

AMENDED IN ASSEMBLY AUGUST 6, 2014
AMENDED IN ASSEMBLY JUNE 30, 2014
AMENDED IN ASSEMBLY JUNE 18, 2014
AMENDED IN ASSEMBLY JUNE 10, 2014
AMENDED IN SENATE MAY 27, 2014
AMENDED IN SENATE APRIL 21, 2014
AMENDED IN SENATE APRIL 1, 2014

SENATE BILL

No. 1014

Introduced by Senator Jackson
(Principal coauthor: Senator Leno)
(Coauthors: Senators Evans, Hancock, Liu, and Pavley)
(Coauthors: Assembly Members Ammiano, Skinner, and Williams)

February 13, 2014

An act to add ~~Section 4068.1 to the Business and Professions Code, to amend Section 117700 of, and to add Section 117670.1 to, the Health and Safety Code, and to add Article 3.4 (commencing with Section 47120) to Chapter 1 of Part 7 of Division 30 of the Public Resources Sections 4027.5 and 4108 to the Business and Professions Code, relating to pharmaceutical waste.~~

LEGISLATIVE COUNSEL'S DIGEST

SB 1014, as amended, Jackson. Pharmaceutical waste: home generated: collection.

The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy establishments by the California State Board of Pharmacy. Existing law required the Department of Resources

Recycling and Recovery, pursuant to provisions repealed on January 1, 2013, to develop, in consultation with appropriate state, local, and federal agencies, model programs for the collection and proper disposal of drug waste. The Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, including pharmaceutical waste, as defined.

This bill would, upon the enactment of federal regulations, require the California State Board of Pharmacy, in consultation with the Department of Resources Recycling and Recovery and the State Department of Public Health, to adopt regulations to implement California drug takeback programs for the collection and destruction of home-generated pharmaceutical waste, as defined. The bill would provide that the regulations adopted pursuant to these provisions only apply to licensees of the board.

~~(1) The Department of Resources Recycling and Recovery was required, pursuant to provisions repealed on January 1, 2013, to develop, in consultation with appropriate state, local, and federal agencies, model programs for the collection and proper disposal of drug waste.~~

~~This bill would require the department and the California State Board of Pharmacy, on or before January 1, 2016, to jointly develop and adopt regulations to authorize a participant to establish a program to collect and properly dispose of home-generated pharmaceutical waste, based upon the model guidelines developed by the department pursuant to those repealed provisions and to include specified provisions in those regulations. The bill would deem a participant operating a program in accordance with those regulations to be in compliance with all state laws and regulations concerning the handling, management, and disposal of home-generated pharmaceutical waste.~~

~~(2) The Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, including pharmaceutical waste, as defined. Existing law defines the term medical waste and excludes certain types of waste from that definition.~~

~~This bill would define the term “home-generated pharmaceutical waste” for purposes of that act. The bill would exclude, from the definition of medical waste, home-generated pharmaceutical waste that is handled by a collection and disposal program operating in accordance with the regulations specified above.~~

~~(3) The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy establishments by the California State Board of Pharmacy, and makes a knowing violation of that law a misdemeanor.~~

~~The bill would also authorize a pharmacy to accept the return of home-generated pharmaceutical waste from a consumer, consistent with specified federal laws. Because a knowing violation of this provision would be a crime, the bill would impose a state-mandated local program.~~

~~(4) 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.~~

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: *yes-no*.

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

1 SECTION 1. Section 4027.5 is added to the Business and
2 Professions Code, to read:

3 4027.5. “Home-generated pharmaceutical waste” means a
4 prescription or over-the-counter human or veterinary
5 home-generated pharmaceutical drug, as defined in Section 4022
6 or 4025.1, that is a waste generated by a household or households.
7 “Home-generated pharmaceutical waste” shall not include waste
8 generated by a business, corporation, limited partnership, or an
9 entity involved in a wholesale transaction between a distributor
10 and retailer.

11 SEC. 2. Section 4108 is added to the Business and Professions
12 Code, to read:

13 4108. (a) Within 18 months of the enactment of federal
14 regulations regarding the collection of unwanted or expired
15 controlled substances from the public, the board, in consultation
16 with the Department of Resources Recycling and Recovery and
17 the State Department of Public Health, shall adopt regulations to
18 implement California drug takeback programs for the collection
19 and destruction of home-generated pharmaceutical waste.

20 (b) The regulations promulgated pursuant to this section shall
21 require a participant in a program to take all of the following
22 actions:

1 (1) Provide, at no additional cost to the consumer, for the safe
2 take back and proper disposal of home-generated pharmaceutical
3 waste.

4 (2) Ensure the protection of the public health and safety, the
5 environment, and the health and safety of consumers and
6 employees.

7 (3) Report annually to the board and the State Department of
8 Public Health for purposes of evaluating the safety, efficiency, and
9 effectiveness of the implemented program on an annual basis. The
10 report shall contain both qualitative and quantitative measures,
11 as determined by the board and the State Department of Public
12 Health.

