

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, and to add Sections 117670.5, 117748, and 118312 to the Health and Safety Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 1229, as amended, Jackson. ~~Pharmacies:—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.

~~This bill would require a pharmacy that owns or operates a secure drug take-back bin, as defined, in a publicly accessible location to take reasonable steps to ensure the proper disposal of the pharmaceutical waste contained in the bins. The bill would provide that the owner or operator is not liable for civil damages arising from the use of the secure drug take-back bin if the owner or operator takes reasonable steps, as specified, to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of the pharmaceutical waste contained in the bins. By expanding the application of a crime, the 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.~~

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 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: ~~yes-no~~. State-mandated local program: ~~yes-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*
 5 *referred to as the Disposal Act) was enacted. Before the Disposal*
 6 *Act, individuals who wanted to dispose of unused, unwanted, or*
 7 *expired pharmaceutical controlled substances had limited disposal*
 8 *options. The federal Controlled Substances Act (21 U.S.C. Sec.*
 9 *801 et seq.; hereafter referred to as CSA) only permitted*
 10 *individuals to destroy those substances themselves (e.g., by flushing*
 11 *or discarding), surrender them to law enforcement, or seek*
 12 *assistance from the federal Drug Enforcement Agency (DEA).*
 13 *These 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*

1 individuals, referred to as “ultimate users,” to deliver their
2 pharmaceutical controlled substances to another person for the
3 purpose of disposal in accordance with regulations promulgated
4 by the United States Attorney General.

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

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

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

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

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

30 1714.24. (a) For purposes of this section, the following
31 definitions shall apply:

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

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

1 *compensate for the costs incurred in obtaining, installing, or*
2 *maintaining a secure drug take-back bin.*

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

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

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

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

22 (b) *Any collector that maintains a secure drug take-back bin,*
23 *in good faith and not for compensation, shall not be liable in a*
24 *civil action, or be subject to criminal prosecution, for maintaining*
25 *a secure drug take-back bin on its premises if the collector takes*
26 *all of the following steps to ensure the health and safety of*
27 *consumers and employees and the proper disposal in the waste*
28 *stream of the home-generated pharmaceutical waste contained in*
29 *a secure drug take-back bin:*

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

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

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

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

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

13 (6) Regularly inspects the area surrounding the secure drug
14 take-back bin for potential tampering or diversion. Record logs
15 of those inspections shall be maintained and retained for four
16 years, reflecting the date and time of the inspection, and the initials
17 of the employee inspecting the area. Other records or reports
18 mandated by federal or state regulations shall also be retained
19 for a minimum of four years unless regulations mandate a longer
20 period.

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

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

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

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

38 ~~SECTION 1. (a) It is the intent of the Legislature to encourage~~
39 ~~the good faith participation of pharmacies in hosting secure drug~~
40 ~~take-back bins on their premises for the convenience and public~~

1 health and safety of prescription drug consumers and the proper
2 disposal in the waste stream of the pharmaceutical waste contained
3 in the bins.

4 (b) It is the intent of the Legislature to prescribe the standards
5 of reasonable care necessary for pharmacies that host secure drug
6 take-back bins on their premises.

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

8 1714.24. Any pharmacy that owns or operates a secure drug
9 take-back bin in a publicly accessible location shall not be liable
10 for civil damages arising from the use of the secure drug take-back
11 bin if the owner or operator takes reasonable steps pursuant to
12 Section 118312 of the Health and Safety Code to ensure the health
13 and safety of consumers and employees and the proper disposal
14 in the waste stream of the pharmaceutical waste contained in the
15 bins.

16 SEC. 3. Section 117670.5 is added to the Health and Safety
17 Code, to read:

18 117670.5. “Home-generated pharmaceutical waste” means a
19 pharmaceutical that is a waste generated by a household or
20 households.

21 SEC. 4. Section 117748 is added to the Health and Safety Code,
22 to read:

23 117748. “Secure drug take-back bin” means a receptacle that
24 can receive home-generated pharmaceutical waste, that employs
25 a locking mechanism that requires the hazardous waste hauler and
26 the bin owner or operator to use two, nonidentical keys
27 simultaneously to access the contents of the bin, and that is secured
28 to a wall or the ground.

29 SEC. 5. Section 118312 is added to the Health and Safety Code,
30 to read:

31 118312. Any pharmacy that owns or operates a secure drug
32 take-back bin in a publicly accessible location shall take reasonable
33 steps to ensure the proper disposal in the waste stream of the
34 pharmaceutical waste contained in the bins.

35 SEC. 6. No reimbursement is required by this act pursuant to
36 Section 6 of Article XIII B of the California Constitution because
37 the only costs that may be incurred by a local agency or school
38 district will be incurred because this act creates a new crime or
39 infraction, eliminates a crime or infraction, or changes the penalty
40 for a crime or infraction, within the meaning of Section 17556 of

1 ~~the Government Code, or changes the definition of a crime within~~
2 ~~the meaning of Section 6 of Article XIII B of the California~~
3 ~~Constitution.~~

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