
SENATE COMMITTEE ON ENVIRONMENTAL QUALITY

Senator Wieckowski, Chair

2017 - 2018 Regular

Bill No: SB 212

Author: Jackson

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Urgency: No

Fiscal: Yes

Consultant: Rachel Machi Wagoner

SUBJECT: Medical waste

ANALYSIS:

Existing federal law:

1. Under the Food, Drug, and Cosmetic Act, the Food and Drug Administration (FDA) is authorized to oversee the safety of food, drugs, and cosmetics.
2. Under the Resource Conservation and Recovery Act (RCRA) of 1976, the management of solid and hazardous wastes is regulated. In the context of pharmaceuticals, RCRA imposes strict protocols for the collection of controlled substances.
3. The Secure and Responsible Drug Act of 2010 eases the restrictions on the collection of controlled substances; final regulations are currently under development, and are expected to be published in March 2014.

Existing state law:

- 1) Under the California Hazardous Substances Act, the Department of Toxic Substances Control (DTSC) is authorized to regulate hazardous materials and wastes in accordance with RCRA.
- 2) Under the California Integrated Waste Management Act:
 - a) Requires the Department of Resources Recycling and Recovery (CalRecycle) to implement a statewide household hazardous waste substance information and collection program.
 - b) Authorizes local jurisdictions to include in their Household Hazardous Waste Elements a program for the safe management of sharps waste.

- c) Requires pharmaceutical manufacturers that sell or distribute a medication in California that is self-injected at home through the use of a hypodermic needle, pen needle, intravenous needle, or any other similar device to submit to CalRecycle a plan that describes what actions, if any, the manufacturer supports for the safe management of sharps waste.
- 3) Under the Medical Waste Management Act (MWMA):
- a) Requires the California Department of Public Health (DPH) to regulate the management and handling of medical waste.
 - b) Defines “pharmaceuticals” as a prescription or over-the-counter human or veterinary drug. “Pharmaceutical” does not include any pharmaceutical that is regulated pursuant to either RCRA or the Radiation Control Law and certain items, such as household waste, are specifically excluded from the definition of medical waste.
 - c) Defines “pharmaceutical waste” as any pharmaceutical that for any reason may no longer be sold or dispensed for use as a drug and excludes from this definition those pharmaceuticals that still have potential value to the generator because they are being returned to a reverse distributor for possible manufacturer credit.
 - d) Specifies that waste comprised only of pharmaceuticals is biohazardous, and is considered “medical waste.”
 - e) Home-generated pharmaceutical waste *is not defined* in statute or regulations, however, the California Department of Public Health has viewed the consolidation and disposal of pharmaceutical waste as a public health necessity and regulates this waste stream as medical waste.

This bill: Requires entities that sell drugs or 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. Requires the Department of Resources, Recycling and Recovery (CalRecycle) to oversee and enforce each stewardship plan (Plan). **Specifically:**

- 1) 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; and, a drug in a medical device. Exempts from the definition of a "covered

drug" drug for veterinary use. Exempts from the definition of a "covered drug" drugs that are used for animal medicines and dialysate drugs or other saline solutions required to perform kidney dialysis.

- 2) Defines "covered product" as a covered drug or home-generated sharps waste.
- 3) Defines "drug" as an article recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia 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.
- 4) Defines a "covered entity" as a manufacturer of covered products that are sold into the state. If there is not a manufacturer for a covered product, then the covered entity is the distributor of the covered product sold into the state. If there is not a manufacturer or distributor for a covered product, then the covered entity is the owner or licensee of a trademark or brand name under which covered products are sold into the state. If there is not a manufacturer, distributor, or owner or licensee of trademark or brand name, then the covered entity is the importer of the covered product into the state.
- 5) Defines "stewardship organization" as an organization established by a group of covered entities to develop, implement, and administer a stewardship program.
- 6) Defines "stewardship plan (Plan)" as the plan for collecting and properly managing covered products that is developed by a covered entity or stewardship organization.
- 7) Defines "stewardship program" as a stewardship program for the collection, transportation, and disposal of covered products.
- 8) Defines "program operator" as a covered entity, or stewardship organization on behalf of a group of covered entities, that is responsible for operating a stewardship program.
- 9) 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.
- 10) Establishes a process where a stewardship organization can establish a stewardship program for covered drugs, or for home-generated sharps waste, or for both.

