Washington State House of Representatives Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

HB 1161

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

Sponsors: Representatives Peterson, Davis, Pollet and Thai.

Brief Summary of Bill

- Authorizes the Department of Health to approve more than one drug take-back program operator and to solicit new proposals if the sole program operator leaves the drug take-back program.
- Modifies the primary collection system a drug take-back program must utilize.

Hearing Date: 1/27/21

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.

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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.

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. Drug take-back programs must provide a system of promotion, education, and public outreach.

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 Bill:

Program Approval.

The Department of Health (DOH) may approve one or more drug take-back program operators. If there is only a single drug take-back program operator at any time and the operator intends to leave the program, the DOH must solicit new proposals. The DOH may approve a proposal if it

meets the proposal requirements and the applicant pays the appropriate fee. 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.

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. Mail-back distribution locations should account for no more than 25 percent of a program's collection sites and periodic collection events should account for no more than 10 percent of a program's collection sites. For purposes of this calculation, a periodic collection event is considered a single collection site.

Program Funding.

The DOH must determine a fee for drug take-back program proposal review.

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.

Appropriation: None.

Fiscal Note: Available.

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