AMENDED IN SENATE JULY 6, 2015

AMENDED IN SENATE JUNE 3, 2015

SENATE BILL No. 423

Introduced by Senator Bates

February 25, 2015

An act to ~~amend Section 117690 of~~ *add and repeal Article 11.2 (commencing with Section 25230) of Chapter 6.5 of Division 20 of* the Health and Safety Code, relating to ~~medical~~ *hazardous* waste, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

SB 423, as amended, Bates. ~~Pharmaceutical waste: over-the-counter drugs and nutritional supplements.~~ *Retail nonprescription surplus products: determinations for reuse.*

Existing law, the Medical Waste Management Act, administered by the State Department of Public Health, regulates the management, handling, and disposal of medical waste, as defined, including pharmaceutical waste. ~~For purposes of that act, "pharmaceutical waste" is defined as a prescription or over-the counter human or veterinary drug, as specified, that is waste, as defined, but excludes from that definition certain pharmaceuticals being sent out of state to a reverse distributor, or being sent by a reverse distributor offsite for treatment and disposal, as prescribed.~~ *Existing law also provides for the disposition of hazardous waste. A violation of these provisions is a crime.*

~~This bill would additionally exclude from the definition of "pharmaceutical waste," for purposes of regulation under the act, any over-the-counter human or veterinary drug or dietary supplement that is, among other things, characterized and managed as a hazardous or~~

~~solid waste and, with respect to an over-the-counter human or veterinary drug, is not disposed of on land within the state.~~

This bill, until January 1, 2022, would establish criteria to be followed for the handling and management of retail nonprescription pharmaceutical surplus products, as defined, if a reasonable determination for reuse has been made or when a reasonable determination for reuse cannot be made but the product has been recalled as required by law. The bill would authorize the State Department of Public Health to adopt regulations as deemed necessary to establish standards for the proper and safe handling of retail nonprescription pharmaceutical surplus products.

Because a violation of these provisions would be a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: ⅔. Appropriation: no. Fiscal committee: yes. State-mandated local program: ~~no~~ *yes*.

The people of the State of California do enact as follows:

SECTION 1. Article 11.2 (commencing with Section 25230) is added to Chapter 6.5 of Division 20 of the Health and Safety Code, to read:

Article 11.2. Nonprescription Pharmaceutical Surplus Products

25230. (a) The Legislature finds and declares that this section is intended to address the unique circumstances associated with the management of retail nonprescription pharmaceutical surplus products that potentially can be safely diverted from the waste stream for reuse, if appropriate. The Legislature further declares that this section shall not be construed to set a precedent applicable to the management, including disposal, of other hazardous or medical wastes.

(b) For purposes of this section, the following definitions shall apply:

(1) "Retail nonprescription pharmaceutical surplus product" means a pharmaceutical, as that term is defined in Section 117747, that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government, defined as a nonprescription drug in Article 2 (commencing with Section 4015) of Chapter 9 of Division 2 of the Business and Professions Code, in which a waste generator has made a reasonable determination for reuse. A retail nonprescription pharmaceutical surplus product does not include waste that is subject to regulation as a hazardous waste under the federal Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. Sec. 6901 et seq.).

(2) "Reasonable determination for reuse" means, upon removal of a retail nonprescription pharmaceutical surplus product from sale, a generator who has evaluated the product and makes a finding that the product meets all of the following criteria:

(A) The product is in unadulterated packaging.

(B) The product and packaging are in a condition that is suitable for resale.

(C) The product is not designated for disposal by the manufacturer or the manufacturer's agent.

(D) The product is otherwise eligible for liquidation or donation.

(3) "Reverse distributor" or "reverse distribution center" has the same meaning as set forth in Section 4040.5 of the Business and Professions Code that satisfies all of the following:

(A) Is licensed as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4160 of the Business and Professions Code.

(B) Is permitted by the department as a transfer station, if the reverse distributor is located within the State of California.

(C) Is registered with the Department of Toxic Substances Control and any other appropriate state and local agencies as a hazardous waste generator, transfer facility, or storage facility.

(D) Complies with handling, storage, training, emergency response, and recordkeeping requirements, and any other applicable requirements.