13 (4) Protect against the potential for the diversion of
14 home-generated pharmaceutical waste included in a program for
15 unlawful use or sale.

16 (c) The regulations adopted pursuant to this section shall only
17 apply to licensees of the board.

18 ~~SECTION 1. Section 4068.1 is added to the Business and~~
19 ~~Professions Code, to read:~~

20 ~~4068.1. A pharmacy may accept the return of home-generated~~
21 ~~pharmaceutical waste, as defined in Section 117670.1 of the Health~~
22 ~~and Safety Code, from a consumer, consistent with the Federal~~
23 ~~Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) and~~
24 ~~the federal Controlled Substances Act (21 U.S.C. Sec. 801 et seq.).~~

25 ~~SEC. 2. Section 117670.1 is added to the Health and Safety~~
26 ~~Code, to read:~~

27 ~~117670.1. "Home-generated pharmaceutical waste" means a~~
28 ~~prescription or over-the-counter human or veterinary~~
29 ~~home-generated pharmaceutical, including, but not limited to, a~~
30 ~~drug as defined in Section 109925 or in Section 321(g)(1) of Title~~
31 ~~21 of the United States Code, that is a waste, as defined in Section~~
32 ~~25124, derived from a household, including, but not limited to, a~~
33 ~~multifamily residence or household.~~

34 ~~SEC. 3. Section 117700 of the Health and Safety Code is~~
35 ~~amended to read:~~

36 ~~117700. Medical waste does not include any of the following:~~

37 ~~(a) Waste generated in food processing or biotechnology that~~
38 ~~does not contain an infectious agent as defined in Section 117675.~~

39 ~~(b) Waste generated in biotechnology that does not contain~~
40 ~~human blood or blood products or animal blood or blood products~~

1 suspected of being contaminated with infectious agents known to
2 be communicable to humans.

3 (e) ~~Urine, feces, saliva, sputum, nasal secretions, sweat, tears,~~
4 ~~or vomitus, unless it contains fluid blood, as provided in~~
5 ~~subdivision (d) of Section 117635.~~

6 (d) ~~Waste that is not biohazardous, such as paper towels, paper~~
7 ~~products, articles containing nonfluid blood, and other medical~~
8 ~~solid waste products commonly found in the facilities of medical~~
9 ~~waste generators.~~

10 (e) ~~Hazardous waste, radioactive waste, or household waste,~~
11 ~~including, but not limited to, home-generated sharps waste, as~~
12 ~~defined in Section 117671.~~

13 (f) ~~Waste generated from normal and legal veterinarian,~~
14 ~~agricultural, and animal livestock management practices on a farm~~
15 ~~or ranch.~~

16 (g) ~~Home-generated pharmaceutical waste, including, but not~~
17 ~~limited to, consolidated home-generated pharmaceutical waste,~~
18 ~~that is handled by a collection and disposal program operating in~~
19 ~~accordance with the regulations adopted by the Department of~~
20 ~~Resources Recycling and Recovery and the California State Board~~
21 ~~of Pharmacy pursuant to Article 3.4 (commencing with Section~~
22 ~~47120) of Chapter 1 of Part 7 of Division 30 of the Public~~
23 ~~Resources Code.~~

24 ~~SEC. 4. Article 3.4 (commencing with Section 47120) is added~~
25 ~~to Chapter 1 of Part 7 of Division 30 of the Public Resources Code,~~
26 ~~to read:~~

27
28 ~~Article 3.4. Home-Generated Pharmaceutical Waste Collection~~
29 ~~and Disposal~~
30

31 ~~47120. For the purposes of this article, the following terms~~
32 ~~have the following meanings, unless the context clearly requires~~
33 ~~otherwise:~~

34 (a) ~~“Consumer” means an individual purchaser or owner of a~~
35 ~~pharmaceutical. “Consumer” does not include a business,~~
36 ~~corporation, limited partnership, or an entity involved in a~~
37 ~~wholesale transaction between a distributor and retailer.~~

38 (b) ~~“Entity” means a state or local public agency, pharmacy,~~
39 ~~veterinarian clinic, or other office or facility.~~

1 ~~(e) “Home-generated pharmaceutical waste” has the same~~
2 ~~meaning as defined in Section 117670.1 of the Health and Safety~~
3 ~~Code, and includes all of the following:~~

4 ~~(1) Articles recognized in the official United States~~
5 ~~Pharmacopoeia, the official National Formulary, the official~~
6 ~~Homeopathic Pharmacopoeia of the United States, or any~~
7 ~~supplement of the formulary or those pharmacopoeias.~~

8 ~~(2) Articles intended for use in the diagnosis, cure, mitigation,~~
9 ~~treatment, or prevention of disease in humans or other animals.~~

10 ~~(3) Articles, excluding food, intended to affect the structure or~~
11 ~~function of the body of humans or other animals.~~

12 ~~(4) Articles intended for use as a component of an article~~
13 ~~specified in paragraph (1), (2), or (3).~~

