

Introduced by Senator SimitianDecember 1, 2008

An act to add Sections 4001.2, 4068.1, and 4146 to the Business and Professions Code, to amend Sections 117700, 117935, 117945, 117960, 118000, 118040, 118147, and 118165 of, and to add Sections 117642, 117669, 117748, 117904.5, 118031, and 118041 to, the Health and Safety Code, and to amend Section 47200 of the Public Resources Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 26, as introduced, Simitian. Home-generated pharmaceutical waste.

The existing Pharmacy Law establishes the California State Board of Pharmacy, prescribes the licensing, regulatory, and disciplinary functions of the board, and authorizes the board to adopt rules and regulations necessary to administer laws governing the operation of pharmacies and the dispensing of drugs and devices to the public.

This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

Existing law, the California Integrated Waste Management Act of 1989, requires the California Integrated Waste Management Board to adopt regulations that set forth minimum standards for solid waste management and require assurance of financial ability to pay for specified injury and property damage claims resulting from the operation of a disposal facility. The act requires the board to expend moneys from

the Solid Waste Management Account in the Integrated Waste Management Fund, upon appropriation by the Legislature, for the making of grants to cities, counties, or other local agencies with responsibility for solid waste management, and for local programs to help prevent the disposal of hazardous wastes at disposal sites, as provided.

This bill would require that local programs to help prevent the disposal of home-generated sharps waste and home-generated pharmaceutical waste at disposal sites also be included among the types of local programs that may be funded by such a grant.

Existing law, the Medical Waste Management Act, requires the State Department of Public Health to regulate the management and handling of medical waste, as defined. Under existing law, certain items, such as household waste, are specifically excluded from the definition of medical waste.

This bill would also exclude home-generated pharmaceutical waste, as defined, from the definition of medical waste.

Existing law regulates the methods of consolidating, storing, and transporting medical waste and home-generated sharps waste. Violation of these provisions is a crime.

This bill would regulate consolidation points for home-generated pharmaceutical waste, as defined, as well as transportation and disposal of that waste by both hazardous waste haulers and common carriers, as defined. By expanding the definition of 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.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

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

- 1 SECTION 1. Section 4001.2 is added to the Business and
- 2 Professions Code, to read:
- 3 4001.2. To further the purposes of Section 4001.1, and to
- 4 protect the public from hazards caused by the improper
- 5 management and disposal of waste drugs and devices, the

1 California State Board of Pharmacy shall coordinate with other
2 state agencies, local governments, drug manufacturers, and
3 pharmacies to develop sustainable, efficient policies and programs
4 to properly manage pharmaceutical wastes and the disposal of
5 these wastes.

6 SEC. 2. Section 4068.1 is added to the Business and Professions
7 Code, to read:

8 4068.1. A pharmacy may accept the return of home-generated
9 pharmaceutical waste, as defined in Section 117769 of the Health
10 and Safety Code, from the public.

11 SEC. 3. Section 4146 is added to the Business and Professions
12 Code, to read:

13 4146. A pharmacy may accept the return of home-generated
14 sharps waste, as defined in Section 117671 of the Health and Safety
15 Code, from a person if the waste is contained in a sharps container.

16 SEC. 4. Section 117642 is added to the Health and Safety Code,
17 to read:

18 117642. “Common carrier” means a person or company that
19 hauls for hire goods, including, but not limited to, pharmaceutical
20 waste or home-generated pharmaceutical waste. Home-generated
21 pharmaceutical waste must have been consolidated at a location
22 approved by the enforcement agency as a home-generated
23 pharmaceutical waste consolidation point.

24 SEC. 5. Section 117669 is added to the Health and Safety Code,
25 to read:

26 117669. “Home-generated pharmaceutical waste” means
27 prescribed and over-the-counter drugs derived from a household.

28 SEC. 6. Section 117700 of the Health and Safety Code is
29 amended to read:

30 117700. Medical waste does not include any of the following:

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

33 (b) Waste generated in biotechnology that does not contain
34 human blood or blood products or animal blood or blood products
35 suspected of being contaminated with infectious agents known to
36 be communicable to humans.

37 (c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears,
38 or vomitus, unless it contains fluid blood, as provided in
39 subdivision (d) of Section 117635.

1 (d) Waste ~~which~~ *that* is not biohazardous, such as paper towels,
2 paper products, articles containing nonfluid blood, and other
3 medical solid waste products commonly found in the facilities of
4 medical waste generators.

