
Environment Committee

HB 1845

Brief Description: Concerning pharmaceutical waste.

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

Brief Summary of Bill

- Requires the Department of Ecology to initiate a negotiated rulemaking process with pharmaceutical waste generators and processors by September 1, 2015 in order to revise interim pharmaceutical waste management enforcement guidelines.
- Requires the Department of Ecology to update the Legislature on the status of the negotiated rulemaking process by September 1, 2016.
- Applies a presumption that pharmaceutical wastes generated by health facilities are being characterized in compliance with state requirements, until a rule is adopted as a result of the negotiated rulemaking process.

Hearing Date: 2/12/15

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 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 certain types of waste.

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.

Several types 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 wastes 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 a facility permitted to incinerate municipal solid waste or that meets 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.

The state Administrative Procedures Act, which establishes the criteria for rulemaking by state agencies, provides an option for a negotiated rulemaking process in which representatives of the agency and affected interests attempt to reach consensus on the rule negotiation process and proposed rule terms prior to the agency posting notice of a proposed rule and holding public hearings on a proposed rule.

Summary of Bill:

The Department is directed to begin a negotiated rulemaking process with hospitals, pharmaceutical waste-handling facilities, and others by September 1, 2015. The Department is directed to update the Legislature on the status of the negotiated rulemaking by September 1, 2016.

Until the Department adopts a new rule under the negotiated rulemaking process, the documentations prepared by hospitals, clinics, and other health facilities for the wastes received by processing facilities are presumed to contain accurate characterizations under state dangerous waste laws. In addition, pharmaceutical waste-handling facilities may dispose of the pharmaceutical wastes they receive through the process for incinerating state-only dangerous pharmaceutical wastes.

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 that are not hazardous wastes under the federal RCRA.

An intent section declares that the 2008 interim enforcement policy has created confusion among health care providers despite their best efforts to comply with pharmaceutical waste-handling requirements and that the Department should develop a new approach for regulating pharmaceutical waste.

Appropriation: None.

Fiscal Note: Requested on February 2, 2015.

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