AMENDED IN ASSEMBLY JUNE 21, 2016

AMENDED IN SENATE AUGUST 31, 2015

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 ~~add and repeal Article 11.2 (commencing with Section 25230) of Chapter 6.5 of Division 20 of~~ *amend, repeal, and add Section 118215 of, and to add and repeal Section 118216 of,* the Health and Safety Code, relating to hazardous ~~waste, and declaring the urgency thereof, to take effect immediately.~~ *waste.*

LEGISLATIVE COUNSEL'S DIGEST

SB 423, as amended, Bates. ~~Retail nonprescription surplus products: determinations for reuse.~~ *Pharmaceutical and consumer product waste: management.*

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. *Existing law requires a person generating or treating medical waste to ensure that the medical waste is treated by a specified method, thereby rendering it a solid waste, before disposal, except in prescribed circumstances.* Existing law also provides for *regulation of* the disposition of hazardous waste by the Department of Toxic Substances Control. A violation of these provisions is a crime.

~~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.~~

This bill, until January 1, 2022, would require a pharmaceutical that is offered for sale without a prescription, upon discard, to be managed in accordance the hazardous waste provisions if the pharmaceutical is a hazardous waste, or, if the pharmaceutical is not a hazardous waste, in accordance with the above-described medical waste provisions or specified solid waste provisions.

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

This bill would require the Department of Toxic Substances Control to convene a Retail Waste Working Group, as prescribed, to identify regulatory and policy directives that need clarification or specification when applied to consumer products and to adopt consensus recommendations to facilitate and increase sustainable practices and waste reduction opportunities for consumer products and to encourage safe and efficient options for managing the flow of surplus household consumer products through the reverse supply chain. The bill would require the working group to identify a list of issues for discussion and resolution by March 1, 2017, and to report consensus recommendations to the Legislature by June 1, 2017.

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: ~~2/3~~ *majority*. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

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

SECTION 1. Section 118215 of the Health and Safety Code is amended to read:

118215. (a) Except as provided in subdivisions (b) and ~~(c),~~ *(c) and Section 118216,* a person generating or treating medical waste shall ensure that the medical waste is treated by one of the following methods, thereby rendering it solid waste, as defined in Section 40191 of the Public Resources Code, ~~prior to~~ *before* disposal:

(1) (A) Incineration at a permitted medical waste treatment facility in a controlled-air, multichamber incinerator, or other method of incineration approved by the department ~~which~~ *that* provides complete combustion of the waste into carbonized or mineralized ash.

(B) Treatment with an alternative technology approved pursuant to paragraph (3), which, due to the extremely high temperatures of treatment in excess of ~~1300~~ *1,300* degrees Fahrenheit, has received express approval from the department.

(2) Steam sterilization at a permitted medical waste treatment facility or by other sterilization, in accordance with all of the following operating procedures for steam sterilizers or other sterilization:

(A) Standard written operating procedures shall be established for biological indicators, or for other indicators of adequate sterilization approved by the department, for each steam sterilizer, including time, temperature, pressure, type of waste, type of container, closure on container, pattern of loading, water content, and maximum load quantity.

(B) Recording or indicating thermometers shall be checked during each complete cycle to ensure the attainment of ~~121° Centigrade (250°~~ *121 degrees centigrade (250 degrees* Fahrenheit) for at least one-half hour, depending on the quantity and density of the load, to achieve sterilization of the entire load. Thermometers, thermocouples, or other monitoring devices identified in the facility operating plan shall be checked for calibration annually. Records of the calibration checks shall be maintained as part of the facility's files and records for a period of two years or for the period specified in the regulations.

(C) Heat-sensitive tape, or another method acceptable to the enforcement agency, shall be used on each biohazard bag or sharps container that is processed onsite to indicate that the waste went through heat treatment. If the biohazard bags or sharps containers are placed in a large liner bag within the autoclave for treatment,

heat-sensitive tape or another method acceptable to the enforcement agency only needs to be placed on the liner bag and not on every hazardous waste bag or sharps container being treated.

(D) The biological indicator Geobacillus stearothermophilus, or other indicator of adequate sterilization as approved by the department, shall be placed at the center of a load processed under standard operating conditions at least monthly to confirm the attainment of adequate sterilization conditions.

(E) Records of the procedures specified in subparagraphs (A), (B), and (D) shall be maintained for a period of not less than two years.

(3) (A) Other alternative medical waste treatment methods ~~which~~ *that* are both of the following:

(i) Approved by the department.

(ii) Result in the destruction of pathogenic ~~micro-organisms.~~ *microorganisms*.

(B) Any alternative medical waste treatment method proposed to the department shall be evaluated by the department and either approved or rejected pursuant to the criteria specified in this subdivision.

(b) Fluid blood or fluid blood products may be discharged to a public sewage system without treatment if its discharge is consistent with waste discharge requirements placed on the public sewage system by the California regional water quality control board with jurisdiction.

(c) (1) A medical waste that is a biohazardous laboratory waste, as defined in subparagraph (B) of paragraph (1) of subdivision (b) of Section 117690, may be treated by a chemical disinfection if the waste is liquid or semiliquid and the chemical disinfection method is recognized by the National Institutes of Health, the Centers for Disease Control and Prevention, or the American Biological Safety Association, and if the use of chemical disinfection as a treatment method is identified in the site's medical waste management plan.

(2) If the waste is not treated by chemical disinfection, in accordance with paragraph (1), the waste shall be treated by one of the methods specified in subdivision (a).

