COUNTY OF SANTA BARBARA
LEGISLATIVE ANALYSIS FORM

This form is required for the Legislative Program Committee to consider taking an advocacy position on an issue or legislative item.

<table>
<thead>
<tr>
<th>BILL NUMBER:</th>
<th>AUTHOR:</th>
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<tbody>
<tr>
<td>SB 1229</td>
<td>Senators Jackson and Stone</td>
</tr>
<tr>
<td>INTRO/AMEND DATE:</td>
<td></td>
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<tr>
<td>February 18, 2016</td>
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<td>BILL STATUS:</td>
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<tr>
<td>Set for hearing in the Senate Environmental Quality Committee on April 6, 2016</td>
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<td>BILL SUBJECT:</td>
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<tr>
<td>Secure drug take-back bins in pharmacies</td>
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<td>FROM DEPARTMENT:</td>
<td></td>
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<tr>
<td>Public Health and Public Works</td>
<td></td>
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<tr>
<td>IS THIS ITEM SPECIFICALLY REFERENCED IN THE LEGISLATIVE PLATFORM?</td>
<td>No</td>
</tr>
<tr>
<td>WHICH POLICY-RELATED MATTER IS OF CONCERN WITH THIS BILL?</td>
<td>Public Safety: Safe disposal of leftover household-generated medications</td>
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<tr>
<td>HOW WOULD THIS BILL IMPACT THE COUNTY? (Current practices, responsibility, authority, pros/cons, affected programs and/or services, etc.)</td>
<td>The Public Health Department is currently drafting an Extended Producer Responsibility (EPR) ordinance that would provide for a safe, convenient, and sustainable program for the collection of unwanted household medications in our county. The proposed program would place a high priority on recruiting local pharmacies as public collection sites. SB 1229 would aid in the recruitment process by providing liability protections for pharmacies that host take-back bins. Furthermore, as more community members bring their leftover medications back to local pharmacies, it is possible that fewer medications will be disposed of through the County’s Operation Medicine Cabinet program, which could result in cost savings to the County. A number of other counties in the state have already adopted EPR ordinances and would similarly benefit from this proposed legislation.</td>
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<tr>
<td>IMPACT ON COUNTY PROGRAM:</td>
<td>□ Major □ Minor □ None</td>
</tr>
<tr>
<td>SANTA BARBARA COUNTY IMPACT:</td>
<td>□ Major □ Minor □ None</td>
</tr>
<tr>
<td>STATEWIDE IMPACT:</td>
<td>□ Major □ Minor □ None</td>
</tr>
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Explanation of Impacts:
Current county program has limited drop off sites through Sheriff. New legislation would expand number of sites and opportunities for our residents to safely dispose of unused medications. Costs for the current program with Sheriff would be assumed by third party.

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<tr>
<th>WOULD THIS BILL IMPACT:</th>
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<tbody>
<tr>
<td>a. Efficient service delivery and operations?</td>
<td>□ YES □ NO</td>
</tr>
<tr>
<td>b. Fiscal stability?</td>
<td>□ YES □ NO</td>
</tr>
</tbody>
</table>
c. Inter-agency cooperation? YES ☐ NO ☒
d. Local control? YES ☐ NO ☒
e. Protection of safety net services? YES ☐ NO ☒
f. Community sustainability/economic stability? YES ☒ NO ☐

Additional Comments:
The issue of safe disposal of medications and an extended producer responsibility ordinance has been heard by the Board of Supervisors on two occasions in 2015. We anticipate bringing this draft ordinance forward to the Board of Supervisors in the next few months.

8) FISCAL IMPACT ON THE COUNTY:
☐ Revenue Increase ☐ Revenue Decrease
☐ Cost Increase ☐ Cost Decrease
☐ None ☒ Undetermined

Additional Comments:

9) OTHER AGENCIES THAT SHOULD REVIEW THIS BILL:

Please list other agencies below:
Sheriff, Behavioral Wellness

10) CSAC POSITION ON BILL:
☐ Support ☐ Oppose
☐ Oppose unless Amended ☐ Watch
☐ Support if Amended ☒ No position taken

11) OTHER LOCAL OR STATEWIDE ORGANIZATIONS THAT HAVE TAKEN A POSITION ON THIS BILL:
(Indicate support or opposition for each)
California Product Stewardship Council (support); San Luis Obispo County Integrated Waste Management Authority (support)

12) PROPOSED AMENDMENTS: (Attach separate sheet)

13) RECOMMENDATION:
☒ Active Support* ☐ Passive Support ☐ Support if Amended*
☒ Active Opposition* ☐ Passive Opposition ☐ Oppose unless Amended*
☐ Watch ☐ Concerns (Why? Explain in #6) ☐ No Position (Why?)
☐ No Change since Last Position

* Indicates that the department believes that the Board of Supervisors should take a formal position on this bill

Additional Comments:
14) LEGISLATIVE ANALYSIS FORM PREPARED BY: Susan Klein-Rothschild and Leslie Robinson

Telephone extension:  5435

E-mail address:  skl@sbcpd.org
SUMMARY

In order to help protect the public from prescription drug abuse and to protect water quality from home-generated pharmaceutical waste, SB 1229 would encourage pharmacies to host secure drug take-back bins by:

1. Establishing a duty of care for the proper oversight of secure drug take-back bins.
2. Providing limited civil and criminal liability immunity for pharmacies hosting drug take-back bins if they meet that duty of care.

