

HOUSE BILL REPORT

HB 1845

As Reported by House Committee On:
Environment

Title: An act relating to pharmaceutical waste.

Brief Description: Concerning pharmaceutical waste.

Sponsors: Representatives DeBolt, Fitzgibbon, Orcutt, Short, Smith and Jinkins.

Brief History:

Committee Activity:

Environment: 2/12/15, 2/19/15 [DPS].

Brief Summary of Substitute Bill

- Requires the Department of Ecology (Department) to convene a stakeholder workgroup in order to evaluate pharmaceutical waste management policies and encourages the Department to use enforcement discretion until the work group completes its evaluation.
- Requires the stakeholder workgroup to submit recommendations to the Legislature by December 15, 2015.
- Authorizes pharmaceutical waste management facilities permitted to accept pharmaceutical dangerous waste that is not federal hazardous waste to manage all pharmaceutical waste that they receive in accordance with state dangerous waste regulations.

HOUSE COMMITTEE ON ENVIRONMENT

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 9 members: Representatives Fitzgibbon, Chair; Peterson, Vice Chair; Short, Assistant Ranking Minority Member; Farrell, Fey, Goodman, Harris, McBride and Pike.

Minority Report: Do not pass. Signed by 1 member: Representative Taylor.

Minority Report: Without recommendation. Signed by 1 member: Representative Shea, Ranking Minority Member.

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.

Staff: Jacob Lipson (786-7196).

Background:

The federal Resource Conservation and Recovery Act (RCRA) authorizes the Environmental Protection Agency to control the generation, transport, treatment, storage, and disposal of hazardous wastes. The Department of Ecology (Department) is the designated lead agency for implementing the RCRA requirements in Washington. State law also provides separate authority for the Department to control the management of dangerous wastes designated under state law. Certain types of waste, including certain pharmaceutical medicines, that are not designated as hazardous under federal law are designated as dangerous by the state. Both hazardous and dangerous wastes must be identified by generating facilities and must be managed in accordance with regulations that apply to various specific types of wastes generated. Facilities that receive, sort, treat, and dispose of dangerous and hazardous wastes must receive a state or federal permit that authorizes the facility to handle those types of waste.

Several categories of pharmaceutical medicine are established in state law. Controlled substances are those drugs that are regulated under the federal Controlled Substances Act and restricted in use because of their potential for abuse or dependency. Legend drugs are drugs which must be dispensed through a prescription unless being dispensed by a medical practitioner. Over-the-counter medications are available to customers without a prescription.

In 2008 the Department published an interim policy for the enforcement of dangerous waste regulations as applied to pharmaceutical wastes of retail pharmacies and patient care facilities including hospitals. Generators managing pharmaceutical waste under the 2008 interim policy must either send waste to a RCRA-permitted incinerator for disposal or must segregate dangerous wastes designated as state-only dangerous waste but not as federal hazardous waste. State-only dangerous waste must be managed in accordance with the state's dangerous waste rules, which allows certain state-only pharmaceuticals to be disposed of in facilities permitted to incinerate municipal solid waste or that meet certain other combustion temperature requirements. Dangerous waste that is also infectious waste must either be sent to a RCRA-permitted facility, or, if it is state-only dangerous waste, may be sent to a disposal facility with a permit to accept both state-only dangerous and infectious wastes. Salt-water, sugar-water, and other water solutions without vitamins or additives may be disposed of as sewage with approval from the local wastewater treatment facility. The 2008 interim enforcement guidance also details rules for waste accumulation practices, empty container management, recordkeeping, and for reverse distribution of unwanted pharmaceuticals that are intact and can still be used for their original intended purposes.

Summary of Substitute Bill:

By September 1, 2015, the Department must convene a stakeholder workgroup that includes state agencies, hospitals, pharmaceutical waste-handling facilities, and others. The workgroup is to be facilitated by a consultant with expertise in the RCRA and is directed to submit its recommendations by December 31, 2015. Until the workgroup submits its

recommendations, the Department is encouraged to use its enforcement discretion, and is prohibited from using information shared during the workgroup process for enforcement purposes unless there is a substantial human health risk or a probability of environmental harm.

The Department must designate an employee in the agency's headquarters office to oversee pharmaceutical waste-handling facilities that receive statewide waste. Pharmaceutical waste-handling facilities may dispose of the pharmaceutical waste they receive through the process for incinerating state-only dangerous pharmaceutical waste.

The types of pharmaceutical waste-handling facilities covered by these provisions include facilities that handle controlled substances, legend drugs, and over-the-counter medications that qualify as dangerous waste under state regulations but are not hazardous wastes under the federal RCRA.

An intent section declares a legislative goal to develop a consistent statewide pharmaceutical waste management system that helps regulated businesses comply with dangerous waste laws.

Substitute Bill Compared to Original Bill:

The substitute bill makes the following changes to the original bill:

- eliminates the requirement that the Department engage in negotiated rule-making to revise pharmaceutical waste management policies;
- directs the Department to convene a workgroup charged with submitting pharmaceutical waste management policy recommendations to the Legislature by December 31, 2015;
- directs the Department to refrain from using information uncovered during the workgroup process in enforcement actions unless there is an imminent threat of death or bodily harm to a person or a probability of environmental harm;
- directs the Department to designate an employee in its headquarters office to oversee statewide regulation of pharmaceutical waste-handling facilities; and
- changes intent language to reference legislative goals of developing a consistent statewide pharmaceutical waste management system that helps regulated businesses comply with dangerous waste laws.

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) The intention of this bill is to narrowly focus on new dangerous waste management practices for pharmaceuticals. The pharmaceutical waste generators, waste handlers, and the Department should enter into an open dialogue for how to improve management without the regulated parties being afraid of enforcement action being taken. Pharmaceutical wastes bring up unique management issues as compared to other types of dangerous wastes. The Department's current enforcement guidelines have not been able to eliminate confusion and mismanagement by waste generators. It is difficult for waste handlers to identify and sort dangerous medical wastes once they receive them from the hospitals and health care facilities that generate the wastes.

(Opposed) If you apply a blanket presumption that facilities generating wastes are labeling correctly, it allows for improper mixing of wastes. This then allows for the waste processing facility to later dispose of the wastes in improper ways. This bill removes responsibility for waste-handling facilities. Dangerous waste rules are in place to ensure that toxic and other dangerous substances are closely managed from cradle to grave in order to protect public health and safety. A dialogue process with stakeholders on how to improve technical compliance with dangerous waste laws should take place before beginning a negotiated rulemaking. This bill would require the Department to ignore violations of federal hazardous waste-handling laws, which could threaten federal delegation to implement the hazardous waste program.

Persons Testifying: (In support) Selin Hoboy and Lisa Thatcher, Stericycle.

(Opposed) K Seiler, Department of Ecology.

Persons Signed In To Testify But Not Testifying: None.