SENATE BILL REPORT
ESHB 1047

As Reported by Senate Committee On:
Health & Long Term Care, February 22, 2018

Title: An act relating to protecting the public's health by creating a system for safe and secure collection and disposal of unwanted medications.

Brief Description: Protecting the public's health by creating a system for safe and secure collection and disposal of unwanted medications.

Sponsors: House Committee on Health Care & Wellness (originally sponsored by Representatives Peterson, Appleton, Stanford, Robinson, Lytton, Ormsby, Senn, Jinkins, Bergquist, Frame, Gregerson, Doglio, Fey, Tharinger, Ryu, Kilduff, Macri, Hudgins, Farrell, Sawyer and Cody).

Brief History: Passed House: 2/09/18, 86-12.
Committee Activity: Health & Long Term Care: 2/19/18, 2/22/18 [DPA-WM].

Brief Summary of Amended Bill

- Requires manufacturers that sell drugs in Washington to operate a drug take-back program to collect and dispose of prescription and over-the-counter drugs from residential sources.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Majority Report: Do pass as amended and be referred to Committee on Ways & Means.
Signed by Senators Cleveland, Chair; Kuderer, Vice Chair; Rivers, Ranking Member; Bailey, Becker, Conway, Fain, Keiser, Mullet and Van De Wege.

Staff: Greg Attanasio (786-7410)

Background: Federal Law on Disposal of Household Medications. The Drug Enforcement Administration (DEA) has adopted rules that permit a person to transfer unused, unwanted, or expired household pharmaceutical products to law enforcement or entities registered with the DEA—such as pharmacies—for disposal. Authorized methods for collection and disposal include take-back events, mail-back programs, and collection receptacles, and the rules contain detailed guidance on the use of these methods.

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

Drug Take-Back Programs in Other Jurisdictions. Pharmaceutical product stewardship laws have been enacted in Massachusetts and Vermont, as well as several counties in Washington —King, Snohomish, Kitsap, and Pierce Counties—and California. These programs generally require drug manufacturers to fund a system for the collection and disposal of unwanted medications.

Disposal of Pharmaceuticals from Household Sources. Although it is not required, the Environmental Protection Agency recommends that household pharmaceuticals collected through a take-back program be disposed of at a permitted hazardous waste combustor, or when that is not feasible, a large or small municipal waste combustor.

Summary of Amended Bill: Drug Take-Back Program Participation. Drug manufacturers that sell drugs in Washington must establish a drug take-back program to collect covered drugs, which include prescription drugs, non-prescription drugs, veterinary drugs, and drugs in medical devices, from state residents. Manufacturers may establish a program independently, jointly with other manufacturers, or through drug take-back organization designated by a manufacturer to develop and implement a program on behalf of the manufacturer.

Program Approval. Program operators, including manufacturers, a group of manufacturers, and drug take-back organizations, must submit a proposal for a drug take-back program to the Department of Health (DOH) by July 1, 2019. The program must, among other requirements, provide for a collection system, a handling and disposal system, ensure security of patient information on drug packaging, provide for the promotion of the program, and demonstrate adequate funding.

DOH must approve or reject the proposal within 120 days of receipt, and if rejected, the program operator must submit a revised proposal within 90 days. After approval, the program operator must initiate operation within 180 days. DOH must make all submitted proposals available to the public and provide an opportunity for written comment.

Collection System. At least 120 days before submitting a proposal to DOH, operators must notify potential authorized collectors of the opportunity to participate in the program and conduct good faith negotiations with any collector interested in participating. An authorized collector is a person or entity registered with the DEA that qualifies to modify its registration to collect controlled substances for purposes of destruction; a law enforcement agency; or an entity authorized by DOH to provide an alternative collection mechanism. An operator must accept as an authorized collector any pharmacy, hospital or clinic with an on-site pharmacy, or law enforcement agency that is otherwise qualified and offers to participate without compensation.

