

AMENDED IN ASSEMBLY APRIL 30, 2007

CALIFORNIA LEGISLATURE—2007—08 REGULAR SESSION

ASSEMBLY BILL

No. 501

Introduced by Assembly Members Swanson and Hancock

February 20, 2007

An act to add Section ~~119404~~ 118288 to the Health and Safety Code, relating to pharmaceutical devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 501, as amended, Swanson. Pharmaceutical devices.

The existing Medical Waste Management Act, administered by the State Department of Health Services, regulates the management and handling of medical waste, as defined. Effective July 1, 2007, these duties will be transferred to the State Department of Public Health. Under existing law, certain items, such as home-generated sharps waste, as defined, are specifically excluded from the definition of medical waste. The act also prohibits, on or after September 1, 2008, a person from knowingly placing home-generated sharps waste in certain types of containers, provides that home-generated sharps waste is to be transported only in a sharps container, as defined, or other container approved by the department or local enforcement agency, and requires this waste to only be managed at specified locations consistent with existing law.

This bill would require a pharmaceutical company whose product is dispensed through a prefilled syringe, prefilled pen needle, or other prefilled injection device to provide each person for whom the product is prescribed with a specified method for the patient to safely dispose of the syringe, pen needle, or other injection device.

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

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

1 SECTION 1. The Legislature finds and declares all of the
2 following:

3 (a) An estimated 1 million Californians must self-inject
4 prescription medications annually to treat a broad range of serious
5 health problems.

6 (b) The use of prefilled syringes, pens, and devices with needles
7 is an effective method of prescription drug delivery and is expected
8 to increase significantly in the future. *Prefilled syringes, pens, and*
9 *devices with needles are clearly identified and linked to specific*
10 *pharmaceutical manufacturers for the provision of their product*
11 *to California residents.*

12 (c) The increased use of prefilled syringes, pens, and devices
13 with needles will generate millions of home-generated sharps each
14 year. *Prefilled pen needles are being used for the treatment of*
15 *some of the most serious health conditions such as HIV/AIDS,*
16 *hepatitis C, and many other diseases.* If improperly disposed in
17 solid waste and recycling containers these needles will result in
18 significant public health risks.

19 (d) The Legislature has found that sharps mail-back programs
20 utilizing containers and packaging approved by the United States
21 Postal Service offer one of the most convenient means for
22 collecting and destroying home-generated sharps and that the
23 cooperative efforts of the pharmaceutical industry is needed to
24 develop a safe needle disposal system for California.

25 ~~SEC. 2. Section 119404 is added to the Health and Safety Code,~~
26 ~~to read:~~

27 ~~119404. (a) Every pharmaceutical company whose product is~~
28 ~~dispensed through a prefilled syringe, prefilled pen needle, or other~~
29 ~~prefilled injection device shall provide each person for whom the~~
30 ~~product is prescribed in this state with a method described in this~~
31 ~~section to safely dispose of the syringe, pen needle, or other~~
32 ~~injection device. If the person receives this syringe, pen needle,~~
33 ~~or other injection device as part of a patient starter kit, the~~
34 ~~pharmaceutical company shall make available to the person, at no~~
35 ~~additional charge, a postage prepaid, mail-back sharps container~~

1 ~~by including this container or a coupon for this container in the~~
2 ~~patient starter kit or by providing the person with a distribution~~
3 ~~point chosen by the pharmaceutical company. The pharmaceutical~~
4 ~~company shall also make available, at no additional charge and~~
5 ~~through an annually renewable program, postage prepaid, mail-back~~
6 ~~sharps containers to any person who uses this pharmaceutical~~
7 ~~company's product.~~

8 *SEC. 2. Section 118288 is added to the Health and Safety Code,*
9 *to read:*

10 *118288. (a) Effective January 1, 2008, pharmaceutical*
11 *manufacturers whose product is dispensed via a prefilled syringe,*
12 *prefilled pen needle, or other prefilled injection device shall*
13 *provide each new patient for whom the product is dispensed in*
14 *this state with a method described in this section to safely dispose*
15 *of the prefilled syringe, prefilled pen needle, or other prefilled*
16 *injection device after it is used. If the new patient receives this*
17 *prefilled syringe, prefilled pen needle, or other prefilled injection*
18 *device as part of the patient's treatment, the pharmaceutical*
19 *manufacturer shall make available to the new patient, at no*
20 *additional charge, a postage prepaid, mail-back sharps container,*
21 *or an alternative safe needle disposal method. The safe needle*
22 *disposal method shall be accountable and substantiated by*
23 *documented evidence that these prefilled syringes, prefilled pen*
24 *needles, and prefilled devices are being disposed of properly and*
25 *are diverted from the solid waste stream. If using a mail-back*
26 *container as a safe needle disposal method of choice, the container*
27 *shall be approved by the United States Postal Service and State*
28 *Department of Public Health.*

29 *(b) The pharmaceutical manufacturer shall also make available,*
30 *at no additional charge, an annually renewable program which*
31 *provides postage prepaid mail-back sharps containers or an*
32 *alternative disposal method to any person who continues to use*
33 *the pharmaceutical manufacturer's product.*

34 *(c) This section shall not apply to drugs compounded or*
35 *dispensed for use within a hospital.*

36 ~~(b)~~

37 *(d) For purposes of this section, the following definitions shall*
38 *apply:*

39 *(1) "Coupon" means any written material that allows a person*
40 *who uses a pharmaceutical company's product pursuant to a*

- 1 prescription to receive a postage prepaid, mail-back sharps
2 container from a distribution point chosen by the pharmaceutical
3 company.
- 4 (2) *“New patient” means a new start or treatment-naive patient*
5 *who is initiating self-injected drug therapy.*
6 ~~(2)~~
- 7 (3) *“Patient starter kit” means a package of educational, training,*
8 *or otherwise instructional materials prepared by, or on behalf of,*
9 *the pharmaceutical company to educate a person on how to safely*
10 *use the pharmaceutical company’s self-injectable pharmaceutical*
11 *product.*
- 12 ~~(3)~~
- 13 (4) *“Sharps container” has the same meaning as in Section*
14 *117750.*