FINAL BILL REPORT
ESHB 1047

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Synopsis as Enacted

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).

House Committee on Health Care & Wellness
House Committee on Appropriations
Senate Committee on Health & Long Term Care

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. The DEA requires that collected controlled substances be rendered non-retrievable.

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 and California. These programs generally require drug manufacturers to fund a system for the collection and disposal of unwanted medications. In 2014 the Ninth Circuit Court of Appeals upheld a California ordinance against a challenge under the Commerce Clause of the United States Constitution, finding that the ordinance did not directly regulate or discriminate against interstate commerce.

Disposal of Pharmaceuticals from Household Sources. The generation, transport, storage, and disposal of hazardous waste is regulated by federal and state law, but hazardous waste generated by households is exempt from such regulation. Although it is not required, the Environmental Protection Agency recommends that household pharmaceuticals collected

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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.

Sunset Review.
The Sunset Act requires the Joint Legislative Audit and Review Committee to conduct a sunset review of a program or agency and provide a report with recommendations regarding whether the program should be retained, modified, or allowed to terminate.

Summary:

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 drug does not include vitamins, minerals, supplements, herbal or homeopathic remedies, schedule I controlled substances, personal care products, certain biological drug products, drugs administered in a clinical setting, emptied injector products or medical devices, exposed needles or sharps, and drugs for which manufacturers provide certain a drug take-back programs.

A "covered manufacturer" includes any person, corporation, or entity engaged in the manufacture of covered drugs sold in or into Washington state, but does not include a private label distributor, a retail pharmacy that sells a drug under the pharmacy's store label, a repackager, or a nonprofit health care corporation that repackages drugs solely for the purpose of supplying a drug to facilities or retail pharmacies operated by the corporation or an affiliate.

Ninety days after the effective date of the drug take-back law, a drug wholesaler must provide the DOH with a list of covered manufacturers. The wholesaler must update the list upon request, but no more than once a year. A retailer, private label distributor, and repackager must notify the DOH of the covered manufacturer from which it obtains a drug sold under its own label. A person that receives a letter from the DOH regarding whether it is a covered manufacturer must respond within 60 days.

Program Approval. By July 1, 2019, a drug take-back program operator must submit a proposal for the establishment and implementation of a drug take-back program to the 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 make proposals available to the public for comment, but any proprietary information is exempt from public disclosure. The DOH must approve or reject proposals within 120 days, unless the deadline is extended for good cause. If a proposal is rejected, the applicant must submit a revised proposal to the DOH within 90 days. If the DOH rejects a revised proposal, it may require submission of another revised proposal, impose changes to address deficiencies, require the manufacturer to participate in another program, or take enforcement action.

Once a proposal is approved, the program operator must initiate operation within 180 days. The program operator must notify the DOH of any substantial changes and obtain approval for substantial changes. Approved programs must submit updated proposals to the DOH every four years.

Collection System. Authorized collectors may participate in a drug take-back program, with or without compensation. An "authorized collector" is any of the following persons or entities that enters into an agreement with a program operator to collect covered drugs: a person or entity registered with the Drug Enforcement Administration that qualifies to modify its registration to collect controlled substances for purposes of destruction; a law enforcement agency; or an entity authorized by the DOH to provide an alternative collection mechanism.

At least 120 days before submitting a proposal, program operators must notify potential authorized collectors of the opportunity to participate, and they must commence good faith negotiations if a potential authorized collector expresses interest in participating. A program must include any retail pharmacy, hospital or clinic with an on-site pharmacy, or law enforcement agency that offers to participate for free. A program may also locate collection sites at: a long-term care facility under certain circumstances; a substance use disorder treatment program; or any other authorized collector willing and able to meet the relevant requirements.

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 "population center" is a city or town and the unincorporated area within a 10-mile radius from the center of the city or town. On islands and outside population centers, a program must provide a collection site at every potential authorized collector that is qualified, willing, and regularly open to the public.

Collection sites must accept all covered drugs during normal business hours, but a site at a long-term care facility may only accept covered drugs in residents' possession. 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. Signage on secure collection receptacles must display a phone number and website.

Program operators must either establish mail-back distribution locations or hold periodic collection events at least twice a year to supplement service to underserved areas. Any periodic collection events must be arranged in advance with law enforcement. Upon request, a program must provide a free mail-back program to residents and pharmacies that offer to distribute mailers. Alternative collection methods approved by the DOH are permitted for certain non-controlled substances.

