

Date of Hearing: June 26, 2018

ASSEMBLY COMMITTEE ON ENVIRONMENTAL SAFETY AND TOXIC MATERIALS

Bill Quirk, Chair

SB 212 (Jackson) – As Amended June 18, 2018

SENATE VOTE: Not relevant

SUBJECT: Solid waste: pharmaceutical and sharps waste stewardship

SUMMARY: Requires manufacturers that sell covered products (drugs or sharps) in the state to individually or with other manufacturers develop and implement a statewide pharmaceutical and sharp stewardship plan for the collection and proper disposal of home generated pharmaceutical and sharps waste. Requires the Department of Resources, Recycling and Recovery (CalRecycle) to oversee and enforce the stewardship plan (Plan). Specifically, **this bill:**

- 1) Defines "authorized collector" as a person or entity that has entered into an agreement with a program operator to collect covered products, including, but not limited to, a person or entity registered with the United States Drug Enforcement Administration (US DEA) to collect controlled substances for the purposes of destruction; a law enforcement agency; an entity authorized by the State Board of Pharmacy (Board) or the Department of Public Health (CDPH) to provide an alternative collection mechanism for covered products that are not controlled substances; and, retail pharmacies.
- 2) Defines "covered drug" as a drug, including a brand name or generic drug, sold, offered for sale, or dispensed in the state in any form, including, but not limited to, prescription and nonprescription drugs approved by the United States Food and Drug Administration (FDA); a drug marketed as an over-the-counter drug; a drug in a medical device; and, a drug for veterinary use.
- 3) Defines "covered manufacturer" as a person, corporation, or other entity engaged in the manufacture of covered products sold, offered for sale, or introduced into the State of California.
- 4) Defines "covered product" as a covered drug or home-generated sharps waste.
- 5) Defines "Department" as CalRecycle.
- 6) Defines "drug" as an article recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopeia of the United States, or any supplement of the formulary or those pharmacopoeias; a substance intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; a substance, other than food, intended to affect the structure or any function of the body of humans or other animals; or, a substance intended for use as a component of any substance specified in the bill.
- 7) Defines "pharmaceutical and sharps stewardship organization" as an organization established by a group of covered manufacturers to develop, implement, and administer a stewardship program.

- 8) Defines "pharmaceutical and sharps stewardship plan (Plan)" as the plan for collecting and properly managing covered products that is developed by a covered manufacturer or pharmaceutical and sharps stewardship organization.
- 9) Defines "pharmaceutical and sharps stewardship program" as a stewardship program for the collection, transportation, and disposal of covered products.
- 10) Defines "program operator" as a covered manufacturer, or stewardship organization on behalf of a group of covered manufacturers, that is responsible for operating a stewardship program.
- 11) Defines "retail pharmacy" as an independent pharmacy, a supermarket pharmacy, a chain pharmacy, a hospital pharmacy or clinic pharmacy, or a mass merchandiser pharmacy possessing a license from the Board to operate a pharmacy.
- 12) Defines "sharps" as hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications.
- 13) Requires a covered manufacturer, no later than April 1, 2019, to provide a list of covered products, and a list and description of any drugs or sharps that are not covered products, that it sells or offers for sale in the state to the Board and CDPH.
- 14) Requires a retail pharmacy, no later than April 1, 2019, that sells a drug under its own label to provide notification to the Board and CDPH identifying the covered manufacturer from which the retail pharmacy obtains that drug.
- 15) Requires the Board and CDPH to verify the information received from covered manufacturers and retail pharmacies and within six months of receiving that information, provide it to CalRecycle.
- 16) Provides that a covered manufacturer is not in compliance with this bill and is subject to penalties if, on or after July 1, 2020, it sells a covered product that is not subject to a Plan.
- 17) Requires a program operator to do all of the following: promote its stewardship program to ultimate users by placing signage on covered drug collection receptacles and sharps collection containers; provide outreach materials for pharmacies and pharmacists; provide outreach materials for ultimate users; prepare additional outreach materials as needed; and, encourage ultimate users to separate products that are not covered products from covered products, when appropriate, before taking covered products to a collection site.
- 18) Requires a program operator, within six months of adoption of regulations by CalRecycle, to submit a Plan for the establishment and implementation of a pharmaceutical and sharps stewardship program to CalRecycle, for approval.
- 19) Requires CalRecycle to approve a Plan submitted to it that meets the requirements of this bill.
- 20) Authorizes CalRecycle, before approving a Plan, to require a program operator to submit its proposed Plan to the Board, CDPH, the Department of Toxic Substances Control (DTSC), or any other state agency with authority or expertise relative to the Plan.

