AMENDED IN SENATE APRIL 3, 2013

SENATE BILL No. 727

Introduced by Senator Jackson
(Coauthor: Senator Hancock)

February 22, 2013

An act to add Section ~~117647 to, and to add Chapter 12 (commencing with Section 118365) to Part 14 of Division 104 of, the Health and Safety Code, relating to public health.~~ *117670.1 to the Health and Safety Code, and to add Article 3.4 (commencing with Section 47122) to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, relating to waste management.*

LEGISLATIVE COUNSEL'S DIGEST

SB 727, as amended, Jackson. Medical waste: pharmaceutical product stewardship program.

The ~~existing~~ Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, including pharmaceutical waste, as defined. Existing law requires, among other things, that all medical waste be hauled by either a registered hazardous waste hauler or by a person with an approved limited-quantity exemption granted pursuant to specified provisions of law. ~~Under the law, an enforcement agency may bring an action to enjoin the violation or threatened violation of those provisions or issue a specified order to a person who is responsible for a violation or threatened violation. A violation of that order, and other provisions of law, is a crime.~~

Existing law requires a pharmaceutical manufacturer selling or distributing medication that is intended to be self-injected at home to submit, on an annual basis, to the Department of Resources Recycling

and Recovery a plan supporting the safe collection and proper disposal of specified waste devices.

This bill would require a producer of a pharmaceutical sold in the state to, individually or through a stewardship organization, to submit a plan, on or before January 1, 2015, to the Department of Resources Recycling and Recovery. The bill would require the plan to provide for the development of a program to collect, transport, and process home-generated pharmaceutical drugs and to include specified aspects, including the minimum amount of collection sites, including by January 1, 2016, at least one collection service within 10 miles per person in the state.

The bill would require the department to post on its Internet Web site a list of the producers or stewardship organizations that have submitted a plan within 10 days of receipt of the plan. The bill would provide for the review and approval of the plan by the department, within 90 days of receipt of the plan. The bill would require the department to post on its Internet Web site a list of producers for which the department has approved a plan and the bill would require the department to update this list no less than once every 6 months.

The bill would require a producer or stewardship organization, on or after April 1, 2016, and every year thereafter, to prepare and submit to the department an annual report describing the activities carried out pursuant to the plan during the previous calendar year.

The bill would require the producer or stewardship organization to pay the department an annual administrative fee in an amount that is sufficient to cover the department's costs of administering and enforcing these provisions. The bill would require the department to deposit the fees in the Drug Abuse Prevention and Safe Disposal Program Account, which the bill would establish in the Integrated Waste Management Fund, and the department would be authorized to expend the moneys in that account upon appropriation by the Legislature, to administer and enforce the bill's requirement.

The bill would require the department to enforce these provisions and would authorize the department to impose an administrative civil penalty on a person who violates the bill's requirements or impose a fine on a producer or stewardship organization if a stewardship plan is not submitted by January 1, 2015. The bill would require the department to deposit these fines and penalties into the Drug Abuse Prevention and Safe Disposal Program Penalty Account, which this bill would establish in the Integrated Waste Management Fund, and

the department would be authorized to expend the moneys in that account upon appropriation by the Legislature, to enforce the bill's requirements.

~~This bill would, effective January 1, 2015, prohibit a producer of a pharmaceutical that is a cover drug, as defined, from selling or distributing that pharmaceutical in the state unless it is included in a product stewardship plan that is approved by the department. This bill would require each producer to operate, individually or jointly with other producers, an approved product stewardship program or to enter into an agreement with a stewardship organization, as defined, to operate that program on the producer's behalf. This bill would require a producer, group of producers, or stewardship organization, if applicable, to pay all associated costs with its product stewardship program, as specified, including the costs incurred by the state for administration and enforcement of the program. The bill would prohibit the producer from charging specified fees to recover the costs of its program.~~

