SB-212 Solid waste: pharmaceutical and sharps waste stewardship. (2017-2018)

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CALIFORNIA LEGISLATURE— 2017–2018 REGULAR SESSION

SENATE BILL No. 212

Introduced by Senator Jackson
(Principal coauthors: Assembly Members Gray and Ting)

February 01, 2017

An act to add Chapter 2 (commencing with Section 42030) to Part 3 of Division 30 of the Public Resources Code, relating to solid waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 212, Jackson. Solid waste: pharmaceutical and sharps waste stewardship.

The California Integrated Waste Management Act of 1989, administered by the Department of Resources Recycling and Recovery (CalRecycle), generally regulates the disposal, management, and recycling of solid waste.

Former law, repealed as of January 1, 2013, required CalRecycle to develop, in consultation with appropriate state, local, and federal agencies, model programs for the collection and proper disposal of pharmaceutical drug waste, and to make the model programs available to eligible participants, as specified.

Existing law, the Medical Waste Management Act administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Existing regulations authorize pharmacies, hospitals or clinics with onsite pharmacies, distributors, and reverse distributors licensed by the California State Board of Pharmacy to offer, subject to prescribed requirements, specified prescription drug take-back services through collection receptacles or mail back envelopes or packages to provide options for the public to discard unwanted, unused, or outdated prescription drugs.

This bill would establish a stewardship program, under which a manufacturer or distributor of covered drugs or sharps, or other entity defined to be covered by the bill, would be required to establish and implement, either on its own or as part of a group of covered entities through membership in a stewardship organization, a stewardship program for covered drugs or for sharps, as applicable. The bill would impose various requirements on a covered entity or stewardship organization that operates a stewardship program, including submitting a proposed stewardship plan, an initial stewardship program budget, an annual budget, annual report, and other specified information to CalRecycle. The bill would provide that all reports and records provided to CalRecycle pursuant to the bill are provided under penalty of perjury. By expanding the scope of the crime of perjury, the bill would impose a state-mandated local program. The bill would require proprietary information, as defined, submitted pursuant to the bill to be kept confidential.

The bill would require a stewardship plan for covered drugs to contribute to meeting specified minimum requirements for authorized collection sites in each county in which the plan will be implemented, including, as applicable, a minimum of one authorized collection site per 50,000 people in the county and a minimum of 5 collection sites in the county. The bill would authorize an operator of a stewardship program for covered drugs, if authorized by the department, after the stewardship plan has been approved, to establish a mail-back program or alternative collection program for covered products, or both, for a county in which it operates that does not have the minimum number of authorized collection sites, as specified. The bill would require a retail pharmacy to make a reasonable effort to serve as an authorized collector as part of a stewardship program for covered drugs and would require a retail pharmacy chain operating in a county to have at least one location or 15% of its store locations, whichever is greater, in the county serve as authorized collectors if the above-specified minimum authorized collection site requirements for the county are not met.

The bill would require each covered entity, either individually or through the stewardship organization of which it is a part, to pay all administrative and operational costs associated with establishing and implementing the stewardship program in which it participates. The bill would also require a covered entity to pay a quarterly administrative fee in the amount adequate to cover any regulatory costs incurred by a state agency in administering and enforcing the provisions of the bill, to be deposited in the Pharmaceutical and Sharps Stewardship Fund, which the bill would create. The bill would authorize moneys in the fund to be expended, upon appropriation by the Legislature, for the regulatory activities of state agencies of administering and enforcing the bill.

The bill would authorize CalRecycle to impose an administrative penalty on a covered entity, program operator, stewardship organization, or authorized collector that sells, offers for sale, or provides a covered product in violation of the bill's provisions, to be deposited in the Pharmaceutical and Sharps Stewardship Penalty Account, which the bill would create.

The bill would require CalRecycle to adopt regulations for the administration of the bill's provisions, with an effective date of no later than January 1, 2021, and would authorize the state board to adopt regulations for the administration of the portions of these provisions for which it has been given responsibilities.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

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.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Chapter 2 (commencing with Section 42030) is added to Part 3 of Division 30 of the Public Resources Code, to read:

CHAPTER 2. Pharmaceutical and Sharps Waste Stewardship
Article 1. Definitions

42030. For purposes of this chapter, the following terms have the following meanings:

(a) "Authorized collection site" means a location where an authorized collector operates a secure collection receptacle for collecting covered products.

(b) "Authorized collector" means a person or entity that has entered into an agreement with a program operator to collect covered drugs, including, but not limited to, any of the following:

(1) A person or entity that is registered with the United States Drug Enforcement Administration and that qualifies under federal law to modify that registration to collect controlled substances for the purpose of destruction.

(2) A law enforcement agency.

(3) A retail pharmacy that offers drug take-back services in compliance with Article 9.1 (commencing with Section 1776) of Title 16 of the California Code of Regulations.

(c) "Controlled substance" means a substance listed under Sections 11053 to 11058, inclusive, of the Health and Safety Code or Section 812 or 813 of Title 21 of the United States Code, or any successor section.

(d) "Cosmetic" means an article, or a component of an article, intended to be rubbed, poured, sprinkled, sprayed, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. "Cosmetic" includes articles with or without expiration dates.

