

Senate Bill No. 1229

CHAPTER 238

An act to add Section 1714.24 to the Civil Code, relating to pharmaceutical waste.

[Approved by Governor August 29, 2016. Filed with
Secretary of State August 29, 2016.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1229, Jackson. Home-generated pharmaceutical waste: secure drug take-back bins.

Under existing law, the Medical Waste Management Act, the State Department of Public Health regulates the management and handling of medical waste, including pharmaceutical waste, as defined. The act generally prohibits a person from transporting, storing, treating, disposing, or causing the treatment of medical waste in a manner not authorized by the act. A violation of that provision is a crime.

Under existing law, everyone is generally responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person, except so far as the latter, has willfully or by want of ordinary care, brought the injury upon himself or herself.

This bill would provide that a collector, as defined, is not liable for civil damages, or subject to criminal prosecution, for any injury or harm that results from the collector maintaining a secure drug take-back bin on its premises provided that the collector, not for compensation, acts in good faith to take specified steps, including that the collector regularly inspects the area surrounding the secure drug take-back bin for potential tampering or diversion, to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of home-generated pharmaceutical waste, as defined, contained in the bins.

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

SECTION 1. (a) The Legislature finds and declares the following:

(1) On October 12, 2010, the federal Secure and Responsible Drug Disposal Act of 2010 (Public Law 111-273; hereafter referred to as the Disposal Act) was enacted. Before the Disposal Act, individuals who wanted to dispose of unused, unwanted, or expired pharmaceutical controlled substances had limited disposal options. The federal Controlled Substances Act (21 U.S.C. Sec. 801 et seq.; hereafter referred to as the CSA) only permitted individuals to destroy those substances themselves (e.g., by

flushing or discarding), surrender them to law enforcement, or seek assistance from the federal Drug Enforcement Administration (DEA). These restrictions resulted in the accumulation of pharmaceutical controlled substances in household medicine cabinets that were available for abuse, misuse, diversion, and accidental ingestion. The Disposal Act amended the CSA to authorize specified individuals, referred to as “ultimate users,” to deliver their pharmaceutical controlled substances to another person for the purpose of disposal in accordance with regulations promulgated by the United States Attorney General.

(2) On September 9, 2014, the DEA issued its final rule governing the secure disposal of controlled substances by registrants and ultimate users. Those regulations implement the Disposal Act by expanding the options available to collect controlled substances from ultimate users for the purpose of disposal, including take-back events, mail-back programs, and collection receptacle locations. Those regulations, among other things, allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an onsite pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles.

(b) It is the intent of the Legislature, with the enactment of this act, to do both of the following:

(1) Encourage the good faith participation of federally authorized entities to maintain secure drug take-back bins on their premises for the convenience and public health and safety of prescription drug consumers and the proper disposal in the waste stream of the pharmaceutical waste contained in the bins.

(2) Limit the civil and criminal liability of participating entities that meet certain minimum standards and take reasonable care to ensure the health and safety of consumers and employees when maintaining secure drug take-back bins on their premises.

(c) The terms and conditions provided by subdivision (b) of Section 1714.24 of the Civil Code, as added by this act, shall be construed in a manner consistent with the requirements imposed by the DEA’s final rule governing the secure disposal of controlled substances (79 Fed. Reg. 53519-70 (September 9, 2014)) and any regulations promulgated by the state.

SEC. 2. Section 1714.24 is added to the Civil Code, to read:

1714.24. (a) For purposes of this section, the following definitions shall apply:

(1) “Collector” includes only those entities authorized by and registered with the federal Drug Enforcement Administration to receive a controlled substance for the purpose of destruction, if the entity is in good standing with any applicable licensing authority.

(2) “Compensation” means reimbursement or funds received from a customer to compensate for the cost incurred in obtaining, installing, or maintaining a secure drug take-back bin. “Compensation” does not include reimbursement or funds received from any other person or entity, other than

a customer, to compensate for the costs incurred in obtaining, installing, or maintaining a secure drug take-back bin.

(3) “Home-generated pharmaceutical waste” means a pharmaceutical that is no longer wanted or needed by the consumer and includes any delivery system, such as pills, liquids, and inhalers.

(4) “Maintains” includes owning, leasing, operating, or otherwise hosting a secure drug take-back bin on the collector’s premises.

(5) “Pharmaceutical” means a prescription or over-the-counter human or veterinary drug, including, but not limited to, a drug as defined in Section 109925 of the Health and Safety Code and Section 321(g)(1) of Title 21 of the United States Code. “Pharmaceutical” includes controlled substances included in Schedule II, III, IV, or V of the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code), but does not include a controlled substance included in Schedule I.

(6) “Secure drug take-back bin” means a collection receptacle as described in Section 1317.75 of Title 21 of the Code of Federal Regulations.

(b) Any collector that maintains a secure drug take-back bin shall not be liable in a civil action, or be subject to criminal prosecution, for any injury or harm that results from the collector maintaining a secure drug take-back bin on its premises provided that the collector, not for compensation, acts in good faith to take all of the following steps to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of the home-generated pharmaceutical waste contained in a secure drug take-back bin, unless the injury or harm results from the collector’s gross negligence or willful and wanton misconduct:

(1) Complies with all applicable state and federal laws and regulations relating to the collection of home-generated pharmaceutical waste for disposal in secure drug take-back bins, including, but not limited to, the federal Secure and Responsible Drug Disposal Act of 2010 (Public Law 111-273).

(2) Notifies local law enforcement and any local environmental health department as to the existence and location of any secure drug take-back bin on the collector’s premises and the status of the collector’s registration as a collector with the federal Drug Enforcement Administration.

(3) Ensures that the secure drug take-back bin is placed in a location that is regularly monitored by employees of the registered collector.

(4) Ensures that conspicuous signage is posted on the secure drug take-back bin that clearly notifies customers as to what controlled and noncontrolled substances are and are not acceptable for deposit into the bin, as well as the hours during which collection is allowed.

(5) Ensures that public access to the secure drug take-back bin is limited to hours in which employees of the registered collector are present and able to monitor the operation of the secure drug take-back bin.

(6) Regularly inspects the area surrounding the secure drug take-back bin for potential tampering or diversion. Record logs of those inspections shall be maintained and retained for two years, reflecting the date and time

of the inspection, and the initials of the employee inspecting the area. The logs shall be maintained in writing or electronically and may be combined with logs required by state or federal regulations. The logs may be used to demonstrate regular inspection of the area. Other records or reports mandated by federal or state regulations shall also be retained for a minimum of two years unless regulations mandate a longer period.

(7) Notifies local law enforcement authorities of any suspected or known tampering, theft, or significant loss of controlled substances, within one business day of discovery. If the collector maintains daily business hours, this notification shall be made within one calendar day.

(8) Notify local law enforcement as to any decision to discontinue its voluntary collection of controlled substances and provide documentation of its written notification to the federal Drug Enforcement Administration's Registration Unit as otherwise required under federal laws and regulations.

(c) Nothing in this section shall be construed to require entities that may qualify as a collector to acquire, maintain, or make available to the public a secure drug take-back bin on its premises.