~~This bill would require a producer, individually or jointly with other producers, in consultation with specified entities, to develop a product stewardship plan that includes, among other things, certification that the product stewardship program will accept all unwanted products, except as specified, contact information for the individual or entity submitting the plan and for each producer participating in the program, and a description of the methods by which unwanted products will be collected in the state. This bill would require the producer, group of producers, or stewardship organization operating the program to prepare and submit a written report to the department, as prescribed. This bill would require the department to administer any penalties under those provisions. By expanding the definition of a crime, this bill would impose a state-mandated local program.~~

~~The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.~~

~~This bill would provide that no reimbursement is required by this act for a specified reason.~~

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

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

SECTION 1. The Legislature finds and declares the following:

(a) The stockpiling of unused and unwanted pharmaceuticals has increased rapidly in recent years, creating access to potentially dangerous drugs to children and adults alike. Accidental poisoning from ingestion of drugs among children often occurs in homes where medicine is easily accessible. The Partnership for a Drug-Free America released a report in February 2010 indicating that over 60 percent of teenagers are able to obtain prescription painkillers free of charge from family and friends.

(b) Poisoning is the fastest rising cause of accidental death among older adults, particularly from overdoses of prescription drugs and over-the-counter medications. Unintentional poisoning of adults over 60 years of age resulting in hospitalization increased by 43 percent in the County of Alameda from 1998 to 2006.

(c) Pharmaceutical residues have been accumulating in groundwater and drinking water. Drugs enter the environment through multiple sources, including flushing toilets or through leaks in landfills. Even the most advanced wastewater treatment plants are not currently able to account for these chemicals. The cost of developing this waste treatment for wastewater is extremely high. Thus, many drugs will continue to pass through wastewater treatment systems and contaminate receiving waters unless the source of the problem is addressed.

(d) Safe and convenient medical waste recovery programs are critical in reducing the negative social and environmental health impacts of improper or illegal disposal.

(e) Product stewardship programs in Canada and Europe for hazardous wastes, medical wastes, and hard-to-handle wastes, including electronic waste, packaging, beverage containers, batteries, mercury-containing lamps, and other mercury-containing products have demonstrated that shared producer responsibility results in significant improvements in safe end-of-life management and reductions in taxpayer and ratepayer costs.

SEC. 2. 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 drug, including, but not limited to, a drug as defined in Section 109925 or in Section 321 (g)(1) of Title 21 of the United States Code, that is a waste, as defined in Section 25124, derived from a household, including, but not limited to, a multifamily residence or household.

Home-generated pharmaceutical waste may be handled through a home-generated pharmaceutical waste stewardship plan pursuant to Article 3.4 (commencing with Section 47122) of the Public Resources Code.

SEC. 3. Article 3.4 (commencing with Section 47122) is added to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, to read:

Article 3.4. Drug Abuse Prevention and Safe Disposal Program

47122. The purpose of the Drug Abuse Prevention and Safe Disposal Program established pursuant to this article is to require the producers of pharmaceuticals to develop and implement a program to collect, transport, and process home-generated pharmaceutical drug waste to reduce the costs, public health risk, and environmental impacts of the illegal and unsafe disposal of this medical waste.

47123. For purposes of this article, the following terms have the following meanings:

(a) "Consumer" means a purchaser or owner of home-generated pharmaceuticals, including a person, business, corporation, limited partnership, nonprofit organization, or governmental entity.

(b) "Department" means the Department of Resources Recycling and Recovery.

(c) "Distributor" means a person that sells or provides for free pharmaceuticals to the general public, which may include, but is not limited to, retailers, hospitals, veterinarians, and health clinics.

(d) "Drug abuse prevention and safe disposal plan" or "plan" means a plan written by an individual producer, or stewardship organization, on behalf of one or more producers.

(e) "Home-generated pharmaceutical waste" means pharmaceutical waste as defined in Section 117670.1 of the Health and Safety Code.

