Date of Hearing: June 28, 2016

ASSEMBLY COMMITTEE ON ENVIRONMENTAL SAFETY AND TOXIC MATERIALS
Luis Alejo, Chair
SB 423 (Bates) – As Amended June 21, 2016

SENATE VOTE: 40-0 (vote not relevant to current version of the bill)

SUBJECT: Pharmaceutical and consumer product waste: management.

SUMMARY: Exempts non-prescription pharmaceutical products from the Medical Waste Management Act (MWMA). Specifically, **this bill**:

1) Requires, until January 1, 2022, a pharmaceutical that is offered for sale without a prescription to be managed as hazardous waste if it meets the definition of hazardous waste.

2) Requires, until January 1, 2022, a pharmaceutical that is offered for sale without a prescription, if it is not a hazardous waste, to be managed either as a medical waste or a solid waste.

3) Requires the California Department of Toxic Substances Control (DTSC) to convene a Retail Waste Working Group to identify regulatory and policy directives that need clarification for managing consumer products, and adopt consensus recommendations for waste reduction opportunities.

4) Requires, by March 1, 2017, the Retail Waste Working Group to identify a list of issues for discussion and resolution, and requires, by June 1, 2017, to report to the Legislature the consensus recommendations to the Legislature.

EXISTING LAW:

1) Defines "drug" under the Federal Food, Drug, and Cosmetic Act as any article recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them. (21 United States Code Sec. 231 (g)(1))

2) Establishes the MWMA to govern medical waste management at any facility where waste is generated, at transfer stations, and at treatment facilities. (Health & Safety Code (H&S) § 117600, et seq.)

3) Defines "pharmaceutical waste" as a prescription or over-the-counter human or veterinary drug, including, but not limited to, a drug as defined in Section 109925 of the Federal Food, Drug, and Cosmetic Act. (H&S § 117747 (a))

4) Exempts from the definition of pharmaceutical waste any pharmaceutical that is regulated pursuant to the federal Resource Conservation and Recovery Act (RCRA) or the Radiation Control Law. (H&S § 117747 (b)) Exempts from the definition of pharmaceutical waste any pharmaceutical that is being sent offsite to or by a reverse distributor for treatment and disposal by a reverse distributor that is licensed as a wholesaler of dangerous drugs. (H&S § 117690 (b)(3)(A)-(B))

5) Requires, under the California Hazardous Waste Control Act (HWCA) of 1972, DTSC to regulate the appropriate handling, processing and disposal of hazardous and extremely hazardous waste to protect the public, livestock, and wildlife from hazards to health and safety. (H&S § 25100)

6) Defines hazardous waste as a waste that may cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; pose a substantial present or potential hazard to human health or the environment, due to factors including, but not limited to, carcinogenicity, acute toxicity, chronic toxicity, bioaccumulative properties, or persistence in the environment, when improperly treated, stored, transported, or disposed of, or otherwise managed. (H&S § 25141) Hazardous waste includes hazardous waste covered under RCRA. (H&S § 25117)

7) Defines reverse distributor as every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or non-saleable dangerous drugs. (Business & Professions Code (BP) § 4040.5)

8) Authorizes the establishment of a voluntary drug repository and distribution program for the purpose of distributing surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. (BP § 150200)

FISCAL EFFECT: Unknown. The Senate Appropriations Committee analyzed a previous version of the bill.

COMMENTS:

Need for the bill: According to the author, SB 423 is intended to build on recent California legislation that has helped to streamline the safe and efficient handling of pharmaceuticals, other health care products, and household consumer products sold by retailers in this state. The author states that when these products are not sold at an initial point of sale for various reasons, the products are often processed at a reverse distribution center where the center performs various activities such as consolidation, repackaging, donation, disposal upon completion of any of these management activities. The author further states that jurisdiction over these products at the point they are considered discarded or recycled under current law, including when they are considered stored or accumulated for discard or recycling, can fall under either the MWMA or hazardous and solid waste provisions of the Health and Safety Code. The author asserts that this dual jurisdiction has led to confusion in the regulated community and threatens to undermine positive aspects of the reverse distribution system for managing pharmaceuticals, including over-the-counter pharmaceuticals in California. The author believes that SB 423 would provide clear waste management options for over the counter pharmaceutical products by explicitly allowing these products to be scrutinized under existing hazardous waste laws when disposed rather than only the MWMA.

The author also states that multiple stakeholder discussions have taken place on the issues of retail waste, including over-the-counter pharmaceutical waste in California. DTSC created a Retail Waste Workgroup a few years ago to identify the regulatory requirements that are in need of clarification for retailers. SB 423 provides goals for the Retail Waste Workgroup to work towards developing consensus policy recommendations on these outstanding waste management

issues in CA. This will ensure both the regulators and the regulated community have a defined timeline by which agreement on these issues is to be attained.

Regulating pharmaceuticals: The MWMA vests the California Department of Public Health (CDPH) with authority to regulate the generation, handling, storage, treatment, and disposal of medical waste.