(e) (1) "Covered drug" means a drug, including a brand name or generic drug, sold, offered for sale, or dispensed in the State of California in any form, including, but not limited to, any of the following:

(A) Prescription and nonprescription drugs approved by the United States Food and Drug Administration pursuant to Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or Section 351 of the federal Public Health Service Act (42 U.S.C. 262).

(B) A drug marketed pursuant to an over-the-counter drug monograph.

(C) A drug in a medical device, or a combination product containing a drug and a medical device.

(2) "Covered drug" does not include any of the following:

(A) Vitamins or supplements.

(B) Herbal-based remedies and homeopathic drugs, products, or remedies.

(C) Cosmetics, soap, with or without germicidal agents, laundry detergent, bleach, household cleaning products, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or any other personal care product that is regulated as both a cosmetic and a nonprescription drug under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.).

(D) A drug for which a pharmaceutical product stewardship program or drug takeback program is provided in the state as part of a United States Food and Drug Administration managed risk evaluation and mitigation strategy under 21 U.S.C. Sec. 355-1.

(E) Biological drug products, as defined by 42 U.S.C. 262(i)(1), including those products currently approved in the state under a new drug application that will be deemed to be licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to Section 7002(e) of the federal Biologics Price Competition and Innovation Act of 2009 (Public Law 111-148).

(F) A medical device, or a component part or accessory of a medical device, if it does not contain a covered drug.

(G) Drugs that are used for animal medicines, including, but not limited to, parasiticide products for animals.

(H) Dialysate drugs or other saline solutions required to perform kidney dialysis.

(f) (1) (A) "Covered entity" means the manufacturer of covered products that are sold in or into the state.

(B) If no entity that meets the definition in subparagraph (A) is in the state, "covered entity" means the distributor of covered products that are sold in or into the state that is licensed as a wholesaler, as defined in Section 4043 of the Business and Professions Code, but does not include a warehouse of a retail pharmacy chain that is licensed as

a wholesaler if it engages only in intracompany transfers between any division, affiliate, subsidiary, parent, or other entity under complete common ownership and control.

(C) If no entity that meets the definition in subparagraph (A) or (B) is in the state, "covered entity" means a repackager, as defined in Section 4044 of the Business and Professions Code, of covered products that are sold in or into the state.

(D) If no entity that meets the definition in subparagraph (A), (B), or (C) is in the state, "covered entity" means the owner or licensee of a trademark or brand under which covered products are sold in or into the state, regardless of whether the trademark is registered.

(E) If no entity that meets the definition in subparagraph (A), (B), (C), or (D) is in the state, "covered entity" means the importer of the covered products that are sold in or into the state.

(2) The department shall adopt regulations on the process for determining what entity is a covered entity following the priority order set forth in paragraph (1).

(g) "Covered product" means a covered drug or home-generated sharps waste.

(h) "Department" means the Department of Resources Recycling and Recovery, and any successor agency.

(i) "Distributor" means a wholesaler, as that term is defined in Section 4043 of the Business and Professions Code.

(j) "Drug" means any of the following:

(1) An article recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias.

(2) A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

(3) A substance, other than food, intended to affect the structure or any function of the body of humans or other animals.

(4) A substance intended for use as a component of any substance specified in this subdivision.

(k) "Generic drug" means a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strengths, route of administration, quality, performance, characteristics, and intended use, though inactive ingredients may vary.

(l) (1) "Home-generated sharps waste" has the same meaning as defined in Section 117671 of the Health and Safety Code.

(2) "Home-generated sharps waste" does not include either of the following:

(A) Components manufactured for use with external ambulatory insulin pump therapy systems or continuous glucose monitoring systems, including, but not limited to, insulin infusion sets, glucose sensors that are sterile goods indicated for single subcutaneous use, sterile drug delivery channels indicated for single subcutaneous use, and injection ports.

(B) A biological product, as defined in Section 262(i)(1) of Title 42 of the United States Code, including a combination product, as defined in Section 3.2(e) of Title 21 of the Code of Federal Regulations.

(m) "Mail-back program" means a method of collecting covered products from ultimate users by using prepaid, preaddressed mailing envelopes as described in Section 1776.2 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations.

(n) "Nonprescription drug" means any drug that may be lawfully sold without a prescription.

(o) "Pharmacy" has the same meaning as defined in Section 4037 of the Business and Professions Code.

(p) "Prescription drug" means a drug, including, but not limited to, a controlled substance, that is required under federal or state law to be dispensed with a prescription, or is restricted to use by practitioners only.

(q) "Program operator" means a covered entity, or stewardship organization on behalf of a group of covered entities, that is responsible for operating a stewardship program in accordance with this chapter.

(r) "Proprietary information" means information that is all of the following:

(1) Submitted pursuant to this chapter.

(2) A trade secret, or commercial or financial information, that is privileged or confidential, and is identified as such by the entity providing the information to the department.

(3) Not required to be disclosed under any other law or any regulation affecting a covered product or covered entity.

(s) "Retail pharmacy" means an independent pharmacy, a supermarket pharmacy, a chain pharmacy, or a mass merchandiser pharmacy possessing a license from the state board to operate a pharmacy.

(t) "Retail pharmacy chain" means a retail pharmacy with five or more stores in the state.

(u) "Sharps" means hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications.

(v) "State board" means the California State Board of Pharmacy.