(f) "Pharmaceutical" means a prescription or over-the-counter human or veterinary drug as defined in Section 117747 of the Health and Safety Code. For purposes of this article, "pharmaceutical" includes any pharmaceutical that is regulated pursuant to (1) the federal Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. Sec. 6901 et seq.), and (2) the Radiation Control Law (Chapter 8 (commencing with Section

114960) of Part 9). For purposes of this article, "pharmaceutical" does not include the following items:

(1) Vitamins or supplements.

(2) Herbal-based remedies and homeopathic drugs.

(3) Cosmetics, soap (with or without germicidal agents), laundry detergent, bleach, household cleaning products, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.).

(4) Drugs for which the producers provide a take-back program as part of a federal Food and Drug Administration managed risk evaluation and mitigation strategy (21 U.S.C. Sec. 355-1).

(5) Drugs that are biological products as defined by Section 600-3(h) of Title 21 of the Code of Federal Regulations as it exists on January 1, 2014 if the producer already provides a take-back program.

(6) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other delivery systems.

(g) "Prescription drug" means any drug that by federal or state law may be dispensed lawfully only on prescription.

(h) (1) "Producer" shall be determined with regard to a pharmaceutical that is sold, offered for sale, or distributed in California as meaning one of the following:

(A) The person that manufactures a pharmaceutical and that sells, offers for sale, or distributes that pharmaceutical in California under that person's own name or brand.

(B) If there is no person who sells, offers for sale, or distributes the pharmaceutical in California under the person's own name or brand, the producer of the pharmaceutical is the owner or licensee of a trademark or brand under which the pharmaceutical is sold or distributed in California, whether or not the trademark is registered.

(C) If there is no person who is a producer of the pharmaceutical for purposes of subparagraphs (A) and (B), the producer of that pharmaceutical is the person who brings the pharmaceutical into California for sale or distribution.

(2) "Producer" does not include (A) a retailer that puts its store label on a pharmaceutical or (B) a pharmacist who dispenses

prescription drugs to, or compounds a prescribed individual drug product for a consumer.

(i) "Retailer" means a person that sells a pharmaceutical in the state to a consumer. A sale includes, but is not limited to, transactions conducted through sales outlets, catalogs, or the Internet or any other similar electronic means.

(j) "Stewardship organization" means a nonprofit organization created by the producers, including at a minimum, four representatives one each from local government, a distributor, a waste hauler, and a consumer health organization, to implement the Drug Abuse Prevention and Safe Disposal Program stewardship program.

47124. A producer of any pharmaceutical sold in this state shall, individually or through a stewardship organization, submit a drug abuse prevention and safe disposal stewardship plan pursuant to Section 47125 to the department to develop and implement a recovery program to manage home-generated pharmaceutical waste in an environmentally sound and medically safe fashion, including collection, transportation, processing, and disposal.

47125. (a) (1) On or before January 1, 2015, a producer or the designated stewardship organization for producers of pharmaceuticals shall submit a stewardship plan to the department.

(2) The plan shall be posted on the producer or stewardship organization's Internet Web site.

(b) A producer, group of producers, or stewardship organization shall consult with stakeholders during the development of the stewardship plan, including soliciting stakeholder comments, and responding to stakeholder comments, and document the comments and responses in the plan prior to submitting the stewardship plan.

(c) A stewardship plan shall include, at a minimum, all of the following elements:

(1) Contact information for all participating producers.

(2) The number of collection services for the home-generated pharmaceuticals subject to the plan. A baseline of the number of home-generated pharmaceutical collection services shall be at least one collection service within 10 miles per person in the state.

(d) The minimum number of collection sites for each plan submitted to the department shall be as follows:

(1) On and after January 1, 2016, there shall be at least one collection service within 10 miles per person in the state.

(2) On and after January 1, 2017, the number of collection services shall increase 20 percent from the reported number of collection services in 2016.

