HOUSE BILL REPORT
HB 1161

As Reported by House Committee On:
Health Care & Wellness

Title: An act relating to modifying the requirements for drug take-back programs.

Brief Description: Modifying the requirements for drug take-back programs.

Sponsors: Representatives Peterson, Davis, Pollet and Thai.

Brief History:
Committee Activity:
Health Care & Wellness: 1/27/21, 2/3/21 [DPS].

Brief Summary of Substitute Bill

- Authorizes the Department of Health (DOH) to approve more than one drug take-back program.
- Establishes requirements for program operator collaboration and allows the DOH to identify specific requirements for program promotion and consistent reporting in rule.
- Modifies the primary collection system a drug take-back program must utilize.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 13 members: Representatives Cody, Chair; Bateman, Vice Chair; Schmick, Ranking Minority Member; Caldier, Assistant Ranking Minority Member; Bronoske, Davis, Harris, Macri, Riccelli, Rude, Simmons, Stonier and Tharinger.

Minority Report: Without recommendation. Signed by 2 members: Representatives Maycumber and Ybarra.

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

Staff: Kim Weidenaar (786-7120).

Background:

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 for household pets, and drugs in medical devices and combination products. A "covered manufacturer" includes any person, corporation, or entity engaged in the manufacture of covered drugs sold in or into Washington, but does not include a private label distributor, a retail pharmacy that sells a drug under the pharmacy's store label, or a repackager.

Program Approval.
By July 1, 2019, a drug take-back program operator must have submitted a proposal for the establishment and implementation of a drug take-back program to the Department of Health (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 approve or reject proposals within 120 days, unless the deadline is extended for good cause. Once a proposal is approved, the program operator must initiate operation within 180 days. No later than four years after a drug take-back program initiates operations and every four years after, the program operator must submit an updated proposal to the DOH describing any substantive changes.

The statewide safe medication return program launched on November 21, 2020.

Collection System.
A program's collection system must be safe, secure, and convenient on an ongoing, year-round basis and must provide equitable and reasonably convenient 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 50,000 residents of the city or town within the population center. 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. Upon request, a program must provide a free mail-back program to residents and pharmacies that offer to distribute mailers.

Program Promotion.
Drug take-back programs must provide a system of promotion, education, and public outreach. Requirements include: establishing a toll-free telephone number and website publicizing collection options and sites and discouraging improper disposal; preparing and disseminating materials; and developing a consistent design and standardized instructions

for collection receptacles.

Program Funding.
Covered manufacturers must pay all administrative and operational costs associated with establishing and implementing a drug take-back program. By July 1, 2019, the DOH must have: determined its costs for administration, oversight, and enforcement; set fees at a level to recover those costs; and adopted rules establishing program proposal requirements. Fees may not exceed the actual administrative, oversight, and enforcement costs, and the fees collected from each program operator after 2019 may not exceed 10 percent of the program's annual expenditures as reported to the DOH.

Sunset Review.
The drug take-back program authorizing statutes are subject to a sunset review. The authorization is terminated January 1, 2029, and the statutes regulating drug take-back programs are repealed on January 1, 2030.

Summary of Substitute Bill:

Program Approval.
The Department of Health (DOH) may approve drug take-back programs proposed by one or more program operators. To be approved by the DOH, a proposed drug take-back program must meet the requirements independent of any other program.

On July 1, 2021, the DOH will begin the review of new proposals from entities seeking to become a program operator. Beginning July 1, 2024, and every four years after, the DOH will review new proposals from entities seeking to become a program operator.

Beginning July 1, 2024, and every four years after, all program operators must submit an updated proposal to the DOH describing any substantive changes.

Drug Take-Back Program Participation.
If there is only a single drug take-back program operator at any time and the operator intends to leave the program, participating manufacturers must find a new entity to take over operations of the existing program without a break in services. The new entity may not make any changes to the operations of the approved program or each covered manufacturer or group of covered manufacturers must identify a new program operator and develop a new program proposal. The DOH must accept new proposals for at least four months from the date the DOH is notified of the program operator intending to cease operations, or until a new proposal is approved. The DOH may approve a proposal if it meets the proposal requirements and the applicant pays the appropriate fee.

A covered manufacturer may change the approved program it participates in if it maintains continuous participation in an established drug take-back program. If a program operator

leaves a drug take-back program for any reason, all covered manufacturers that participated in that program must immediately join an existing approved drug take-back program or if there is no approved program, covered manufacturers must join an approved program as soon as one is available.