BACKGROUND

Home-generated pharmaceutical waste (i.e., prescription or over-the-counter human or veterinary drugs that are “left over” from treatment or have expired), has become an increasing problem nationwide and in California. With the rise of prescription drug abuse, these excess drugs—often stored in medicine cabinets or under sinks for years—have found their way into recreational use by teens or are otherwise misused by seniors or others. People taking un-prescribed or expired drugs are creating a growing public health and safety risk. Without a safe means of disposal, many people with excess drugs are turning to throwing them in the trash or flushing them in a toilet. This creates serious problems with soil and water quality, especially since our water treatment plants are not capable of removing pharmaceuticals from wastewater.

Law enforcement and pioneering pharmacies concerned with public safety and environmental health have been hosting drug take-back programs and bins voluntarily. These early efforts are laudable, but the scope of these drug take-back options has remained relatively small in relation to the demand for convenient and safe disposal. Many pharmacies have raised concerns regarding potential liability as the reason behind their reluctance to host a drug take-back bin.

A number of California counties have either adopted, are in the process of adopting, or have explored adopting ordinances requiring pharmaceutical manufacturers to develop and operate prescription drug take-back programs. Alameda County was the first in California to do so and has been followed by the City and County of San Francisco, and the Counties of Marin, Santa Clara, San Mateo, and Santa Cruz. Los Angeles and Santa Barbara Counties are considering adopting such ordinances. Many, but not all, of these ordinances rely on pharmacies voluntarily participating in the program by hosting secure drug take-back bins. More recently, the Supreme Court declined to hear a challenge to Alameda County’s drug take-back ordinance, which upheld the Ninth Circuit decision that it is constitutional for Alameda County to require pharmaceutical manufacturers to fund drug take-back programs within its borders.

In the first ongoing national effort of its kind by a retailer, Walgreen’s announced in early February that it will install drug take-back “kiosks” in more than 500 locations in 39 states, including California, primarily at locations open 24 hours. The program will make the disposal of medications—including opioids and other controlled substances—easier and more convenient while helping to reduce the misuse of medications and the rise in overdose deaths. The program will be provided at no cost to consumers.

SOLUTION

SB 1229 would establish a duty of care for pharmacies that host drug take-back bins. If a pharmacy hosting a drug take-back bin meets the minimum standards in taking reasonable care established by SB 1229—whether hosting the bin is voluntary or is required by a local ordinance—then SB 1229 would grant limited civil and criminal liability immunity to that pharmacy. This should eliminate the concerns raised by many pharmacies regarding liability and encourage their voluntary participation in hosting secure drug take-back bins.

CONTACT

Linda Barr, Legislative Director
David Ernest Garcia, Ph.D., Legislative Consultant
Office of Senator Hannah-Beth Jackson; (916) 651-4019;
Linda.Barr@sen.ca.gov; David.E.Garcia@sen.ca.gov
Senate Bill 1229
Pharmacies: Secure Drug Take-Back Bins
Senators Jackson & Stone

SUPPORT

California Product Stewardship Council (SPONSOR)
San Luis Obispo County Integrated Waste Management Authority
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


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.


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 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 Agency (DEA).

2. These restrictions resulted in the accumulation of pharmaceutical controlled substances in household medicine cabinets that were available for abuse, misuse, diversion, and accidental ingestion.

3. 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 on-site 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) To 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) To 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.

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 Agency 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 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, in good faith and not for compensation, shall not be liable in a civil action, or be subject to criminal prosecution, for maintaining a secure drug take-back bin on its premises if the collector takes 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:

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

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

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

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 four years, reflecting the date and time of the inspection, and the initials of the employee inspecting the area. Other records or reports mandated by federal or state regulations shall also be retained for a minimum of four years unless regulations mandate a longer period.

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.

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 Agency’s Registration Unit as otherwise required under federal laws and regulations.

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

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.

SECTION 1. (a) It is the intent of the Legislature to encourage the good faith participation of pharmacies in hosting 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.
(b) It is the intent of the Legislature to prescribe the standards
of reasonable care necessary for pharmacies that host secure drug
take-back bins on their premises.
SEC. 2. Section 1714.24 is added to the Civil Code, to read:
1714.24. Any pharmacy that owns or operates a secure drug
take-back bin in a publicly accessible location shall not be liable
for civil damages arising from the use of the secure drug take-back
bin if the owner or operator takes reasonable steps pursuant to
Section 118312 of the Health and Safety Code 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.
SEC. 3. Section 117670.5 is added to the Health and Safety
Code, to read:
117670.5. "Home-generated pharmaceutical waste" means a
pharmaceutical that is a waste generated by a household or
households.
SEC. 4. Section 117748 is added to the Health and Safety Code,
to read:
117748. "Secure drug take-back bin" means a receptacle that
can receive home-generated pharmaceutical waste, that employs
a locking mechanism that requires the hazardous waste hauler and
the bin owner or operator to use two, nonidentical keys
simultaneously to access the contents of the bin, and that is secured
to a wall or the ground.
SEC. 5. Section 118312 is added to the Health and Safety Code,
to read:
118312. Any pharmacy that owns or operates a secure drug
take-back bin in a publicly accessible location shall take reasonable
steps to ensure the proper disposal in the waste stream of the
pharmaceutical waste contained in the bins.
SEC. 6. No reimbursement is required by this act pursuant to
Section 6 of Article XIII B of the California Constitution because
the only costs that may be incurred by a local agency or school
district will be incurred because this act creates a new crime or
infraction, eliminates a crime or infraction, or changes the penalty
for a crime or infraction, within the meaning of Section 17556 of
the Government Code, or changes the definition of a crime within
the meaning of Section 6 of Article XIII B of the California
Constitution.