(w) "Stewardship organization" means an organization exempt from taxation under Section 501(c)(3) of the federal Internal Revenue Code of 1986 (21 U.S.C. 501(c)(3)) that is established by a group of covered entities in accordance with this chapter to develop, implement, and administer a stewardship program established pursuant to this chapter.

(x) "Stewardship plan," or "plan" means the plan for collecting and properly managing covered products that is developed by a covered entity or stewardship organization pursuant to this chapter.

(y) "Stewardship program" means a stewardship program for the collection, transportation, and disposal of covered products.

(z) "Ultimate user" means a state resident or other nonbusiness entity and includes a person who has lawfully obtained, and who possesses, a covered product, including a controlled substance, for his or her own use or for the use of a member of his or her household. "Ultimate user" does not include a needle exchange program established under Section 121349 of the Health and Safety Code, or a medical waste generator, as defined in Section 117705 of the Health and Safety Code.

Article 2. Covered Entities and Stewardship Organizations

42031. (a) (1) No later than 90 days after the effective date of this section, a covered entity shall provide a list of covered products, and a list and description of any drugs or sharps that are not covered products, that it sells or offers for sale in the state to the state board.

(2) A covered entity, or a stewardship organization on behalf of a group of covered entities, shall update the lists described in paragraph (1) and provide the updated lists to the state board on or before January 15 of each year or upon request of the department.

(b) No later than 90 days after the effective date of this section, a retail pharmacy that sells a covered product under its own label shall provide written notification to the state board identifying the covered entity from which the retail pharmacy obtains a covered product that the retail pharmacy sells under its store label.

(c) The state board shall verify the information received pursuant to subdivisions (a) and (b) and make it available to the department upon request.

(d) The state board may issue a letter of inquiry to any entity listed in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (f) of Section 42030. requesting a list of all drugs and sharps it distributes in California, regardless of whether the drugs or sharps are covered under this chapter, the name of the manufacturer of such products, and any additional information necessary to carry out this chapter. An entity that is issued a letter of inquiry pursuant to this subdivision shall respond in writing no later than 60 days after receipt of the letter. Responses to those inquiries may be shared with the department, but are otherwise deemed proprietary and exempt from disclosure. If the entity does not believe it is a covered entity for purposes of this chapter, it shall submit all of the following to the state board in response to the letter of inquiry:

(1) The basis for the claim that it is not a covered entity.

(2) A list of any drugs and sharps it sells, distributes, repackages, or otherwise offers for sale within the state.

(3) If applicable, the name and contact information of the person or entity from which it obtains a drug or sharp identified pursuant to paragraph (2).

(e) The state board shall obtain and verify and, within 30 days of receipt or upon request by the department, submit to the department a list of drugs and sharps sold or offered for sale in the state excluded from the definition of "covered drugs" pursuant to paragraph (2) of subdivision (e) of Section 42030 or excluded from the definition of "home-generated sharps waste" in subdivision (l) of Section 42030.

(f) Notwithstanding Section 42036.4, information submitted by the state board to the department under this chapter may include proprietary information.

(g) The state board shall notify the department if any covered entity or stewardship organization is in violation of this section for purposes of enforcement by the department.

42031.2. (a) The department shall adopt regulations for the implementation of this chapter with an effective date of no later than January 1, 2021.

(b) The state board may adopt regulations for the administration of the portions of this chapter for which it has been given responsibilities.

42031.4. (a) Except as specified in subdivision (d) of Section 42035, a covered entity is not in compliance with this chapter and is subject to penalties pursuant to Article 6 (commencing with Section 42035) if, commencing one year from the adoption of regulations pursuant to Section 42031.2, a covered product sold or offered for sale by the covered entity is not subject to an approved stewardship plan, which is submitted by the covered entity or by a stewardship organization that includes the covered entity, that has been approved by the department pursuant to Section 42032.

(b) In order to comply with the requirements of this chapter, a covered entity may establish and implement a stewardship program independently, or as part of a group of covered entities through membership in a stewardship organization exempt from taxation under Section 501(c)(3) of the federal Internal Revenue Code of 1986 (21 U.S.C. 501(c)(3)).

42031.6. (a) A program operator shall conduct a comprehensive education and outreach program intended to promote participation in the stewardship program. At a minimum, the education and outreach program shall do all of the following:

(1) Promote its stewardship program to ultimate users by providing signage for hospitals, pharmacies, and other locations, as necessary.

(2) Provide educational and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate users, and others, as necessary.

(3) Establish an Internet Web site that publicizes the location of authorized collectors and provides other information intended to promote the use of the stewardship program.

(4) Prepare and provide additional outreach materials not specified in this section, as needed to promote the collection and proper management of covered drugs and home-generated sharps waste.

(5) Encourage ultimate users to separate products that are not covered products from covered products, when appropriate, before submitting the covered products to an authorized collection site or mail-back program.

(b) A program operator shall not, as part of the education and outreach program, promote the disposal of a covered product in a manner inconsistent with the services offered to ultimate users by the stewardship program.

Article 3. Stewardship Plans

42032. (a) (1) Within six months of the adoption date of regulations by the department pursuant to Section 42031.2, a program operator shall submit to the department for approval a complete stewardship plan that meets the requirements of Section 42032.2 for the establishment and implementation of a stewardship program, in a format determined by the department.

(2) The department shall approve a proposed stewardship program if the program operator submits a completed plan that meets the requirements of this section.