- 21) Requires, in order to be complete, a Plan to do all of the following: identify and provide contact information for the stewardship organization, and each participating covered manufacturer, and identify each covered product sold by each covered manufacturer; identify and provide contact information for the authorized collectors; demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered manufacturers; provide for a handling, transport, and disposal system that complies with state and federal laws; and, provide for a collection system that complies with the requirements of the bill and meets both of the following for authorized collection sites in each county in which the Plan will be implemented: provides a minimum of five authorized collection sites or one authorized collection site per 50,000 people, whichever is greater, and provides for a reasonable geographic spread of authorized collection sites.
- 22) Requires a 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.
- 23) 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 have at least fifteen percent of its store locations serve as authorized collectors.
- 24) A Plan shall require an authorized collection site to accept all covered products from ultimate users during the hours that the authorized collector is normally open for business.
- 25) Requires CalRecycle, within 30 days of receiving a Plan from a program operator, to determine if a Plan is complete and notify the submitting program operator.
- 26) Requires CalRecycle, within 90 days of receiving a complete Plan, to review the completed Plan and approve, disapprove, or conditionally approve the Plan.
- 27) Requires a program operator to initiate operation of an approved stewardship program no later than 270 days after approval of the Plan by CalRecycle.
- 28) Requires CalRecycle to make all Plans submitted to it available to the public, except for proprietary information in the Plan.
- 29) Requires a program operator, on or before an unknown date, to submit to CalRecycle an initial stewardship program budget for the first calendar year of operation.
- 30) Requires a program operator, on or before an unknown date, and each year thereafter, to prepare and submit to CalRecycle both of the following: a written report describing the stewardship program activities during the previous reporting period of one year, and a written program budget for stewardship program implementation for the upcoming calendar year.
- 31) Requires CalRecycle to review the annual report and program budget, and, within 90 days of receipt, to approve, disapprove, or conditionally approve the annual report and program budget.
- 32) Requires the program operator to keep minutes, books, and records that clearly reflect the activities and transactions of the program operator's stewardship program and requires the

program operator to be audited by an independent certified public accountant at least once each calendar year. Requires the program operator to provide the audit to CalRecycle.

- 33) Requires each covered manufacturer, individually or through a stewardship organization, to pay all administrative and operational costs associated with establishing and implementing the stewardship program, including the cost of collecting, transporting, and disposing of covered products, as well as the regulatory and oversight costs of CalRecycle and any other state agency involved in this regulatory program.
- 34) Requires CalRecycle, on or before an unknown date, and at least annually thereafter, to post on its Internet Web site a list of covered manufacturers, stewardship organizations, authorized collections sites, retail pharmacies, and retail pharmacy chains in compliance with the stewardship program.
- 35) Authorizes CalRecycle to impose a civil penalty on any covered manufacturer, stewardship organization, authorized collector, retail pharmacy, or retail pharmacy chain that sells, offers for sale, or provides a covered product in violation of the provisions of this bill. Prohibits the violation from exceeding one thousand dollars (\$1,000) per day unless the violation is intentional, knowing, or reckless, in which case the civil penalty shall not exceed five thousand dollars (\$5,000) per day.
- 36) Requires all handling, transport, and disposal undertaken as part of a stewardship program to comply with applicable state and federal laws, including, but not limited to, regulations adopted by the US DEA.
- 37) Provides that this bill shall preempt a local stewardship program for covered products enacted by an ordinance that has an effective date on or after April 18, 2018.
- 38) Allows a local stewardship program enacted prior to April 18, 2018 to continue to operate; however, prohibits that local stewardship program and its participants from receiving any funds from CalRecycle that it received pursuant to a pharmaceutical and sharps stewardship program, unless that local stewardship program dissolves.
- 39) Requires CalRecycle, on or before an unknown date, to adopt regulations for the administration of this bill.

