HOUSE BILL REPORT
HB 1047

As Reported by House Committee On:
Health Care & Wellness

Title: An act relating to protecting the public's health by creating a system for safe and secure collection and disposal of unwanted medications.

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 History:
Committee Activity:
Health Care & Wellness: 1/24/17, 2/15/17 [DPS].

Brief Summary of Substitute 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.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 10 members: Representatives Cody, Chair; Macri, Vice Chair; Caldier, Clibborn, Jinkins, Riccelli, Robinson, Slatter, Stonier and Tharinger.

Minority Report: Do not pass. Signed by 5 members: Representatives Schmick, Ranking Minority Member; Graves, Assistant Ranking Minority Member; Harris, MacEwen and Maycumber.

Minority Report: Without recommendation. Signed by 2 members: Representatives DeBolt and Rodne.

Staff: Alexa Silver (786-7190).

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.

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) 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 a California ordinance against a challenge under the Commerce Clause of the United States 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 Substitute 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. A drug wholesaler must provide the Department of Health (DOH) with a list of covered manufacturers and update the list annually. A retail pharmacy 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.

Program Approval. By October 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 satisfy certain requirements, such as ensuring the security of patient information and demonstrating adequate funding, with costs apportioned according to Washington sales revenues. 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, timelines are established for revised proposals. 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. The program operator must notify the DOH of any nonsubstantive 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, with or without 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 if a potential authorized collector expresses interest in participating. A program must include any retail pharmacy, hospital or clinic with an on-site pharmacy, or law enforcement agency that offers to participate for free within. A program may also locate collection sites at: a long-term care facility under certain circumstances; a substance use disorder treatment program; or any other authorized collector willing and able to meet the relevant requirements.

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 collection sites at pharmacies, hospitals and clinics with an on-site pharmacy, and law enforcement locations. A program must provide a minimum of one collection 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 unincorporated area within a 10-mile radius from the center of the city or town. On islands and outside population centers, a program must provide a collection site at every potential authorized collector that is qualified, willing, and regularly open to the public.

Collection sites must accept all covered drugs during normal business hours, but a site at a long-term care facility may only accept covered drugs in residents' possession. A collection site must use secure collection receptacles, and a program operator must ensure that receptacles are serviced as often as necessary to avoid reaching capacity. Signage on secure collection receptacles must display a phone number and website.

Program operators must hold periodic collection events at least twice a year to supplement service to underserved areas. Such events must be arranged in advance with law enforcement. Upon request, a program must provide a free mail-back program to residents

and pharmacies that offer to distribute mailers. Alternative collection methods approved by the DOH are permitted for certain non-controlled substances.

Program Promotion. Drug take-back programs must provide a system of promotion, education, and public outreach. Requirements include, for example: establishing a toll-free telephone number and website publicizing collection options and sites and discouraging improper disposal; preparing and disseminating materials; developing a consistent design and standardized instructions for collection receptacles; evaluating the program's effectiveness; and surveying 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 results available on their websites.

Pharmacies and local government agencies are encouraged to promote the use of drug take-back programs. Certain state agencies are required to promote safe storage and secure disposal and provide program contact information for programs through their 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 (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 Ecology, must approve a petition if the technology or process provides equivalent or superior protection with respect to specified factors.

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. A specific point-of-sale or point-of-collection fee may not be charged.

By July 1, 2018, the DOH must: determine its costs for administration, oversight, and enforcement; set fees at a level to recover those costs; and adopt rules establishing program proposal requirements. Fees must be collected annually and 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 notice warning of the penalties and assess a penalty if the manufacturer 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 violates the law or does not conform to its proposal, the DOH may send a notice warning of the penalties

for noncompliance and assess a penalty if it does not come into compliance within 30 days. If a wholesaler or retail pharmacy fails to provide a list of manufacturers to the DOH, the DOH must provide a notice warning of the penalties and may assess a penalty if the wholesaler or retail pharmacy does not come into compliance within 60 days.

The DOH may suspend a program and assess a penalty if a violation poses an immediate hazard. It may also 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, but it may not prohibit a covered manufacturer from selling a drug in the state. 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.

Reporting Requirements. By April 30 after the first full year of implementation and annually thereafter, a program operator must submit a report to the DOH describing program implementation. The DOH must make these reports available online.

Within 30 days of approving the first program, the DOH must submit an update to the Legislature. By November 15 after the first full year of operation and biennially thereafter, the DOH must submit a report to the Legislature: (1) describing the status of approved programs; (2) evaluating the collection and disposal system and the promotion requirements; (3) using available data sources, evaluating the impact of approved programs on specified outcomes; and (4) providing recommendations for legislation.