(b) (1) Before submitting a stewardship plan to the department pursuant to this section, a program operator shall submit its proposed stewardship plan to the state board for review, and to any other applicable state agencies with areas of authority relative to the stewardship plan. The duration of time that the state board takes to review a stewardship plan pursuant to this paragraph shall not count toward the time limit specified in paragraph (1) of subdivision (a).

(2) An agency that receives a plan shall review the plan for compliance with state and federal laws and regulations related to the agency's respective authority. The agency shall determine compliance or noncompliance with those laws and regulations, and provide to the program operator that determination and an explanation for any finding of noncompliance, within 90 days of receipt of the plan.

(3) A program operator may submit an updated proposed plan to an agency that issued a determination of noncompliance to attempt to obtain a determination of compliance. A program operator shall submit any determination received from an agency when it submits its stewardship plan to the department.

(4) If, 90 days after submitting a plan to an applicable agency, a program operator has not received a response from the applicable agency, the program operator may submit a certification to the department that the stewardship plan is consistent with all other applicable laws and regulations.

(c) (1) The department shall determine if a stewardship plan is complete, including the determinations required pursuant to subdivision (b), and notify the submitting program operator within 30 days of receipt.

(2) If the department finds that the stewardship plan is complete, the department's 90-day review period for consideration of approval of the plan set forth in subdivision (d) shall commence upon the original date of receipt.

(3) If the department determines the stewardship plan is incomplete, the department shall identify for the program operator the required additional information, and the program operator shall resubmit the plan within 30 days.

(4) If the department determines upon resubmission that the stewardship plan is complete, the department's 90-day review period for consideration of approval of the plan shall commence upon the date of receipt of the resubmitted plan.

(d) (1) The department shall review a complete submitted stewardship plan and shall approve, disapprove, or conditionally approve the plan within 90 days of receipt of the complete plan.

(2) The department may consult with, or submit a stewardship plan for review to, the state board or another state agency it determines is necessary to determine the completeness of the stewardship plan or for making a determination on the approval of the stewardship plan or an amendment to the stewardship plan. The duration of time that the department takes to review a stewardship plan pursuant to this paragraph shall not count toward the 90-day time limit specified in paragraph (1).

(e) A program operator shall submit any significant changes to a stewardship plan in writing for approval by the department, and shall not implement the changes prior to that approval.

(f) (1) If the department disapproves a submitted stewardship plan pursuant to subdivision (d), the department shall explain, in writing within 30 days, how the plan does not comply with this chapter, and the program operator shall resubmit a revised plan to the department.

(2) If the department finds that the revised stewardship plan submitted by the program operator does not comply with the requirements of this chapter and disapproves the plan, the covered entity operating its own stewardship program, or the stewardship organization and the covered entities that are members of the stewardship organization, are not in compliance with this chapter until the program operator submits a plan that the department approves.

(g) A program operator shall fully implement operation of an approved stewardship program no later than 270 days after approval by the department of the stewardship plan that establishes the stewardship program.

(h) If a stewardship plan is revoked pursuant to subdivision (a) of Section 42035.4 or terminated by the program operator that submitted the plan, a covered entity no longer subject to that plan may, without being subject to penalties pursuant to Article 6 (commencing with Section 42035), sell or offer for sale covered products in the

state for a period of up to one year after the plan terminated or was revoked if the covered entity continues to operate under the most recent approved stewardship plan to which the covered entity was subject.

(i) The department shall make all stewardship plans submitted pursuant to this section available to the public, except proprietary information in the plans protected pursuant to Section 42036.4.

42032.2. (a) (1) To be complete, a stewardship plan for covered drugs shall do all of the following:

(A) Identify and provide contact information for the stewardship organization, if applicable, and each participating covered entity, and identify each covered drug sold or offered for sale by each participating covered entity.

(B) Identify and provide contact information for the authorized collectors for the stewardship program, as well as the reasons for excluding any potential authorized collectors from participation in the program.

(C) Include any determinations provided by a state agency pursuant to subdivision (b) of Section 42032. Any determination of noncompliance shall be accompanied by a superseding determination of compliance.

(D) Demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities.

(E) Provide for a handling, transport, and disposal system that complies with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration.

(F) Provide for a collection system that complies with the requirements of this chapter and meets all of the following requirements for authorized collection sites in each county in which the plan will be implemented:

(i) Provides for a minimum of five authorized collection sites or one authorized collection site per 50,000 people, whichever is greater.

(ii) Provides for a reasonable geographic spread of authorized collection sites and an explanation for the geographic spread.

(iii) Provides for a mail-back program covering any counties where there is not an authorized retail pharmacy operating as an authorized collection site.

(G) Require a program operator to do all of the following:

(i) Permit an ultimate user who is a homeless, homebound, or disabled individual to request prepaid, preaddressed mailing envelopes, or an alternative form of a collection and disposal system, as described in paragraph (2) of subdivision (c), that would render the covered drug inert. A program operator shall accept that request through an Internet Web site and toll-free telephone number that it shall maintain to comply with the requests.

(ii) Provide alternative methods of collection from ultimate users for any covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs in secure collection receptacles or through a mail-back program, to the extent technically feasible and permissible under applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations.