Collection sites must accept all covered drugs during the hours the collector is normally open for business and 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 population center is a city or town and the unincorporated area within a ten-mile radius from the center of the city or town. Program operators must also either establish mail-

back distribution locations or hold collection events at least twice a year to supplement service to underserved areas.

Program Promotion. A drug take-back program must provide a system of promotion, education, and public outreach that discourages residents from disposing covered drugs in sewers, septic systems, or through solid waste collection; promotes the use of collection sites; establishes a toll-free number and website; disseminates educational and outreach materials; and provides consistent and recognizable collection receptacles.

Disposal and Handling of Covered Drugs. Collected drugs must be disposed of at a permitted hazardous waste disposal facility. DOH, in consultation with the Department of Ecology, may grant approval to dispose of covered drugs at a permitted large municipal waste combustor facility if use of a hazardous waste disposal facility is unfeasible. A program operator may also petition DOH for approval to use an alternative disposal technology or process.

Program Funding. A manufacturer or group of manufacturers jointly operating a take-back program must pay all operational and administrative costs associated with the operation of the program and manufacturers may not charge a point-of-sale or point-of-collection fee.

By July 1, 2019, DOH must determine its costs for administration, oversight, and enforcement and set fees to be imposed upon program operators at a level to recover those costs.

Reporting Requirements. By July 1 after the first full year of implementation, and each July 1 thereafter, a program operator must submit a report to DOH providing details about the drug take-back program.

DOH must submit an update to the Legislature, within 30 days of approving the first program. DOH must submit a report to the Legislature describing the status of approved programs and the impact they are having on specified outcomes, by November 15 after the first full year of operation and biennially thereafter.

Enforcement. DOH may audit or inspect the activities and records of a drug take-back program to determine compliance. If DOH determines a drug manufacturer or program operator is in violation of the act and does not come into compliance within 60 days of notice, DOH may order the entities to engage in or refrain from engaging in certain activities pertaining to drug take-back programs, and assess a fine of up to $2,000 per day, but it may not prohibit a covered manufacturer from selling a drug in the state.

Local Laws. A county may enforce a grandfathered ordinance for 12 months after a DOH approved program begins operating, and a manufacturer in compliance with a grandfathered ordinance is in compliance with the state law for purposes of that county. At the end of the 12-month period, this act preempts all current and future local laws in the state.

Termination and Repeal. The authorization for drug take-back programs created in this act is terminated January 1, 2029, and the statutes regulating drug take-back programs are repealed on January 1, 2030.

EFFECT OF HEALTH & LONG TERM CARE COMMITTEE AMENDMENT(S):

- Clarifies that covered manufacturers do not include private label distributors, repackagers, and certain nonprofit corporations and that the act preempts all existing and future local laws related to drug-take back or similar programs.

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.

Staff Summary of Public Testimony on Engrossed Substitute House Bill: *The committee recommended a different version of the bill than what was heard.* PRO: Unused medications in the home are easily accessible to anyone in the house. Regular collection will reduce the number of pills that are available for abuse. Household medications are commonly used in suicide attempts and death and fewer medications in the home would lead to fewer deaths. Pharmacies and law enforcement agencies want to participate in programs to help address the opioid epidemic in the state.

OTHER: Manufacturers and other entities who already operate drug take-back programs should be allowed to continue those programs separate from this bill.

Persons Testifying: PRO: Representative Strom Peterson, Prime Sponsor; James McMahan, Washington Association of Sheriffs & Police Chiefs; Mark Johnson, Washington Retail Association; Jeff Rochon, Washington State Pharmacy Association; David Yamashita, Forefront Suicide Prevention; M Haynes, Washington Association for Substance Abuse Prevention.

OTHER: Cliff Webster, Pharmaceutical Research & Manufacturers of America; Bill Clarke, Biotechnology Innovation Organization; Michael Transue, Novo Nordisk.

Persons Signed In To Testify But Not Testifying: No one.