

FISCAL IMPACT OF PROPOSED LEGISLATION

80th Oregon Legislative Assembly – 2019 Regular Session
Legislative Fiscal Office

Measure: HB 3273 - 7

*Only Impacts on Original or Engrossed
Versions are Considered Official*

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Measure Description:

Directs each manufacturer of prescription drugs that are sold within this state to develop and implement drug take-back program for purpose of collecting from individuals and nonbusiness entities prescription drugs for disposal.

Government Unit(s) Affected:

Department of Justice (DOJ), Department of Environmental Quality (DEQ), Oregon Judicial Department (OJD), Oregon Board of Pharmacy (OBOP)

Analysis:

This fiscal impact statement is for the purpose of transmitting the measure from the House Committee on Health Care to the Joint Committee on Ways and Means.

The measure with the -7 amendment requires certain specified manufacturers to participate in a drug take-back program. Covered manufacturers must pay all costs associated with participating in a drug take-back program. The measure exempts the drug take-back programs from antitrust laws. A manufacturer is not required to participate in a drug take-back program if they manufacture covered drugs for fewer than 50 patients in Oregon. However, they must provide mail-back services to those patients. The measure stipulates that governing body of a city or a county may not enact an ordinance requiring, or otherwise establishing a program for, the collection of covered drugs by nongovernmental entities through the use of drop-off sites or mail-back services.

The measure is anticipated to have an impact on the Department of Environment Quality, the Oregon Board of Pharmacy, the Oregon Judicial Department, and the Department of Justice.

A more complete fiscal analysis on the measure will be prepared as the measure is considered in the Joint Committee on Ways and Means.

Further Analysis Required

With passage of the measure, the Department of Environmental Quality (DEQ), will be is responsible for compliance with the drug take-back program. A program operator of a drug take-back program must be organized as an entity that is exempt from income taxes under section 501(c)(3) of the Internal Revenue Code. A program operator must pay a fee to DEQ and submit to DEQ a plan for participating in a drug take-back program. The measure specifies required elements of the plan. DEQ is responsible for evaluating and approving or rejecting the plan within 90 days after receiving a plan. If DEQ rejects the plan, it must provide the reasons for the rejection. Not later than 60 days after DEQ rejects the plan the program operator must submit to DEQ a revised plan. If DEQ rejects a revised plan the department may require the operator to further revise the plan or impose a penalty on each covered manufacturer participating in the proposed drug take-back program.

Within four years after DEQ approves a plan, the operator must submit to DEQ an updated plan for continued operation of the program. An operator must request preapproval from DEQ for any change to a drug take-back program that substantively alters the drug take-back program. A program operator must make this request not later than 30 days before the change is to occur. DEQ is authorized to approve or reject the changes.

A program operator must submit an annual report to DEQ for review and approval. If DEQ does not approve the report, the department must provide the operator with written notice of necessary revisions and a timeline for resubmittal. DEQ must publish approve reports on its website.

DEQ must send notices to manufacturers that fail to participate in a drug take-back program. The notices must explain possible penalties.

Operators must conduct a survey once every two years of covered entities and pharmacists, health care providers and veterinarians who interact with covered entities. DEQ must prescribe the form and manner of the survey. Operators must submit proposed survey questions to DEQ for preapproval. Operator must submit to DEQ an annual report on the development, implementation and operation of the drug take-back program.

The measure authorizes DEQ to assess fees to pay the costs of administering the program. The measure specifies fines and penalties that DEQ may impose an manufacturers and operators not in compliance. The measure establishes the Secure Drug Take-Back Account and moneys in the account are continually appropriated to DEQ. DEQ is required to deposit moneys collected through the imposition of civil penalties and fees into the Secure Drug Take-Back Account.

DEQ must report to the Legislature by July 1, 2021 describing the administration of the drug take-back program.

The measure directs DEQ to enter into an agreement with Oregon Board of Pharmacy (OBOP) for routine inspections of retail drug outlets drop-off sites and audits of program operators records. OBOP is to inform DEQ of sites not in compliance. Drop-off site must use a secure repository in compliance with all state laws and rules and federal laws and regulations governing the keeping of covered drugs in repositories, as identified by the State Board of Pharmacy by rule.

Further Analysis Required