## **Introduced by Senator Jackson**

February 13, 2014

An act to add Section 4068.1 to the Business and Professions Code, to amend Section 117700 of, and to add Section 117670.1 to, the Health and Safety Code, and to add Article 3.4 (commencing with Section 47120) to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, relating to pharmaceutical waste.

## LEGISLATIVE COUNSEL'S DIGEST

SB 1014, as introduced, Jackson. Pharmaceutical waste: home-generated.

(1) The Department of Resources Recycling and Recovery was required, pursuant to provisions repealed on January 1, 2013, to develop, in consultation with appropriate state, local, and federal agencies, model programs for the collection and proper disposal of drug waste.

This bill would enact the Home-Generated Pharmaceutical Waste Collection Disposal Act and would define terms for purposes of the act. The bill would require a producer of covered pharmaceuticals to submit to the Department of Resources Recycling and Recovery, by July 1, 2015, except as specified, a product stewardship plan and would authorize one or more producers to submit a plan or designate a stewardship organization to act as an agent on behalf of the producers to submit a plan. The bill would require the stewardship plan to contain specified elements with regard to the collection and disposal of home-generated pharmaceutical waste, including provisions for the payment of all administrative and operational fees associated with the product stewardship program.

The bill would specify procedures for the approval of the plan by the department and would require a producer, group of producers, or

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stewardship organization operating a stewardship program to take specified actions with regard to the disposal of home-generated pharmaceutical waste and promoting product stewardship programs to consumers, pharmacists, retailers of covered pharmaceuticals, and health care practitioners.

The bill would require a producer, group of producers, or stewardship organization operating a product stewardship program to prepare and submit to the department an annual written report describing the program's activities during the previous calendar year by July 1, 2016, or at a later date as approved by the department, and on or before July 1 annually thereafter.

The bill would authorize the department to adopt regulations to implement the act and would require the department to adopt regulations to provide for the appropriate management of consolidated home-generated pharmaceutical waste, to establish a schedule of fees to be charged to cover the department's costs of administering and enforcing the act, and to adopt a schedule setting the amounts of administrative civil penalties that the department would be authorized to impose. The bill would require a producer, group of producers, or a stewardship organization submitting a plan to the department to pay the fees set by the department and would require the department to deposit the fees into the Home-Generated Pharmaceutical Waste Program Account, which the bill would create in the Integrated Waste Management Fund. The department would be authorized to expend the fees, upon appropriation by the Legislature, to administer and enforce the act.

The bill would authorize the department to issue an administrative order to, or impose a civil penalty upon, a producer who is in violation of the act or a regulation adopted pursuant to the act. The bill would require the department to deposit the penalties into the Home-Generated Pharmaceutical Waste Penalty Account, which the bill would create in the Integrated Waste Management Fund, and would authorize the department to expend the moneys in that account, upon appropriation by the Legislature, to enforce the act.

(2) The 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 defines the term medical waste and excludes certain types of waste from that definition.

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This bill would define the term "home-generated pharmaceutical waste" for purposes of that act. The bill would exclude, from the definition of medical waste, home-generated pharmaceutical waste that is handled by a collection and disposal program operating in accordance with the act specified above. This exclusion would not become operative until the Secretary of State posts a notice regarding the effective date of the regulations that the department is required to adopt pursuant to that act.

(3) The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy establishments by the California State Board of Pharmacy, and makes a knowing violation of that law a misdemeanor.

The bill would also authorize a pharmacy to accept the return of home-generated pharmaceutical waste from a consumer, consistent with specified federal laws. Because a knowing violation of this provision would be a crime, the bill would impose a state-mandated local program.

(4) 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.

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

- 1 SECTION 1. Section 4068.1 is added to the Business and 2 Professions Code, to read:
- 4068.1. A pharmacy may accept the return of home-generated pharmaceutical waste, as defined in Section 117670.1 of the Health
  - pharmaceutical waste, as defined in Section 117670.1 of the Health and Safety Code, from a consumer, consistent with the Federal
- 6 Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) and
- 7 the Controlled Substances Act (21 U.S.C. Sec. 801 et seq.).
- 8 SEC. 2. Section 117670.1 is added to the Health and Safety 9 Code, to read:
- 10 117670.1. "Home-generated pharmaceutical waste" means a
- 11 prescription or over-the-counter human or veterinary
- 12 home-generated pharmaceutical, including, but not limited to, a
- drug, as defined in Section 109925 or in Section 321(g)(1) of Title
- 14 21 of the United States Code, that is a waste, as defined in Section

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1 25124, derived from a household, including, but not limited to, a multifamily residence or household.

