Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

HB 1047

Brief Description: Protecting the public's health by creating a system for safe and secure collection and disposal of unwanted medications.

Sponsors: Representatives Peterson, Appleton, Stanford, Robinson, Lytton, Ormsby, Senn, Jinkins, Bergquist, Frame, Gregerson, Doglio, Fey, Tharinger, Ryu, Kilduff, Macri, Hudgins, Farrell, Sawyer and Cody.

Brief Summary of Bill

- Requires manufacturers that sell drugs into Washington to operate a drug take-back program to collect and dispose of prescription and over-the-counter drugs from residential sources.

Hearing Date: 1/24/17

Staff: Alexa Silver (786-7190).

Background:

Federal law on disposal of household medications: The Drug Enforcement Administration (DEA) has adopted rules that permit a person to transfer unused, unwanted, or expired household pharmaceutical products to law enforcement or entities registered with the DEA (such as pharmacies, hospitals with an on-site pharmacy, and long-term care facilities) for disposal. Authorized methods for collection and disposal include take-back events, mail-back programs, and collection receptacles, and the rules contain detailed guidance on the use of these methods. The DEA requires that collected controlled substances be rendered non-retrievable.

Drug take-back programs in other jurisdictions: Pharmaceutical product stewardship laws have been enacted in Massachusetts and Vermont, as well as several counties in Washington (King, Snohomish, Kitsap, and Pierce Counties) and California. These programs generally require drug manufacturers to fund a system for the collection and disposal of unwanted medications. In 2014 the Ninth Circuit Court of Appeals upheld the first California ordinance against a challenge

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under the Commerce Clause of the U.S. Constitution, finding that the ordinance did not directly regulate or discriminate against interstate commerce.

Disposal of pharmaceuticals from household sources: The generation, transport, storage, and disposal of hazardous waste is regulated by federal and state law, but hazardous waste generated by households is exempt from such regulation. Although it is not required, the Environmental Protection Agency recommends that household pharmaceuticals collected through a take-back program be disposed of at a permitted hazardous waste combustor, or when that is not feasible, a large or small municipal waste combustor.

Summary of Bill:

Drug take-back program participation: Manufacturers that sell drugs into Washington must establish and implement a drug take-back program to collect covered drugs. A "covered drug" is a drug from a state resident (not a business source) that the resident no longer wants, including prescription and over-the-counter drugs, brand name and generic drugs, drugs for veterinary use, and drugs in medical devices and combination products. A covered manufacturer may implement a program independently, as part of a group of manufacturers, or through a drug take-back organization.

Within 60 days of a request from the Department of Health (DOH), a drug wholesaler must provide the DOH with a list of covered manufacturers. The wholesaler must update the list upon request, but no more than once a year. A retailer must notify the DOH of the covered manufacturer from which it obtains a drug sold under the store's label. A person that receives a letter from the DOH regarding whether it is a covered manufacturer must respond within 60 days and provide specified information. The DOH must provide lists of compliant and noncompliant manufacturers on its website.

Program approval: By January 1, 2018, a drug take-back program operator must submit a proposal for the establishment and implementation of a drug take-back program to the DOH. To be approved, a proposal must: provide contact information for the program operator and participating manufacturers; identify authorized collectors; provide compliant collection, handling, and disposal systems; identify transporters and disposal facilities; adopt procedures for handling drugs; ensure security of patient information; provide for program promotion; demonstrate adequate funding, with costs apportioned according to Washington sales revenues; set goals for collection amounts and public awareness; and consider the use of existing transportation and disposal service providers, separation of packaging from drugs, and recycling of packaging. The DOH must make proposals available to the public for comment, but any proprietary information is exempt from public disclosure.

The DOH must approve or reject proposals within 120 days, unless the deadline is extended for good cause. If a proposal is rejected, the applicant must submit a revised proposal within 60 days, and the DOH must approve or reject it within 90 days. If the DOH rejects a revised proposal, it may require submission of another revised proposal, impose changes to address deficiencies, require the manufacturer to participate in another program, or take enforcement action.

Once a proposal is approved, the program operator must initiate operation within 90 days. To make changes, the program operator must notify the DOH of non-substantive changes and obtain approval for substantive changes. Deadlines are provided for updates to certain types of information. Approved programs must submit updated proposals to the DOH every four years.

Collection system: Authorized collectors may (but are not required to) participate in a drug take-back program, and they may participate voluntarily or in exchange for compensation. An "authorized collector" is any of the following persons or entities that enters into an agreement with a program operator to collect covered drugs: a person or entity registered with the Drug Enforcement Administration that qualifies to modify its registration to collect controlled substances for purposes of destruction; a law enforcement agency; or an entity authorized by the DOH to provide an alternative collection mechanism. At least 120 days before submitting a proposal, program operators must notify potential authorized collectors of the opportunity to participate, and they must commence good faith negotiations within 30 days of a potential authorized collector expressing interest in participating. A program must include as an authorized collector any retail pharmacy, hospital or clinic with an on-site pharmacy, or law enforcement agency that offers to participate for free within 90 days of the offer to participate. An authorized collector must comply with applicable state and federal laws, including rules related to collection and transportation standards.

A program's collection system must be safe, secure, and convenient on an ongoing, year-round basis and must provide equitable access for residents across the state. A program must prioritize locating drop-off sites at pharmacies, hospitals and clinics with an on-site pharmacy, and law enforcement locations. A program must provide a minimum of one drop-off site per population center, plus one site for every 20,000 residents of the city or town within the population center. A "population center" is a city or town and the area within a 10-mile radius from the center of the city or town. On islands and in areas outside population centers, a program must provide a drop-off site at every potential authorized collector that is regularly open to the public, unless the potential authorized collector is unqualified or unwilling to participate.