(c) Notwithstanding Sections 25189.5, 25201, and 117747, if a reasonable determination for reuse has been made, a retail

nonprescription pharmaceutical surplus product may be handled in accordance with all of the following:

(1) The retail nonprescription pharmaceutical surplus product shall be transported to a reverse distributor or reverse distribution center for any of the following purposes:

(A) Evaluating the manufacturer's or supplier's credit or other financial reconciliation.

(B) Liquidation.

(C) Donation.

(D) Transferring back to a manufacturer, distributor, or supplier, or its respective agent.

(2) The retail nonprescription pharmaceutical surplus product shall be transported with a tracking document that identifies all of the following information:

(A) The product, the UPC label, and the lot number.

(B) Name, address, and telephone number of the generator of the waste.

(C) Name, address, and telephone number of the reverse distributor or reverse distribution center receiving the shipment.

(D) The purpose for which the retail nonprescription pharmaceutical surplus product is being shipped to the reverse distributor or reverse distribution center.

(3) Shipments of retail nonprescription pharmaceutical surplus products to a reverse distributor or a reverse distribution center shall be made via a transporter registered with the United States Department of Transportation Federal Motor Carrier Safety Administration. Transporters shall use due diligence to ensure safe handling, which includes, but is not limited to, ensuring that the packaging does not become damaged or adulterated during shipment and that the shipment is handled in appropriate moisture and temperature conditions.

(4) The reverse distributor or reverse distribution center shall do all of the following:

(A) Maintain the specified tracking documents for a period of three years following receipt date of a shipment and shall make those documents available for inspection by any applicable enforcement agencies.

(B) Submit a hazardous materials business plan to the appropriate state and local agencies, as required by Article 1 (commencing with Section 25500) of Chapter 6.95 and any

regulations promulgated by either the department or any certified unified program agency.

(d) A retail nonprescription pharmaceutical surplus product that has been transported to a reverse distributor or reverse distribution center for any of the purposes listed in paragraph (1) of subdivision (c) shall not be stored or held at the reverse distributor or reverse distribution center for more than 364 calendar days. A retail nonprescription pharmaceutical surplus product held or stored for 365 or more days shall immediately be considered waste and, if hazardous, managed in accordance with applicable federal and state hazardous waste management laws and regulations.

(e) Notwithstanding Sections 25189.5, 25201, and 117747, the provisions of subdivision (c) may be used for a retail nonprescription pharmaceutical surplus product for which a reasonable determination for reuse cannot be made if the product has been recalled as required by law, including safety recalls for secure destruction.

(f) The department may adopt regulations as deemed necessary to establish standards for the proper and safe handling of retail nonprescription pharmaceutical surplus products.

(g) This article shall remain in effect only until January 1, 2022, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2022, deletes or extends that date.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SEC. 3. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to make statutory changes needed to address the unique circumstances associated with the management, handling, and reasonable determination of reuse or retail nonprescription

pharmaceutical surplus products as soon as possible, it is necessary that this act take effect immediately.

~~SECTION 1. Section 117690 of the Health and Safety Code is amended to read:~~

~~117690. (a) "Medical waste" means any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the federal Resource Conservation and Recovery Act of 1976 (Public Law 94-580), as amended; sharps and trace chemotherapy wastes generated in a health care setting in the diagnosis, treatment, immunization, or care of humans or animals; waste generated in autopsy or necropsy; waste generated during preparation of a body for final disposition such as cremation or interment; waste generated in research pertaining to the production or testing of microbiologicals; waste generated in research using human or animal pathogens; sharps and laboratory waste that poses a potential risk of infection to humans generated in the inoculation of animals in commercial farming operations; waste generated from the consolidation of home-generated sharps; and waste generated in the cleanup of trauma scenes. Biohazardous, pathology, pharmaceutical, sharps, and trace chemotherapy wastes that meet the conditions of this section are not subject to any of the hazardous waste requirements found in Chapter 6.5 (commencing with Section 25100) of Division 20.~~

~~(b) For purposes of this part the following definitions apply:~~

~~(1) "Biohazardous waste" includes all of the following:~~

~~(A) (i) Regulated medical waste, clinical waste, or biomedical waste that is a waste or reusable material derived from the medical treatment of a human or from an animal that is suspected by the attending veterinarian of being infected with a pathogen that is also infectious to humans, which includes diagnosis and immunization; or from biomedical research, which includes the production and testing of biological products.~~

~~(ii) Regulated medical waste or clinical waste or biomedical waste suspected of containing a highly communicable disease.~~