EXISTING LAW:

- 1) Pursuant to the Medical Waste Management Act (MWMA), requires CDPH to regulate the management and handling of medical waste and authorizes off-site medical waste treatment facilities, oversees transfer stations, approves alternative treatment technologies, and acts as the local enforcement agency in 25 jurisdictions where local agencies have elected not to conduct their own enforcement. (Health and Safety Code (HSC) § 117600, et seq.)
- 2) Exempts household pharmaceutical waste from hazardous waste classifications and as medical waste. (HSC § 117700)
- 3) Defines "home-generated sharps waste" as hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of

medications derived from a household, including a multifamily residence or household. (HSC § 117671)

- 4) Defines "medical waste" to include, among other things, pharmaceutical waste, which includes a prescription or over-the-counter human or veterinary drug, including, but not limited to, a drug as defined in the Federal Food, Drug, and Cosmetic Act. (HSC § 117690 and § 117747)
- 5) Prohibits a person from hauling medical waste unless the person is a registered hazardous waste hauler; a mail-back system approved by the United States Postal Service; a common carrier allowed to haul pharmaceutical waste; a small- or large-quantity generator transporting limited quantities of medical waste with an exemption; or, a registered trauma scene waste practitioner. (HSC § 117900)
- 6) Requires a person that generates or treats medical waste to ensure that the medical waste is treated by one of the following methods rendering it solid waste:
 - a. Incineration at a permitted medical waste treatment facility in a controlled-air, multichamber incinerator, or other method of incineration approved by CDPH which provides complete combustion of the waste into carbonized or mineralized ash;
 - b. Treatment with an alternative technology approved by CDPH that treats the waste with temperatures in excess of 1300 degrees Fahrenheit;
 - c. Steam sterilization at a permitted medical waste treatment facility or by other sterilization, in accordance with specified operating procedures for steam sterilizers or other sterilization; or,
 - d. Other alternative medical waste treatment methods which are approved by CDPH and result in the destruction of pathogenic micro-organisms. (HSC § 118215(a))
- 7) Prohibits the disposal of home-generated sharps waste in the trash or recycling containers, and requires that all sharps waste be transported to a collection center in a sharps container approved by the local enforcement agency. (HSC § 118286)
- 8) Authorizes a city and a county Household Hazardous Waste (HHW) element to include a program for the safe collection, treatment, and disposal of sharps waste generated by households. (Public Resources Code (PRC) § 41502)
- 9) Requires manufacturers of self-injectable medications to annually submit a plan describing how it provides for the safe collection and proper disposal of medical sharps. (PRC § 47115)
- 10) Requires pharmaceutical takeback programs to be in compliance with the Controlled Substances Act and its implementing regulations. (21 U.S.C. § 801-971 and 21 Code of Federal Regulations 1300-1321)

FISCAL EFFECT: Unknown.

COMMENTS:

Need for the bill: 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."

What is medical waste?: Medical waste is 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 (OTC) human or veterinary drugs.

Medical Waste Management Act (MWMA): The 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. Under the MWMA, pharmaceutical waste has to be incinerated at a permitted medical waste treatment facility; treated at temperatures in excess of 1300 degrees Fahrenheit; or, steam sterilized at a permitted medical waste treatment facility. The MWMA is administered by CDPH.