(3) Following treatment by chemical disinfection, the medical waste may be discharged to the public sewage system if the discharge is consistent with waste discharge requirements placed

on the public sewage system by the California regional water *quality* control board, and the discharge is in compliance with the requirements imposed by the owner or operator of the public sewage system. If the chemical disinfection of the medical waste causes the waste to become a hazardous waste, the waste shall be managed in accordance with the requirements of Chapter 6.5 (commencing with Section 25100) of Division 20.

(d) This section 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. Section 118215 is added to the Health and Safety Code, to read:

118215. (a) Except as provided in subdivisions (b) and (c), a person generating or treating medical waste shall ensure that the medical waste is treated by one of the following methods, thereby rendering it solid waste, as defined in Section 40191 of the Public Resources Code, before disposal:

(1) (A) Incineration at a permitted medical waste treatment facility in a controlled-air, multichamber incinerator, or other method of incineration approved by the department that provides complete combustion of the waste into carbonized or mineralized ash.

(B) Treatment with an alternative technology approved pursuant to paragraph (3), which, due to the extremely high temperatures of treatment in excess of 1,300 degrees Fahrenheit, has received express approval from the department.

(2) Steam sterilization at a permitted medical waste treatment facility or by other sterilization, in accordance with all of the following operating procedures for steam sterilizers or other sterilization:

(A) Standard written operating procedures shall be established for biological indicators, or for other indicators of adequate sterilization approved by the department, for each steam sterilizer, including time, temperature, pressure, type of waste, type of container, closure on container, pattern of loading, water content, and maximum load quantity.

(B) Recording or indicating thermometers shall be checked during each complete cycle to ensure the attainment of 121 degrees centigrade (250 degrees Fahrenheit) for at least one-half hour, depending on the quantity and density of the load, to achieve

sterilization of the entire load. Thermometers, thermocouples, or other monitoring devices identified in the facility operating plan shall be checked for calibration annually. Records of the calibration checks shall be maintained as part of the facility's files and records for a period of two years or for the period specified in the regulations.

(C) Heat-sensitive tape, or another method acceptable to the enforcement agency, shall be used on each biohazard bag or sharps container that is processed onsite to indicate that the waste went through heat treatment. If the biohazard bags or sharps containers are placed in a large liner bag within the autoclave for treatment, heat-sensitive tape or another method acceptable to the enforcement agency only needs to be placed on the liner bag and not on every hazardous waste bag or sharps container being treated.

(D) The biological indicator Geobacillus stearothermophilus, or other indicator of adequate sterilization as approved by the department, shall be placed at the center of a load processed under standard operating conditions at least monthly to confirm the attainment of adequate sterilization conditions.

(E) Records of the procedures specified in subparagraphs (A), (B), and (D) shall be maintained for a period of not less than two years.

(3) (A) Other alternative medical waste treatment methods that are both of the following:

(i) Approved by the department.

(ii) Result in the destruction of pathogenic microorganisms.

(B) Any alternative medical waste treatment method proposed to the department shall be evaluated by the department and either approved or rejected pursuant to the criteria specified in this subdivision.

(b) Fluid blood or fluid blood products may be discharged to a public sewage system without treatment if its discharge is consistent with waste discharge requirements placed on the public sewage system by the California regional water quality control board with jurisdiction.

(c) (1) A medical waste that is a biohazardous laboratory waste, as defined in subparagraph (B) of paragraph (1) of subdivision (b) of Section 117690, may be treated by a chemical disinfection if the waste is liquid or semiliquid and the chemical disinfection

method is recognized by the National Institutes of Health, the Centers for Disease Control and Prevention, or the American Biological Safety Association, and if the use of chemical disinfection as a treatment method is identified in the site's medical waste management plan.

(2) If the waste is not treated by chemical disinfection, in accordance with paragraph (1), the waste shall be treated by one of the methods specified in subdivision (a).

(3) Following treatment by chemical disinfection, the medical waste may be discharged to the public sewage system if the discharge is consistent with waste discharge requirements placed on the public sewage system by the California regional water quality control board, and the discharge is in compliance with the requirements imposed by the owner or operator of the public sewage system. If the chemical disinfection of the medical waste causes the waste to become a hazardous waste, the waste shall be managed in accordance with the requirements of Chapter 6.5 (commencing with Section 25100) of Division 20.

(d) This section shall become operative on January 1, 2022.

SEC. 3. Section 118216 is added to the Health and Safety Code, to read:

118216. (a) Notwithstanding Section 117690, a pharmaceutical that is offered for sale without a prescription shall, upon discard, be managed in accordance with Chapter 6.5 (commencing with Section 25100) of Division 20 if it is a hazardous waste as defined in Section 25117 and implementing regulations. If the pharmaceutical is not a hazardous waste, it shall be managed in accordance with one of the following:

(1) Section 118215.

(2) Provisions relating to solid waste pursuant to Division 30 (commencing with Section 40000) of the Public Resources Code.

(b) This section 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. 4. (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, the State Department of Public Health, manufacturers, reverse distributors, and other stakeholders to do both of the following:

(1) Identify regulatory and policy directives that need clarification or specification when applied to consumer products.

(2) Adopt consensus recommendations to facilitate and increase sustainable practices and waste reduction opportunities for consumer products and to encourage safe and efficient options for managing the flow of surplus household consumer products through the reverse supply chain.

(b) By March 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.

SEC. 5. 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.

~~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 State Department of Public Health 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 of Toxic Substances Control 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 State Department of Public Health may adopt regulations as deemed necessary to establish standards for the proper and safe handling of retail nonprescription pharmaceutical surplus products.~~

~~(g) A facility that elects to manage its retail nonprescription pharmaceutical surplus products pursuant to this article is not subject to regulation of those products under either the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104) or any other provision of this chapter.~~

~~(h) 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.~~

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