(e) On January 1, 2018, and annually thereafter, the department shall consult with the producers and stewardship organizations, local government, haulers, health community, and all stakeholders on how the program is performing, and to set fair and reasonable collection services for each year forward toward the goal of ultimately achieving safe management of all home-generated pharmaceuticals. The producer shall demonstrate to the department that it has achieved maximum improvement in the collection services.

(f) A baseline of the number of home-generated pharmaceuticals collected by all producers, or stewardship organizations, subject to a plan, shall be calculated by weight based on the percentage of home-generated pharmaceuticals collected during the preceding three years.

(g) The plan shall address collecting both solid and liquid home-generated pharmaceuticals.

(h) The methods of collection must be consistent with the requirements of Section 47115.5. Collection shall involve the use of two-key system whereby two individuals are needed to unlock the disposal bin, or if a one-key system is used, whereby only one person is needed to unlock the bin, the bin system shall render the medication unusable.

(i) The plan shall demonstrate sufficient funding for the stewardship program as described in the plan, including a funding mechanism for securing and dispersing funds to cover administrative, operational, and capital costs.

(j) The plan shall address the coordination of the stewardship program with existing local medical waste collection programs as much as is reasonably feasible and is mutually agreeable between those programs.

(k) The plan shall include goals to reduce the number of home-generated pharmaceuticals that are improperly disposed, and to maximize the proper end-of-life management of home-generated pharmaceuticals, including collection of

home-generated pharmaceuticals, as practical, based on current medical waste program information.

(l) The plan shall include consumer, medical community, and retailer education and outreach efforts to promote the collection of home-generated pharmaceuticals. This information may include, but is not limited to, developing, and updating as necessary, educational and other outreach materials aimed at all distributors of pharmaceuticals. These materials shall be made available to those parties. These materials may include, but are not limited to, one or more of the following:

(1) Signage that is prominently displayed and easily visible to the consumer.

(2) Written materials and templates of materials for reproduction by retailers to be provided to the consumer at the time of purchase or delivery, or both. Written materials shall include information on proper disposal of home-generated pharmaceuticals.

(3) Advertising or other promotional materials, or both, that include references to home-generated pharmaceuticals collection opportunities.

(m) Any retailer may participate, on a voluntary basis, at a home-generated pharmaceuticals collection point pursuant to the home-generated pharmaceuticals stewardship program.

47126. (a) The department shall post on its Internet web-site a list of the producers or stewardship organizations that have submitted a stewardship plan within 10 days of receipt of the plan.

(b) The department shall review the plan within 90 days of receipt, and make a determination whether or not to approve the plan. The department shall approve the plan if it provides for the establishment of a home-generated pharmaceuticals stewardship program that meets the requirements of Section 47125.

(c) (1) The approved plan shall be a public record, except that financial, production, or sales data reported to the department by a producer or the stewardship organization is not a public record under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code) and shall not be open to public inspection.

(2) Notwithstanding paragraph (1), the department may release a summary form of financial, production, or sales data if it does

not disclose financial, production, or sales data of a producer or stewardship organization.

(d) Three months after a plan is approved, the producer or stewardship organization shall implement the home-generated pharmaceuticals stewardship program described in the approved plan.

(e) (1) Within five days of the department approving the plan, the department shall post on its Internet Web site a list of producers for which the department has approved a plan pursuant to subdivision (b). The department shall update this posting that includes a list of producers that are in compliance with this article no less than once every six months thereafter.

(2) A producer that is not listed on the department's Internet Web site pursuant to this section, but demonstrates to the satisfaction of the department that it is in compliance with this article before the next update of the list of compliant producers by the department, pursuant to paragraph (1), may request a certification letter from the department stating that the producer is in compliance. The producer who receives the letter shall be deemed to be in compliance with this article.

47127. (a) On or before April 1, 2016, and every year thereafter, a producer or stewardship organization implementing a stewardship plan shall prepare and submit to the department an annual report describing the activities carried out pursuant to the plan during the previous calendar year. The annual report shall include, but is not limited to, all of the following elements:

(1) The number of home-generated pharmaceuticals collected by the program in the prior year and the collection services achieved in the prior year.