Scope of the problem: According to the U.S. Centers for Medicare & Medicaid Services, approximately \$275.9 billion in prescription drugs were predicted to be prescribed in the U.S. in 2014. By 2020, that number is projected to reach \$379.9 billion. An estimated 10 to 33 percent of prescribed medicines are not consumed. With a lack of safe, secure, and convenient disposal options, consumers traditionally turn to trashing, flushing, or storing these medicines at home.

Medical sharps: An estimated one million Californians inject medications outside traditional health care facilities, which generate approximately 936 million sharps each year, and the numbers of patients using injectable medications will continue to grow because it is an effective delivery method for various medications. The most common home use of sharps is to manage diabetes. Other reasons to inject at home include hepatitis, multiple sclerosis, infertility, migraines, allergies, hemophilia, and medications for pets. According to statistics from CalRecycle, 43% of all self-injectors throw needles in the trash.

Sharps collection: Home-generated sharps waste is required to be put into an approved sharps container before being transported out to an approved drop-off location or via mail-back program. CalRecycle maintains the Facility Information Toolbox (FacIT) Website, which currently lists more than 600 facilities where residents can take their home-generated sharps such as hospitals, pharmacies, or household hazardous waste (HHW) facilities.

While disposal of sharps is illegal, there is no statewide statutory program in place to require the management of sharps by manufacturers, pharmaceutical companies, pharmacies, or others. Current law allows for a streamlined oversight structure for those that do wish to provide a voluntary disposal for sharps to their customers or the general public, but there is no mandate for them to do so. Some pharmacies and health care providers have developed programs as a way to assist their customers and have reported some success.

Sharps collection requirements under the MWMA: CDPH has the authority to approve locations as points of consolidation for the collection of home-generated sharps waste, which, after collection, is transported and treated as medical waste. An approved consolidation location is known as a "home-generated sharps consolidation point." A home-generated sharps consolidation point must comply with all of the following requirements: (1) All sharps waste shall be placed in sharps containers; and, (2) sharps containers ready for disposal shall not be held for more than seven days without the written approval of the enforcement agency.

California Board of Pharmacy (Board): The Board regulates the pharmacy practice of pharmacists, interns, pharmacy technicians, and exemptees (those who are involved with the wholesale or manufacturer of drugs and medical devices, but not required to hold a pharmacist license). The Board also regulates all types of firms that distribute prescription drugs and devices in California, including community pharmacies and those located in hospitals, clinics, home and community support services facilities, and out-of-state mail order pharmacies that fill prescriptions and deliver them in California.

Confusion over where/how to dispose of household pharmaceutical and sharps waste: The guidance by the federal and state government is not clear on how consumers should dispose of their sharps and pharmaceutical waste.

According to the FDA website, it states that there are two ways for consumers to dispose of medicine, depending on the drug:

"Flushing medicines: Because some medicines could be especially harmful to others, they have specific directions to immediately flush them down the sink or toilet when they are no longer needed. Check the label or the patient information leaflet with your medicine. Or consult the FDA's list of medicines recommended for disposal by flushing.

Disposing medicines in household trash: Almost all medicines can be thrown into your household trash. These include prescription and over-the-counter (OTC) drugs in pills, liquids, drops, patches, creams, and inhalers."

However, CalRecycle's website on managing household pharmaceutical and sharps waste states the following:

"There are no laws that forbid households from putting medication into the trash. Household waste is exempt from classification as hazardous waste and as medical. If take-back programs or mail back options are not available to you, and if your local household hazardous waste facility does not accept pharmaceuticals, then as a last resort, disposing nonchemotherapy medication in the trash is probably your best option. Mix medicines (do not crush tablets or capsules) with an unpalatable substance such as dirt, kitty litter, or used coffee grounds; place the mixture in a container such as a sealed plastic bag; then throw the container in your household trash. Wastewater treatment plants are not designed to remove pharmaceuticals and studies show exposure to even low levels of drugs has negative effects on fish and other aquatic species, and also may negatively affect human health. Thus, we recommend households do not dispose of waste medication down the drain or down the toilet. This includes any prescription or nonprescription substances intended to be swallowed, inhaled, injected, applied to the skin or eyes, or otherwise absorbed.

