FISCAL IMPACT OF PROPOSED LEGISLATION

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

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

Summary of Fiscal Impact:

Costs related to the measure may require budgetary action - See analysis.

Summary of Expenditure Impact:

	2019-21 Biennium	2021-23 Biennium
Other Funds - DEQ		
Personal Services	183,811	101,875
Services and Supplies	74,391	42,711
Total Other Funds	\$258,202	\$144,586
Positions	2	1
FTE	0.94	0.50

Summary of Revenue Impact:

	2019-21 Biennium	2021-23 Biennium
Other Funds - DEQ		
Fees	350,000	175,000
Total Other Funds	\$350,000	\$175,000

Analysis:

HB 3273 with the -A14 amendment requires certain specified manufacturers to use program operators to participate in a drug take-back program. Covered manufacturers must pay all costs associated with participating in a 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. The measure exempts program operators from antitrust laws. With passage of the measure, the Department of Environmental Quality (DEQ) and the Oregon Board of Pharmacy (OBOP) will be is responsible for ensuring compliance with the drug take-back program.

The -A14 amendment:

- Defines terms including analogous product, antitoxin, therapeutic serum, toxin and virus.
- Stipulates that this 2019 Act supersedes and preempts any local ordinance or other regulation enacted before, on or after the effective date of this 2019 Act.
- Removes the September 15, 2031 sunset.

- Changes the calculations of allocating the cost of the program among manufacturers.
- Changes "prescription drugs" to "covered drugs" in reference to calculations of allocating the cost of the program among manufacturers.
- Adds \$258,202 in Other Funds limitation for the Department of Environmental Quality to establish the Drug Take Back Program.

Department of Environmental Quality (DEQ)

DEQ estimates the fiscal impact of this bill to be \$258,202 Other Funds and 2 positions (0.94 FTE) for the 2019-21 biennium; and \$144,586 Other Funds and 1 position (0.50 FTE) for the 2021-23 biennium. These amounts reflect one limited duration, half-time Operations and Policy Analyst 1 position to help create the program and one permanent half-time Operations and Policy Analyst 2 position to oversee the operation of the drug take-back program, including working with program operators to evaluate and update plans. The measure specifies required elements of the plan that a program operator of a drug take-back program must submit to DEQ in order to participate in a 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. In addition, 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 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. Program 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. Program operators must submit proposed survey questions to DEQ for preapproval. Program operator must submit to DEQ an annual report on the development, implementation and operation of the drug take-back program. DEQ must report to the Legislature by July 1, 2021 describing the administration 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. Although fees charged will be based on actual costs, and the amount of the specific fees will need to be established through the rule making process, DEQ projects the need for revenues from fees to be about \$350,000 for the first biennium and \$175,000 for subsequent biennia.

Oregon Board of Pharmacy (OBOP)

Passage of this bill is anticipated to have a minimal fiscal impact on OBOP. The measure directs DEQ to enter into an agreement with 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. OBOP anticipates incorporating drop-off site inspections and audits into its existing inspection process. The bill also authorizes OBOP to assess a fine against manufacturers not participating in a drug take-back program.

Oregon Judicial Department (OJD)

Passage of this bill is anticipated to have a minimal fiscal impact on OJD. In the event that covered manufacturers subject to civil penalties request judicial review in the Court of Appeals, OJD anticipates using existing staff and resources to handle the number of additional case filings.