AMENDED IN ASSEMBLY JUNE 18, 2018

SENATE BILL No. 212

Introduced by Senator Jackson
(Principal coauthor: Assembly Member Gray)

February 1, 2017

An act to add ~~Section 117670.1 to the Health and Safety Code, relating to medical waste.~~ *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, as amended, Jackson. ~~Medical waste.~~ *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Former law, repealed as of January 1, 2013, required CalRecycle to develop, in consultation with appropriate state, local, and federal agencies, model programs for the collection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mail back envelopes or packages, to provide options for the public to discard unwanted, unused, or outdated prescription drugs.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 add to the act a definition of "home-generated pharmaceutical waste" as a prescription or over-the-counter human or veterinary home-generated pharmaceutical that is waste and is derived from a household, including, but not limited to, a multifamily residence or household.~~

This bill would establish a pharmaceutical and sharps waste stewardship program, under which each manufacturer of covered drugs or sharps, as defined, in the state would be required to establish and implement, either on its own or as part of a group of covered manufacturers through membership in a pharmaceutical and sharps waste stewardship organization, a pharmaceutical and sharps waste stewardship program. The bill would impose various requirements on a covered manufacturer or stewardship organization that operates a stewardship program, including submitting an initial stewardship plan, and 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 the State Department of Public Health, the state board, the Department of Toxic Substances Control, and other state agencies with authority or expertise relative to pharmaceutical and sharps waste stewardship, as determined by CalRecycle, to accept and verify specified information from program operators and retail pharmacies under the 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 to contribute to meeting specified minimum requirements for authorized collection sites in the county in which the plan will be implemented, including a minimum of one authorized collection site per 50,000 people in the county, as applicable, and a minimum of 5 collection sites in the county. The bill would require a program operator in a county that does not meet those minimum requirements, as determined by CalRecycle, in consultation with the public health department of the county, to establish either a mail-back program or alternative collection program for covered products, as specified. By imposing new requirements on county public health departments, the bill would impose a state-mandated local program. The bill would require a retail pharmacy to make a reasonable

effort to serve as an authorized collector as part of a stewardship program and would require a retail pharmacy chain to have at least 15% of its store locations serve as authorized collectors if the above-specified minimum authorized collection site requirements for a county are not met.

The bill would require each covered manufacturer, 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 manufacturer 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 regulatory activities of state agencies of administering and enforcing the bill.

The bill would authorize CalRecycle to impose a civil penalty on a covered manufacturer, stewardship organization, authorized collector, retail pharmacy, or retail pharmacy chain 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 administration of the bill's provisions.

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 with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains

costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~ *yes*. State-mandated local program: ~~no~~ *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 products, 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) An entity authorized by the state board or the State Department of Public Health to provide an alternative collection mechanism under the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104 of the Health and Safety Code) for covered products that are not controlled substances.

(4) Retail pharmacies.

(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.

(D) A drug for veterinary use.

(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 cosmetics and nonprescription drugs 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 device subject to a collection and disposal plan as described in Section 47115.

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

(f) "Covered manufacturer" means a person, corporation, or other entity engaged in the manufacture of covered products sold, offered for sale, or introduced into the State of California.

(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) "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.

(j) "Generic drug" means a drug that is chimerically 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.

(k) "Home-generated sharps waste" has the same meaning as defined in Section 117671 of the Health and Safety Code. "Home-generated sharps waste" does not include biological products, as defined by 42 U.S.C. 262(i)(1).

(l) "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.

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

(n) "Pharmaceutical and sharps stewardship organization" or "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 manufacturers in accordance with this chapter to develop, implement, and administer a stewardship program established pursuant to this chapter.

(o) "Pharmaceutical and sharps stewardship plan," "stewardship plan," or "plan" means the plan for collecting and properly managing covered products that is developed by a covered manufacturer or pharmaceutical and sharps stewardship organization pursuant to this chapter.

(p) "Pharmaceutical and sharps stewardship program" or "stewardship program" means a stewardship program for the collection, transportation, and disposal of covered products.

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

(r) "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.

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

(t) "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 manufacturer.

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

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

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

(x) "Ultimate user" means a state resident or other nonbusiness entity and includes an ultimate user, as defined by regulations adopted by the United States Drug Enforcement Administration pursuant to 21 U.S.C. 802(27). "Ultimate user" does not include a business generator of pharmaceutical waste, such as a hospital, clinic, health care provider's office, veterinary clinic, pharmacy, or law enforcement agency.