Note: Due to security concerns, the FDA lists a small number of drugs that it recommends flushing including Oxycodone, Duragesic (Fentanyl) patch, Demerol, Methadone, Morphine, and Percocet."

In summary, the FDA says to trash most medications and flush some of the rest, and CalRecycle says that it is ok to trash most medications; however, specific packaging instructions need to be followed before placing in the garbage and do not flush them; however, it is ok to flush the medications that the FDA says to flush, which is clearly confusing.

Extended Producer Responsibility (EPR): Extended Producer Responsibility (EPR), also known as Product Stewardship, is a strategy to place a shared responsibility for end-of-life product management on the producers, and all entities involved in the product chain, instead of the general public; while encouraging product design changes that minimize a negative impact on human health and the environment at every stage of the product's lifecycle. This allows the costs of treatment and disposal to be incorporated into the total cost of a product. It places primary responsibility on the producer, or brand owner, who makes design and marketing decisions. It also creates a setting for markets to emerge that truly reflect the environmental impacts of a product, and to which producers and consumers respond. CalRecycle has developed an EPR framework and checklists to guide statutory proposals that would allow CalRecycle and other stakeholders to implement product stewardship programs.

Current State EPR Programs: There are several statewide EPR programs, all of which are overseen by CalRecycle. They include: Carpet Materials Management (Carpet), Paint Product Management (Paint), and Mattress Product Management (Mattresses). One important distinction between these EPR programs and SB 212, for the current state EPR programs the focus is not only on collection of the waste but ways to recycle these wastes. However, for pharmaceutical and sharps waste, they cannot be recycled and must be destroyed.

Carpet: California is the first state to establish a private-sector designed and managed statewide EPR carpet recycling program. This program, started in 2011, follows EPR principles for the proper management of discarded carpets. It also includes a long-term, sustainable funding plan based on manufacturer assessments. The amount of the assessment shall be sufficient to meet, but not exceed, the anticipated cost of carrying out the plan. The law allows flexibility in the method and associated costs in implementing the plan, provided goals are met.

Paint: California was the second state in the nation to enact an industry-led, statewide program to reduce the generation of leftover paint, promote its reuse, and properly manage unwanted leftover paint. The Paint Stewardship Program follows EPR principles to ensure that leftover paint is properly managed in a manner that is sustainably funded by an assessment on paint sold by manufacturers into the state.

Mattresses: It is estimated that millions of mattresses and box springs reach the end of their lives in California every year. The bulky nature of mattresses and the lack of affordable, convenient recycling options have resulted in significant illegal dumping costs to local jurisdictions throughout the state.

The Mattress EPR Program established an industry-run, statewide program to increase the recovery and recycling of mattresses at their end-of-use funded by a charge added to the purchase price of each mattress sold in the state.

Key differences between the Mattress EPR program and the pharmaceutical/sharp EPR program envisioned in SB 212: The Mattress EPR Program was enacted a few years after the first EPR programs and that statute reflected changes based upon lessons learned with the earlier EPR programs. While both the Mattress EPR program and SB 212 use EPR principles, there are several key differences.

First, the Mattress EPR program uses a broader definition of "manufacturer" that includes not only the manufacturer, but the distributor and the importer of the mattress into the state if there is not a manufacturer. However, SB 212 only includes the manufacturer of a covered product.

Second, under the Mattress EPR program, a retailer is prohibited from selling a mattress into the state unless the retailer and manufacturer are complying with the mattress EPR program. SB 212 does not have a product prohibition (it is important to note that SB 212 is focused on medications).

Third, the Mattress EPR program has detailed language that requires the Mattress Stewardship Organization to set an amount of a mattress recycling charge that is to be added to the purchase price of a mattress and that that charge shall be sufficient to fund the program. Additionally, the Mattress Stewardship Organization, as part of their annual budget to be submitted to CalRecycle, shall include the amount of the mattress recycling charge and itemization of costs. In SB 212, the language states that the funding must be sufficient to cover the Plan's costs; however, there is not much of detail on what the funding is or who pays in the budget that is submitted to CalRecycle.

