HOUSE OF REPRESENTATIVES
THIRTY-FIRST LEGISLATURE, 2021
STATE OF HAWAII

H.B. NO. 386

A BILL FOR AN ACT

RELATING TO CONTROLLED SUBSTANCES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The Hawaii Revised Statutes is amended by adding a new chapter to be appropriately designated and to read as follows:

"CHAPTER

DRUG TAKE-BACK PROGRAM

§ -1 Definitions. As used in this chapter, unless the context otherwise requires:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(1) A practitioner or, in the practitioner's presence or at the practitioner's direction, by a licensed or registered health care provider acting as the practitioner's authorized agent; or

(2) The patient or research subject at the direction or in the presence of the practitioner.

"Authorized collector" means any of the following persons or entities that have entered into an agreement with a program operator to collect covered drugs:

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

(2) A law enforcement agency; or

(3) An entity authorized by the department to provide an alternative collection method for certain covered drugs that are not controlled substances.

"Collection site" means the location where an authorized collector operates a secure collection receptacle for collecting covered drugs.

"Controlled substance" means a drug, substance, or immediate precursor in schedules I through V of part II of chapter 329.

"Covered drug" means a drug from a covered entity that the covered entity no longer wants and that the covered entity has abandoned or discarded or intends to abandon or discard.

"Covered drug" includes legend drugs and nonlegend drugs, brand name and generic drugs, drugs for veterinary use for household pets, and drugs in medical devices and combination products. "Covered drug" does not include:

(1) Vitamins, minerals, or supplements;

(2) Herbal-based remedies and homeopathic drugs, products, or remedies;

(3) Controlled substances contained in schedule I of part II of chapter 329;

(4) Cosmetics, shampoos, sunscreens, lip balm, toothpaste, 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. §§ 301-395);

(5) Drugs for which manufacturers provide a pharmaceutical product stewardship or drug take-back program as part of a United States Food and Drug Administration risk evaluation and mitigation strategy under title 21 United States Code section 355-1;

(6) Biological drug products, as defined by title 21 Code of Federal Regulations section 600.3(h) as it exists

on the effective date of this Act, for which manufacturers:

(A) Provide a pharmaceutical product stewardship or drug take-back program;

(B) Provide the department with a report describing the program, including how the drug product is collected and safely disposed and how patients are made aware of the drug take-back program; and

(C) Update the department on changes that substantially alter the manufacturers' drug take-back program;

(7) Drugs that are administered in a clinical setting;

(8) Emptied injector products or emptied medical devices and their component parts or accessories;

(9) Exposed needles or sharps, or used drug products that are medical wastes; or

(10) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms.

"Covered entity" 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. "Covered entity" 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.

"Covered manufacturer" means a person, corporation, or other entity engaged in the manufacture of covered drugs sold in or into the State. "Covered manufacturer" does not include:

(1) A private label distributor or retail pharmacy that sells a drug under the retail pharmacy's store label if the manufacturer of the drug is identified under section -3;

(2) A repackager if the manufacturer of the drug is identified under section -3; or

(3) A charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986, as amended, that repackages drugs solely for the purpose of supplying a drug to facilities or retail pharmacies operated by the corporation or an affiliate of the corporation if the manufacturer of the drug is identified under section -3.

"Department" means the department of public safety.

"Director" means the director of public safety.

"Drug" means:

(1) Substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;

(2) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;

(3) Substances (other than food) intended to affect the structure or any function of the body of man or animals; and

(4) Substances intended for use as a component of any article specified in paragraphs (1), (2), or (3).

"Drug" does not include devices or their components, parts, or accessories.

"Drug take-back organization" means an organization designated by a manufacturer or group of manufacturers to act as an agent on behalf of each manufacturer to develop and implement a drug take-back program.

"Drug take-back program" or "program" means a program implemented by a program operator for the collection, transportation, and disposal of covered drugs.