Article 2. Covered Manufacturers and Pharmaceutical and Sharps Stewardship Organizations

42031. (a) (1) No later than 90 days after the effective date of this section, a covered manufacturer 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 and the State Department of Public Health.

(2) A covered manufacturer, or a stewardship organization on behalf of a group of covered manufacturers, shall update the lists described in paragraph (1) and provide the updated lists to the state board and the State Department of Public Health on or before January 15 of each year.

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

(c) The state board and the State Department of Public Health, either separately or together, shall verify the information received pursuant to subdivisions (a) and (b) and make it available to the department within six months of receipt.

(d) The state board or the State Department of Public Health may issue a letter of inquiry to a manufacturer of drugs or sharps regarding whether it is a covered manufacturer. A person or entity that receives a letter of inquiry from the state board or the State Department of Public Health shall respond in writing no later than 60 days after receipt of the letter. If the person or entity does not believe it is a covered manufacturer for purposes of this

chapter, it shall submit all of the following to the agency that issued the letter of inquiry:

(1) The basis for the belief that it is not a covered manufacturer.

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

(3) If applicable, the name and contact information of the manufacturer of the covered products from which it obtains a drug identified pursuant to subdivision (b).

(e) The state board and the State Department of Public Health shall obtain, verify, and submit the following information to the department by ____:

(1) A list of drugs and sharps sold or offered for sale in the state excluded from the definition of "covered product" pursuant to subparagraphs (D) and (E) of paragraph (2) of subdivision (e) of Section 42030.

(2) A list of entities authorized to provide an alternative collection mechanism pursuant to the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104 of the Health and Safety Code) for covered products that are not controlled substances.

(f) Notwithstanding Section 42036.4, information submitted by the state board or the State Department of Public Health to the department under this chapter may include proprietary information.

42031.2. (a) Except as specified in subdivision (d) of Section 42035, a covered manufacturer is not in compliance with this chapter and is subject to penalties pursuant to Article 6 (commencing with Section 42035) if, on or after July 1, 2020, a covered product sold or offered for sale by the covered manufacturer is not subject to a stewardship plan, which is submitted by the covered manufacturer or by a stewardship organization that includes the covered manufacturer, that has been approved by the department pursuant to Section 42032.

(b) A manufacturer of drugs or sharps that becomes a covered manufacturer on or after July 1, 2020, shall, no later than six months after the date on which the manufacturer becomes a covered manufacturer, participate in an approved stewardship program or establish and implement a stewardship program that complies with the requirements of this chapter.

(c) In order to comply with the requirements of this chapter, a covered manufacturer may establish and implement a stewardship program independently, or as part of a group of covered manufacturers 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)).

42031.4. A program operator shall do all of the following:

(a) Promote its stewardship program to ultimate users by placing signage on covered drug collection receptacles and sharps collection containers.

(b) Provide outreach materials for pharmacies and pharmacists.

(c) Provide outreach materials for ultimate users.

(d) Prepare additional outreach materials not specified in this section, as needed.

(e) 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.

42031.6. Notwithstanding any other law, a program operator may petition the department for approval to use final disposal technologies not permitted under existing law for covered products that provide superior environmental and human health protection than provided by current disposal technologies for covered products if and when those technologies are proven and available. To be approved by the department, the proposed technology shall provide equivalent protection in each, and superior protection in one or more, of the following areas:

(a) Monitoring of any emissions or waste.

(b) Worker health and safety.

(c) Air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution.

(d) Overall impact on the environment and human health.

Article 3. Pharmaceutical and Sharps Stewardship Plan

42032. (a) Within six months of the adoption date of regulations by the department pursuant to Section 42036.6, a program operator shall submit a pharmaceutical and sharps stewardship plan for the establishment and implementation of a pharmaceutical and sharps stewardship program to the department for approval, in a format determined by the department. The

department shall approve a proposed stewardship program if the manufacturer or stewardship organization submits a completed plan that meets the requirements of this section.

(b) Before approving a plan pursuant to subdivision (a), the department may require a program operator to submit its proposed plan to the state board, the State Department of Public Health, the Department of Toxic Substances Control, or any other state agency with authority or expertise relative to the stewardship plan, as determined by the department. 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 expertise. 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 60 days of receipt of the plan. 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 to the department.

(c) To be complete, a plan shall do all of the following:

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

(2) 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.

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

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

(5) 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.