Joint Legislative Audit Committee (JLAC) audit of pharmaceutical and sharps waste: In 2016, JLAC approved Assemblymembers Ting and Grays audit request that the State Auditor provide independently developed and verified information related to CDPH, CalRecycle, and a selection of counties' waste disposal standards for home-generated sharps and pharmaceutical waste. In May 2017, the audit was submitted to the Legislature and here is a summary of the audit's recommendations:

- 1) To foster consumers' proper disposal of sharps and pharmaceutical waste, the Legislature should provide CalRecycle statutory oversight responsibility for home generated sharps and pharmaceutical waste disposal and provide CalRecycle additional resources to the extent that it can justify the need. This responsibility should include the following actions:
 - a) Developing and implementing a public education campaign about home generated sharps pharmaceutical waste disposal. CalRecycle should coordinate this campaign with local, state, and, to the extent possible, federal agencies to ensure consumers receive consistent guidance regarding proper disposal methods;
 - b) Maintaining an up-to-date, well-publicized, and accessible statewide list of free sharps and pharmaceutical waste collection sites. CalRecycle should create this list by either improving its FacIT database or by establishing a new database, potentially using Recyclewhere.org as a model;

- c) Increasing consumers' access to proper disposal methods in underserved locations. It could increase access by subsidizing prepaid mail-back options or by encouraging municipalities to include the collection of sharps and pharmaceutical waste in their contracts with waste haulers;
 - d) Determining the characteristics of other government programs, such as New York State's consumer education program, that might benefit California; and,
- 2) To increase in-state options for processing California's home-generated pharmaceutical waste, the Legislature should expressly authorize municipal solid waste incinerators to burn limited quantities of home-generated pharmaceutical waste, but only after considering environmental impacts. To ensure consistency throughout the State, the Legislature should adopt standard requirements for counties to follow when implementing EPR programs. These requirements should limit any additional costs the programs may impose on consumers.

Existing Pharmaceutical/Sharp EPR programs: Currently, there are a few local pharmaceutical and sharps EPR programs, including a program in Alameda County.

Alameda County: The Alameda County Board of Supervisors passed the Alameda County Safe Drug Disposal (SDD) Ordinance on July 24, 2012. The Alameda County Board of Supervisors passed the Alameda County Safe Consumer-Generated Sharps Disposal (SSD) Ordinance on November 15, 2015, adding Chapter 6.54 to the Alameda County General Ordinance Code. The SSD Ordinance places certain requirements on pharmaceutical and Sharps manufacturers that sell or distribute products in Alameda County usually intended for administration outside of a healthcare setting. The SSD Ordinance took effect December 18, 2015.

The SDD and SSD requires pharmaceutical producers to develop a product stewardship program (Program) to finance and manage the collection, transportation, treatment, and disposal of consumer-generated Sharps waste within Alameda County including unincorporated areas. The costs of implementing the program will be allocated in a fair and reasonable manner, such that the portion of costs paid by each producer is reasonably related to the amount of sharps and medication usually injected outside a healthcare setting that producer sells in the County. The program will accept sharps regardless of who produced them or their compatibility with producers' drugs, unless excused from this requirement by the Alameda County Department of Environmental Health.

According to the Alameda County website, "There are now 41 collection sites throughout Alameda County where residents can drop-off their unwanted prescription and OTC drugs, including 40 sites that can accept Schedule II-IV Controlled Substances. This updated information includes 37 sites now managed by the Alameda MED-Project Stewardship Organization, as well as a pair of Walgreen's stores that initiated an independent collection program during 2016."

Ordinances similar to Alameda County's have been enacted in the City and County of San Francisco, Marin County, San Mateo County, and Santa Clara County.

