

FISCAL IMPACT OF PROPOSED LEGISLATION

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

Measure: HB 3273 - 5

*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 -5 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. Operators or authorized collectors are prohibited from imposing a charge against covered entities for the purpose of recouping the costs of a drug take-back program. The measure exempts the drug take-back programs from antitrust laws. Operators must submit a plan to the Department of Environment Quality by November 1, 2020. Take-back programs must be operational by July 1, 2021.

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 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 manufacturer is not required to participate in a drug take-back program if they can provide sufficient proof to DEQ that they manufacture covered drugs for fewer than 50 patients in Oregon.

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 approved 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. The measure specifies fines and penalties that DEQ may impose on 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. The measure authorizes DEQ to assess fees to pay the costs of administering the program.

DEQ must report to the Legislature by July 1, 2023 with an evaluation 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. If a manufacturer does not participate in a drug take-back program, the measure authorizes OBOP to assess a fine against the operator, not to exceed \$10,000 a day for each day that covered drugs manufactured by the covered manufacturer are sold in this state.

Further Analysis Required