- 11) Requires a stewardship program for covered drugs to have specific requirements of its program operator including the requirement of a minimum number of collection sites; provisions for handling, transporting, and disposing of the covered drugs; the allowance of a mail-back program; an alternative form of collection and disposal of covered drugs if allowed under state and federal law; provisions for the collection of covered drugs from an ultimate user who is homeless, homebound, or disabled; provides for a service schedule that meets the needs of a collection site so that it is serviced often enough to avoid reaching capacity; and, demonstrated adequate funding for all administrative and operation costs to be borne by participating covered entities.
- 12) Requires a stewardship program for home-generated sharps waste to be a mail-back program; maintain an internet website and toll-free number for providing information about the program; provide for the handling, transport, and disposal of home-generated sharps waste; provide containers and mail-back materials at no cost to the ultimate user; provide the sharps waste container and mail-back materials at the point of sale to the extent allowed by law; provide reimbursement to local agencies for disposal costs related to home-generated sharps waste; and, demonstrate adequate funding for all administrative and operation costs to be borne by participating covered entities.
- 13) 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.
- 14) Requires a program operator to conduct a comprehensive education and outreach program intended to promote participation in the stewardship program.
- 15) 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.
- 16) Requires CalRecycle to approve a Plan submitted to it that meets the requirements of this bill.
- 17) 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.
- 18) 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.

- 19) Requires a program operator to initiate operation of an approved stewardship program no later than 270 days after approval of the Plan by CalRecycle.
- 20) Requires CalRecycle to make all Plans submitted to it available to the public, except for proprietary information in the Plan.
- 21) 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.
- 22) Requires a program operator, on or before March 31, 2022, 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.
- 23) 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.
- 24) Requires each covered entity, 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.
- 25) Requires CalRecycle, on or before June 30, 2022, and at least annually thereafter, to post on its Internet Web site a list of covered entities, stewardship organizations, authorized collections sites, retail pharmacies, and retail pharmacy chains in compliance with the stewardship program.
- 26) 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 United State Drug Enforcement Agency (US DEA).
- 27) Requires CalRecycle to adopt regulations for implementation of the bill with an effective date no later than January 1, 2021.

- 28) Requires a covered entity to be in compliance with the provisions of the bill one year from the adoption of regulations by CalRecycle.
- 29) Requires a stewardship plan for covered drugs or home-generated sharps waste or both 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.
- 30) 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.
- 31) Provides that the bill does not apply to a drug or sharp within a jurisdiction that is subject to a local stewardship program if that local program took effect before April 18, 2018. Requires, if that local ordinance is repealed, covered drugs or home-generated sharps waste to be in compliance with this bill within 270 days after the date the ordinance is repealed.
- 32) 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.

Background

- 1) *Pharmaceuticals.* According to the U.S. Centers for Medicare & Medicaid Services, which publishes the National Health Expenditure Projections 2012-2022, approximately \$275.9 billion in prescription drugs were predicted to be prescribed in the US in 2014. However, 2014 expenditures were almost \$100 billion more than predicted according to the IMS Institute for Healthcare Informatics. In an April 2015 study, IMS stated that spending rose 13%, to a total of \$374 billion. After accounting for population growth and inflation, the increase equaled 10%. A record 4.3 billion prescriptions were filled in 2014.”
- 2) *Environmental contamination.* There are two general sources of pharmaceutical contamination in the environment: human excretion and disposal. Estimates suggest that 3 to 50% of prescriptions become waste. United States hospitals and long-term care facilities annually flush approximately 250 million pounds of unused pharmaceuticals down the drain.

It is unknown (if not impossible) to determine how much household pharmaceutical waste is flushed down the toilet. However, anecdotally waste water treatment facilities note that scraping pills off of water filtration systems is a problem, in addition to the removal of pharmaceutical agents from the water.

A study conducted by the United States Geological Survey from 1999-2000 sampled 139 streams across 30 states and found that 80% had measurable concentrations of prescription and nonprescription drugs, steroids, and reproductive hormones. Since the USGS released its report in 2002, a number of studies have demonstrated the low-level presence of pharmaceutical agents throughout the environment and water supply.