New York: In June 2018 the New York State Legislature passed S.9100 (Hannon) to require certain manufacturers to operate a drug take back program to accept and dispose of covered drugs and provides that, in any city with a population of 125,000 or more, regulations shall be established for a distribution plan that ensures that on-site collection receptacle or dropbox placement shall be reasonably accessible to all residents.

Issues for the author and committee to consider: While this bill has many program details, the author and committee may wish to carefully examine the language and should the committee pass the bill, the author may wish to consider continuing to work on the following aspects of the bill.

How to ensure that this EPR program will be effective? This is a key component of any EPR program. SB 212 uses a couple of key components: first, it requires program promotion; in essence, getting the word out about how and where to properly dispose of used pharmaceuticals and sharps and a convenience standard, which is a floor of having at least five sites in a county or one per 50,000 people, whichever is greater, which is to make it convenient for the consumer and for the program operator to drop off and collect covered drugs. Other approaches to consider include using the convenience standard within the bill, and allowing CalRecycle, based on how the EPR program is working, to adjust this standard. This type of adjustment will allow the program to be flexible in a way that acknowledges that California is a very diverse state and may require different approaches in different parts of the state. Another approach is to require each pharmacy in the state to accept pharmaceutical and sharps waste, either on-site or very near to their store.

Definition of covered manufacturer: SB 212 defines a covered manufacturer as a person, corporation, or other entity engaged in the manufacture of covered products sold, offered for sale, or introduced into the State. However, what if a manufacturer is located outside of California? Can CalRecycle compel an out-of-state manufacturer to comply with the provisions of this bill? Other EPR programs under CalRecycle's purview, including mattresses, include a definition of manufacturer that also includes the importer of the product into the state. This is one way to ensure that the product is covered in the event an out-of-state manufacturer chooses not to comply and the State is unable to enforce. *This issue could use some further exploring, especially since the entire program is funded by the manufacturer. Therefore, getting this right could be vital to ensuring the efficacy of the program.*

Definition of retail pharmacy chain: The bill has a definition for retail pharmacy, but not a retail pharmacy chain; however, the bill imposes specific requirements on retail pharmacy chains. Under certain circumstances, the bill compels retail pharmacy chains to ensure that at least 15 percent of their stores in a given county accept covered products. However, the definition of retail pharmacy includes an independent pharmacy, a supermarket pharmacy, a chain pharmacy, and a hospital or clinic pharmacy. *The author may wish to clarify this definition, which will make it clear as to which pharmacies are "chain" pharmacies and therefore could be compelled to participate, as well as ensure that CalRecycle knows who must comply with what.*

Overlap with local programs: Though SB 212 preempts local governments from adopting ordinances for pharmaceutical and sharps EPR programs as of April 18, 2018, it is unclear how the state EPR program will operate within jurisdictions that already have enacted similar ordinances. The bill does not preclude the state program from operating within jurisdictions that already have ordinances, and the bill specifically prohibits existing local EPR programs from

receiving funding from the statewide program. Presumably, the state program could operate collection sites within all jurisdictions of the state, regardless of whether or not there is a local program. However, it seems possible that the intent is to allow the local programs to continue and the state EPR program would only operate in those areas that do not have a local program. At the very least, it is unclear how this would work as currently drafted. *The author may wish to consider how to reconcile this issue.*

Enforcement: The bill contains a penalty provision of up to \$1,000 or up to \$5,000, depending on the type of violation. The bill also allows for enforcement against a covered manufacturer, stewardship organization, authorized collector, retail pharmacy, or retail pharmacy chain. *Given the lack of clarity with some of the definitions of these categories, the author may wish to continue to work on this to ensure that each entities role is clear and that CalRecycle has a clear understanding of who to enforce against in the event that becomes necessary.* Additionally, it is important to note that the other EPR programs under CalRecycle include a product ban as part of enforcement. However, there is a difference in banning the sale of carpet, paint, and mattresses versus banning the sale of pharmaceuticals and sharps. *Therefore, instead of a product ban, the author may wish to consider whether or not the penalties in the bill are enough to ensure compliance.*

