and complementary approach to the storage, treatment, transportation, and disposal of medical waste.

Medical waste is defined as waste materials generated at health care facilities, such as hospitals, clinics, physician's offices, dental practices, blood banks, and veterinary hospitals/clinics, as well as medical research facilities and laboratories. Medical waste includes pharmaceutical waste, including prescription or over-the-counter human or veterinary drugs.

Under the MWMA, pharmaceutical waste has to be incinerated at a permitted medical waste treatment facility, treated at temperatures in excess of 1,300 degrees Fahrenheit, or steam sterilized at a permitted medical waste treatment facility.

Pharmaceutical wastes were added to the MWMA in 1996 (SB 1996, Wright, Chapter 536, Statutes of 1996).

An estimated one million Californians inject medications outside traditional health care facilities, which generate approximately 936 million sharps each year. The numbers of patients using injectable medications will continue to grow because it is an effective delivery method. The most common home use of sharps is to manage diabetes. Other reasons to home-inject include multiple sclerosis, infertility, migraines, allergies, hemophilia, and medications for pets.

California was one of the first states to address the problems of sharps with the passage of SB 1305 (Figueroa), Chapter 64, Statutes of 2006, to prohibit the disposal of medical sharps in California's landfills. According to CalRecycle, 43% of all self-injectors still throw needles in the trash.

- 3) **Product Stewardship/Expanded Producer Responsibility (EPR).** Product stewardship refers to a policy model that includes manufacturers in the end-of-life management for products that they produce.

According to the California Product Stewardship Council, EPR is a strategy to place a shared responsibility for end-of-life product management on all entities involved in the product chain. Successful EPR programs result in products that are better designed for reuse and recycling, make recycling more convenient for consumers, reduce illegal disposal of hazardous materials, and encourage the use of recycled materials in new products.

In 2007, CalRecycle adopted strategic directives to guide solid waste management in California. Strategic Directive 5: Producer Responsibility states that "it is a core value of [CalRecycle] that producers assume the responsibility for the safe stewardship of their materials in order to promote environmental sustainability."

There are several statewide stewardship programs in California, all of which are overseen by CalRecycle. They include: carpet materials management, paint product management, and mattress product management. One important distinction between these stewardship programs and SB 212 is that the current state programs focus notably on collection of the waste, but also on ways to recycle the waste. In contrast, pharmaceutical and sharps waste cannot be recycled and must be destroyed.

- 4) **Recent Amendments.** This bill was significantly amended since it was passed from this committee's suspense file and sent to the assembly floor. The major changes include clarifying who ultimately pays for this stewardship program. The bill still requires manufacturers to pay for the program, however, if a manufacturer is unwilling to participate (especially if located outside of California), then the responsibility to pay shifts to the distributor, wholesaler, and ultimately to the importer of the sharp or covered drug. Without this provision, the responsibility to pay for the entire stewardship program would be borne by in-state manufacturers.

Another recent change includes allowing for separate management systems for home-generated sharps. The bill now requires sharps to be handled via a mail-back system, at no cost to the consumer. This recognizes the difference between the use and collection of used drugs and sharps.

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