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.

Pharmacies and local government agencies are encouraged to promote the use of drug take-back programs. Certain state agencies are required to promote safe storage and secure disposal and provide program contact information for programs through their educational materials.

The DOH must evaluate the program's effectiveness and survey residents, pharmacists, providers, and veterinarians who interact with covered entities on the use of medicines. The surveys must be conducted after the first full year of operation and then every two years. The DOH may after a review of the survey, direct a program operator to modify the program's promotion and outreach activities to better achieve awareness of the program.

Disposal of Collected Drugs. Collected drugs must be disposed of at a permitted hazardous waste disposal facility. The DOH, in consultation with the Department of Ecology (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 the DOH for approval to use an alternative disposal technology or process. In reviewing a petition, the DOH must take into consideration guidance of the Environmental Protection Agency. The DOH, in consultation with Ecology, must approve a petition if the technology or process provides equivalent or superior protection with respect to specified factors.

A program must notify the DOH of any safety or security problems encountered during collection, transportation, or disposal. An authorized collector is not required to obtain a permit for solid waste handling.

Program Funding. Covered manufacturers must pay all administrative and operational costs associated with establishing and implementing a drug take-back program. A specific point-of-sale or point-of-collection fee may not be charged.

By July 1, 2019, the 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 as reported to the DOH. Fees must be collected annually and deposited in the Secure Drug Take-Back Program Account (Account), which is created in the State Treasury. Moneys from the Account may be used only for administering and enforcing the drug take-back law.

Enforcement and Oversight. If a covered manufacturer fails to participate in a program, the DOH must send a notice warning of the penalties and assess a penalty if the manufacturer does not come into compliance within 60 days. The DOH may audit or inspect the activities and records of a drug take-back program to determine compliance. If a program violates the law or does not conform to its proposal, the DOH may send a notice warning of the penalties for noncompliance and assess a penalty if it does not come into compliance within 30 days. If a wholesaler or retail pharmacy fails to provide a list of manufacturers to the DOH, the

DOH must provide a notice warning of the penalties and may assess a penalty if the wholesaler or retail pharmacy does not come into compliance within 60 days.

The DOH may suspend a program and assess a penalty if a violation poses an immediate hazard. It may also require an informal administrative conference, order entities to engage in or refrain from engaging in certain activities pertaining to drug take-back programs, and assess a fine of up to $2000 per day, but it may not prohibit a covered manufacturer from selling a drug in the state. The DOH must adopt any rules necessary to implement and enforce the law.

The Legislature intends to exempt from state antitrust laws and provide immunity through the state action doctrine from federal antitrust laws any activities that are undertaken, reviewed, and approved by the DOH.

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 DOH must make these reports available online.

Within 30 days of approving the first program, the DOH must submit an update to the Legislature. By November 15 after the first full year of operation and biennially thereafter, the DOH must submit a report to the Legislature: (1) describing the status of approved programs; (2) evaluating the collection and disposal system and the promotion requirements, in conjunction with an academic institution; (3) using available data sources, evaluating the impact of approved programs on specified outcomes; and (4) providing recommendations for legislation.

The DOH must contract with the statewide program of poison and drug information for a survey of residents to measure whether the collection system and promotion requirements have led to statistically significant changes in resident attitudes on storage and disposal, as well as rates of abuse, misuse, and accidental exposure to drugs. The survey must be conducted before the system is implemented and then no earlier than four years later. Results must be reported to the Legislature within six months.

Federal and Local Laws. The drug take-back law is void if federal law establishes a national program for the collection of covered drugs that substantially meets the intent of the law. A political subdivision may not enact or enforce a local ordinance requiring a pharmacy, clinic, hospital, or law enforcement agency to collect and dispose of covered drugs.

A county may enforce a grandfathered ordinance for 12 months after an 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. A program operator must work with the county and the DOH to incorporate the local program into the approved state-level program before the end of the 12-month period. A "grandfathered ordinance" is a pharmaceutical product stewardship or drug take-back ordinance that: (1) is in effect on the effective date of the law; and (2) meets or exceeds the requirements of the state law, as determined by the DOH. At the end of the 12-month period, all existing and future local laws regarding drug take-back programs or other programs for the collection, transportation, and disposal of covered drugs, or education, promotion, and public outreach are preempted.

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.

Votes on Final Passage:

House	86	12	
Senate	49	0	(Senate amended)
House	84	12	(House concurred)

Effective: June 7, 2018