

HOUSE BILL REPORT

HB 1422

As Reported by House Committee On:
Health Care & Wellness

Title: An act relating to modifying the drug take-back program by modifying fee and enforcement regulations and addressing program operator performance parity.

Brief Description: Modifying the drug take-back program.

Sponsors: Representatives Peterson, Davis, Thai, Ormsby, Hill, Macri and Timmons; by request of Department of Health.

Brief History:

Committee Activity:

Health Care & Wellness: 2/11/25, 2/18/25 [DPS].

Brief Summary of Substitute Bill

- Modifies the annual operating fee the Department of Health can charge a program operator.
- Modifies the annual reporting requirements for program operators.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 12 members: Representatives Bronoske, Chair; Lekanoff, Vice Chair; Rule, Vice Chair; Davis, Macri, Obras, Parshley, Shavers, Simmons, Stonier, Thai and Tharinger.

Minority Report: Do not pass. Signed by 7 members: Representatives Schmick, Ranking Minority Member; Caldier, Assistant Ranking Minority Member; Marshall, Assistant Ranking Minority Member; Engell, Low, Manjarrez and Stuebe.

Staff: Kim Weidenaar (786-7120).

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.

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, 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.

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. 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 after, all program operators must submit an updated proposal to the DOH describing any substantive changes.

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 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, preaddressed 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 that all state residents can easily identify, understand, and access services provided by any approved drug take-back program.

Reporting Requirements.

By July 1 after the first full year of implementation and annually thereafter, a program operator must submit a report to the DOH describing program implementation. The report

must include:

- a list of covered manufacturers participating in the drug take-back program;
- the amount, by weight, of covered drugs collected, including the amount by weight from each collection method used;
- a list of collection sites with addresses;
- the number and locations of mailers provided;
- dates and locations of collection events held;
- the transporters and disposal facility or facilities used;
- whether any safety or security problems occurred during collection, transportation, or disposal of covered drugs, and if so, any completed or anticipated changes to policies or procedures;
- a description of the public education, outreach, and evaluation activities implemented;
- a description of how collected packaging was recycled to the extent feasible;
- a summary of the program's goals for collection amounts and public awareness, the degree of success in meeting those goals, and if any goals have not been met, what effort will be made to achieve those goals the following year; and
- the program's annual expenditures, itemized by program category.

Program Fees.

The DOH must determine its costs for the administration, oversight, and enforcement of the requirements of the program, and set fees at a level sufficient to recover the costs associated with administration, oversight, and enforcement. The DOH may not impose any fees in excess of its actual administrative, oversight, and enforcement costs. The fees collected from each program operator in calendar year 2020 and any subsequent year may not exceed 10 percent of the program's annual expenditures as reported to the DOH in the annual report and determined by the DOH. Adjustments to the department's fees may be made annually and may not exceed actual administration, oversight, and enforcement costs. Adjustments for inflation may not exceed the percentage change in the consumer price index for all urban consumers in the United States. The annual fee set by the DOH must be evenly split among each approved program operator. All fees collected must be deposited in the Secure Drug Take-Back Program Account (Account). Moneys from the Account may be used only for administering and enforcing the drug take-back law.

Enforcement and Oversight.

The DOH may audit or inspect the activities and records of a drug take-back program to determine compliance. The DOH must send a written notice to the following entities, which must include a warning of the penalties:

- a covered manufacturer that fails to participate in a drug take-back program;
- a program operator for noncompliance of state laws or for failing to conform to the DOH-approved proposal; and
- a drug wholesaler or a retail pharmacy that fails to provide a list of drug manufacturers to the DOH.

Covered manufacturers, drug wholesalers, and retail pharmacies that receives a notice may

be assessed a penalty if, 60 days after receipt of the notice, the covered manufacturer, drug wholesaler, or retail pharmacy continues to fail to comply. The DOH may assess a penalty on the program operator and participating covered manufacturers if the program does not come into compliance by 30 days after receipt of the notice. The DOH may immediately suspend operation of a drug take-back program and assess a penalty if it determines that the program's violation creates a condition that constitutes an immediate hazard to the public or the environment.

In enforcing these requirements, the DOH may:

- require an informal administrative conference;
- require a person or entity to engage in or refrain from engaging in certain activities; and
- assess a civil fine of up to \$2,000 for each violation. Each day upon which a violation occurs or is permitted to continue constitutes a separate violation.

Sunset Review.

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

Summary of Substitute Bill:

Program Reports.

A program operator must submit to the DOH a report describing implementation of the drug take-back program during the previous year, which must include the following, in addition to the existing requirements:

- a summary of the program's goals for collection amounts and public awareness, the degree of success in meeting those goals, and if the program's goals have not been met, an explanation on why the goals were not met; and
- an estimated budget for the next year, itemized by program category.

The DOH must make the reports available to the public through the internet. The DOH must include a description of the status of these reports, including whether they have been approved by the DOH. The DOH must evaluate the reports for compliance with applicable laws, rules, and the program operator's DOH-approved plan. The DOH must either approve reports or request revisions to bring them into compliance with applicable laws or the program operator's approved plan. Program operators must submit any requested revisions to the DOH within 30 days.