"Generic drug" means a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use, regardless of whether the inactive ingredients in a generic drug are identical to the inactive ingredients in the chemically identical or bioequivalent brand name drug.

"Legend drug" means a drug limited by section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act to being dispensed by prescription only or restricted to use by practitioners only.

"Mail-back distribution location" means a facility, such as a town hall or library, that offers prepaid, preaddressed mailing envelopes to covered entities.

"Mail-back program" means a method of collecting covered drugs from covered entities by using prepaid, preaddressed mailing envelopes.

"Manufacture" means the production, preparation, propagation, compounding, conversion, or processing of a

controlled substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. "Manufacture" does not include the preparation or compounding of a controlled substance by an individual for the individual's own use or the preparation, compounding, packaging, or labeling of a controlled substance:

(1) By a practitioner as an incident to the practitioner's administering or dispensing of a controlled substance in the course of the practitioner's professional practice; or

(2) By a practitioner, or by the practitioner's authorized agent under the practitioner's supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

"Nonlegend drug" means a drug that may be lawfully sold without a prescription.

"Pharmacy" means a place of business operating as a pharmacy as permitted under chapter 461.

"Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator, or other person licensed and registered under section 329-32 to distribute, dispense, or conduct research with respect to a controlled substance in the course of professional practice or research in the State;

(2) An advanced practice registered nurse with prescriptive authority licensed and registered under section 329-32 to prescribe and administer controlled substances in the course of professional practice in the State; and

(3) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in the State.

"Private label distributor" means a company that has a valid labeler code under title 21 Code of Federal Regulations part 207 and markets a drug product under its own name, but does not perform any manufacturing.

"Program operator" means a drug take-back organization, covered manufacturer, or group of covered manufacturers that implements or intends to implement a drug take-back program approved by the department.

"Repackager" means a person who owns or operates an establishment that repacks and relabels a product or package containing a covered drug for further sale, or for distribution without further transaction.

"Retail pharmacy" has the same meaning as "retail community pharmacy" under section 431R-1.

"Wholesale prescription drug distributor" means a person licensed under section 461-8.6.

§ -2 Requirement to participate in a drug take-back program. A covered manufacturer shall establish and implement a drug take-back program that complies with the requirements of this chapter. A manufacturer that becomes a covered manufacturer on or after July 1, 2021, shall, no later than six months after the date on which the manufacturer became a covered manufacturer, participate in an approved drug take-back program or establish and implement a drug take-back program that complies with the requirements of this chapter. A covered

manufacturer may establish and implement a drug take-back program independently, as part of a group of covered manufacturers, or through membership in a drug take-back organization.

§ -3 Identification of covered manufacturers. (a) No later than October 1, 2020, a wholesale prescription drug distributor that sells a drug within the State shall provide a list of drug manufacturers to the department in a form prescribed by the department. A wholesale prescription drug distributor shall provide an updated list to the department on January 15th of each year.

(b) No later than October 1, 2020, a retail pharmacy, private label distributor, or repackager shall provide written notification to the department identifying the drug manufacturer from which the retail pharmacy, private label distributor, or repackager obtains a drug that it sells under its own label.

(c) A person or entity that receives a letter of inquiry from the department regarding whether or not it is a covered manufacturer under this chapter shall respond in writing no later than sixty 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:

(1) State the basis for this belief;

(2) Provide a list of any drugs it sells, distributes, repackages, or otherwise offers for sale within the State; and

(3) Identify the name and contact information of the manufacturer of the drugs identified under paragraph (2).

§ -4 **Drug take-back program approval; program modifications.** (a) By July 1, 2022, a program operator shall submit a proposal for the establishment and implementation of a drug take-back program to the department for approval. The department shall approve a proposed program if the:

(1) Applicant submits a completed application;

(2) Proposed program meets the requirements of subsection (b); and

(3) Applicant pays the appropriate fee established by the department under section -11.