~~(B) Laboratory waste such as human specimen cultures or animal specimen cultures that are infected with pathogens that are also infectious to humans; cultures and stocks of infectious agents from research; wastes from the production of bacteria, viruses, spores, discarded live and attenuated vaccines used in human health care or research, discarded animal vaccines, including Brucellosis~~

~~and Contagious Ecthyma, as defined by the department; culture dishes, devices used to transfer, inoculate, and mix cultures; and wastes identified by Section 173.134 of Title 49 of the Code of Federal Regulations as Category B "once wasted" for laboratory wastes.~~

~~(C) Waste that, at the point of transport from the generator's site or at the point of disposal contains recognizable fluid human blood, fluid human blood products, containers, or equipment containing human blood that is fluid, or blood from animals suspected by the attending veterinarian of being contaminated with infectious agents known to be contagious to humans.~~

~~(D) Waste containing discarded materials contaminated with excretion, exudate, or secretions from humans or animals that are required to be isolated by the infection control staff, the attending physician and surgeon, the attending veterinarian, or the local health officer, to protect others from highly communicable diseases or diseases of animals that are communicable to humans.~~

~~(2) Pathology waste includes both of the following:~~

~~(A) Human body parts, with the exception of teeth, removed at surgery and surgery specimens or tissues removed at surgery or autopsy that are suspected by the health care professional of being contaminated with infectious agents known to be contagious to humans or having been fixed in formaldehyde or another fixative.~~

~~(B) Animal parts, tissues, fluids, or carcasses suspected by the attending veterinarian of being contaminated with infectious agents known to be contagious to humans.~~

~~(3) "Pharmaceutical waste" means a pharmaceutical, as defined in Section 117747, including trace chemotherapy waste, that is a waste, as defined in Section 25124. For purposes of this part, "pharmaceutical waste" does not include a pharmaceutical that meets any of the following criteria:~~

~~(A) The pharmaceutical is being sent out of the state to a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, that is licensed as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4161 of the Business and Professions Code.~~

~~(B) The pharmaceutical is being sent by a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, offsite for treatment and disposal in accordance with applicable laws, or to a reverse distributor that is licensed as a wholesaler of~~

~~dangerous drugs by the California State Board of Pharmacy pursuant to Section 4160 of the Business and Professions Code and as a permitted transfer station if the reverse distributor is located within the state.~~

~~(C) The pharmaceutical is an over-the-counter human or veterinary drug or dietary supplement that meets all of the following requirements:~~

~~(i) Is offered for sale without a prescription.~~

~~(ii) Is labeled with information entitled "Drug Facts" or "Supplement Facts," in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, as amended, (21 U.S.C.A. Sec. 321 et seq.).~~

~~(iii) Is characterized and managed as either a hazardous waste pursuant to Chapter 6.5 (commencing with Section 25100) of Division 20, or a solid waste pursuant to Division 30 (commencing with Section 40000) of the Public Resources Code.~~

~~(iv) With respect to an over-the-counter human or veterinary drug, is not disposed of on land within the state.~~

~~(4) "Sharps waste" means a device that has acute rigid corners, edges, or protuberances capable of cutting or piercing, including, but not limited to, hypodermic needles, hypodermic needles with syringes, blades, needles with attached tubing, acupuncture needles, root canal files, broken glass items used in health care such as Pasteur pipettes and blood vials contaminated with biohazardous waste, and any item capable of cutting or piercing from trauma scene waste.~~

~~(5) "Trace chemotherapeutic waste" means waste that is contaminated through contact with, or having previously contained, chemotherapeutic agents, including, but not limited to, gloves, disposable gowns, towels, and intravenous solution bags and attached tubing that are empty. A biohazardous waste that meets the conditions of this paragraph is not subject to the hazardous waste requirements of Chapter 6.5 (commencing with Section 25100) of Division 20.~~

~~(6) "Trauma scene waste" means waste that is a regulated waste, as defined in Section 5193 of Title 8 of the California Code of Regulations, and that has been removed, is to be removed, or is in the process of being removed, from a trauma scene by a trauma scene waste management practitioner.~~

~~SEC. 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:~~

~~In order to make statutory changes needed to exempt over-the-counter human or veterinary drugs or dietary supplements from laws regulating the management, handling, and disposal of medical waste, as soon as possible, it is necessary that this act take effect immediately.~~

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