Enforcement.

The DOH may audit or inspect the activities and records of a drug take-back program to determine compliance with applicable laws and rules or investigate a complaint. Drug take-back programs must fully cooperate with the DOH during an audit, inspection, or

investigation.

Program Fees.

The DOH must set fees, including the annual operating fee, for proposal reviews, and the survey at a level sufficient to cover the costs associated with the administration, oversight, and enforcement. The annual operating fee must be split evenly among each approved program operator. The provisions prohibiting the DOH from charging a fee of more than 10 percent of the program's annual expenditures are removed.

Substitute Bill Compared to Original Bill:

The substitute bill:

- removes requirements that a drug take-back program operator's collection goals meet or exceed the collection goals of the other program operators for the upcoming year or the actual collections of other program operators for the reporting year;
- removes the authorization for the DOH to assess civil fines on program operators that fail to collect 80 percent of the covered drugs collected by another program operator or 90 percent of the covered drugs the program operator collected in the previous year;
- removes the provision requiring a program operator to explain why a lower budget will not result in less access or weight collected, if the program operator's estimated budget is less than 80 percent of the reporting period's budget;
- restores underlying law prohibiting the DOH from imposing any fees in excess of its actual administrative, oversight, and enforcement costs;
- removes the requirement for the DOH to include a description of the status of program operator reports on the internet;
- removes the provision authorizing the DOH to initiate enforcement actions if a program operator's revisions to their annual report do not comply with applicable laws or the program operator's approved plan;
- removes the provisions that modified the DOH's enforcement authorities and penalties for covered manufacturers, program operators, and drug wholesalers and pharmacies, and reverts back to the underlying law; and
- removes the provisions changing what the funds deposited in the Secure Drug Take-Back Program Account can be used for and reverts these provisions back to the underlying law.

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 program collects and disposes of unwanted and expired medications. At the time the bill passed there was only one program operator, but since then some changes have had to be made to address having two operators. This original bill had a lot more language, but this proposed substitute is limited to the core parts of the bill. Both program operators are doing very well and there is good oversight from DOH. However, as things have changed, the costs for DOH have gone up. One program operator is doing quite a bit more, and there is an interest in making sure the program is robust and fair to both providers. It is understood that there are some concerns about the bill, but the DOH cannot charge more in fees than the program costs.

The goal of the drug take-back program is to not have these things go to the landfill. It is also about suicide prevention, poison prevention, and is an important prevention strategy to address the opioid crisis. It has been a very successful program. People are using the program, and often the bins are overflowing. As the program progresses tweaks are needed to address issues as they arise. The primary focus of this bill is to remove the 10 percent cap, which has led to a budget shortfall. The removal of this cap will not result in uncapped fees, but will instead ensure equitable access to this program, particularly for those in rural areas or with transportation challenges. This bill helps ensure that the states costs are fully covered.

(Opposed) MED-Project is a nonprofit that has unparalleled experience in operating drug take-back programs. MED-Project was the first and only program operator when the state program began in 2020. By all accounts, MED-Project has exceeded service and convenience goals.

The bill was not shared with the program operators and there was no opportunity for feedback. While some revisions were made to address serious concerns, more are needed. Uncapped operating fees are unsustainable and there must be a transparent and direct process for the oversight and administration of the program.

While there is support for transparency and accountability, this bill introduces problematic changes that could undermine program effectiveness. While robust reporting requirements are important, the expanded mandates in the bill create excessive administrative burdens without improving public safety or program efficiency. This bill also grants the DOH broad authority to audit and inspect program operators without clear standards and safeguards, which could lead to inconsistent enforcement. Most concerning, this bill removes critical language ensuring that fees reflect actual administrative costs. Sustainable programs require predictable and fair regulatory costs and this bill removes key guardrails that protect against excessive financial burdens. This bill is not ready for consideration.

(Other) There is support for the program, but there is confusion in the marketplace with the two programs. There were recent changes that caused the program operators to remove

collection bins from some pharmacies and pharmacies were told to tell their customers to mail the product back to law enforcement offices. People are less likely to bring in medications to the police station. The easier you make it, the more likely people are to use it. There are concerns that the original bill talks about pharmacies and confusion about what the pharmacies need to do to comply with the bill. Program operators should allow any opportunity to have the drop off at the pharmacy be maintained and should not just rely on mail back options. Opioid use went down 20 percent after implementing the drug take-back program.

Persons Testifying: (In support) Representative Strom Peterson, prime sponsor; Heather Trim, Zero Waste Washington; and Carly Bartz-Overman, Washington State Department of Health.

(Opposed) Ann Bailey, Inmar Rx Solutions, Inc.; and Michael VanWinkle, MED-Project WA LLC.

(Other) Rick Hughes, Ray's Pharmacy, Orcas Island.

Persons Signed In To Testify But Not Testifying: None.