(2) A report of the total sales data for pharmaceuticals sold to distributors in the state for the previous calendar year.

(3) A report on the feedback from a stakeholders' meeting, hosted by producers or the stewardship organization, that was made available by Web cast, prior to submittal of the annual report.

(4) Independently audited financial statements that detail the financing method selected to sustainably fund the implementation of the plan to achieve the identified collection services described in the plan, pursuant to Section 47125.

(5) A description of methods used to collect, transport, and process home-generated pharmaceuticals in this state.

(6) A description of how solid and liquid home-generated pharmaceuticals are collected.

(7) A description of how pharmaceuticals regulated pursuant to the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. Sec. 6901 et seq.), and the Radiation Control Law (Chapter 8 (commencing with Section 114960) of Part 9 of the Health and Safety Code) are collected.

(8) Locations, hours, and contact information for all California collection points set up by the producers covered by the plan.

(9) Examples and descriptions of educational materials distributed to various stakeholders aimed to increase collection.

(10) An evaluation of the effectiveness of the program specific to collection, public awareness, convenience, and reduced improper disposal by both legal and illegal drug use.

(11) Any programmatic changes the producer, the stewardship organization, or both recommend based on new data provided in the annual report.

(b) The department shall review an annual report by doing all of the following:

(1) For the reports submitted for the 2016 calendar year, and each year thereafter, producers and stewardship organizations shall certify the accuracy of the collection points listed in the annual report and that they are located in every county in the state and established at a minimum of one site per 5,000 people.

(2) Reviewing sales data and collection numbers provided for the state to verify collection services.

(3) If a collection service pursuant to Section 47125 is not achieved, the department shall direct the producer or the stewardship organization to determine the most effective way to improve collection services.

(4) Verifying that all annual report elements specified in subdivision (a) have been addressed in the report.

(c) If the department does not act on a report within 45 days of receipt, the report shall be approved.

(d) The department shall make all reports submitted pursuant to this section available to the public on the department's Internet Web site.

(e) If the collection service for the home-generated pharmaceuticals subject to the plan meets the collection service, specified in Section 47125, or if the producer or stewardship organization demonstrates compliance with this article that is consistently and significantly above mandated performance levels, the department may reduce the frequency of reporting pursuant to this section.

(f) The department shall review the annual report required pursuant to this section and, within 90 days of receipt, shall adopt a finding of compliance or noncompliance with this article.

47128. (a) The department shall enforce this chapter.

(b) (1) The producer or stewardship organization shall pay the department an annual administrative fee pursuant to paragraph (2).

(2) The department shall impose fees in an amount that is sufficient to cover the department's full costs of administering and enforcing this chapter, including any program development costs or regulatory costs incurred by the department prior to the submittal of the stewardship plans. Fee revenues collected pursuant to this section shall only be used to administer and enforce this article. The total fee revenue collected shall not exceed $500,000 per year.

(3) The department shall deposit all fees collected pursuant to this subdivision into the Drug Abuse Prevention and Safe Disposal Program Account, which is hereby created in the Integrated Waste Management Fund. Upon appropriation by the Legislature, moneys deposited into the account may be expended by the department to administer and enforce this article.

(c) (1) A civil penalty may be administratively imposed by the department on any person who violates this article in an amount of up to one thousand dollars ($1,000) per violation per day.

(2) A person who intentionally, knowingly, or negligently violates this article may be assessed a civil penalty by the department of up to ten thousand dollars ($10,000) per violation per day.

(A) In assessing any fine and penalty, the department shall consider any exigent circumstance that contributed to the stewardship organization or individual producer not meeting the required recovery targets.

(B) The department may require the producer or stewardship organization to increase expenditure on program compliance in lieu of part of any fine or penalty to be imposed for not meeting the required recovery targets.