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

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

(B) Provides for a reasonable geographic spread of authorized collection sites.

(d) (1) At least 120 days before submitting a stewardship plan to the department, a program operator 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 subparagraph (A) of paragraph (6) of subdivision (c) is not met in each county in which a retail pharmacy chain has store locations, the retail pharmacy chain shall have at least 15 percent of its store locations serve as authorized collectors in a stewardship program.

(3) A program operator shall include as an authorized collector under its stewardship program any retail pharmacy or law enforcement agency that offers to participate in the stewardship program without compensation in a county that meets the minimum threshold described in subparagraph (A) of paragraph (6) of subdivision (c).

(e) (1) A stewardship plan shall require an authorized collection site to accept all covered products from ultimate users during the hours that the authorized collector is normally open for business with the public.

(2) An authorized collection site shall use secure collection receptacles in compliance with state and federal law.

(3) A program operator shall 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 products are transported to final disposal in a timely manner.

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

(f) A stewardship plan shall require a program operator to do all of the following:

(1) To supplement service in a county in which it operates that does not have the minimum number of authorized collection sites required by subparagraph (A) of paragraph (6) of subdivision (c), as determined by the department, in consultation with the public health department of the county, establish one or both of the following:

(A) A mail-back program with places at which it distributes prepaid, preaddressed mailing envelopes. The department, in consultation with the program operator and appropriate community leaders, shall determine the locations of these envelope distribution places.

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

(2) Permit an ultimate user who is a homeless, homebound, or disabled individual, or who is a home health care worker providing care to a person in the person's home, to request prepaid, preaddressed mailing envelopes, or an alternative form of a collection and disposal system, as described in paragraph (1), that would render the covered product inert. A program operator shall accept such a request through an Internet Web site and toll-free telephone number that it shall maintain and shall comply with the requests.

(3) Provide alternative methods of collection from ultimate users for any covered products, other than controlled substances, that cannot be accepted or commingled with other covered products 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.

42032.2. (a) (1) The department shall determine if a stewardship plan is complete 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 (b) shall commence upon the original date of receipt.

(3) If the department determines the 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 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.

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

(c) 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.

(d) If the department disapproves a submitted plan pursuant to subdivision (b), 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. If the department finds that the revised plan submitted by the program operator does not comply with the requirements of this chapter and disapproves the plan, the covered manufacturer operating its own stewardship program, or the stewardship organization and the covered manufacturers 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.

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

(f) The department may terminate or revoke a plan's approval pursuant to subdivision (a) of Section 42035.4 if it finds the plan is no longer in compliance with this chapter. If a stewardship plan that was previously approved by the department pursuant to

subdivision (b) is terminated or is revoked by the department, or terminated by the stewardship organization that submitted the plan, a covered manufacturer 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 California for a period of up to one year after the plan terminated or was revoked if the covered manufacturer does one of the following:

(1) Continues to operate under the most recent approved stewardship plan to which the covered manufacturer was subject.

(2) Provides the department with an alternative plan governing stewardship of its own covered products that the department formally approves.

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

Article 4. Reports, Budgets, and Records

42033. On or before _____, a program operator shall submit to the department an initial stewardship program budget for the first calendar year 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 in a prudent and responsible manner.

42033.2. (a) On or before ____, 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) If applicable, a list of covered manufacturers participating in the stewardship organization.

(2) The updated list provided pursuant to paragraph (2) of subdivision (a) of Section 42031 of covered products that each covered manufacturer 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) The name and location of authorized collection sites at which covered products were collected.

(5) 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.

(6) 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.

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

(8) 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 manufacturers pursuant to Section 42034 or by a covered manufacturer 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 manufacturer 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 15 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 and 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.

(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, 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 audit to be delivered to the department, along with the annual report and

program budget submitted pursuant to subdivision (a) of Section 42033.2. The department shall review the 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 audit. The program operator may obtain copies of the audit, including proprietary information contained in the audit, from the auditor upon request. The department shall not disclose any confidential proprietary information protected pursuant to Section 42036.4 that is included in the audit.

(c) The department may conduct its own audit of a program operator if it determines that the audit conducted pursuant to subdivision (b) is not adequate to enforce the requirements of this chapter.

Article 5. Financial Provisions

42034. In order to further the objective that covered manufacturers establish and implement stewardship programs that comply with the requirements of this chapter, each covered manufacturer, 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 ____ 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 manufacturer, 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 manufacturers 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 manufacturers 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, the State Department of Public Health, the Department of Toxic Substances Control, 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 to reimburse any outstanding loans made from other funds used to finance 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.