(b) To be approved by the department, a proposed drug take-back program shall:

(1) Identify and provide contact information for the program operator and each participating covered manufacturer;

(2) Identify and provide contact information for the authorized collectors for the proposed program and as the reasons for excluding any potential authorized collectors from participation in the program;

(3) Provide for a collection system that complies with section -5;

(4) Provide for a disposal and handling system that complies with section -7;

(5) Identify any transporters and waste disposal facilities that the program will use;

(6) Adopt policies and procedures to be followed by persons handling covered drugs collected under the program to ensure safety, security, and compliance with regulations adopted by the Drug Enforcement Administration, as well as any applicable laws;

(7) Ensure the security of patient information on drug packaging during collection, transportation, recycling, and disposal;

(8) Promote the program by providing consumers, pharmacies, and other entities with educational and outreach materials as required by section -6;

(9) Demonstrate adequate funding for all administrative and operational costs of the drug take-back program, with costs apportioned among participating covered manufacturers;

(10) Set long-term and short-term goals with respect to collection amounts and public awareness; and

(11) Consider:

(A) The use of existing providers of pharmaceutical waste transportation and disposal services;

(B) Separation of covered drugs from packaging to reduce transportation and disposal costs; and

(C) Recycling of drug packaging.

(c) No later than one hundred twenty days after receipt of a drug take-back program proposal, the department shall either approve or reject the proposal in writing to the applicant. The department may extend the deadline for approval or rejection of a proposal for good cause. If the department rejects the proposal, it shall provide the reason for rejection in writing.

(d) No later than ninety days after receipt of a notice of rejection under subsection (c), the applicant shall submit a revised proposal to the department. The department shall either approve or reject the revised proposal in writing to the applicant within ninety days after receipt of the revised proposal, including the reason for rejection, if applicable.

(e) If the department rejects a revised proposal, the department may:

(1) Require the program operator to submit a further revised proposal;

(2) Develop and impose changes to some or all of the revised proposal to address deficiencies;

(3) Require the covered manufacturer or covered manufacturers that proposed the rejected revised proposal to participate in a previously approved drug take-back program; or

(4) Determine that the covered manufacturer is out of compliance with the requirements of this chapter and take enforcement action as provided in section -10.

(f) The program operator shall initiate operation of an approved drug take-back program no later than one hundred eighty days after approval of the proposal by the department.

(g) Proposed changes to an approved drug take-back program that substantially alter program operations shall have prior written approval of the department. A program operator shall submit to the department any proposed change in writing at least fifteen days before the change is scheduled to occur. Changes requiring prior approval of the department include changes to participating covered manufacturers, collection methods, collection system requirements described in section -5(h), policies and procedures for handling covered drugs, education and promotion methods, and selection of disposal facilities.

(h) For changes to a drug take-back program that do not substantially alter program operations, a program operator shall notify the department at least seven days before implementing the change. Changes that do not substantially alter program operations include changes to collection site locations, methods for scheduling and locating periodic collection events, and methods for distributing prepaid, preaddressed mailers.

(i) A program operator shall notify the department of any changes to the official point of contact for the program no later than fifteen days after the change. A program operator shall notify the department of any change in ownership or contact information for participating covered manufacturers no later than ninety days after the change.

(j) No later than four years after a drug take-back program initiates operations, and every four years thereafter, the program operator shall submit an updated proposal to the department describing any substantive changes to program elements described in subsection (b). The department shall approve or reject the updated proposal using the process described in subsection (c).

(k) The department shall make all proposals submitted under this section available to the public and provide an opportunity for written public comment on each proposal.

§ -5 **Collection system.** (a) At least one hundred twenty days prior to submitting a proposal under section -4, a program operator shall notify potential authorized collectors of the opportunity to serve as an authorized collector for the proposed drug take-back program. A program operator shall

commence good faith negotiations with a potential authorized collector no later than thirty days after the potential authorized collector expresses interest in participating in a proposed program.