5 (e) Hazardous waste, radioactive waste, or household waste,
6 including, but not limited to, home-generated sharps waste, as
7 defined in Section 117671, *and home-generated pharmaceutical*
8 *waste, as defined in Section 117669.*

9 (f) Waste generated from normal and legal veterinarian,
10 agricultural, and animal livestock management practices on a farm
11 or ranch.

12 SEC. 7. Section 117748 is added to the Health and Safety Code,
13 to read:

14 117748. “Pharmaceutical waste” means any pharmaceutical,
15 prescription, or over-the-counter human or veterinary drug,
16 including, but not limited to, a drug, as defined in Section 109925,
17 or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec.
18 321(g)(1)) that meets any of the following requirements:

19 (a) The drug may no longer be sold or dispensed because it has
20 expired.

21 (b) The drug can no longer be used for its intended purpose.

22 (c) The drug has been discarded.

23 (d) The drug has been consolidated at a location approved by
24 the enforcement agency as a home-generated pharmaceutical waste
25 consolidation point.

26 SEC. 8. Section 117904.5 is added to the Health and Safety
27 Code, to read:

28 117904.5. (a) In addition to the consolidation points authorized
29 pursuant to Section 118147, the enforcement agency may approve
30 a location as a point of consolidation for the collection of
31 home-generated pharmaceutical waste. These locations may
32 include, but are not limited to, pharmacies, health care facilities,
33 veterinarian offices, clinics, household hazardous waste programs,
34 solid waste facilities, senior centers, or government offices.

35 (b) A consolidation location approved pursuant to this section
36 shall be known as a home-generated pharmaceutical waste
37 consolidation point.

38 (c) A home-generated pharmaceutical waste consolidation point
39 is not subject to the requirements of Chapter 9 (commencing with
40 Section 118275) of Part 14 of Division 4, to the permit

1 requirements of this part, or to any permit or registration fees, with
2 regard to the activity of consolidating home-generated
3 pharmaceutical waste pursuant to this section.

4 (d) A home-generated pharmaceutical waste consolidation point
5 shall comply with all of the following requirements:

6 (1) It shall be approved by the enforcement agency for this
7 purpose.

8 (2) The home-generated pharmaceutical waste collected and
9 consolidated at the facility shall be collected and contained in a
10 leak-resistant container and placed in a secure area that does not
11 allow the waste to be accessed or salvaged by unauthorized persons.

12 (3) Containers ready for disposal shall not be held for more than
13 90 days without the written approval of the enforcement agency.

14 (e) An operator of a home-generated pharmaceutical waste
15 consolidation point that is approved pursuant to this section shall
16 not be considered a generator of that waste.

17 (f) The end disposal facility that treats the home-generated
18 pharmaceutical waste shall maintain the tracking documents
19 required by Section 118040 or 118041, as applicable, and Section
20 118165 with regard to the pharmaceutical waste.

21 (g) Nothing in this section shall exempt any person from any
22 federal or state law governing pharmaceuticals.

23 SEC. 9. Section 117935 of the Health and Safety Code is
24 amended to read:

25 117935. Any small quantity generator required to register with
26 the enforcement agency pursuant to Section 117930 shall file with
27 the enforcement agency a medical waste management plan, on
28 forms prescribed by the enforcement agency containing, but not
29 limited to, all of the following:

30 (a) The name of the person.

31 (b) The business address of the person.

32 (c) The type of business.

33 (d) The types, and the estimated average monthly quantity, of
34 medical waste generated.

35 (e) The type of treatment used onsite.

36 (f) The name and business address of the registered hazardous
37 waste hauler used by the generator for backup treatment and
38 disposal, for waste when the onsite treatment method is not
39 appropriate due to the hazardous or radioactive characteristics of
40 the waste, ~~or~~ the name of the registered hazardous waste hauler

1 used by the generator to have untreated medical waste removed
2 for treatment and disposal, *and, if applicable, the name of the*
3 *common carrier used by the generator to transport pharmaceutical*
4 *waste offsite for treatment and disposal.*

5 (g) A statement indicating that the generator is hauling the
6 medical waste generated in his or her business pursuant to Section
7 118030 and the name and any business address of the treatment
8 and disposal facilities to which the waste is being hauled, if
9 applicable.

10 (h) The name and business address of the registered hazardous
11 waste hauler service provided by the building management to
12 which the building tenants may subscribe or are required by the
13 building management to subscribe and the name and business
14 address of the treatment and disposal facilities used, if applicable.