The DOH must contract with the statewide program of poison and drug information for a survey of residents to measure whether the collection system and promotion requirements have led to statistically significant changes in resident attitudes on storage and disposal, as well as rates of abuse, misuse, and accidental exposure to drugs. The survey must be conducted before the system is implemented and then no earlier than four years later. Results must be reported to the Legislature within six months.

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 political subdivision may not enact or enforce a local ordinance requiring a pharmacy, clinic, hospital, or law enforcement agency to collect and dispose of covered drugs.

A county may enforce a grandfathered ordinance for 18 months after an approved program begins operating, and a manufacturer in compliance with a grandfathered ordinance is in compliance with the state law for purposes of that county. A program operator must work with the county and the DOH to incorporate the local program into the approved state-level program before the end of the 18-month period. 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, as determined by the DOH.

Substitute Bill Compared to Original Bill:

The substitute bill:

- modifies the timelines for wholesalers to provide a list of manufacturers to the DOH and removes the requirement that the DOH post a list of manufacturers on its website;
- extends the deadline for submitting program proposals;
- specifies locations where a program may locate collection sites and requires program operators to service collection sites;
- requires programs to provide explanatory materials and, upon request, mailers to pharmacies, requires programs' biennial survey to assess covered entities' practices, changes the deadline for program operators to submit an initial report, and encourages (rather than requires) local agencies to promote approved programs;
- expands the prohibition on point-of-sale and point-of-collection fees, changes the timeframe for the DOH to set and collect fees, and removes provisions related to an annual fee divided among programs;
- provides penalties for wholesalers and pharmacies and specifies that the DOH may not prohibit the sale of a drug;
- limits the time period for enforcing a grandfathered ordinance to 18 months and prohibits local laws requiring certain entities to collect and dispose of covered drugs;
- modifies the deadline for the DOH report to the Legislature, adds the requirement that the DOH report evaluate the impact of approved programs on certain outcomes, and adds the requirement that the statewide program of poison and drug information survey residents; and
- modifies several definitions, adds a legislative finding, and makes several technical corrections.

Appropriation: None.

Fiscal Note: Available.

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

Staff Summary of Public Testimony:

(In support) This bill will save lives and the environment. Addressing the opioid epidemic is a top priority. Kids first experiment with painkillers from their own medicine cabinet. Addiction, poisonings, and overdoses are caused by medications used in homes. Secure medicine take-back is a key aspect of poison control. Residents want a safe place to dispose of leftover medications. The DEA take-back days have been threatened to be discontinued. People are more likely to drop drugs off at a pharmacy than at law enforcement. It is difficult to create these programs county by county. Law enforcement operates drop box sites, but it is costly and time-consuming to dispose of the collected drugs. Law enforcement does not mind collecting the drugs, but the drug industry should coordinate and pay for this system. Manufacturers have refused to be part of the solution. They have billions of dollars in sales and spend hundreds of millions of dollars on advertising. The federal government has identified drug take-back as the best method for disposal. Some local laws prohibit in-home disposal. Flushing drugs puts them in the wastewater stream, but it is costly and difficult to

remove them from wastewater. Take-back programs have been established for other products. There are safety concerns with recycling medications.

(Opposed) Drug take-back programs are expensive and have not worked. In British Columbia, there have been low participation rates and no positive impact for the environment. It is difficult to find collectors willing to participate. Take-back programs may raise the cost of over-the-counter drugs. These drugs are meant to be stored. Education is the most effective solution. Drugs should be stored up, away, and out of sight. In-home disposal is fast, safe, and convenient. This bill focuses on just one part of the drug supply chain. The problems are with safe storage and over-prescribing. Local programs would need to be preempted to avoid confusion.

Persons Testifying: (In support) Representative Peterson, prime sponsor; Alex Garrard, Washington Poison Center; Patrick Slack, Snohomish Regional Drug and Gang Task Force; Jeff Myers, Hoquiam Police Department; David Baker, Sound Cities Association; Scott Hazelgrove, Washington Association of Sewer and Water Districts; Keith Sinay, HealthPoint; and Sean Graham, Washington State Medical Association.

(Opposed) Carlos Gutierrez, Consumer Healthcare Products Association; Cliff Webster, Pharmaceutical Research and Manufacturers of America; and Bill Clarke, Biotechnology Innovation Organization.

Persons Signed In To Testify But Not Testifying: None.