(b) A person or entity may serve as an authorized collector for a drug take-back program voluntarily or in exchange for compensation; provided that nothing in this chapter shall be construed to require a person or entity to serve as an authorized collector.

(c) A drug take-back program shall include as an authorized collector any retail pharmacy, hospital, or clinic with an on-site pharmacy, or law enforcement agency that offers to participate in the program without compensation and meets the requirements of subsection (e). A pharmacy, hospital, clinic, or law enforcement agency that meets the requirements of subsection (a) shall be included as an authorized collector in the program no later than ninety days after receiving an invitation to participate.

(d) A drug take-back program may also locate collection sites at:

(1) A long-term care facility where a pharmacy, or a hospital or clinic with an on-site pharmacy, operates a secure collection receptacle;

(2) A substance use disorder treatment program; or

(3) An authorized collector that meets the requirements of subsection (e).

(e) A collection site shall:

(1) Accept all covered drugs from covered entities during the hours that the authorized collector is normally open for business to the public;

(2) If located at a long-term care facility, only accept covered drugs that are in the possession of individuals who reside or have resided at the facility;

(3) Use secure collection receptacles in compliance with state and federal law, including any applicable on-site storage and collection standards and Drug Enforcement Administration regulations.

(f) The program operator shall provide a service schedule that meets the needs of each collection site to ensure that each secure collection receptacle is serviced as often as necessary

to avoid reaching capacity and that collected covered drugs are transported to final disposal in a timely manner, including a process for additional prompt collection service upon notification from the collection site. Secure collection receptacle signage shall prominently display a toll-free telephone number and website for the program so that members of the public may provide feedback on collection activities.

(g) An authorized collector shall comply with state and federal law, including rules or laws concerning collection and transportation standards, and federal laws and regulations governing the handling of covered drugs, including Drug Enforcement Administration regulations.

(h) A drug take-back program's collection system shall be safe, secure, and convenient on an ongoing, year-round basis and shall provide equitable and reasonably convenient access for residents across the state.

(i) In establishing and operating a collection system, a program operator shall give preference to locating collection sites at retail pharmacies, hospitals, or clinics with on-site pharmacies, and law enforcement agencies. Each county shall have a minimum of one collection site. The department may adopt

rules to require a greater minimum number of collection sites for a county.

(j) A program operator shall establish mail-back distribution locations or hold periodic collection events to supplement service to any area of the State that is underserved by collection sites, as determined by the department. The program operator, in consultation with the department, county law enforcement agencies, and the local community, shall determine the number and locations of mail-back distribution locations or the frequency and location of these collections events, to be held at least twice a year, unless otherwise determined through consultation with the local community. The program shall arrange any periodic collection events in advance with county law enforcement agencies and conduct periodic collection events in compliance with Drug Enforcement Administration regulations and protocols and applicable state laws.

(k) Upon request, a drug take-back program shall provide a mail-back program free of charge to covered entities and retail pharmacies that offer to distribute prepaid, preaddressed mailing envelopes for the drug take-back program. A drug take-

back program shall permit covered entities to request prepaid, preaddressed mailing envelopes through the program's web site, the program's toll-free telephone number, and a request to a pharmacist at a retail pharmacy distributing the program's mailing envelopes.

(l) The program operator shall provide alternative collection methods for any covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs in secure collection receptacles, through a mail-back program, or at periodic collection events, to the extent permissible under applicable state and federal laws. The department shall review and approve of any alternative collection methods prior to their implementation.