(d) (1) The department shall impose a fine on a producer or stewardship organization if a stewardship plan required pursuant to Section 47125 is not submitted by January 1, 2015.

(2) The fine in paragraph (1) shall be effective on the 120th day after the list described in Section 47126 is posted on the department's Internet Web site, and shall apply to any producer that is not listed on the department's Internet Web site, and shall remain in effect until the producer is listed on the department's Internet Web site or can demonstrate compliance with the requirements of Section 47125. A two-thousand-five-hundred-dollar ($2,500) fine will be imposed on the first day, and will increase by 50 percent with interest each day thereafter until a plan is submitted.

(e) The department shall deposit all fines and penalties collected pursuant to subdivisions (c) and (d) into the Drug Abuse Prevention and Safe Disposal Program Penalty Account, which is hereby created in the Integrated Waste Management Fund. Upon appropriation by the Legislature, moneys deposited into the account may be expended by the department to enforce this article.

47129. (a) Except as provided in subdivision (c), an action solely to increase the collection of home-generated pharmaceuticals by a producer, stewardship organization, or retailer that affects the types or quantities being recycled, or the cost and structure of any return program, is not a violation of the statutes specified in subdivision (b).

(b) The following statutes are not violated by an action specified in subdivision (a):

(1) The Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code).

(2) The Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code).

(c) Subdivision (a) shall not apply to any agreement establishing or affecting the price of home-generated pharmaceuticals, except for the home-generated pharmaceuticals stewardship assessment,

or the output or production of home-generated pharmaceuticals, or any agreement restricting the geographic area or customers to which home-generated pharmaceuticals will be sold.

~~SECTION 1. Section 117647 is added to the Health and Safety Code, to read:~~

~~117647. (a) "Covered drugs" means all drugs as defined in Section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 321(g)(1)), and covered under Section 503 of the act (21 U.S.C. Section 353(b)(1)), including both brand name and generic drugs.~~

~~(b) Covered drugs do not include any of the following:~~

~~(1) Vitamins or supplements.~~

~~(2) Herbal-based remedies, or homeopathic drugs, products, or remedies.~~

~~(3) Cosmetics, soap, with or without germicidal agents, laundry detergent, bleach, household cleaning products, shampoo, sunscreen, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the FFDCA.~~

~~(4) Drugs for which a producer provides a take-back program as part of an FFDCA managed risk evaluation and mitigation strategy.~~

~~(5) Drugs that are biological products, as defined in Section 262(i) of Title 42 of the United States Code, if the producer already provides a take-back program~~

~~(6) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other delivery systems.~~

~~(7) Nonprescription drugs.~~

~~SEC. 2. Chapter 12 (commencing with Section 118365) is added to Part 14 of Division 104 of the Health and Safety Code, to read:~~

~~CHAPTER 12. PHARMACEUTICAL PRODUCT STEWARDSHIP PROGRAM~~

~~118365. For purposes of this chapter, "stewardship organization" means a nonprofit organization created by a producer to implement the pharmaceutical product stewardship program described in Section 118365.1.~~

~~118365.1. (a) Effective January 1, 2015, a producer of a pharmaceutical that is a covered drug shall not sell or distribute that pharmaceutical in the state unless it is included in a product stewardship plan approved by the department.~~

~~(b) Each producer shall do one of the following:~~

~~(1) Operate, individually or jointly with other producers, a product stewardship program approved by the department.~~

~~(2) Enter into an agreement with a stewardship organization to operate, on the producer's behalf, a product stewardship program approved by the department.~~

~~(c) (1) A producer, group of producers, or stewardship organization shall pay all administrative and operational fees associated with its product stewardship program, including the costs of collecting, transporting, and disposing of unwanted products collected from residential generators and the recycling or disposal, or both, of packaging collected with the unwanted product.~~