SB 212 applies to drugs for both human use and animal use. Should it? The EPR program envisioned in this bill includes drugs for use for both humans and animals. In addition to acquiring medications for pets from a veterinarian versus a local drug store, there is also the consideration of use of drugs on animals in an agriculture setting, including the use of medicated feedstock. While some local ordinances have included both human and animal drugs in their programs, when looking at California, it is quite diverse, including a very large and diverse farming and agriculture industry. *The author and Committee may wish to consider whether or not it is appropriate to include drugs for use on animals or just focus on establishing an effective statewide EPR program on human drugs and sharps.*

Another area to explore: The bill, on page 11, authorizes CalRecycle to ask the program operator to provide the submitted Plan to the Board, CDPH, and DTSC before CalRecycle reviews this plan. *The author and committee may wish to consider requiring CalRecycle to require the program operator to give the Plan to these other agencies first, primarily because these agencies have the regulatory responsibility over medical waste, controlled substances, hazardous waste and hazardous and medical waste haulers, where CalRecycle does not have that expertise or authority.*

Related legislation:

- 1) AB 2039 (Ting, 2016). Would have required the development and implementation of industry-generated plans to collect and recycle home-generated sharps. Held in the Assembly Environmental Safety and Toxic Materials Committee.
- 2) SB 1229 (Jackson, Chapter 238 Statutes of 2016). Provides qualified immunity from civil and criminal liability of participating entities that take reasonable care to ensure the health and safety of consumers and employees when maintaining secure drug take-back bins on their premises.

- 3) AB 1159 (Gordon, 2015). Proposed establishing a pilot product stewardship program for the management of medical sharps and household primary batteries. Held in the Assembly Appropriations Committee.

REGISTERED SUPPORT / OPPOSITION:

Support

Alameda County Board of Supervisors
Butte County Board of Supervisors
California Association of Environmental Health Administrators
California State Association of Counties
California Hospital Association
California Product Stewardship Council
California Resource Recovery Association
California School Employees Association, AFL-CIO
Californians Against Waste
Central Contra Costa Sanitary District
City of Chula Vista
City of Santa Monica
City of Sunnyvale
City of Torrance
City of West Hollywood
Communities Against Abuse of Prescription Drugs
County Health Executives Association of California
County of Sacramento
County of Santa Clara
County of Mendocino
County Sanitation Districts of Los Angeles County
Covanta
Del Norte Solid Waste Management Authority
Delta Diablo
Dublin San Ramon Public Services District
Gallinas Watershed Council
GreenWaste
Las Gallinas Valley Sanitary District
League of California Cities
Long Beach Gray Panthers
Los Angeles County Solid Waste Management Committee/Integrated Management Task Force
Medical Waste Services
Mendocino Solid Waste Management Authority
Metropolitan Recycling, LLC
Monterey County Prescribe Safe Initiative
Monterey Regional Waste Management District
Mojave Desert & Mountain Recycling Authority
National Stewardship Action Council
Orange County Sanitation District
Prescribe Safe Monterey County

ReThinkWaste
Riverside County Department of Waste Resources
Rural County Representatives of California
Salinas Valley Solid Waste Authority
San Benito County Integrated Waste Management
San Joaquin County
Save the Bay
Solid Waste Association of North America
Sonoma County Waste Management Agency
Stop Waste
Surfrider Foundation
Surfrider Foundation, Los Angeles
Upper Valley Waste Management Agency
Watershed Alliance of Marin
Western Placer Waste Management Authority
7th Generation Advisors

Opposition

Advanced Medical Technology Association (AdvaMed)
Association for Accessible Medicines
Biocom
Biotechnology Innovation Organization
California Life Sciences Association
California Pharmacists Association
California Retailers Association
National Association of Chain Drug Stores

Analysis Prepared by: Josh Tooker / E.S. & T.M. /