15 (i) A statement certifying that the information provided is
16 complete and accurate.

17 SEC. 10. Section 117945 of the Health and Safety Code is
18 amended to read:

19 117945. Small quantity generators who are not required to
20 register pursuant to this chapter shall maintain on file in their office
21 all of following:

22 (a) An information document stating how the generator contains,
23 stores, treats, and disposes of any medical waste generated through
24 any act or process of the generator.

25 (b) Records of any medical waste transported offsite for
26 treatment and disposal, including the quantity of waste transported,
27 the date transported, and the name of the registered hazardous
28 waste hauler or individual hauling the waste pursuant to Section
29 118030, *or the name of the common carrier hauling*
30 *pharmaceutical waste pursuant to Section 118031.* The small
31 quantity generator shall maintain these records for not less than
32 two years.

33 SEC. 11. Section 117960 of the Health and Safety Code is
34 amended to read:

35 117960. Any large quantity generator required to register with
36 the enforcement agency pursuant to Section 117950 shall file with
37 the enforcement agency a medical waste management plan, on
38 forms prescribed by the enforcement agency containing, but not
39 limited to, all of the following:

40 (a) The name of the person.

- 1 (b) The business address of the person.
- 2 (c) The type of business.
- 3 (d) The types, and the estimated average monthly quantity, of
4 medical waste generated.
- 5 (e) The type of treatment used onsite, if applicable. For
6 generators with onsite medical waste treatment facilities, including
7 incinerators or steam sterilizers or other treatment facilities as
8 determined by the enforcement agency, the treatment capacity of
9 the onsite treatment facility.
- 10 (f) The name and business address of the registered hazardous
11 waste hauler used by the generator to have untreated medical waste
12 removed for treatment, if applicable, *or the name of the common*
13 *carrier hauling pharmaceutical waste pursuant to Section 118031.*
- 14 (g) The name and business address of the registered hazardous
15 waste hauler service provided by the building management to
16 which the building tenants may subscribe or are required by the
17 building management to subscribe, if applicable.
- 18 (h) The name and business address of the offsite medical waste
19 treatment facility to which the medical waste is being hauled, if
20 applicable.
- 21 (i) An emergency action plan complying with regulations
22 adopted by the department.
- 23 (j) A statement certifying that the information provided is
24 complete and accurate.

25 SEC. 12. Section 118000 of the Health and Safety Code is
26 amended to read:

27 118000. (a) Except as otherwise exempted pursuant to Section
28 118030 *or 118031*, all medical waste transported to an offsite
29 medical waste treatment facility shall be transported in accordance
30 with this chapter by a registered hazardous waste transporter issued
31 a registration certificate pursuant to Chapter 6 (commencing with
32 Section 118025) and Article 6.5 (commencing with Section
33 25167.1) of Chapter 6.5 of Division 20. A hazardous waste
34 transporter transporting medical waste shall have a copy of the
35 transporter's valid hazardous waste transporter registration
36 certificate in the transporter's possession while transporting
37 medical waste. The transporter shall show the certificate, upon
38 demand, to any enforcement agency personnel or authorized
39 employee of the Department of the California Highway Patrol.

1 (b) Except for small quantity generators transporting medical
2 waste pursuant to Section 118030 or *small quantity generators or*
3 *common carriers transporting home-generated pharmaceutical*
4 *waste pursuant to Section 118031*, medical waste shall be
5 transported to a permitted offsite medical waste treatment facility
6 or a permitted transfer station in leak-resistant and fully enclosed
7 rigid secondary containers that are then loaded into an enclosed
8 cargo body.

9 (c) A person shall not transport medical waste in the same
10 vehicle with other waste unless the medical waste is separately
11 contained in rigid containers or kept separate by barriers from
12 other waste, or unless all of the waste is to be handled as medical
13 waste in accordance with this part.

14 (d) Medical waste shall only be transported to a permitted
15 medical waste treatment facility, or to a transfer station or another
16 registered generator for the purpose of consolidation before
17 treatment and disposal, pursuant to this part.

18 (e) Facilities for the transfer of medical waste shall be annually
19 inspected and issued permits in accordance with the regulations
20 adopted pursuant to this part.

21 (f) Any persons manually loading or unloading containers of
22 medical waste shall be provided by their employer at the beginning
23 of each shift with, and shall be required to wear, clean and
24 protective gloves and coveralls, changeable lab coats, or other
25 protective clothing. The department may require, by regulation,
26 other protective devices appropriate to the type of medical waste
27 being handled.