Recent studies have found a variety of drugs in crops, such as cholesterol medications, caffeine, and triclosan. In a recent study, researchers found that the anticonvulsive epilepsy drug, carbamazepine, can accumulate in crops irrigated with recycled water and end up in the urine of produce-eaters not on the drug. The researchers found that while the amounts of the drug in a produce-eater's urine were four orders of magnitude lower than what is seen in the urine of patients purposefully taking the drug, there is a possibility that trace amounts could still have health effects in some people, such as those with a genetic sensitivity to the drugs, pregnant women, children, and those who eat a lot of produce, such as vegetarians.

With the growing practice of reclaiming wastewater for crop irrigation, the produce contamination could become more common and more potent.

California, which grows a large portion of US produce, currently uses reclaimed water for 6% of its irrigation needs.

Additionally, as California's climate continues to change and the state endures longer droughts, recycling and reusing groundwater and surface water recharge will become more important and ensuring contamination prevention and removal will be more crucial.

While the human effects of pharmaceutical agents in the environment are not fully understood, harm to aquatic organisms and ecosystems due to low levels of pharmaceutical agents are clearly established.

Life-long exposure to ppb levels of an estrogen-based synthetic hormone resulted in complete population failure in fish due to the males failing to develop properly.

Mood altering drugs, such as Prozac, lead to changes in the behavior of fish, making them easier prey.

The presence of persistent antibiotics, particularly downstream from hospitals,

has been partially credited for the rise in resistant bacterial strains, which may also have an indirect human impact.

3) *Diversion.*

- a) *President Bush's Administration Recommendations.* In February 2007, the White House Office of National Drug Control Policy, the Health and Human Services Agency, and the US Environmental Protection Agency released new Federal prescription drug disposal guidelines urging Americans to utilize pharmaceutical take-back locations because “improper drug disposal is a prescription for environmental and societal concern.”
- b) *Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health (NSDUH).* According to the 2011 NSDUH more than six million Americans abuse prescription drugs. That same study revealed more than 70% of people abusing prescription pain relievers got them through friends or relatives, a statistic that includes raiding the family medicine cabinet.
- c) *President Obama's Administration's National Drug Control Strategy.* In 2011, President Obama released a statement to Congress stating, “Every sector of our society is affected by drug use and the consequences of drug use. Drug use and its consequences hamper our Nation's ability to out-educate our global competitors and increase graduation rates. It lessens the ability of our workforce to be fully productive, and it takes the lives of too many fellow Americans.

“Prescription drug abuse is America's fastest-growing drug problem, and one largely fed by an unlikely source—Americans' medicine cabinets. The passage of the Secure and Responsible Drug Disposal Act of 2010 will save lives by providing patients with safe, environmentally sound ways to dispose of unused or expired prescription drugs.

“By taking a balanced approach to drug policy, one that emphasizes both public health and public safety, we can help make our neighborhoods and communities even stronger.”

- d) *National Strategy on Preventing Prescription Drug Abuse.* The Obama administration has identified four major areas to reduce prescription drug abuse: education, monitoring, proper medication disposal, and enforcement. In particular, the national strategy includes action to “develop convenient and environmentally responsible prescription drug

disposal programs to help decrease the supply of unused prescription drugs in the home.”

- 4) *United States Drug Enforcement Agency (DEA) regulation.* Prior to 2010, as a matter of federal law, individuals who wanted to dispose of unused, unwanted, or expired pharmaceutical controlled substances only had limited disposal options because the federal Controlled Substances Act (21 U.S.C. Sec. 801 et seq.) only permitted individuals to either destroy those substances themselves (such as by flushing or discarding), surrender them to law enforcement, or otherwise seek assistance from the Drug Enforcement Administration (DEA).

According to the DEA, these restrictions resulted in the accumulation of pharmaceutical controlled substances in household medicine cabinets that were available for abuse, misuse, diversion, and accidental ingestion.

In 2010, the federal Secure and Responsible Drug Disposal Act of 2010 (Disposal Act) was enacted, amending the Controlled Substances Act to authorize certain individuals (“ultimate users”) to deliver their pharmaceutical controlled substances to another person for the purpose of disposal in accordance with regulations promulgated by the US Attorney General.