Drop-off sites must accept all covered drugs during normal business hours, but a drop-off site at a long-term care facility may only accept covered drugs from people who reside or have resided at the facility. A drop-off site must use secure drop boxes, which must be adequately serviced. Signage on secure drop boxes must display a phone number and website.

Program operators must hold periodic collection events to supplement service to underserved areas, as determined by the DOH in consultation with the local health jurisdiction. Such events must be arranged in advance with law enforcement and held at least twice a year. Upon request, a program must provide free mail-back services. Alternative collection methods approved by the DOH are permitted for non-controlled substances that cannot be accepted in drop boxes, through mail-back services, or at collection events.

Program promotion: Drug take-back programs must provide a system of promotion, education, and public outreach. At a minimum, each program must:

- Promote the safe storage of drugs by residents and discourage residents from disposing of covered drugs in solid waste collection, sewer, or septic systems;
- Promote the program so that where and how to return covered drugs is widely understood;

- Establish a toll-free phone number and website publicizing collection options and drop-off sites and discouraging improper disposal;
- Prepare and disseminate materials to pharmacies, health care facilities, and other interested parties;
- Work with authorized collectors to develop a consistent design and standardized instructions for drop boxes;
- Annually evaluate the program's effectiveness;
- Coordinate outreach efforts with other approved programs, including by providing residents with a single phone number and website to access information; and
- Survey residents, as well as pharmacists, providers, and veterinarians who interact with residents on the use of medicines. The surveys must be conducted after the first full year of operation and then every two years. Programs must submit survey questions covering specified topics to the DOH for review and approval, report their data and results to the DOH, and make survey results available on the programs' websites.

Pharmacies are encouraged to promote the use of drug take-back programs and may provide explanatory materials upon request. Certain state and local agencies are required to promote safe storage and secure disposal of medications and provide the phone number and website for approved programs through their standard educational materials.

Disposal of collected drugs: Collected drugs must be disposed of at a permitted hazardous waste disposal facility. The DOH, in consultation with the Department of Ecology, may grant approval to dispose of covered drugs at a permitted large municipal waste combustor facility if use of a hazardous waste disposal facility is unfeasible. A program operator may also petition the DOH for approval to use an alternative disposal technology or process. In reviewing a petition, the DOH must take into consideration guidance of the Environmental Protection Agency. The DOH, in consultation with the Department of Ecology, must approve a petition if the technology or process provides equivalent or superior protection with respect to: waste or emissions monitoring; worker health and safety; air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and overall impact to the environment and human health.

A program must notify the DOH of any safety or security problems encountered during collection, transportation, or disposal.

An authorized collector is not required to obtain a permit for solid waste handling.

Program funding: Covered manufacturers must pay all administrative and operational costs associated with establishing and implementing a drug take-back program, including collection and transportation supplies for drop-off sites, purchase of secure drop boxes, maintenance and replacement of drop boxes, prepaid mailers, collection events (including the cost of law enforcement staff time), compensation of authorized collectors (if applicable), transportation of drugs for disposal, environmentally sound disposal, and program promotion. A program operator or authorized collector may not charge a point-of-sale or point-of-collection fee.

The DOH must annually determine its costs for administration, oversight, and enforcement and set a fee at a level to recover those costs. The DOH must make the proposed fee available for public review and comment for at least 30 days. If there is more than one program operating, the fee must be divided equally between programs. Fees must be deposited in the Secure Drug Take-

Back Program Account (Account), which is created in the State Treasury. Moneys from the Account may be used only for administering and enforcing the drug take-back law.

Enforcement and oversight: If a covered manufacturer fails to participate in a program, the DOH must send a written notice warning of the penalties. A covered manufacturer may be assessed a penalty if it does not come into compliance within 60 days. The DOH may audit or inspect the activities and records of a drug take-back program to determine compliance. If a program is in violation of the law or does not conform to its approved proposal, the DOH may send a written notice warning of the penalties for noncompliance. If the program does not come into compliance within 30 days, the DOH may assess a penalty. If a violation poses an immediate hazard to the public or the environment, the DOH may immediately suspend the program and assess a penalty. The DOH may require an informal administrative conference, order entities to engage in or refrain from engaging in certain activities, and assess a fine of up to $2000 per day.

The DOH must adopt any rules necessary to implement and enforce the law.

The Legislature intends to exempt from state antitrust laws and provide immunity through the state action doctrine from federal antitrust laws any activities that are undertaken, reviewed, and approved by the DOH pursuant to the law.

Reporting requirements: By March 1, 2019, and annually thereafter, a program operator must submit a report to the DOH describing program implementation, including: a list of participating manufacturers; the amount of covered drugs collected by collection method; details regarding the collection system; safety or security problems; education, outreach, and evaluation activities; program survey results; a description of how packaging was recycled; a summary of the program's goals and its success in meeting those goals; and the program's annual expenditures. The DOH must make these reports available online.

By November 15, 2018, and biennially thereafter, the DOH must submit a report to the Legislature regarding the status of approved drug take-back programs, an evaluation of the collection and disposal system, and recommendations for legislation.

Federal and local laws: The drug take-back law is void if federal law establishes a national program for the collection of covered drugs that substantially meets the intent of the law.

A county may enforce a grandfathered ordinance, and a manufacturer in compliance with a grandfathered ordinance is in compliance with the state law for purposes of that county. A "grandfathered ordinance" is a pharmaceutical product stewardship or drug take-back ordinance that: (1) is in effect on the effective date of the law; and (2) meets or exceeds the requirements of the state law with respect to safe and secure collection and disposal of medicines from residents, as determined by the DOH.

Appropriation: None.

Fiscal Note: Requested on January 19, 2017.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.