Pharmaceutical wastes were added to the MWMA in 1996 (SB 1996, Wright, Chapter 536). That legislation moved the regulation of pharmaceutical waste as hazardous waste by DTSC to the Department of Healthcare Services (now the Department of Public Health) because pharmaceutical waste was not considered hazardous waste under federal law or as medical waste under the MWMA. SB 1996 did not, however, include under the definition of "pharmaceutical wastes" any pharmaceutical wastes regulated as solid waste pursuant to the California Integrated Waste Management Act.

AB 1442 (Wieckowski, Chapter 689, Statutes of 2012) excluded pharmaceuticals being sent to reverse distributors from the storage, disposal, and transport requirements of the MWMA. It also relaxed hauling requirements for pharmaceutical medical waste that is not reverse-distributed if the generator meets certain conditions. As a result, any non-saleable pharmaceutical that is returned to a licensed reverse distributor (and that is not hazardous under RCRA or radioactive under the federal Radiation Control Law) is not considered pharmaceutical or medical waste, and is therefore not regulated by the MWMA. This has the effect of allowing most non-saleable pharmaceuticals to be transferred to reverse distributors without fear of violating the strict disposal and transportation requirements for medical waste.

Regulatory confusion: Despite AB 1442, much regulatory confusion remains. DTSC has authority over hazardous materials and hazardous wastes. CDPH has authority over cosmetics, pharmaceuticals and medical waste. The Department of Resources Recycling and Recovery has authority over solid wastes and universal wastes.

According to federal and state law, a pharmaceutical is anything that contains a “drug fact” label. A drug fact label is affixed to any product that makes a health claim. These products must meet specified federal Food and Drug Administration ingredient testing, disclosure, labeling and verification of health claim requirements. This includes prescription and over-the-counter drugs as well as some consumer products that make health claims.

Retail establishments argue that the various statutory and regulatory requirements of when a product becomes a waste and how it must be handled make it difficult for their employees to determine the appropriate handling of a product. Retailers argue that because of the complexity of the current regulatory scheme, they are currently not separating products that may be able to be donated or liquidated from those that are deemed waste if there is any question that they may be risking violation of various statutory waste handling requirements. The retailers assert that the result is a far greater than necessary rate of disposal or destruction of items that could have been retained for their useful life.

Retail Waste Workgroup: Retailers that operate stores in California and those that sell goods in California through the Internet, mail-order catalogs, door-to-door sales and other outlets are all subject to California's medical waste and/or hazardous waste laws and regulations.

In an effort to clarify California's hazardous waste regulatory requirements, DTSC is gathering information and developing an understanding of hazardous waste management practices at various types of retailers.

In 2015, DTSC created a Retail Waste Workgroup to identify regulatory requirements that need clarification and to provide that clarification. The Retail Waste Workgroup consists of large and small retailers, District Attorneys from multiple counties, Certified Unified Program Agency representatives, consultants, non-government organizations, California Department of Public Health and DTSC. The most recent meeting was June 2, 2016.

The Retail Waste Workgroup is an ongoing process working through the issues for which SB 423 is raising. SB 423 is proposing to turn the fruits of those discussions into policy recommendations for broader consumer product management by codifying the Retail Waste Working Group and establishing a date-certain for consensus policy recommendations to be made to the Legislature.

The bill proposes a slightly different scope of work than the Retail Waste Workgroup is currently working on, which may narrow the goal to identify and clarify policy and regulatory requirements for products that are eventually considered hazardous wastes.

The Committee may wish to consider amending the provision of the bill codifying the Retail Waste Workgroup to clarify the intent and the goals.

Federal action to eliminate retail confusion: The US EPA has indicated that the issue of regulating the management of surplus consumer products is larger than pharmaceuticals; it has acknowledged the challenges regarding the regulation of retail hazardous waste, has provided data on retail hazardous waste generation, and has invited public comment on issues specific to retail hazardous waste.

Using 2007 census data, the US EPA identified 13 retail sectors (including vehicle service stations, electronics and appliance stores, food and beverage stores) comprising 1.6 million facilities that generate hazardous waste. Only about 41,000 (4.6%) of this total are registered as hazardous waste generators in the RCRAInfo database, which is a federal program management and inventory system about hazardous waste handlers.

It is likely that some retailers do not view themselves as hazardous waste generators who may be subject to regulation. For example, retailers may not be aware that products returned to them by the purchaser may be RCRA hazardous waste. The US EPA acknowledged the uncertainty faced by retailers in managing the wide range of retail products that may become wastes if unsold, returned, or removed from shelves for inventory changes.

Regulation of hazardous waste, including medical wastes, generated by the retail sector presents unique challenges. The retail sector handles a large number of diverse products (for example, one retailer has reported to the US EPA about a million products and 4,000 facilities nationwide), many of which may potentially become regulated as medical or hazardous waste when discarded. Thus, retailers are required to make numerous medical and hazardous waste determinations at thousands of sites, generally by store employees with limited experience with the RCRA, HWCA, or MWMA regulations.