In September of 2014, the DEA issued its final rule implementing the Disposal Act and governing the secure disposal of controlled substances by registrants and ultimate users. Those regulations have expanded the options available to collect controlled substances from ultimate users for the purpose of disposal, including take-back events, mail-back programs, and collection receptacle locations and, among other things, allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles.

While the changes to federal law are rather recent, there has already been a significant push to increase the use and availability of secure drug take-back programs both across the nation and in this state.

For example, one major retailer, Walgreens, announced in 2016 that it has begun to install safe medication disposal kiosks in more than 500 drugstores in 39 states and Washington, D.C. to make the disposal of medications — including opioids and other controlled substances — easier and more convenient while also helping to reduce the misuse of medications and the rise in overdose deaths.

- 5) *Medical sharps:* An estimated one million Californians inject medications outside traditional health care facilities, which generate approximately 936

million sharps each year which then need to be properly disposed. 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.

- 6) *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 in landfills 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.

- 7) *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.

- 8) *Background on take-back programs.*

- a) *DEA Take-back programs.* The DEA's Take-Back events are a significant piece of the White House's prescription drug abuse prevention strategy released in 2011 by the Office of National Drug Control Policy. "Drug Take-Back Days," which are typically administered by law enforcement in conjunction with county health offices or other local government agencies, are one-time events that allow for individuals to dispose of prescription or non-prescription medications; following the collection, the pharmaceuticals

are taken to a safe disposal site.

The DEA's seventh National Take-Back Day in October 2013 collected 324 tons of expired and unwanted medications across all 50 states. Since the inception of the National Take-Back Day in 2010, the DEA has collected over 3.4 million pounds of medicine from circulation. The next national collection event is scheduled for April 29, 2017.

- b) *International take-back programs.* In 1999, British Columbia established the "Post-Consumer Pharmaceutical Stewardship Association" (PCPSA) to establish a pharmaceutical drug take-back program funded by manufacturers. Manufacturers are required to pay for the cost of collecting and managing the program; they are not required to pay for cost of agency oversight. Currently, over 100 companies participate in the PCPSA.

Within British Columbia, 95% of pharmacies choose to participate in the program, accounting for over 1,000 collection sites. In 2009, the program diverted 112,000 pounds of medication from improper disposal or abuse for an estimated cost of \$400,000.

Australia established a national collection system in place since 1998.

The European Union has required a national collection system for unused or expired medicines since 2004.

- c) *Take-back programs in the US.* Locally run take-back programs are prevalent throughout the US. A few states, such as Michigan and Maine, have enacted laws to facilitate the collection of pharmaceutical waste at locations such as pharmacies (MI) or to create mail-back programs for pharmaceutical waste (ME).

Recreational marijuana is now legal in Colorado, however it remains highly regulated at the federal level and has a high diversion potential. In response to Colorado's recreation marijuana use statute, the Colorado Springs Airport installed two marijuana take-back bins, providing a location for travelers to safely and legally dispose of their marijuana.

- d) *SB 966 Model Guidelines in CA.* Under the California Integrated Waste Management Act (SB 966, Simitian, Kuehl, Chapter 542, 2007), CalRecycle created a model collection program for household hazardous substances, such as pharmaceuticals, and evaluated how local programs implemented take-back programs. Programs that followed the model

guidelines were released from any liability associated with collecting home-generated pharmaceuticals. The model program sunsetted on January 1, 2013.

- e) *Local programs in CA.* In 2010, CalRecycle identified 297 take-back programs in California. This includes one-time take-back events, continuous take-back programs, and mail-back programs. The majority of these programs are funded and run by local governments, although San Francisco has a program that is partially funded by PhRMA and Genetech.

In 2012, Alameda County passed a first in the nation Safe Drug Disposal Ordinance (based on the British Columbian model) that requires producers of covered drugs to operate take-back programs, including the creation, administration, promotion, and payment of the program. The ordinance was challenged by Pharmaceutical Research and Manufacturers of America, Generic Pharmaceutical Association, and Biotechnology Industry Organization on the basis that the ordinance violates the dormant Commerce Clause for interstate commerce and discriminates against out-of-county producers. In August 2013, the US District Court upheld the ordinance, although litigation is ongoing. Several other California counties are considering similar ordinances.