§ -6 Drug take-back program promotion. (a) A drug take-back program shall develop and provide a system of promotion, education, and public outreach about the safe storage and secure collection of covered drugs. This system may include signage, written materials to be provided at the time of purchase or delivery of covered drugs, and advertising or other promotional materials. At a minimum, each program shall:

(1) Promote the safe storage of legend drugs and nonlegend drugs by residents before secure disposal through a drug take-back program;

(2) Discourage residents from disposing of covered drugs in solid waste collection, sewer, or septic systems;

(3) Promote the use of the drug take-back program so that where and how to return covered drugs is widely understood by residents, pharmacists, retail pharmacies, health care facilities, health care providers, veterinarians, and veterinary hospitals;

(4) Establish a toll-free telephone number and website publicizing collection options and collection sites and discouraging improper disposal practices for covered drugs, such as flushing covered drugs or placing covered drugs in the garbage;

(5) Prepare educational and outreach materials that promote safe storage of covered drugs; discourage the disposal of covered drugs in solid waste collection, sewer, or septic systems; and describe how to return covered drugs to the drug take-back program. The materials shall use plain language and explanatory

images to make collection services and discouraged disposal practices readily understandable to all residents, including residents with limited English proficiency;

(6) Disseminate the educational and outreach materials described in paragraph (5) to pharmacies, health care facilities, and other interested parties for dissemination to covered entities;

(7) Work with authorized collectors to develop a readily recognizable, consistent design of collection receptacles and standardized instructions for covered entities on the use of collection receptacles. The department may provide guidance to program operators on the development of the instructions and design; and

(8) Include its promotion, outreach, and public education activities in its annual report required by section -9.

(b) If more than one drug take-back program is approved by the department, the programs shall coordinate their promotional activities to ensure that all residents can easily identify, understand, and access the collection services provided by any

drug take-back program. Coordination efforts shall include providing residents with a single toll-free telephone number and single website to access information about collection services for every approved program.

(c) Pharmacies and other entities that sell medication in the State may promote secure disposal of covered drugs through the use of one or more approved drug take-back programs. Upon request, a pharmacy shall provide materials explaining the use of approved drug take-back programs to its customers. The program operator shall provide pharmacies with these materials upon request and at no cost to the pharmacy.

(d) The department, the department of health, and any other state or county agency that is responsible for health, solid waste management, and wastewater treatment shall, through their standard educational methods, promote safe storage of prescription and nonprescription drugs by covered entities, secure disposal of covered drugs through a drug take-back program, and the toll-free telephone number and website for approved drug take-back programs.

(e) The department:

(1) Shall conduct a survey of covered entities and a survey of pharmacists, health care providers, and veterinarians who interact with covered entities on the use of medicines after the first full year of operation of the drug take-back program, and again every two years thereafter. Survey questions shall:

(A) Measure consumer awareness of the drug take-back program;

(B) Assess the extent to which collection sites and other collection methods are convenient and easy to use;

(C) Assess knowledge and attitudes about risks of abuse, poisonings, and overdoses from drugs used in the home; and

(D) Assess covered entities' practices with respect to unused, unwanted, or expired drugs, both currently and prior to implementation of the drug take-back program; and

(2) May, upon review of results of public awareness surveys, direct a program operator for an approved

drug take-back program to modify the program's promotion and outreach activities to better achieve widespread awareness among residents and health care providers about where and how to return covered drugs to the drug take-back program.

§ -7 **Disposal and handling of covered drugs.** (a) Covered drugs collected under a drug take-back program shall be disposed of at a permitted hazardous waste disposal facility that meets the requirements of title 40 Code of Federal Regulations parts 264 and 265, as they exist on the effective date of this Act.

(b) If use of a hazardous waste disposal facility described in subsection (a) is unfeasible based on cost, logistics, or other considerations, the department, in consultation with the department of health, may grant approval for a program operator to dispose of some or all collected covered drugs at a permitted large municipal waste combustor facility that meets the requirements of title 40 Code of Federal Regulations parts 60 and 62, as they existed on July 1, 2021.

(c) A program operator may petition the department for approval to use final disposal technologies or processes that

provide superior environmental and human health protection than that provided by the technologies described in subsections (a) and (b), or equivalent protection at less cost. In reviewing a petition under this subsection, the department shall take into consideration regulations or guidance issued by the United States Environmental Protection Agency on the disposal of pharmaceutical waste. The department, in consultation with the department of health, shall approve a disposal petition under this section if the disposal technology or processes described in the petition provides equivalent or superior protection in the following areas:

(1) Monitoring of any emissions or waste;

(2) Worker health and safety;

(3) Air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and

(4) Overall impact to the environment and human health.

