

AMENDED IN ASSEMBLY JUNE 14, 2016

AMENDED IN SENATE APRIL 19, 2016

AMENDED IN SENATE MARCH 28, 2016

SENATE BILL

No. 1229

Introduced by Senators Jackson and Stone

February 18, 2016

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

LEGISLATIVE COUNSEL'S DIGEST

SB 1229, as amended, 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 maintaining a secure drug take-back bin on its premises if the collector, ~~in good faith~~ *and not for compensation, takes 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.

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

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

1 SECTION 1. (a) The Legislature finds and declares the
 2 following:
 3 (1) On October 12, 2010, the federal Secure and Responsible
 4 Drug Disposal Act of 2010 (Public Law 111-273; hereafter referred
 5 to as the Disposal Act) was enacted. Before the Disposal Act,
 6 individuals who wanted to dispose of unused, unwanted, or expired
 7 pharmaceutical controlled substances had limited disposal options.
 8 The federal Controlled Substances Act (21 U.S.C. Sec. 801 et seq.;
 9 hereafter referred to as the CSA) only permitted individuals to
 10 destroy those substances themselves (e.g., by flushing or
 11 discarding), surrender them to law enforcement, or seek assistance
 12 from the federal Drug Enforcement Administration (DEA). These
 13 restrictions resulted in the accumulation of pharmaceutical
 14 controlled substances in household medicine cabinets that were
 15 available for abuse, misuse, diversion, and accidental ingestion.
 16 The Disposal Act amended the CSA to authorize specified
 17 individuals, referred to as “ultimate users,” to deliver their
 18 pharmaceutical controlled substances to another person for the
 19 purpose of disposal in accordance with regulations promulgated
 20 by the United States Attorney General.
 21 (2) On September 9, 2014, the DEA issued its final rule
 22 governing the secure disposal of controlled substances by
 23 registrants and ultimate users. Those regulations implement the
 24 Disposal Act by expanding the options available to collect
 25 controlled substances from ultimate users for the purpose of
 26 disposal, including take-back events, mail-back programs, and
 27 collection receptacle locations. Those regulations, among other
 28 things, allow authorized manufacturers, distributors, reverse
 29 distributors, narcotic treatment programs, hospitals/clinics with
 30 an ~~on-site~~ *onsite* pharmacy, and retail pharmacies to voluntarily
 31 administer mail-back programs and maintain collection receptacles.

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

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

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

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

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

19 1714.24. (a) For purposes of this section, the following
20 definitions shall apply:

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

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

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

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

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

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

13 (b) Any collector that maintains a secure drug take-back bin
14 shall not be liable in a civil action, or be subject to criminal
15 prosecution, for maintaining a secure drug take-back bin on its
16 premises if the collector, *not for compensation, acts* in good faith
17 ~~and not for compensation, takes to take~~ all of the following steps
18 to ensure the health and safety of consumers and employees and
19 the proper disposal in the waste stream of the home-generated
20 pharmaceutical waste contained in a secure drug take-back bin:

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

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

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

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

39 (5) Ensures that public access to the secure drug take-back bin
40 is limited to hours in which employees of the registered collector

1 are present and able to monitor the operation of the secure drug
2 take-back bin.

3 (6) Regularly inspects the area surrounding the secure drug
4 take-back bin for potential tampering or diversion. Record logs of
5 those inspections shall be maintained and retained for two years,
6 reflecting the date and time of the inspection, and the initials of
7 the employee inspecting the area. *The logs shall be maintained in*
8 *writing or electronically and may be combined with logs required*
9 *by state or federal regulations. The logs may be used to*
10 *demonstrate regular inspection of the area.* Other records or reports
11 mandated by federal or state regulations shall also be retained for
12 a minimum of two years unless regulations mandate a longer
13 period.

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

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

24 (c) The protection specified in subdivision (b) shall not apply
25 in a case of personal injury or wrongful death that results from the
26 collector's gross negligence or willful or wanton misconduct in
27 maintaining a secure drug take-back bin.

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