14 ~~(d) “Participant” means an entity that the department and the~~
15 ~~California State Board of Pharmacy deems appropriate for~~
16 ~~implementing and evaluating a program in accordance with the~~
17 ~~regulations adopted pursuant to this article and that chooses to~~
18 ~~participate.~~

19 ~~(e) “Sale” includes, but is not limited to, transactions conducted~~
20 ~~through sales outlets, catalogs, or the Internet, or any other similar~~
21 ~~electronic means, but does not include a sale that is a wholesale~~
22 ~~transaction with a distributor or retailer.~~

23 ~~47121. On or before January 1, 2016, the department and the~~
24 ~~California State Board of Pharmacy shall jointly develop~~
25 ~~regulations, to be approved by both agencies before adoption,~~
26 ~~authorizing a participant to establish a program to collect and~~
27 ~~properly dispose of home-generated pharmaceutical waste. The~~
28 ~~regulations shall be based upon the model guidelines developed~~
29 ~~by the department pursuant to former Section 47122, as that section~~
30 ~~read on January 1, 2012, and shall include both of the following:~~

31 ~~(a) Provisions that do all of the following:~~

32 ~~(1) Specify the types of participants authorized to maintain~~
33 ~~permanent collection locations.~~

34 ~~(2) Specify any requirements for obtaining state permits or~~
35 ~~approvals.~~

36 ~~(3) Specify which home-generated pharmaceutical wastes may~~
37 ~~be included in a program, including requirements for the collection~~
38 ~~of a controlled substance, as defined in Section 11007 of the Health~~
39 ~~and Safety Code.~~

- 1 ~~(4) Require participants to enter into arrangements with medical~~
2 ~~or hazardous waste haulers, including ensuring that all~~
3 ~~home-generated pharmaceutical waste included in a program is~~
4 ~~appropriately picked up and transported by registered waste haulers.~~
- 5 ~~(5) Specify methods for handling wastes commingled in~~
6 ~~containers with other household waste or hazardous waste.~~
- 7 ~~(6) Provide methods for collecting and storing home-generated~~
8 ~~pharmaceutical waste included in a program, including the use of~~
9 ~~secured containers, and ensure that collected home-generated~~
10 ~~pharmaceutical waste is not resold, reused, sold, donated, or~~
11 ~~provided to anyone other than a registered medical or hazardous~~
12 ~~waste hauler.~~
- 13 ~~(7) Provide that a facility that collects home-generated~~
14 ~~pharmaceutical waste included in a program is responsible for~~
15 ~~ensuring that the storage, removal, and transportation of containers~~
16 ~~and the disposal of the waste are in compliance with state laws~~
17 ~~and regulations.~~
- 18 ~~(8) Require the collection and retention of detailed information~~
19 ~~and invoices for each collection site.~~
- 20 ~~(9) Impose requirements for one-time or periodic collection~~
21 ~~events.~~
- 22 ~~(10) Impose requirements for mail-back collection and disposal~~
23 ~~programs.~~
- 24 ~~(11) Impose requirements for the appropriate public education~~
25 ~~and management of consolidated home-generated pharmaceutical~~
26 ~~waste included in a program to ensure the public health and safety.~~
- 27 ~~(b) Provisions requiring a participant to take all of the following~~
28 ~~actions:~~
 - 29 ~~(1) Provide, at no additional cost to the consumer, for the safe~~
30 ~~take back and proper disposal of pharmaceuticals.~~
 - 31 ~~(2) Ensure the protection of the public health and safety, the~~
32 ~~environment, and the health and safety of consumers and~~
33 ~~employees.~~
 - 34 ~~(3) Report annually to the department, for purposes of evaluating~~
35 ~~the safety, efficiency, and effectiveness of the implemented~~
36 ~~program on an annual basis. The report shall contain both~~
37 ~~qualitative and quantitative measures, as determined by the~~
38 ~~department and the California State Board of Pharmacy.~~

1 ~~(4) Protect against the potential for the diversion of~~
2 ~~pharmaceutical waste included in a program for unlawful use or~~
3 ~~sale.~~

4 ~~47122. A participant operating a program in accordance with~~
5 ~~the regulations adopted pursuant to this article shall be deemed in~~
6 ~~compliance with all state laws and regulations concerning the~~
7 ~~handling, management, and disposal of home-generated~~
8 ~~pharmaceutical waste.~~

9 ~~47123. Regulations adopted pursuant to this article shall~~
10 ~~conform to any requirements of a federal drug take-back program.~~

11 ~~SEC. 5. No reimbursement is required by this act pursuant to~~
12 ~~Section 6 of Article XIII B of the California Constitution because~~
13 ~~the only costs that may be incurred by a local agency or school~~
14 ~~district will be incurred because this act creates a new crime or~~
15 ~~infraction, eliminates a crime or infraction, or changes the penalty~~
16 ~~for a crime or infraction, within the meaning of Section 17556 of~~
17 ~~the Government Code, or changes the definition of a crime within~~
18 ~~the meaning of Section 6 of Article XIII B of the California~~
19 ~~Constitution.~~