In 2010, San Francisco introduced a Safe Drug Disposal Ordinance. However, in 2012 the city chose to instead accept \$110,000 from PhRMA and Genentech to fund a pilot project to collect data on the issue. In August 2013 the same two organizations provided another payment of \$125,000 to fund the pilot project an additional year. A separate Safe Drug Disposal Information Ordinance was passed in May 2011 to supplement the PhRMA-funded pilot program by requiring pharmacies that won't host a bin to advertise those that do.

The Safe Medicine Disposal Pilot program has been well-utilized, with over 37,000 pounds collected in the first 26 months.

Following the US 9th Circuit Court of Appeals ruling upholding Alameda's ordinance, San Francisco Board President David Chiu reintroduced a San Francisco ordinance on October 21, 2014. Board President Chiu was elected to the California State Assembly in November 2014 and Supervisor London Breed became the author of the ordinance which was passed unanimously and was signed by Mayor Lee on March 26, 2015 and enacted 30 days after signing.

In recent years numerous other local governments have either adopted or are considering adoption of similar ordinances, including, but not limited to: Contra Costa, Marin, San Luis Obispo, San Mateo, Santa Barbara, Santa Clara and Los Angeles.

- 7) *Walgreens' National Retail Leadership*. In 2016 Walgreens became the first retailer to implement an ongoing national stewardship program by installing safe medication disposal kiosks in more than 500 drugstores in 39 states and Washington, D.C. to make the disposal of medications — including opioids and other controlled substances — easier and more convenient while helping to reduce the misuse of medications and the rise in overdose deaths. In a Walgreens press release announcing the program, Richard Ashworth, Walgreens president of pharmacy and retail operations said “Walgreens pharmacists play an important role in counseling patients on the safe use of their medications, and now we are leading the way in retail pharmacy’s fight against prescription drug abuse.”
- 8) *Extended producer responsibility*. CalRecycle defines EPR as 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.

By shifting costs and responsibilities of product disposal to producers and others who directly benefit, EPR provides an incentive to eliminate waste and pollution through product design changes.

There are a number of existing, statewide EPR programs for various products, including, but not limited to, paint, used oil, and, most recently, mattresses.

Comments

- 1) *Purpose of 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."

- 2) *Referral to the Committee pursuant to Senate Rule 29.10.* SB 212, as heard by the Senate Environmental Quality Committee, would have defined "Home-generated pharmaceutical waste" as a prescription or over-the-counter human or veterinary home-generated pharmaceutical, as defined in Section 109925 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C.A. Sec. 321(g)(1)), that is a waste, as defined in Section 25124, derived from a household, including, but not limited to, a multifamily residence or household.

The bill was amended to its current form in the Assembly. Consistent with Senate Rule 29.10(d) the Senate Rules Committee has referred the amended bill to the Senate Environmental Quality Committee for a hearing of the amendments.

Related/Prior Legislation

SB 1229 (Jackson and Stone, Chapter 238, Statutes of 2016) This bill provides certain collectors that are authorized under federal law to engage in drug take-back collection with limited protection from civil and criminal liability (or "qualified immunity") for any injury or harm that results from a collector maintaining a secure drug take-back bin on its premises, provided that the collector, not for compensation, acts in good faith to take specified steps to ensure the health and safety of consumers and employees and the proper disposal of the home-generated pharmaceutical waste contained in the secure drug take-back bin. This qualified immunity shall not apply in the case of personal injury or wrongful death which results from the collector's gross negligence or willful or wanton misconduct in maintaining a secure drug take-back bin.

AB 45 (Mullin, 2016) requires CalRecycle, in consultation with affected industries, to adopt one or more model ordinances for a comprehensive program for the collection of HHW for adoption by a local jurisdiction that provides for the residential collection and disposal of solid waste. AB 45 was discussed in the Senate Committee on Environmental Quality, however a vote of the committee was not taken at request of the author.