(iii) (I) Provide a service schedule that meets the needs of each authorized collection site to ensure that each secure collection receptacle is serviced as often as necessary to avoid reaching capacity and that collected covered drugs are transported to final disposal in a timely manner. Additionally, a receipt or collection manifest shall be left with the authorized collection site to support verification of the service. The authorized collection site shall maintain and make available to the department this documentation.

(II) An authorized collector shall comply with applicable federal and state laws regarding collection and transportation standards, and the handling of covered drugs, including United States Drug Enforcement Administration regulations.

(H) Provide the policies and procedures for the safe and secure collection, transporting, and disposing of the covered drug, describe how and where records will be maintained and how, at a minimum, instances of security problems that occur will be addressed, and explain the processes that will be taken to change the policies, procedures, and tracking mechanisms to alleviate the problems and to improve safety and security.

(2) Paragraph (1) shall apply only with regard to covered drugs.

(b) (1) At least 120 days before submitting a stewardship plan to the department, the operator of a stewardship program for covered drugs shall notify potential authorized collectors in the county or counties in which it operates of the opportunity to serve as an authorized collector for the proposed stewardship program. If a potential authorized collector expresses interest in participating in a stewardship program, the program operator shall commence good faith negotiations with the potential authorized collector within 30 days.

(2) A retail pharmacy shall make a reasonable effort to serve as an authorized collector as part of a stewardship program in the county in which it is located. If the minimum threshold described in clause (i) of subparagraph (F) of paragraph (1) of subdivision (a) is not met in each county in which a retail pharmacy chain has store locations, the retail pharmacy chain shall have at least one location or 15 percent of its store locations, whichever is greater, in that county serve as authorized collectors in a stewardship program.

(3) A program operator shall include as an authorized collector under its stewardship program any entity listed in subdivision (b) of Section 42030 that offers to participate in the stewardship program, in writing and without compensation, even if the minimum convenience standards set in clause (i) of subparagraph (F) of paragraph (1) of subdivision (a) have been achieved. The program operator shall include the offering entity as an authorized collector in the program within 90 days of receiving the written offer to participate. A program operator shall not be required to respond to offers pursuant to this paragraph until the program operator's stewardship plan has been approved by the department.

(c) After a stewardship plan for covered drugs has been approved, the program operator may supplement service, if approved by the department, for a county in which it operates that does not have the minimum number of authorized collection sites due to circumstances beyond the program operator's control, by establishing one or both of the following:

(1) A mail-back program. The mail-back program may include providing information on where and how to receive mail-back materials or providing the locations at which it distributes prepaid, preaddressed mailing envelopes. The program operator shall propose the locations of those envelope distribution locations as part of the stewardship plan. Prepaid mailing envelopes may be mailed to an ultimate user upon request.

(2) An alternative form of collection and disposal of covered drugs that complies with applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations.

(d) (1) To be complete, a stewardship plan for home-generated sharps waste shall do all of the following:

(A) Identify and provide contact information for the stewardship organization, if applicable, and each participating covered entity, and identify each covered product sold or offered for sale by each participating covered entity.

(B) Include any determinations provided by a state agency pursuant to subdivision (b) of Section 42032. Any determination of noncompliance shall be accompanied by a superseding determination of compliance.

(C) Demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities.

(D) Provide for a handling, transport, and disposal system, at no cost to the ultimate user, that complies with applicable state and federal laws.

(E) Maintain an Internet Web site and toll-free telephone number for purposes of providing information on the program, including disposal options, and to receive requests for sharps waste containers from ultimate users.

(F) Provide that a stewardship program for home-generated sharps waste shall be a mail-back program for home-generated sharps waste that complies with this chapter and that meets all the following requirements:

(i) The program provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law. Containers and mail-back materials shall be provided at no cost to the ultimate user. The program operator shall select and distribute a container and mail-back materials sufficient to accommodate the volume of sharps purchased by an ultimate user over a selected time period.

(I) For any sharps, the packaging, an insert or instructions, or separate information provided to the ultimate user shall include information on proper sharps waste disposal.

(II) All sharps waste containers shall include on a label affixed to the container or packaging, or on a separate insert included in the container or packaging, the program operator's Internet Web site and toll-free telephone number.

(III) All sharps waste containers shall include prepaid postage affixed to the container or to the mail-back packaging.

(ii) Upon request, the program provides for reimbursement to local agencies for disposal costs related to home-generated sharps waste, unless the program operator provides for the removal of the home-generated sharps waste from the local household hazardous waste facility.

(I) A local agency shall not knowingly request reimbursement for disposal expenses pursuant to this subparagraph for disposal costs resulting from a municipal needle exchange program or a medical waste generator.

(II) Reimbursement costs shall be limited to the actual costs of transportation from the household hazardous waste facility and for the actual costs of disposal.

(III) A request for reimbursement pursuant to this clause shall be submitted with a declaration under penalty of perjury that the local agency has not knowingly requested reimbursement for expenses prohibited by this section.

(IV) A cost is eligible for reimbursement pursuant to this clause if the cost is incurred 270 days or more after the approval of a stewardship plan for home-generated sharps waste.

(2) Paragraph (1) shall apply only with regard to home-generated sharps waste.

(e) A stewardship plan shall include provisions to expand into jurisdictions not included in the stewardship plan pursuant to Section 42036.2, in the event a jurisdiction repeals its local stewardship program ordinance.

