

AMENDED IN SENATE AUGUST 31, 2015

AMENDED IN SENATE JULY 6, 2015

AMENDED IN SENATE JUNE 3, 2015

**SENATE BILL**

**No. 423**

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**Introduced by Senator Bates**

February 25, 2015

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An act to 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 hazardous waste, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

SB 423, as amended, Bates. 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. Existing law also provides for the disposition of hazardous ~~waste~~. *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.

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:  $\frac{2}{3}$ . Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

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

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

4  
 5 Article 11.2. Nonprescription Pharmaceutical Surplus Products  
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7 25230. (a) The Legislature finds and declares that this section  
 8 is intended to address the unique circumstances associated with  
 9 the management of retail nonprescription pharmaceutical surplus  
 10 products that potentially can be safely diverted from the waste  
 11 stream for reuse, if appropriate. The Legislature further declares  
 12 that this section shall not be construed to set a precedent applicable  
 13 to the management, including disposal, of other hazardous or  
 14 medical wastes.

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

17 (1) “Retail nonprescription pharmaceutical surplus product”  
 18 means a pharmaceutical, as that term is defined in Section 117747,  
 19 that may be sold without a prescription and that is labeled for use  
 20 by the consumer in accordance with the requirements of the laws  
 21 and rules of this state and the federal government, defined as a  
 22 nonprescription drug in Article 2 (commencing with Section 4015)  
 23 of Chapter 9 of Division 2 of the Business and Professions Code,  
 24 in which a waste generator has made a reasonable determination

1 for reuse. A retail nonprescription pharmaceutical surplus product  
2 does not include waste that is subject to regulation as a hazardous  
3 waste under the federal Resource Conservation and Recovery Act  
4 of 1976, as amended (42 U.S.C. Sec. 6901 et seq.).

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

9 (A) The product is in unadulterated packaging.

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

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

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

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

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

21 (B) Is permitted by the ~~department~~ *State Department of Public*  
22 *Health* as a transfer station, if the reverse distributor is located  
23 within the State of California.

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

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

30 (c) Notwithstanding Sections 25189.5, 25201, and 117747, if  
31 a reasonable determination for reuse has been made, a retail  
32 nonprescription pharmaceutical surplus product may be handled  
33 in accordance with all of the following:

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

37 (A) Evaluating the manufacturer’s or supplier’s credit or other  
38 financial reconciliation.

39 (B) Liquidation.

40 (C) Donation.

- 1 (D) Transferring back to a manufacturer, distributor, or supplier,  
2 or its respective agent.
- 3 (2) The retail nonprescription pharmaceutical surplus product  
4 shall be transported with a tracking document that identifies all of  
5 the following information:
  - 6 (A) The product, the UPC label, and the lot number.
  - 7 (B) Name, address, and telephone number of the generator of  
8 the waste.
  - 9 (C) Name, address, and telephone number of the reverse  
10 distributor or reverse distribution center receiving the shipment.
  - 11 (D) The purpose for which the retail nonprescription  
12 pharmaceutical surplus product is being shipped to the reverse  
13 distributor or reverse distribution center.
- 14 (3) Shipments of retail nonprescription pharmaceutical surplus  
15 products to a reverse distributor or a reverse distribution center  
16 shall be made via a transporter registered with the United States  
17 Department of Transportation Federal Motor Carrier Safety  
18 Administration. Transporters shall use due diligence to ensure safe  
19 handling, which includes, but is not limited to, ensuring that the  
20 packaging does not become damaged or adulterated during  
21 shipment and that the shipment is handled in appropriate moisture  
22 and temperature conditions.
- 23 (4) The reverse distributor or reverse distribution center shall  
24 do all of the following:
  - 25 (A) Maintain the specified tracking documents for a period of  
26 three years following receipt date of a shipment and shall make  
27 those documents available for inspection by any applicable  
28 enforcement agencies.
  - 29 (B) Submit a hazardous materials business plan to the  
30 appropriate state and local agencies, as required by Article 1  
31 (commencing with Section 25500) of Chapter 6.95 and any  
32 regulations promulgated by either the ~~department~~ *Department of*  
33 *Toxic Substances Control* or any certified unified program agency.
  - 34 (d) A retail nonprescription pharmaceutical surplus product that  
35 has been transported to a reverse distributor or reverse distribution  
36 center for any of the purposes listed in paragraph (1) of subdivision  
37 (c) shall not be stored or held at the reverse distributor or reverse  
38 distribution center for more than 364 calendar days. A retail  
39 nonprescription pharmaceutical surplus product held or stored for  
40 365 or more days shall immediately be considered waste and, if

1 hazardous, managed in accordance with applicable federal and  
2 state hazardous waste management laws and regulations.

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

9 (f) ~~The department~~ *State Department of Public Health* may  
10 adopt regulations as deemed necessary to establish standards for  
11 the proper and safe handling of retail nonprescription  
12 pharmaceutical surplus products.

13 (g) *A facility that elects to manage its retail nonprescription  
14 pharmaceutical surplus products pursuant to this article is not  
15 subject to regulation of those products under either the Medical  
16 Waste Management Act (Part 14 (commencing with Section  
17 117600) of Division 104) or any other provision of this chapter.*

18 ~~(g)~~

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

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

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

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

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

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