AB 2039 (Ting, 2016) proposes building on the models of the aforementioned programs to develop EPR for home-generated medical sharps. This bill was referred to the Assembly Committee on Environmental Safety and Toxic Materials. Hearing was cancelled at request of the author.

SB 1014 (Jackson, 2014) establishes the Home-Generated Pharmaceutical Waste Collection and Disposal Act. SB 1014 passed the Senate Committee on Environmental Quality on a vote of 5 to 1. The bill was held in the Assembly Appropriations Committee by request of the author.

AB 403 (Stone/Eggman, 2013) proposed requiring manufacturers that sell medical sharps to establish a product stewardship plan for home-generated medical waste. AB 403 was held in the Assembly Appropriations Committee by request of the author.

AB 333 (Wieckowski, Chapter 564, Statutes of 2013) makes various changes to the Medical Waste Management Act.

AB 467 (Stone, Chapter 10, Statutes of 2013) creates a licensure category for a surplus medication collection and distribution intermediary.

SB 727 (Jackson, 2013) requires a producer of a pharmaceutical sold in this state, individually or through a stewardship organization, to submit a plan to CalRecycle by January 1, 2015. This bill was referred to the Senate Environmental Quality Committee. Hearing was cancelled at request of the author.

AB 1442 (Wieckowski, Chapter 689, Statutes of 2012) defines pharmaceutical waste, exempted the waste generator from certain hauling requirements, and allowed the waste to be transported by a common carrier in order to reduce costs for handling expired pharmaceutical wastes.

SB 966 (Simitian/Kuehl, Chapter 542, Statutes of 2007) requires the Integrated Waste Management Board to identify and develop model programs for the safe disposal of household generated pharmaceutical waste.

AB 2335 (Saldana, Chapter 166, Statutes of 2006) makes various clarifying changes to the MWMA with the aim of reducing medical waste management costs and clarifying the complex regulatory framework.

SB 1305 (Figueroa, Chapter 64, Statutes of 2006) prohibits a person from knowingly placing home-generated sharps waste in the commercial and residential solid waste collection containers after September 1, 2008.

SB 1362 (Figueroa, Chapter 157, Statutes of 2004) allows a household hazardous waste collection facility to operate as a home-generated sharps consolidation point if certain conditions are met. The bill also allows a city or county HHW Element to collect, treat, and dispose of household sharps.

SB 407 (Alpert, Chapter 139, Statutes of 1999) authorizes the use of chemical disinfection as a treatment method for certain types of laboratory-generated medical waste if specified requirements were met.

SB 1966 (Wright, Chapter 536, Statutes of 1996) moved the management and handling of waste pharmaceuticals under DPH and the MWMA and reestablished fee authorities for DPH for small quantity medical waste generators.

SB 372 (Wright, Chapter 877, Statutes of 1995) makes various changes to the MWMA, including revisions to the definition of large quantity generator, medical waste exclusions, and storage. The bill also incorporated additional classes into the definition of medical waste and authorized the use of high temperatures to treat medical waste prior to disposal.

SB 1360 (Committee on Health and Human Services, Chapter 415, Statutes of 1995) moved the MWMA to the DPH during Governor Wilson's reorganization of the Department of Health Services to DPH and the California Environmental Protection Agency.

SOURCE: Author

SUPPORT:

Alameda County Board of Supervisors
Butte County Board of Supervisors
California Association of Environmental Health Administrators
California Cattlemen's Association
California Product Stewardship Council
California Resource Recovery Association
California School Employees Association, AFL-CIO
California State Association of Counties
California Teamsters
Californians Against Waste
Central Contra Costa Sanitary District
City of Chula Vista
City of Palo Alto
City of Santa Monica
City of Sunnyvale
City of Thousand Oaks
City of Torrance
City of West Hollywood

Communities Against Abuse of Prescription Drugs
County Health Executives Association of California
County of Humboldt
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
East Bay Municipal Utility District
Gallinas Watershed Council
GreenWaste
Groundwater Resources Association of California
Heal the Bay
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
Shasta County
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
Western United Dairymen
7th Generation Advisors

OPPOSITION:

Association for Accessible Medicines
Health Distributors Alliance
Lupin Pharmaceuticals
Otay Water District
Pharmaceutical Research and Manufacturers of America (PhRMA)

-- END --