- SEC. 3. Section 117700 of the Health and Safety Code is amended to read:
  - 117700. Medical waste does not include any of the following:
- (a) Waste generated in food processing or biotechnology that does not contain an infectious agent as defined in Section 117675.
- (b) Waste generated in biotechnology that does not contain human blood or blood products or animal blood or blood products suspected of being contaminated with infectious agents known to be communicable to humans.
- (c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomitus, unless it contains fluid blood, as provided in subdivision (d) of Section 117635.
- (d) Waste which is not biohazardous, such as paper towels, paper products, articles containing nonfluid blood, and other medical solid waste products commonly found in the facilities of medical waste generators.
- (e) Hazardous waste, radioactive waste, or household waste, including, but not limited to, home-generated sharps waste, as defined in Section 117671.
- (f) Waste generated from normal and legal veterinarian, agricultural, and animal livestock management practices on a farm or ranch.
- (g) (1)Home-generated pharmaceutical waste, including, but not limited to, consolidated home-generated pharmaceutical waste, that is handled by a collection and disposal program operating in accordance with Article 3.4 (commencing with Section 47120) of Chapter 1 of Part 7 of Division 30 of the Public Resources Code.
- (2) The Department of Resources Recycling and Recovery shall notify the Secretary of State of the effective date of the regulations adopted pursuant to subdivision (b) of Section 47129 of the Public Resources Code. The Secretary of State shall post this notification on its Internet Web site within 15 days after receiving that notice.
- (3) Paragraph (1) shall not become operative until the Secretary
  of State posts the notice described in paragraph (2) on its Internet
  Web site.
- 38 SEC. 4. Article 3.4 (commencing with Section 47120) is added 39 to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, 40 to read:

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Article 3.4. Home-Generated Pharmaceutical Waste Collection and Disposal

- 47120. The Legislature hereby finds and declares all of the following:
- (a) Prescription and nonprescription drugs successfully allow us to live longer, healthier, and more productive lives.
- (b) The public, particularly children and the elderly, are at significant and unnecessary risk of poisoning due to improper or careless disposal of drugs and the illegal resale of drugs.
- (c) Our source water for drinking water is being contaminated by unwanted, leftover, or expired drugs passing through our wastewater and treatment centers.
- (d) There is no mandatory statewide drug stewardship program for unwanted drugs in California.
- (e) It is the intent of the Legislature that all members of the supply chain work together to implement an effective program to maximize the collection and disposal of unused drugs in California.
- 47121. This article shall be known, and may be cited, as the "Home-Generated Pharmaceutical Waste Collection and Disposal Act."
- 47122. For the purposes of this article, the following terms have the following meanings:
- (a) "Consumer" means an individual purchaser or owner of a covered pharmaceutical. "Consumer" does not include a business, corporation, limited partnership, or an entity involved in a wholesale transaction between a distributor and retailer.
- (b) "Controlled substance" means a substance listed in Chapter 1 (commencing with Section 11053) of Division 10 of the Health and Safety Code, or in Section 812 of Title 21 of the United States Code or subject to Section 813 of Title 21 of the United States Code.
- (c) "Cosmetic" means anything defined as a cosmetic in Section
  109900 of the Health and Safety Code.
  - (d) (1) "Covered pharmaceutical" means a prescription drug or an over-the-counter human or veterinary drug.
- 37 (2) "Covered pharmaceutical" does not include any of the 38 following:
- 39 (A) A drug that is regulated pursuant to either of the following:

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1 (i) The federal Resource Conservation and Recovery Act of 2 1976, as amended (42 U.S.C. Sec. 6901 et seq.).

- 3 (ii) The Radiation Control Law (Chapter 8 (commencing with Section 114960) of Part 9) of Division 104 of the Health and Safety 5 Code.
  - (B) A Vitamin or supplement.