(f) A stewardship plan shall include educational and outreach provisions to meet the requirements of Section 42031.6.

Article 4. Reports, Budgets, and Records

42033. With the submission of a stewardship plan, a program operator shall submit to the department an initial stewardship program budget for the first five calendar years of operation of its stewardship program that includes both of the following:

(a) Total anticipated revenues and costs of implementing the stewardship program.

(b) A total recommended funding level sufficient to cover the plan's budgeted costs and to operate the stewardship program over a multiyear period.

42033.2. (a) On or before March 31, 2022, and each year thereafter, a program operator shall prepare and submit to the department both of the following:

(1) A written report describing the stewardship program activities during the previous reporting period of one year.

(2) A written program budget for stewardship program implementation for the upcoming calendar year.

(b) An annual report submitted pursuant to paragraph (1) of subdivision (a) shall include, at a minimum, all of the following for the prior year:

(1) A list of covered entities participating in the stewardship organization.

(2) The updated and reverified list provided pursuant to paragraph (2) of subdivision (a) of Section 42031 of covered products that each covered entity subject to the stewardship plan sells or offers for sale.

(3) The amount, by weight, of covered products collected from ultimate users at each authorized collection site that is part of the stewardship program.

(4) For a stewardship plan for covered drugs, the name and location of authorized collection sites at which covered drugs were collected.

(5) For a stewardship plan for home-generated sharps waste, information on the mail-back program.

(6) Whether policies and procedures for collecting, transporting, and disposing of covered products, as established in the stewardship plan, were followed during the reporting period and a description of each instance of noncompliance, if any occurred.

(7) Whether any safety or security problems occurred during collection, transportation, or disposal of collected covered products during the reporting period and, if so, what changes have been or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security.

(8) How the program operator complied with all elements in its stewardship plan.

(9) Any other information the department reasonably requires.

(c) An annual program budget submitted pursuant to paragraph (2) of subdivision (a) shall include, at a minimum, both of the following for the upcoming calendar year:

(1) An independent financial audit of the stewardship program, as required by subdivision (b) of Section 42033.4, funded by the stewardship organization from the charge paid from its member covered entities pursuant to Section 42034 or by a covered entity if it operates its own stewardship program.

(2) Anticipated costs and the recommended funding level necessary to implement the stewardship program, including, but not limited to, costs to cover the stewardship plan's budgeted costs and to operate the stewardship program over a multiyear period in a prudent and responsible manner.

(d) (1) The department shall determine if a submitted annual report and program budget are complete and notify the submitting stewardship organization or covered entity within 30 days.

(2) If the department finds that an annual report and program budget are complete, the department's 90-day review period for consideration of approval of the annual report and program budget, set forth in subdivision (e), shall commence upon the original date of receipt.

(3) If the department determines either an annual report or a program budget is incomplete, the department shall identify for the program operator within 30 days the required additional information, and the program operator shall submit a revised annual report or program budget, as applicable, within 30 days.

(4) If the department determines upon resubmission that the annual report or program budget is complete, the department's 90-day review period for consideration of approval of the annual report or program budget shall commence upon the date of receipt of the resubmitted report or program budget.

(e) (1) The department shall review the annual report and program budget required pursuant to this section and within 90 days of receipt shall approve, disapprove, or conditionally approve the annual report and program budget.

(2) (A) If the department conditionally approves an annual report or program budget, the department shall identify the deficiencies in the annual report or program budget and the program operator shall comply with the conditions of the conditional approval within 60 days of the notice date, unless the Director of Resources Recycling and Recovery determines that additional time is needed.

(B) If the department conditionally approves an annual report or program budget and the conditions are not met within 60 days of the notice date, unless additional time is granted pursuant to subparagraph (A), the department shall disapprove the annual report or program budget.

(3) If the department disapproves an annual report or program budget, the department shall identify the deficiencies in the annual report or program budget and the program operator shall submit a revised annual report or program budget and provide any supplemental information requested within 60 days of the notice date.

42033.4. (a) A program operator shall keep minutes, books, and records that clearly reflect the activities and transactions of the program operator's stewardship program.

(b) (1) The minutes, books, and records of a program operator shall be audited at the program operator's expense by an independent certified public accountant retained by the program operator at least once each calendar year.

(2) A program operator shall arrange for the independent certified public accountant audit to be delivered to the department, along with the annual report and program budget submitted pursuant to subdivision (a) of Section 42033.2.

(3) The department may conduct its own audit of a program operator. The department shall review the independent certified public accountant audit for compliance with this chapter and consistency with the program operator's stewardship plan, annual report, and program budget submitted pursuant to this chapter. The

department shall notify the program operator of any conduct or practice that does not comply with this chapter or of any inconsistencies identified in the department's audit. The program operator may obtain copies of the department's audit, including proprietary information contained in the department's audit, upon request. The department shall not disclose any confidential proprietary information protected pursuant to Section 42036.4 that is included in the department's audit.

42033.5. For a local jurisdiction that requests removal of home-generated sharps waste or cost recovery or reimbursement for removal pursuant to Section 42032.2, the local jurisdiction shall provide information on home-generated sharps waste to the covered entity or program operator, within a reasonable time upon request by the covered entity or program operator.