Collection System.
To be approved by the DOH, a drug take-back program must ensure that physical collection sites are the primary method of collection across the state. A drug take-back program's use of supplemental mail-back distribution locations or periodic collection events in underserved areas may provide collection services to no more than 15 percent of the state's residents. The program operator must fully implement an approved drug take-back program no later than 180 days after approval.

The DOH may identify or clarify in rule additional requirements for coordination or performance among program operators to ensure smooth operation of the drug take-back program, including consistent drop box appearance and signage, consistent messaging, and consistent metrics included in operator annual reports. Failure to comply with these requirements may result in enforcement action against a program operator.

Program Promotion.
The single website and toll-free telephone number must present all available collection sites, mail-back distribution locations, and take-back events to ensure residents are able to access the most convenient method of collection, regardless of the program operator, and must manage all requests for prepaid, preaddressed mailing envelopes. All program operators must collaborate to ensure that all state residents can easily identify, understand, and access services provided by any approved drug take-back program and ensure all drug take-back programs are harmonized to present a consistent statewide drug take-back system.

Program Funding.
Until January 1, 2024, the DOH must collect a one-time fee of $30,000 for review of proposals from each program operator applicant. The DOH must determine a fee for drug take-back program proposal review. The annual fee set by the DOH must be evenly split among each approved program operator.

Sunset Review.
The provisions of the bill are subjected to the sunset review. The authorization is terminated January 1, 2029, and the statutes regulating drug take-back programs are repealed on January 1, 2030.

Substitute Bill Compared to Original Bill:

The substitute bill:
- authorizes the Department of Health (DOH) to review new drug take-back program proposals beginning July 1, 2021, and to review new proposals every four years

beginning July 1, 2024;
- requires participating manufacturers in a drug take-back program where the program operator intends to leave the program, to find a new entity to take over operations of the existing program without a break in program services;
- requires program operators to fully implement an approved drug take-back program within 180 days of approval;
- requires the program promotion website and toll-free phone number to present all available collection sites, mail-back distribution locations, and take back events, regardless of program operator;
- requires program operators to collaborate to ensure residents are presented a consistent statewide drug take-back program, allows the DOH to identify specific requirements for program promotion and consistent reporting in rule, and provides that a violation of these requirements is subject to enforcement action under the act;
- modifies the collection system requirements;
- provides that the annual fee set by the DOH must be split evenly among each approved program operator;
- sets the proposal review fee for reviews conducted before January 1, 2024, at $30,000;
- clarifies that a proposed drug take-back program must meet the requirements to be approved, independent of any other operating program; and
- clarifies that rather than approving a program operator, the DOH approves a drug take-back program.

Appropriation: None.

Fiscal Note: Available. New fiscal note requested on February 3, 2021.

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) The Washington drug take-back law is the first statewide program and is a model other states are using. This bill corrects some oversights in the original bill that have made it very difficult for a second, third, or fourth program operator to start a drug take-back program. Since 2019 a potential operator has been working with the Department of Health (DOH) to see if the current law would allow approval of a second program. Having more than one operator provides additional resources and coverage for the public and will ensure a robust drug take-back program. This bill will give better access to drug take-back for many communities that are currently underserved, and the competition will better serve the citizens of Washington. There are some additional language changes are being worked on to make sure it does what is intended and improves what is already a fantastic system.

(Opposed) None.

(Other) There is a lot of support for the intent of this bill. However more technical amendments are needed to provide further clarity. This bill is a work in progress, but all parties are at the table talking and working towards agreement.

Allowing more than one program operator is in the best interest of the program. Changes should be made to the bill to ensure that the public have a seamless experience regardless of the program operator.

The DOH supports the concept of this bill but has some technical amendments to provide more clarity and direction, including setting requirements for consistent outreach and performance measures. It is also important to sequence the process with the rulemaking timeline. The DOH is hoping to establish an interval between proposal reviews for new programs to minimize the impact on the DOH and to promote overall stability.

Persons Testifying: (In support) Representative Peterson, prime sponsor; and Ashley Schmidt, Inmar Intelligence, Inc.

(Other) Cliff Webster, Pharmaceutical Research and Manufacturers of America; Blake Maresh, Washington State Department of Health; Scott Sigmon, Consumer Health Care Products Association; and Heather Trim, Zero Waste Washington.

Persons Signed In To Testify But Not Testifying: None.