Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

HB 1422

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 Summary of Bill

- Requires each drug take-back program operator to collect roughly the same amount of covered drugs, by weight, as other program operators each year.
- Establishes civil fines for program operators that do not meet certain drug take-back thresholds.
- Modifies the annual operating fee the Department of Health can charge a program operator and authorizes additional uses of funds in the Secure Drug Take-Back Program Account.
- Modifies the annual reporting requirements for program operators.

Hearing Date: 2/11/25

Staff: Kim Weidenaar (786-7120).

Background:

Drug Take-Back Program Participation.
Manufacturers that sell drugs into Washington must establish and implement a drug takeback 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

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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, and 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 two thousand dollars 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 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;
- the program's annual expenditures, itemized by program category;
- an estimated budget for the next year, itemized by program category, and if the estimated budget is less than 80 percent of the reporting period's budget, the report must explain why the lower budget will not result in less statewide access to the program or less weight collected; and
- the program's collection and public awareness goals for the next year. Collection goals must meet or exceed, the reporting year collection goals, and meet or exceed, the lesser of:
    - the collection goals of the other program operators for the upcoming reporting year; or
    - the actual collections of the other program operators for the reporting year.

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. The DOH may initiate enforcement action if the revisions submitted by the program operator do not comply with the applicable law or the program operator's approved plan.

Enforcement.
The DOH may audit or inspect the activities and records of a drug take-back program to determine compliance with appliable laws and rules or investigate a complaint. Drug take-back programs must fully cooperate with the DOH during an audit, inspection, or investigation. The DOH must send a written notice to a covered manufacturer that fails to participate in a drug take-back program, which must provide a warning regarding the DOH's authority to assess a civil fine. If a program operator's program does not come into compliance within 30 days of receiving

the written notice, in addition to assessing a $2,000 civil fine on the program operator and participating covered manufacturers per violation, the DOH may suspend, restrict, or impose reasonable conditions on the approval of the program operator's drug take-back program.

Enforcement actions taken by the DOH provide a right to an adjudicative proceeding that is governed by the Administrative Procedure Act. The application for an adjudicative proceeding must be in writing, state the basis for contesting the adverse action, include a copy of the DOH's notice, and be received by the DOH within 28 days of the person's receipt of the adverse notice.

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 imposing fees in excess of actual administrative, oversight, and enforcement costs or from charging a fee of more than 10 percent of the program's annual expenditures are removed.

Account.
Expenditures from the Account may be used by the DOH only for administering and enforcing the program, except that civil fines that are deposited into the Account may also be used by the DOH to support department programs that:

- further the legislative findings of the drug take-back laws;
- prevent opioid and other drug misuse;
- identify and treat drug misuse and stimulant use disorder;
- ensure and improve the health and wellness of people who use opioids and other drugs;
- use data and information to detect opioid misuse or abuse, monitor illness, injury, and death, and evaluate interventions; and
- support individuals in recovery.

Program Operator Responsibilities.
Program operators' drug take-back programs must meet all the requirements of the drug take-back laws, rules, and any DOH-approved plan, independent of any other drug take-back programs. Program operators must each successfully implement their drug take-back program each year.

For each program operator, the weight of covered drugs, in pounds, collected by a drug take-back program should be roughly equivalent to the weight of covered drugs collected by the other program operators as reported in the respective program operators' most recent annual report. For each individual program operator, the weight of covered drugs, in pounds, collected by the drug take-back program should be equal to or greater than the weight of covered drugs collected by that program operator as reported in the program operator's most recent annual report.

Upon evaluation of a program operator's annual program report, the DOH may calculate and assess civil fines against the program operator based on the following:

- if the weight, in pounds, of covered drugs collected by a drug take-back program is less than 80 percent of the highest weight, in pounds, of covered drugs collected by another program operator, then the DOH will determine the civil fine to be assessed by:
    - calculating the difference in pounds between the program operator and the highest amount collected by a program operator; and
    - then multiply the difference in collection weight, in pounds, by the average collection cost per pound of all program operators combined;
- if the weight, in pounds, of covered drugs collected by a drug take-back program is less than 90 percent of the collection weight goal established by the program operator in the previous year's annual program report, then the department must determine the civil fine to be assessed by:
    - calculating the difference in pounds between the program operator's collection weight for the reporting period and the goal collection weight for the reporting period; and
    - multiplying the difference in collection weight, in pounds, by the average collection cost per pound of all program operators combined.

Appropriation: None.

Fiscal Note: Requested on February 5, 2025.

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