SB 423 is proposing to ease the regulatory requirements of pharmaceuticals under the MWMA with a blanket exemption, and ease the waste determination made by retailers by offering the option of managing wastes as solid waste if the waste is not hazardous.

SB 423 does not, however, address the outstanding confusion retailers have over when a product (in this case, a pharmaceutical) is a hazardous waste.

Under the MWMA, non-RCRA pharmaceuticals are exempt. In theory, that would mean if a product is exempt from the MWMA, as it would be under SB 423, it would be treated as solid waste since it's not covered under RCRA. But, California's HWCA does not perfectly align with RCRA, and, in many cases, is more stringent. There are, in fact, many nonprescription pharmaceuticals that would have to be treated as hazardous waste. Anything that might fail DTSC's regulatory aquatic toxicity test would be a hazardous waste. Medicated shampoos, pain killers, and vitamin supplements are some examples. It is easy to understand the existing confusion over pharmaceutical product management.

What is a nonprescription pharmaceutical? The bill doesn't define a pharmaceutical that is sold without a prescription, but it includes a broad range of products, from vitamins and supplements, pain killers, allergy and antihistamine drugs, laxatives, spermicides, anti-inflammatory drugs, cough and cold medications, steroids, anti-fungal drugs, as well as products that include anything with a chemical or pharmaceutical element, such as, but not limited to, toothpaste, medicated shampoos (dandruff, lice shampoos), mouthwash, Sun Protection Factor (SPF)-containing lotions and chap sticks, cosmetics, and any other over-the-counter drugs.

What does this bill do, exactly? SB 423 exempts all nonprescription pharmaceuticals from the MWMA and gives retailers the option of managing these pharmaceuticals, once the waste determination has been made, as either a solid waste or a medical waste, unless the pharmaceutical is hazardous waste.

This is problematic because the MWMA exists for a clear and specific reason: to manage medical waste, which includes pharmaceutical waste, in carefully specified ways to protect public health and the environment. Under the MWMA, pharmaceutical waste has to be incinerated at a permitted medical waste treatment facility; treated temperatures in excess of 1300 degrees Fahrenheit; or steam sterilized at a permitted medical waste treatment facility. (H&S § 118215)

Exempting pharmaceuticals from the MWMA would eliminate important protections we have in place to prevent pharmaceutical contamination and threats to the environment.

Contaminants of emerging concern: Our water supplies are increasingly contaminated with chemicals of concerns. Numerous contaminants, such as pharmaceuticals, personal care products (antibacterial soaps, sunscreen, bath gels, etc.), and other constituents of emerging concern, are more likely to be present in municipal wastewater than in other water sources. Although they typically exist in small concentrations, there is growing concern about the impact of constituents of emerging concern, and other unregulated compounds, on public health and the environment. By allowing OTC pharmaceuticals to be treated as solid waste, this bill would be creating a greater risk of pharmaceutical contamination in our water supplies, thus exacerbating the conundrum of contaminants of emerging concern.

Committee amendments: Given the policy concerns around the changes to the MWMA the bill is proposing, the Committee may wish to consider the following amendments:

1. Strike Sections 1, 2 and 3 from the bill, entirely.

2. Clarify the goals of the Retail Waste Working Group to be more consistent with the current goals of the Working Group and the US EPA's efforts to clarify policy requirements for managing consumer products that are considered hazardous waste at the time of disposal. This amendments would be drafted as follows:

(a) The Department of Toxic Substances Control shall convene a Retail Waste Working Group comprised of representatives of large retailers, small retailers, district attorneys, certified unified program agencies, nongovernment organizations, ~~State Department of Public Health, manufacturers,~~ *other relevant state agencies as determined by DTSC*, reverse distributors, and other stakeholders ~~to do both of the following~~ *to consider and make recommendations on the following*:

(1) ~~Identify~~ Regulatory and policy ~~directives~~ *requirements* that *may be considered confusing, and/or may* need clarification or specification when applied to *the overall management of* consumer products *that are wastes, including those that are considered hazardous when the waste determination is made.*

(2) Adopt consensus *policy and/or regulatory* recommendations to facilitate and increase ~~sustainable practices and~~ waste reduction opportunities for consumer products *and clarify hazardous waste management in the retail industry* to encourage safe and efficient options for managing ~~the flow of~~ *waste and* surplus household consumer products ~~through the reverse supply chain~~.

(b) By ~~March 1, 2017~~ *June 1, 2017*, the Retail Waste Working Group shall ~~identify a list of issues for discussion and resolution and, thereafter, shall meet regularly to assist and advise the Legislature, and shall~~ report the consensus recommendations to the Legislature ~~by June 1, 2017~~.

REGISTERED SUPPORT / OPPOSITION:

Support

American Cleaning Institute
California Chamber of Commerce
California Manufacturers and Technology Association
California Retailers Association
Consumer Specialty Products Association
Industrial Environmental Association
National Federation of Independent Businesses

Opposition

None on file

Analysis Prepared by: Paige Brokaw / E.S. & T.M. / (916) 319-3965