(d) If a drug take-back program encounters a safety or security problem during collection, transportation, or disposal of covered drugs, the program operator shall notify the department as soon as practicable after encountering the problem.

§ -8 **Program funding.** (a) A covered manufacturer or group of covered manufacturers shall pay all administrative and operational costs associated with establishing and implementing the drug take-back program in which they participate. Administrative and operational costs shall include but not be limited to:

(1) Collection and transportation supplies for each collection site;

(2) Purchase of secure collection receptacles for each collection site;

(3) Ongoing maintenance or replacement of secure collection receptacles when requested by authorized collectors;

(4) Prepaid, preaddressed mailers;

(5) Compensation of authorized collectors, if applicable;

(6) Operation of periodic collection events, including the cost of law enforcement staff time;

(7) Transportation of all collected covered drugs to final disposal;

(8) Environmentally sound disposal of all collected covered drugs in compliance with section -7; and

(9) Program promotion and outreach.

(b) A program operator, covered manufacturer, authorized collector, or other person shall not charge:

(1) A specific point-of-sale fee to consumers to recoup the costs of a drug take-back program; or

(2) A specific point-of-collection fee at the time covered drugs are collected from covered entities.

§ -9 **Annual program report.** (a) By July 1, 2023, and each July 1 thereafter, a program operator shall submit to the department a report describing implementation of the drug take-back program during the previous calendar year. The report shall include:

(1) A list of covered manufacturers participating in the drug take-back program;

(2) The amount, by weight, of covered drugs collected, including the amount by weight from each collection method used;

(3) The following details regarding the program's collection system:

(A) A list of collection sites with addresses;

(B) The number of prepaid, preaddressed mailers provided;

(C) Locations where prepaid, preaddressed mailers were provided, if applicable;

(D) Dates and locations of collection events held, if applicable; and

(E) The transporters and disposal facility or facilities used;

(4) Whether any safety or security problems occurred during collection, transportation, or disposal of covered drugs, and if so, completed and anticipated changes to policies, procedures, or tracking mechanisms to address the problem and improve safety and security;

(5) A description of the public education, outreach, and evaluation activities implemented;

(6) A description of how collected packaging was recycled to the extent feasible;

(7) A summary of the program's goals for collection amounts and public awareness, the degree of success in meeting those goals, and if any goals have not been

met, what effort will be made to achieve those goals the following year; and

(8) The program's annual expenditures, itemized by program category.

(b) Within thirty days after each annual period of operation of an approved drug take-back program, the program operator shall submit an annual collection amount report to the department that provides the total amount, by weight, of covered drugs collected from each collection site during the prior year.

(c) The department shall make reports submitted under this section available to the public on the department's website.

§ -10 **Enforcement and penalties.** (a) The department may audit or inspect the activities and records of a drug take-back program to determine compliance with this chapter or investigate a complaint.

(b) The department shall send a written notice to a covered manufacturer that fails to participate in a drug take-back program as required by this chapter. The notice shall provide a warning regarding the penalties for violation of this chapter. A covered manufacturer that receives a notice under this subsection may be assessed a penalty if, sixty days after

receipt of the notice, the covered manufacturer continues to sell a covered drug within the State without participating in a drug take-back program approved under this chapter.

(c) The department may send a program operator a written notice warning of the penalties for noncompliance with this chapter if the department determines that the program operator's drug take-back program is in violation of this chapter or does not conform to the proposal approved by the department. The department may assess a penalty on the program operator and participating covered manufacturers if the program does not come into compliance by thirty days after receipt of the notice. The department may immediately suspend the operations of a drug take-back program and assess a penalty if the department determines that the program is in violation of this chapter and the violation creates a condition that, in the judgment of the department, constitutes an immediate hazard to the public or the environment.