42033.6. As part of the administration of this chapter, within 12 months of a program operator's submission of three consecutive complete annual reports submitted pursuant to Section 42033.2, the department shall develop, and post on its Internet Web site, a report analyzing whether the program operator's stewardship program provides adequate access to safe disposal of home-generated sharps waste or covered drugs, as applicable, to the ultimate user.

Article 5. Financial Provisions

42034. In order to further the objective that covered entities establish and implement stewardship programs that comply with the requirements of this chapter, each covered entity, either individually or through a stewardship organization, shall pay all administrative and operational costs associated with establishing and implementing the stewardship program in which it participates, including the cost of collecting, transporting, and disposing of covered products.

42034.2. (a) (1) On or before the end of the 2022–23 fiscal year, and once every three months thereafter, a program operator shall pay to the department an administrative fee. The department shall set the fee at an amount that, when paid by every covered entity, is adequate to cover the department's and any other state agency's full costs of administering and enforcing this chapter. The total amount of fees collected shall not exceed the state's actual and reasonable regulatory costs to implement and enforce this chapter. These costs may include the actual and reasonable costs associated with regulatory activities pursuant to this chapter before submission of stewardship plans pursuant to Section 42032.

(2) For a stewardship organization, the administrative fee paid pursuant to paragraph (1) shall be funded by the covered entities that make up the stewardship organization. This administrative fee shall be in addition to the charge paid pursuant to Section 42034. A stewardship organization may require its participating covered entities to pay the administrative fee and the charge paid pursuant to Section 42034 at the same time.

(b) The department shall deposit administrative fees paid by a program operator pursuant to subdivision (a) into the Pharmaceutical and Sharps Stewardship Fund, which is hereby established. Upon appropriation by the Legislature, moneys in the fund may be expended by the department, the state board, and any other agency that assists in the regulatory activities of administering and enforcing this chapter. Upon appropriation by the Legislature, moneys in the fund may be used for those regulatory activities and to reimburse any outstanding loans made from other funds used to finance the startup costs of the department's activities pursuant to this chapter. Moneys in the fund shall not be expended for any purpose not enumerated in this chapter.

42034.4. (a) (1) A stewardship organization may conduct an audit of covered entities that are required to remit a charge or administrative fee to the stewardship organization pursuant to Sections 42034 and 42034.2 to verify that the administrative fees and charges paid are proper and accurate. In addition, a stewardship organization may conduct an audit of authorized collectors to verify the charges submitted are proper and accurate.

(2) The purpose of the audits described in paragraph (1) is to ensure parties required by this chapter to pay or collect an administrative fee or charge are paying or collecting the proper amount to implement the program.

(b) If a stewardship organization conducts an audit pursuant to subdivision (a), it shall do all of the following:

(1) Conduct the audit in accordance with generally accepted auditing practices.

(2) Limit the scope of the audit of covered entities to confirming whether a charge or administrative fee has been properly paid by the covered entities.

(3) Hire an independent third-party auditor to conduct the audit.

(4) Provide a copy of the audit to the department.

Article 6. Enforcement

42035. (a) (1) On or before June 30, 2022, and at least annually thereafter, the department shall post on its Internet Web site a list of stewardship organizations, including entities with an approved stewardship plan, and covered entities, authorized collection sites, retail pharmacies, and retail pharmacy chains provided in the stewardship plans that are in compliance with this chapter.

(2) The state board shall coordinate with the department to verify that the list posted pursuant to paragraph (1) is consistent with the information submitted to each agency pursuant to Section 42031.

(b) A covered entity or stewardship organization that is not listed on the department's Internet Web site pursuant to subdivision (a), but demonstrates compliance with this chapter before the department is required to post the following year's list pursuant to subdivision (a), may request a certification letter from the department stating that the covered entity or stewardship organization is in compliance with this chapter. A covered entity or stewardship organization that receives a certification letter shall be deemed to be in compliance with this chapter.

(c) A distributor or wholesaler of covered products, and a pharmacy or other retailer that sells or offers for sale a covered product, shall monitor the department's Internet Web site to determine which covered entities and stewardship organizations are in compliance with this chapter. The distributor or wholesaler and the pharmacy or other retailer shall notify the department if it determines that a covered product that it sells or offers for sale is from a covered entity that is not listed on the department's Internet Web site.

(d) The sale, distribution, or offering for sale of any inventory that was in stock before the commencement of a stewardship program is exempt from this chapter and not required to be subject to a stewardship plan.

(e) If the department determines a covered entity or stewardship organization is not in compliance with this chapter, the department shall remove the entity from the list maintained on the department's Internet Web site pursuant to subdivision (a).

42035.2. (a) (1) The department may impose an administrative penalty on any covered entity, program operator, stewardship organization, or authorized collector that sells, offers for sale, or provides a covered product in violation of this chapter.

(2) The amount of the administrative penalty imposed pursuant to this subdivision shall not exceed ten thousand dollars ($10,000) per day unless the violation is intentional, knowing, or reckless, in which case the administrative penalty shall not exceed fifty thousand dollars ($50,000) per day.

(b) The department shall not impose a penalty on a program operator pursuant to this section for failure to comply with this chapter if the program operator demonstrates it received false or misleading information that contributed to its failure to comply, including, for a stewardship organization, from a participating covered entity.