- 7 (C) A herbal-based remedy or a homeopathic drug, product, or 8 remedy.
  - (D) 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 cosmetics under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq).
  - (E) A drug for which a producer provides 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).
  - (F) A drug that is a biological product, as defined in subsection (h) of Section 600.3 of Title 21 of the Code of Federal Regulations, as it read on January 1, 2015, if the producer provides a take-back program.
  - (G) A pet pesticide product contained in a pet collar, powder, shampoo, topical application, or other delivery system.
  - (e) "Drug" means anything defined as a drug in Section 109925 of the Health and Safety Code or in Section 321 (g)(1) of Title 21 of the United States Code.
  - (f) "Home-generated pharmaceutical waste" means a covered pharmaceutical that is a waste, as defined in Section 25124 of the Health and Safety Code, derived from a household, including, but not limited to, a multifamily residence or household.
  - (g) "Mail-back program" means a system whereby a generator of home-generated pharmaceutical waste may obtain a prepaid and preaddressed mailing envelope in which to place home-generated pharmaceutical waste for shipment to an entity that will dispose of it safely and legally.
  - (h) "Over-the-counter drug" means a drug that may be lawfully sold without a prescription.
- 37 (i) "Pharmaceutical wholesaler" means a person that sells or 38 distributes covered pharmaceuticals for resale to an entity other 39 than a consumer.

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(j) "Plan" or "product stewardship plan" means a product stewardship plan to implement a program to collect and dispose of home-generated pharmaceutical waste.

- (k) "Prescription drug" means a drug required by federal or state law to be dispensed lawfully only on prescription.
- (*l*) (1) "Producer" shall be determined with regard to a covered pharmaceutical that is sold, offered for sale, or distributed in the state as meaning one of the following:
- (A) The person that manufactures a covered pharmaceutical and that sells, offers for sale, or distributes that covered pharmaceutical in the state under that person's own name or brand.
- (B) If there is no person who meets the condition specified in subparagraph (A), the producer of the covered pharmaceutical is the owner or licensee of a trademark or brand under which the covered pharmaceutical is sold or distributed in California, whether or not the trademark is registered.
- (C) If there is no person who meets the conditions specified in subparagraph (A) or (B), the producer of that covered pharmaceutical is the person who brings the pharmaceutical into the state for sale or distribution.
  - (2) "Producer" does not include either of the following:
- (A) A retailer that puts its store label on a covered pharmaceutical.
- (B) A pharmacist who dispenses prescription drugs to, or compounds a prescribed individual drug product for, a consumer.
- (m) "Product stewardship program" or "program" means a program financed and operated by one or more producers to collect, transport, and dispose of home-generated pharmaceutical waste.
- (n) "Stewardship organization" means an organization designated by a group of producers to act as an agent on behalf of each producer to operate a product stewardship program.
- 47124. (a) On or before July 1, 2015, or on a later date that may be specified by the department, a producer shall submit to the department a product stewardship plan that complies with the requirements of subdivision (b). One or more producers may submit a plan or designate a stewardship organization to act as an agent on behalf of the producers to submit a plan. A producer that designates a stewardship organization shall enter into an agreement with that stewardship organization to operate, on the producer's behalf, a product stewardship program and the stewardship

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organization shall submit a plan pursuant to this section on or before July 1, 2015, or on a later date that may be specified by the department.

- (b) A product stewardship plan shall contain all of the following elements:
- (1) A certification that the product stewardship program will accept all home-generated pharmaceutical waste that results from a covered pharmaceutical sold by the producer, or by the producers that enter into agreement with the stewardship organization, from all households, including multifamily households, unless excused from this requirement by the department as part of the approval of the plan.
- (2) Contact information for the producer submitting the plan or for each of the producers participating in the product stewardship program submitting the plan.
- (3) A description of the methods by which home-generated pharmaceutical waste will be collected and an explanation of how the collection system will conveniently and adequately serve the residents of the state.
- (4) A description of how the product stewardship plan will provide collection services for home-generated pharmaceutical waste in all areas of that state that are convenient to the public and adequate to meet the needs of the population in the area being served.
- (5) The location of each collection site and locations where envelopes for a mail-back program are available, if applicable.
- (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 home-generated pharmaceutical waste and each medical waste disposal facility proposed to participate in the product stewardship program.
- (7) A description of how the home-generated pharmaceutical waste will be safely and securely tracked and handled from collection through final disposal and the policies and procedures to be followed to ensure security.
- (8) A description of how the public education and outreach activities required by subdivision (c) of Section 47126 will be implemented and how the effectiveness of those activities will be evaluated.