(c) The department shall develop and implement both of the following:

(1) A process for a program operator to appeal expenditures by the department or a state agency of the administrative fees submitted by the program operator to the department pursuant to this section.

(2) A process for a program operator to obtain remedies for unauthorized expenditures by the department of the administrative fees submitted by the program operator to the department pursuant to this section.

42034.4. (a) (1) A stewardship organization may conduct an audit of covered manufacturers 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.

(2) The purpose of the audit 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.

(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 to confirming whether a charge or administrative fee has been properly collected from member covered manufacturers.

(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 ____, and at least annually thereafter, the department shall post on its Internet Web site a list of covered manufacturers, stewardship organizations, authorized collection sites, retail pharmacies, and retail pharmacy chains that are in compliance with this chapter.

(2) The state board and the State Department of Public Health shall 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 manufacturer, stewardship organization, authorized collection site, retail pharmacy, or retail pharmacy chain 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 manufacturer, stewardship organization, authorized collection site, retail pharmacy, or retail pharmacy chain is in compliance with this chapter. A covered manufacturer, stewardship organization, authorized collection site, retail pharmacy, or retail pharmacy chain 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 retail 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 manufacturers and stewardship organizations are in compliance with this chapter.

(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 manufacturer, stewardship organization, authorized collector, retail pharmacy, or retail pharmacy chain 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).

(f) The department shall send a written notice of noncompliance to a covered manufacturer that fails to participate in a stewardship program as required by this chapter.

42035.2. (a) (1) The department may impose a civil penalty on any covered manufacturer, stewardship organization, authorized collector, retail pharmacy, or retail pharmacy chain that sells, offers for sale, or provides a covered product in violation of this chapter. The amount of the civil penalty shall not exceed one thousand dollars ($1,000) per day unless the violation is intentional, knowing, or reckless, in which case the civil penalty shall not exceed five thousand dollars ($5,000) per day.

(2) (A) A covered manufacturer that receives a notice under subdivision (f) of Section 42035 shall be assessed a penalty only if, 60 days after receipt of the notice, the covered manufacturer continues to sell or offer for sale a covered product in the state without participating in a stewardship program approved under this chapter.

(B) No penalty shall be assessed against a covered manufacturer that is operating lawfully pursuant to subdivision (f) of Section 42032.2.

(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 from another party that was the direct cause of its failure to comply, including, for a stewardship organization, from a participating covered manufacturer.

(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, promotion of safe handling and disposal of covered products, grants for related purposes, and administration and enforcement this chapter.

42035.4. Upon a written finding that a covered manufacturer, 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, the state board, the State Department of Public Health, the Department of Toxic Substances Control, or other state agency with authority or expertise relative to this chapter, as determined by the department, may take one or both of the following actions to ensure compliance with the requirements of this chapter, after affording the covered manufacturer, 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 program operator 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 program operator shall maintain and keep accessible all records required to be 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 program operator that fails to provide the department with the access required pursuant to this section, including one or both of the following:

(1) Imposing a civil penalty pursuant to Section 42035.2.

(2) Posting a notice on the department's Internet Web site that it maintains pursuant to paragraph (1) of subdivision (a) of Section

42035 that the program operator is no longer in compliance with this chapter.

(e) The department shall not prohibit as a disciplinary action a covered manufacturer 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 manufacturer 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 manufacturer:

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

(2) 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 shall preempt a local stewardship program for covered products enacted by an ordinance that has an effective date on or after April 18, 2018.

(b) 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 manufacturer or stewardship organization. Proprietary information may be disclosed to the party that submitted the proprietary information.

42036.6. The department shall adopt regulations for administration of this chapter on or before ____.

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 pharmaceutical and sharps stewardship program be confidential.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution for certain costs that may be incurred by a local agency or school district because, in that regard, 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.

However, if the Commission on State Mandates determines that this act contains other costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.

~~SECTION 1. Section 117670.1 is added to the Health and Safety Code, to read:~~

~~117670.1. "Home-generated pharmaceutical waste" means a prescription or over-the-counter human or veterinary home-generated pharmaceutical, as defined in Section 109925 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C.A. Sec. 321(g)(1)), that is a waste, as defined in Section 25124, derived from a household, including, but not limited to, a multifamily residence or household.~~

REVISIONS:

Heading—Line 2.

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