(c) The department shall deposit all penalties collected pursuant to this section in the Pharmaceutical and Sharps Stewardship Penalty Account, which is hereby created in the Pharmaceutical and Sharps Stewardship Fund established in Section 42034.2. Upon appropriation by the Legislature, moneys in the Pharmaceutical and Sharps Stewardship Penalty Account may be expended by the department on activities including, but not limited to, the promotion of safe handling and disposal of covered products, grants for related purposes, and the administration and enforcement this chapter.

42035.4. Upon a written finding that a covered entity, program operator, stewardship organization, or authorized collector has not met a material requirement of this chapter, in addition to any other penalties authorized under this chapter, the department may take one or both of the following actions to ensure compliance with the requirements of this chapter, after affording the covered entity, stewardship organization, or authorized collector a reasonable opportunity to respond to, or rebut, the finding:

(a) Revoke the program operator's stewardship plan approval or require the program operator to resubmit the plan.

(b) Require additional reporting relating to compliance with the material requirement of this chapter that was not met.

42035.6. (a) A covered entity, stewardship organization, program operator, retail pharmacy, or retail pharmacy chain shall do both of the following:

(1) Upon request, provide the department with reasonable and timely access, as determined by the department, to its facilities and operations, as necessary to determine compliance with this chapter.

(2) Upon request, provide the department with relevant records necessary to determine compliance with this chapter.

(b) A covered entity, stewardship organization, program operator, retail pharmacy, or retail pharmacy chain shall maintain and keep accessible all records required to be kept or submitted pursuant to this chapter for a minimum of three years.

(c) All reports and records provided to the department pursuant to this chapter shall be provided under penalty of perjury.

(d) The department may take disciplinary action against a covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain that fails to provide the department with the access to information required pursuant to this section, including one or both of the following:

(1) Imposing an administrative penalty pursuant to Section 42035.2.

(2) Posting a notice on the department's Internet Web site, in association with the list that the department maintains pursuant to paragraph (1) of subdivision (a) of Section 42035, that the covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain is no longer in compliance with this chapter.

(e) The department shall not prohibit as a disciplinary action a covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain from selling a covered product.

42035.8. All handling, transport, and disposal undertaken as part of a stewardship program under this chapter shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration.

Article 7. Miscellaneous Provisions

42036. (a) Except as provided in subdivision (c), an action specified in subdivision (b) that is taken by a stewardship organization or a covered entity pursuant to this chapter is not a violation of the Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code), the Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code), or the Unfair Competition Law (Chapter 5 (commencing with Section 17200) of Part 2 of Division 7 of the Business and Professions Code).

(b) Subdivision (a) shall apply to all of the following actions taken by a stewardship organization or covered entity:

(1) The creation, implementation, or management of a stewardship plan approved by the department pursuant to Article 3 (commencing with Section 42032) and the determination of the types or quantities of covered products collected or otherwise managed pursuant to a stewardship plan.

(2) The determination of the cost and structure of an approved stewardship plan.

(3) The establishment, administration, collection, or disbursement of the charge or administrative fee imposed pursuant to Section 42034 or 42034.2, respectively.

(c) Subdivision (a) shall not apply to an agreement that does any of the following:

(1) Fixes a price of or for covered products, except for an agreement related to costs, charges, or administrative fees associated with participation in a stewardship plan approved by the department and otherwise in accordance with this chapter.

(2) Fixes the output of production of covered products.

(3) Restricts the geographic area in which, or customers to whom, covered products are sold.

42036.2. (a) This chapter does not apply to a drug or sharp within a jurisdiction that is subject to a local stewardship program pursuant to an ordinance that took effect before April 18, 2018. If that ordinance is repealed in the jurisdiction or, if more than one ordinance is applicable, those ordinances are repealed in the jurisdiction, the drug or sharp shall be subject to this chapter in that jurisdiction within 270 days after the date on which the ordinance is, or ordinances are, repealed.

(b) This chapter shall preempt a local stewardship program for drugs or sharps enacted by an ordinance or ordinances with an effective date on or after April 18, 2018.

(c) A local stewardship program for covered products enacted by an ordinance that has an effective date before April 18, 2018, may continue in operation, but the program and its participants shall not receive or benefit from moneys from the Pharmaceutical and Sharps Stewardship Fund or the Pharmaceutical and Sharps Stewardship Penalty Account, including, but not limited to, for administrative or enforcement costs. Participants of a local stewardship program for covered products enacted by an ordinance that has an effective date before April 18, 2018, shall be eligible to participate in a stewardship program under this chapter and thereby become eligible to receive funds from the Pharmaceutical and Sharps Stewardship Fund or the Pharmaceutical and Sharps Stewardship Penalty Account only if the local stewardship program is dissolved.

42036.4. Proprietary information submitted to the department under this chapter shall be protected by all parties as confidential and shall be exempt from public disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code). The department and other parties may only disclose proprietary information in an aggregated form that does not directly or indirectly identify financial, production, or sales data of an individual covered entity or stewardship organization. Proprietary information may be disclosed to the party that submitted the proprietary information.

SEC. 2. The Legislature finds and declares that Section 1 of this act, which adds Section 42036.4 to the Public Resources Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

In order to ensure that the competitive market in the state for the manufacture and sale of drugs and sharps is not compromised, it is necessary that proprietary information collected for the purpose of administering a stewardship program be confidential.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB 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 XIIIB of the California Constitution.