28 SEC. 13. Section 118031 is added to the Health and Safety
29 Code, to read:

30 118031. Pharmaceutical waste may be shipped by a common
31 carrier if the generator or home-generated pharmaceutical waste
32 consolidation point meets the following requirements:

33 (a) The facility shall maintain documentation as required in
34 Sections 118040 and 118041.

35 (b) The waste products are transported to any of the following:

36 (1) A medical waste facility.

37 (2) A hazardous waste facility.

38 (3) A reverse distributor, with the final destination of a medical
39 or hazardous waste facility.

1 SEC. 14. Section 118040 of the Health and Safety Code is
2 amended to read:

3 118040. (a) Except with regard to sharps waste consolidated
4 by a home-generated sharps consolidation point approved pursuant
5 to Section 117904, *pharmaceutical waste or home-generated*
6 *pharmaceutical waste consolidated by a home-generated*
7 *pharmaceutical waste consolidation point approved pursuant to*
8 *Section 117904.5, or home-generated pharmaceutical waste*
9 *transported pursuant to Section 118031*, a hazardous waste
10 transporter or generator transporting medical waste shall maintain
11 a completed tracking document of all medical waste removed for
12 treatment or disposal. A hazardous waste transporter or generator
13 who transports medical waste to a facility, other than the final
14 medical waste treatment facility, shall also maintain tracking
15 documents which show the name, address, and telephone number
16 of the medical waste generator, for purposes of tracking the
17 generator of medical waste when the waste is transported to the
18 final medical waste treatment facility. At the time that the medical
19 waste is received by a hazardous waste transporter, the transporter
20 shall provide the medical waste generator with a copy of the
21 tracking document for the generator's medical waste records. The
22 transporter or generator transporting medical waste shall maintain
23 its copy of the tracking document for three years.

24 (b) The tracking document shall include, but not be limited to,
25 all of the following information:

26 (1) The name, address, telephone number, and registration
27 number of the transporter, unless transported pursuant to Section
28 118030.

29 (2) The type and quantity of medical waste transported.

30 (3) The name, address, and telephone number of the generator.

31 (4) The name, address, telephone number, permit number, and
32 the signature of an authorized representative of the permitted
33 facility receiving the medical waste.

34 (5) The date that the medical waste is collected or removed from
35 the generator's facility, the date that the medical waste is received
36 by the transfer station, the registered large quantity generator, or
37 point of consolidation, if applicable, and the date that the medical
38 waste is received by the treatment facility.

39 (c) Any hazardous waste transporter or generator transporting
40 medical waste in a vehicle shall have a tracking document in his

1 or her possession while transporting the medical waste. The
2 tracking document shall be shown upon demand to any
3 enforcement agency personnel or officer of the Department of the
4 California Highway Patrol. If the medical waste is transported by
5 rail, vessel, or air, the railroad corporation, vessel operator, or
6 airline shall enter on the shipping papers any information
7 concerning the medical waste that the enforcement agency may
8 require.

9 (d) A hazardous waste transporter or a generator transporting
10 medical waste shall provide the facility receiving the medical waste
11 with the original tracking document.

12 (e) Each hazardous waste transporter and each medical waste
13 treatment facility shall provide tracking data periodically and in a
14 format as determined by the department.

15 (f) Medical waste transported out of state shall be consigned to
16 a permitted medical waste treatment facility in the receiving state.
17 If there is no permitted medical waste treatment facility in the
18 receiving state or if the medical waste is crossing an international
19 border, the medical waste shall be treated in accordance with
20 Chapter 8 (commencing with Section 118215) prior to being
21 transported out of the state.

22 SEC. 15. Section 118041 is added to the Health and Safety
23 Code, to read:

24 118041. (a) A person transporting pharmaceutical waste shall
25 maintain a completed tracking document of all pharmaceutical
26 waste removed for treatment or disposal. A copy of the tracking
27 document shall be included with the container holding the
28 pharmaceutical waste.

29 (b) The tracking document shall include, but not be limited to,
30 all of the following information:

31 (1) The name, address, and telephone number of the generator.

32 (2) Specific information indicating that pharmaceutical waste
33 is being transported.

34 (3) The name, address, and telephone number of the person
35 transporting the waste.