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

- (10) A starting date when the collection of home-generated pharmaceutical waste will begin.
- (11) A description of how support will be provided to any law enforcement agencies within the state that have, or later agree to have, a collection program for controlled substances, including all of the following:
- (A) The provision of a collection kiosk with appropriate accessories and signage.
- (B) An ability to accept controlled substances and other home-generated covered pharmaceutical waste.
- (C) Technical support, including an appropriate person to provide onsite assistance with the sorting and separation of controlled substances at no cost to a participating law enforcement agency.
- (12) A description of how collection sites for home-generated pharmaceutical waste may be placed at appropriate retail stores in the state, including a description of the involvement of the retail stores.
- (13) If more than one producer will be involved in a proposed product stewardship program, the product stewardship 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 pharmaceutical sold by the producer in the state.
- (14) (A) Provisions for the payment of all administrative and operational fees associated with the product stewardship program, including the cost of collecting, transporting, and disposing of home-generated pharmaceutical waste and the recycling or disposal, or both, of packaging collected with the home-generated pharmaceutical waste.
- (B) The plan shall not allow a person or producer to charge a specific point-of-sale fee to consumers to recoup the costs of their product stewardship program, or charge a specific point-of-collection fee at the time the home-generated pharmaceutical waste is collected or delivered for disposal.

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47125. (a) A producer, group of producers, or stewardship organization shall not collect home-generated pharmaceutical waste until it has received written approval of its product stewardship plan from the department.

- (b) Within 180 days after receipt and review of a product stewardship plan, the department shall conduct a noticed public hearing and determine whether the plan complies with the requirements of this article and any regulations adopted pursuant to this article. As part of its approval, the department may set reasonable performance goals for the program proposed to be implemented by the plan.
- (c) The department shall notify the applicant in writing of the approval of the plan.
- (d) If the department rejects a plan, it shall notify the applicant in writing of its reasons for rejecting the plan. The department may reject a plan without conducting a public hearing, other than the hearing required by subdivision (b).
- (e) An applicant whose plan has been rejected by the department shall submit a revised plan to the department within 60 days after receiving notice of the rejection. The department may require the submission of a further revised plan or may develop, approve, and impose its own product stewardship plan or an approved plan submitted by other producers pursuant to this article. The department shall present the imposed plan at a public hearing. The department is not required, and nothing in this article shall be interpreted as requiring the department, to create or impose a product stewardship plan.
- (f) If the department rejects a revised product stewardship plan or any other subsequently revised plan, a producer that is subject to the plan shall be considered to be out of compliance with this article and subject to the enforcement provisions contained in this article. If the department imposes its own plan, the producer shall not be considered out of compliance with this article if the producer complies with that plan.
- (g) At least every three years, a producer, group of producers, or stewardship organization operating a product stewardship program shall update the product stewardship plan and submit the updated plan to the department for review and approval.

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(h) Any proposed changes to a product stewardship plan shall be submitted in writing to the department and approved by the department in writing prior to implementation of any change.

- (i) On and after July 1, 2015, a producer who commences to sell a covered pharmaceutical in the state shall submit a product stewardship plan to the department or provide evidence of having joined an existing approved product stewardship program no later than 180 days after the date the producer commences to sell that covered pharmaceutical, following the producer's initial sale of the offer for sale of a covered pharmaceutical.
- 47126. A producer, group of producers, or stewardship organization operating a stewardship program shall comply with all local, state, and federal laws and regulations applicable to its operations, including laws and regulations governing the disposal of medical waste and controlled substances, and shall additionally take all of the following actions when operating the program:
- (a) (1) Dispose of all home-generated pharmaceutical waste, in accordance with paragraph (1) of subdivision (a) of Section 118215 of the Health and Safety Code.
- (2) A producer or stewardship organization operating a stewardship program may petition the department for approval to use a final disposal technology, if lawful, that provides superior environmental and human health protection than provided by current medical waste disposal technology for covered pharmaceuticals, if and when the technology is proven and available. The department may approve that technology, if it provides 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, or toxic pollution.
  - (D) Overall impact on the environment and human health.
- (b) Encourage the separation of home-generated pharmaceutical waste from its original containers, when appropriate, prior to collection or disposal.
- (c) Promote the product stewardship program to consumers, pharmacists, retailers of covered pharmaceuticals, and health care practitioners as to the proper and safe method to dispose of

