

SENATE BILL REPORT

2SHB 1161

As of March 17, 2021

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

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

Sponsors: House Committee on Appropriations (originally sponsored by Representatives Peterson, Davis, Pollet and Thai).

Brief History: Passed House: 3/8/21, 97-0.

Committee Activity: Health & Long Term Care: 3/19/21.

Brief Summary of Bill

- Authorizes the Department of Health (DOH) to approve more than one drug take-back program.
- Establishes the drug take-back program proposal fee for proposals received before January 1, 2024.
- Establishes requirements for program operator collaboration and allows DOH to identify specific requirements for program promotion and consistent reporting in rule.
- Modifies the primary collection system a drug take-back program must use and specifies requirements for managing requests for prepaid mailing envelopes.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Staff: Greg Attanasio (786-7410)

Background: Drug Take-Back Program Participation. Manufacturers that sell drugs into Washington must establish and implement a drug take-back program to collect covered

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drugs. A covered drug is a drug from a state resident 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 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. 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 thereafter, the program operator must submit an updated proposal to 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 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, 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 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 reported to 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. DOH may approve drug take-back programs proposed by one or more program operators. To be approved, a proposed drug take-back program must meet the requirements independent of any other program.

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

The program operator must fully implement an approved drug take-back program no later than 180 days after approval. Beginning July 1, 2024, and every four years thereafter, all program operators must submit an updated proposal to 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. DOH must accept new proposals for at least four months from the date DOH is notified of the program operator intending to cease operations, or until a new proposal is approved. DOH may approve a proposal if it meets the program 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 the 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 DOH, a drug take-back program must ensure 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. 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 requests for prepaid, pre-addressed mailing envelopes from covered entities and retail pharmacies. All program operators must collaborate to present a consistent statewide drug take-back system for residents to ensure all state residents can easily identify, understand, and access services provided by any approved drug take-back program.

Program Funding. Until January 1, 2024, DOH must collect a one-time, non-refundable fee of \$157,000 for review of proposals from each program operator applicant. DOH must determine a fee for drug take-back program proposal review. The annual fee set by DOH must be evenly split among each approved program operator.

Sunset Review. The provisions of the bill are subject 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.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.