(d) The department shall send a written notice to a wholesale prescription drug distributor or a retail pharmacy that fails to provide a list of drug manufacturers to the department as required by section -3. The notice shall

provide a warning regarding the penalties for violation of this chapter. A wholesale prescription drug distributor or retail pharmacy that receives a notice under this subsection may be assessed a penalty if, sixty days after receipt of the notice, the wholesale prescription drug distributor or retail pharmacy fails to provide a list of drug manufacturers to the department.

(e) In enforcing this chapter, the department may:

(1) Require an informal administrative meeting;

(2) Require a person or entity to engage in or refrain from engaging in certain activities pertaining to this chapter; and

(3) Assess a fine of not more than $2,000. Each day a violation continues constitutes a separate violation. In determining the appropriate amount of the fine, the department shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, and the financial burden to the entity in violation;

provided that the department may not prohibit a covered manufacturer from selling a drug within the State.

§ -11 **Department to set program fee.** (a) By July 1, 2022, the department shall:

(1) Determine its costs for the administration, oversight, and enforcement of this chapter;

(2) Set fees, by rules adopted pursuant to chapter 91, at a level sufficient to recover the costs associated with administration, oversight, and enforcement; and

(3) Adopt rules establishing requirements for program operator proposals.

(b) The department shall not impose any fees in excess of its actual administrative, oversight, and enforcement costs. The fees collected from each program operator in calendar year 2022 and any subsequent year may not exceed ten per cent of the program's annual expenditures as reported to the department in the annual report required by section -9 and determined by the department.

(c) The department may adjust its fees annually; provided that the adjusted fees shall not exceed actual administration, oversight, and enforcement costs. Adjustments for inflation may not exceed the percentage change in the consumer price index for all urban consumers as calculated by the United States

Department of Labor for the applicable county for the twelve-month period ending with June of the previous year.

(d) The department shall collect fees from each program operator by October 1, 2022, and annually thereafter.

(e) All fees collected under this section shall be deposited into the general fund.

§ -12 **Immunity from liability.** No cause of action shall arise, nor shall any liability be imposed against any person or entity for activities that are undertaken, reviewed, and approved by the department in compliance with this chapter, if the activities were performed in good faith and without fraudulent intent or the intent to deceive.

§ -13 **Federal preemption.** This chapter shall be deemed repealed if a federal law or a combination of federal laws takes effect that establishes a national program for the collection of covered drugs that substantially meets the intent of this chapter, including the creation of a funding mechanism for collection, transportation, and proper disposal of all covered drugs in the United States.

§ **-14 Financial and proprietary information.** (a) Financial or proprietary information, including trade secrets, commercial information, and business plans, submitted to the department under this chapter shall be considered confidential and from public disclosure to the extent permitted by chapter 92F.

(b) General information collected by the department shall be released or published only in aggregate amounts that do not identify or allow identification of financial, production, or sales data of a covered manufacturer or drug take-back organization.

§ **-15 Rules.** The department may adopt rules pursuant to chapter 91 to implement and enforce this chapter."

SECTION 2. Chapter 329, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"**§329- Drug take-back program.** It is not a violation of this chapter to possess or deliver a controlled substance in compliance with chapter ."

SECTION 3. New statutory material is underscored.

SECTION 4. This Act shall take effect on July 1, 2021.

INTRODUCED BY: _____

JAN 22 2021

H.B. NO. 386

Report Title:
Drug Manufacturers; Drug Take-Back Programs; Department of Public Safety; Covered Drugs; Drug Disposal

Description:
Requires drug manufacturers to establish and implement drug take-back programs or join drug take-back organizations for purposes of collecting and disposing of various types of prescription and nonprescription drugs. Specifies requirements for the department of public safety, covered manufacturers, drug take-back program operators, authorized collectors, and other entities who establish or participate in drug take-back programs.

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.