

Assembly Bill No. 501

Passed the Assembly August 13, 2008

Chief Clerk of the Assembly

Passed the Senate July 14, 2008

Secretary of the Senate

This bill was received by the Governor this _____ day
of _____, 2008, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

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

LEGISLATIVE COUNSEL'S DIGEST

AB 501, Swanson. Pharmaceutical devices.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Under existing law, certain items, such as home-generated sharps waste, as defined, are specifically excluded from the definition of medical waste. The act 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 manufacturer whose product is administered for home use through a prefilled syringe, prefilled pen, or other prefilled injection device to arrange to provide, upon request from a consumer, a postage prepaid, mail-back sharps container that has been approved by the United States Postal Service and the department or a sharps container for the safe storage and transport of sharps to a sharps consolidation location approved by the department or a clinic, physician, or pharmacy that accepts home-generated sharps waste, as defined, along with concise information on safe disposal alternatives and options for sharps and notice of the act's above described prohibition, that commences September 1, 2008. As a means of meeting these above described requirements, the manufacturer may provide the consumer with a coupon that can be exchanged for, or a toll-free telephone number or Web site that can direct the patient to a supplier of, a qualified sharps container. This bill would also prohibit the manufacturer, or any person or agent with whom the manufacturer contracts, from using information collected for this purpose for any other purpose.

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

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

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

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

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

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

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

118288. (a) Upon request of a consumer who has been dispensed a prefilled syringe, prefilled pen, or other prefilled injection device for administration at home, a pharmaceutical manufacturer shall arrange to provide the consumer with either of the following:

(1) A postage prepaid, mail-back sharps container that has been approved by the United States Postal Service and the State Department of Public Health.

(2) A sharps container for the safe storage of, and transport to, a sharps consolidation location that is approved by the State

Department of Public Health or to a clinic, physician, or pharmacy that accepts home-generated sharps waste.

(3) In addition to providing an appropriate sharps container, the manufacturer shall provide information on safe disposal alternatives and options for sharps and notice to the consumer that effective September 1, 2008, California law prohibits a person from knowingly disposing of home-generated sharps in any container used for the collection of solid waste, recyclable materials, or green waste or for the commercial collection of solid waste or recyclable materials from business establishments.

(b) For purposes of this section, “sharps container” has the same meaning as in Section 117750.

(c) As a means of meeting the requirements of subdivision (a), a manufacturer may do either of the following:

(1) Supply a coupon, either to be delivered to the patient or with the device when it is dispensed, that may be exchanged for a sharps container that meets the requirements of paragraph (1) or (2) of subdivision (a).

(2) Provide a toll-free telephone number or Web site, noted on the packaging containing the device, that directs the patient to a supplier of sharps containers that meets the requirements of paragraph (1) or (2) of subdivision (a).

(d) A manufacturer shall not use or disclose information that it receives in the course of complying with this section for any other purpose, including, but not limited to, marketing, without the written consent of the consumer. This prohibition shall apply to any person or agent with whom the manufacturer contracts or otherwise makes arrangements to carry out the requirements of this section.

Approved _____, 2008

Governor