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1 home-generated pharmaceutical waste, in accordance with the 2 following:

- (1) Develop and update as necessary, educational and other outreach materials aimed at retailers of covered pharmaceuticals. These materials may include, but are not limited to, one or more of the following:
- (A) Signage that is prominently displayed and easily visible to the consumer.
- (B) 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.
- (C) Advertising or other promotional materials related to the product stewardship program.
- (2) Prepare education and outreach materials that publicize the location and operation of collection locations in the state and disseminate the materials to health care facilities, pharmacies, and other interested parties.
- (3) Establish an Internet Web site publicizing collection locations and program operations and a toll-free telephone number that residential generators can call to find nearby collection locations and understand how the program works.
- 47127. On or before July 1, 2016, or at a later date as approved in writing by the department, and on or before July 1 annually thereafter, a 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 calendar year. The report shall include all of the following information:
- (a) A list of producers participating in the product stewardship program.
- (b) The amount, by weight, of home-generated pharmaceutical waste collected at each drop-off site and in the entire state and, if applicable, the total amount by weight collected by a mail-back program.
- (c) A description of the collection system, including the location of each collection site and if applicable, locations where envelopes for a mail-back program are provided.
- (d) The name and location of disposal facilities at which home-generated pharmaceutical waste were disposed of and the

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weight of home-generated pharmaceutical waste collected from residential generators disposed of at each facility.

- (e) Whether policies and procedures for collecting, transporting, and disposing of home-generated pharmaceutical waste, as established in the plan, were followed during the previous calendar year and a description of any noncompliance.
- (f) Whether any safety or security problems occurred during collection, transportation, or disposal of home-generated pharmaceutical waste during the previous calendar year 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.
- (g) A description of public education and outreach activities implemented during the reporting period, including the methodology used to evaluate the outreach and program activities.
- (h) How the product stewardship program complied with all other elements in the product stewardship plan approved by the department, including its degree of success in meeting any performance goals set by the department as part of the approval of the plan.
- (i) Any other information that the department may reasonably require.
- 47128. The department shall provide on its Internet Web site a list of all producers participating in product stewardship programs approved by the department and a list of all producers the department has identified as noncompliant with this article or the regulations adopted pursuant to this article.
- 47129. (a) The department may adopt regulations to implement this article.
- (b) The department shall adopt regulations to do all of the following:
- (1) Provide for the appropriate management of consolidated home-generated pharmaceutical waste to ensure public and environmental safety, including, but not limited to, handling, storage, containment, tracking, transportation, and disposal.
- (2) Establish a schedule of fees to be charged to the producers to cover the department's costs of administering and enforcing this article. In setting the fee schedule, the department shall only recover its actual costs of administration and enforcement under

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this article and shall not charge any amounts under this article in excess of its actual administrative and enforcement costs.

- (3) Adopt a schedule setting the amounts of administrative civil penalties that the department may impose pursuant to Section 47130, based on the nature, extent, and severity of the violation and any other relevant factors.
- (c) A producer, group of producers, or a stewardship organization submitting a plan to the department shall pay the fees set by the department pursuant to subdivision (b).
- (d) The department shall deposit all fees collected pursuant to this section into the Home-Generated Pharmaceutical Waste 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.
- 47130. (a) The department may issue an administrative order to, or impose an administrative civil penalty upon, a producer who is in violation of this article or a regulation adopted pursuant to this article, to require compliance with this article or the regulation.
- (b) The department shall deposit all penalties collected pursuant to this article into the Home-Generated Pharmaceutical Waste 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.
- 47134. This article does not require a retailer to host a collection site and nothing in this article shall be interpreted as requiring this participation.
- 47135. A producer or stewardship organization that creates and operates a plan that is approved by the department is not in 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), with regard to actions that are taken in accordance with the plan or this article.
- SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because

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- 1 the only costs that may be incurred by a local agency or school
- 2 district will be incurred because this act creates a new crime or
- 3 infraction, eliminates a crime or infraction, or changes the penalty
- 4 for a crime or infraction, within the meaning of Section 17556 of
- 5 the Government Code, or changes the definition of a crime within
- 6 the meaning of Section 6 of Article XIIIB of the California
- 7 Constitution.