36 (4) The name, address, telephone number, and permit number
37 of the permitted treatment facility or transfer station to which the
38 pharmaceutical waste is being sent.

1 (5) The date that the pharmaceutical waste was collected or
2 removed from the generator or home-generated pharmaceutical
3 waste consolidation point.

4 (c) A person tracking pharmaceutical waste shall have a tracking
5 document for the waste in his or her possession while transporting
6 the waste. The tracking document shall be shown, upon demand,
7 to any enforcement agency personnel or officer of the Department
8 of the California Highway Patrol.

9 (d) A medical waste treatment facility and transfer station shall
10 date and sign a copy of the tracking document upon receipt,
11 periodically provide data in a format determined by the department,
12 and shall maintain a copy of the tracking document for three years.

13 (e) This section does not prohibit the use of a single document
14 to verify the return of more than one container to a parent
15 organization or another health care facility for the purpose of
16 consolidation before treatment and disposal of the pharmaceutical
17 waste over a period of time, if the form or log is maintained in the
18 files of the parent organization or other health care facility that
19 receives the waste.

20 (f) Pharmaceutical waste transported out of state shall be
21 consigned to a permitted medical waste treatment facility in the
22 receiving state. If there is no permitted medical waste treatment
23 facility in the receiving state, or if the waste is crossing an
24 international border, the home-generated pharmaceutical waste
25 shall be treated pursuant to Section 118222 prior to being
26 transported out of state.

27 SEC. 16. Section 118147 of the Health and Safety Code is
28 amended to read:

29 118147. Notwithstanding any other provision of this chapter,
30 a registered medical waste generator, which is a facility specified
31 in subdivisions (a) and (b) of Section 117705, may accept
32 home-generated sharps waste *and home-generated pharmaceutical*
33 *waste*, to be consolidated with the facility's medical waste stream,
34 subject to all of the following conditions:

35 (a) The generator of the *home-generated* sharps waste *or*
36 *home-generated pharmaceutical waste*, a member of the
37 generator's family, or a person authorized by the enforcement
38 agency transports the sharps waste *or pharmaceutical waste* to the
39 medical waste generator's facility.

1 (b) The *home-generated sharps waste or home-generated*
2 *pharmaceutical waste* is accepted at a central location at the
3 medical waste generator's facility.

4 (c) A reference to, and a description of, the actions taken
5 pursuant to this section are included in the facility's medical waste
6 management plan adopted pursuant to Section 117960.

7 SEC. 17. Section 118165 of the Health and Safety Code is
8 amended to read:

9 118165. On and after April 1, 1991, all persons operating a
10 medical waste treatment facility shall maintain individual records
11 for a period of three years and shall report or submit to the
12 enforcement agency upon request, all of the following information:

13 (a) The type of treatment facility and its capacity.

14 (b) All treatment facility operating records.

15 (c) Copies of the tracking documents for all medical waste it
16 receives for treatment from offsite generators or from hazardous
17 waste haulers *or common carriers, pursuant to Section 118041*.

18 SEC. 18. Section 47200 of the Public Resources Code is
19 amended to read:

20 47200. (a) The board shall expend funds from the account,
21 upon appropriation by the Legislature, for the making of grants to
22 cities, counties, or other local agencies with responsibility for solid
23 waste management, and for local programs to help prevent the
24 disposal of *home-generated sharps waste, as defined in Section*
25 *117671 of the Health and Safety Code, home-generated*
26 *pharmaceutical waste, as defined in Section 117669 of the Health*
27 *and Safety Code, and hazardous wastes at disposal sites, including,*
28 but not limited to, programs to expand or initially implement
29 household hazardous waste programs. In making grants pursuant
30 to this section, the board shall give priority to funding programs
31 that provide for the following:

32 (1) New programs for rural areas, underserved areas, and for
33 small cities.

34 (2) Expansion of existing programs to provide for the collection
35 of additional waste types, innovative or more cost-effective
36 collection methods, or expanded public education services.

37 (3) Regional household hazardous waste programs.

38 (b) (1) The total amount of grants made by the board pursuant
39 to this section shall not exceed, in any one fiscal year, three million
40 dollars (\$3,000,000).

1 (2) Notwithstanding paragraph (1), the total amount of grants
2 made by the board pursuant to this section may exceed three
3 million dollars (\$3,000,000) but shall not exceed six million dollars
4 (\$6,000,000), in any one fiscal year, if sufficient funds are
5 appropriated from the Integrated Waste Management Account for
6 this purpose.

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

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