~~(2) A producer, group of producers, or stewardship organization shall pay for all fees associated with obtaining compliance with the California Environmental Quality Act (Division 13 (commencing with Section 21000) of the Public Resources Code), if required, for a product stewardship program and product stewardship plan.~~

~~(3) A person or producer shall not charge a specific point-of-sale fee to a consumer to recover the costs of its product stewardship program, and shall not charge a specific point-of-collection fee at the time the unwanted products are collected from residential generators or delivered for disposal.~~

~~(4) A producer, group of producers, or stewardship organization shall pay all costs incurred by the state, including, but not limited to, the department's costs, for the administration and enforcement of its pharmaceutical product stewardship program. Exclusive of any fines, the state shall only recover the actual costs of administration and enforcement under this chapter, and shall not charge any amounts under this chapter in excess of the actual administrative and enforcement costs.~~

~~118365.2. In consultation with local governments, water districts, sanitation districts, pharmacies, waste haulers, environmental health officers, and all interested stakeholders, the~~

~~producers, individually or jointly with other producers, shall develop a product stewardship plan.~~

~~(a) Each product stewardship plan required under Section 118365.1 shall contain all of the following:~~

~~(1) Certification that the product stewardship program will accept all unwanted products, regardless of who produced them under a joint plan, unless excused from this requirement by the department as part of its approval of the plan.~~

~~(2) Contact information for the individual and the entity submitting the plan and for each of the producers participating in the product stewardship program.~~

~~(3) A description of the methods by which unwanted products from residential generators will be collected in the state and an explanation of how the collection system will be convenient and adequate to serve the needs of all California residents.~~

~~(4) A description of how the product stewardship plan will provide collection services for unwanted products in all areas of California that are convenient to the public and adequate to meet the needs of the population in the area being served.~~

~~(5) If applicable, the location of each collection site and locations where envelopes for a mail-back program are available.~~

~~(6) A list containing the name, location, permit status, and record of any penalties, violations, or regulatory orders received in the previous five years by each person that will be involved in transporting unwanted products and each medical waste or hazardous disposal facility proposed to participate in the product stewardship program.~~

~~(7) A description of how the unwanted products will be safely and securely tracked and handled from collection through final disposal, and the policies and procedures to be followed to ensure security and adherence to highest management standards.~~

~~(8) A description of public education and outreach activities that are consistent with this chapter, and how the effectiveness of those programs and activities will be evaluated.~~

~~(9) A description of how the scope and extent of the product stewardship program is reasonably related to the amount of covered drugs that are sold in the state by the producer, or group of producers.~~

~~(10) A starting date for the collection of unwanted products.~~

~~(11) If applicable, a description of how support will be provided to any law enforcement agencies within the state that operate, or later agree to operate, a collection program for controlled substances, including the provision of a collection kiosk with appropriate accessories and signage, the ability to accept controlled substances and other covered drugs, and technical support, up to and including an appropriate person to provide on-site assistance with the sorting and separation of controlled substances at no cost to a participating law enforcement agency. Otherwise, controlled substances are expressly excluded from this chapter, notwithstanding any other provision.~~

~~(12) A description of how collection sites for unwanted products may be placed at appropriate retail stores in the state, including a description of the involvement of the retail store. Retailers are not required or mandated to host collection sites, and nothing in this chapter shall be interpreted as requiring that participation.~~

~~(13) If more than one producer will be involved in a proposed product stewardship program, the plan for that program shall include a fair and reasonable manner for allocating the costs of the program among the participants in that program, so that the portion of costs paid by each producer is reasonably related to the amount of covered drugs that producer sells in the state.~~

~~118365.3. On or before January 1, 2016, or at a later date as approved in writing by the department, and in each subsequent year, each producer, group of producers, or stewardship organization operating a product stewardship program shall prepare and submit to the department an annual written report describing the program's activities during the previous reporting period.~~

~~118365.4. The department shall administer the penalty provisions for this chapter.~~

~~SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.~~

O