HB 3273 -4, -5 STAFF MEASURE SUMMARY

House Committee On Health Care

Prepared By:Oliver Droppers, LPRO AnalystSub-Referral To:Joint Committee On Ways and MeansMeeting Dates:3/21, 4/4

WHAT THE MEASURE DOES:

Requires manufacturers of certain drugs to participate in drug take-back program. Requires each take-back program operator to submit a plan to the Department of Environmental Quality (DEQ) for collection and disposal of drugs by July 1, 2020 with the programs becoming operational by February 1, 2021. Directs DEQ to review and approve or deny the submitted plans. Specifies that updated plans need to be submitted to DEQ every four years. Defines terms. Directs DEQ to enter into an agreement with the Board of Pharmacy to inspect take-back stations. Establishes the Secure Drug Take-Back Account. Allows for a mail-back option for communities with a population density of fewer than 20,000. Establishes fines to manufacturers of drugs - not pharmacies - for noncompliance. Places a moratorium on cities and counties (with the exception of law enforcement groups) from forming their own kiosk-based take-back programs. Creates civil penalties up to \$10,000 for manufacturers that do not participate in the drug take-back program. Sunsets the program September 15, 2031.

REVENUE:May have revenue impact, but no statement yet issued.FISCAL:May have fiscal impact, but no statement yet issued.

ISSUES DISCUSSED:

- Responsible disposal of prescription drugs, statewide
- Drug and abuse and accidental poisonings from unused drugs
- Limited availability of drug take-back programs, currently; costs associated with managing these programs
- Drug take-back programs in Washington and California, environmental protections and safety with easy and accessible community drug disposals
- Product stewardship and lifecycle for drugs produced by manufacturers
- Manufacturer funded drug take-back programs compared to in-home disposal
- Revenue sources to fund drug take-back programs, brand and generic manufacturers

EFFECT OF AMENDMENT:

-4 Specifies 50 percent of revenue from manufacturers participating in the drug take-back program Is based on *sale* of prescription *drugs*, remaining 50 percent of revenue based on *total volume* of prescription drugs sold in the state.

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-5 Replaces the measure. **Section1**: Defines authorized collector, biologics, covered drug (both prescription and nonprescription drugs, brand and generic), covered entity, covered manufacturer, drop-off site, drug take-back organization, among other key terms. Specifies covered drugs do not include vitamins, supplements, or homeopathic drugs or products, drugs administered in a clinical setting, exposed sharps, certain medical devices, or biologics. **Section2**: Requires manufacturers of certain drugs to participate in the drug take-back program unless they manufacturer drugs for fewer than patients in the state. Authorizes the State Board of Pharmacy to assess a fine up to \$10,000 each day a covered manufacturer does not participate in the drug take-back program. **Section 3**: Specifies that take-back program operator must be organized as a 501(c)(3) entity. **Section 4**: Requires

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each take-back program operator to submit a plan to the Department of Environmental Quality (DEQ) for approval for collection and disposal of drugs. Directs DEQ to review, approve or deny the submitted plans. Specifies that updated plans need to be submitted to DEQ every four years. Section 5: Requires program operators to seek preapproval to substantively change a drug take-back program on later than 30 days before the change is to occur; defines substantively. Sections 6-9: establishes criteria for authorized collectors, drop-off sites, covered drug collection events, and disposal of covered drugs. Section 10: Requires program operators to promote and provide public outreach and education about safe disposal of drugs. Section 11: Requires program operators to submit annual report to DEQ on the development, implementation, and operation of drug take-back program, specifies reporting requirements. Section 12: Requires covered manufacturers to pay all program costs. Sections 13-15: Allows DEQ to enter into an agreement with the Board of Pharmacy to inspect the drop-off sites, provides DEQ with enforcement authority, and establish fees to pay for program administration. Section 16: Establishes the Secure Drug Take-Back Account. Sections 17-18: Prohibits specified organizations from criminal or civil liability for complying with program requirements, and exempts program operators from state antitrust laws. Sections 19-21: Establishes confidentiality of information or data DEQ receives from covered manufacturers, exempts applicability of Uniform Controlled Substances Act, and creates a moratorium on cities and counties (with the exception of law enforcement groups) from forming their own drug take-back program. Sections 22-24: Allows DEQ to enter into interagency agencies with other state agencies, authorizes DEQ to adopt rules to administer the program, and requires DEQ to submit a report to the Legislative Assembly no later than July 1, 2023 and specifies report contents. Section 25: Sunsets the program September 15, 2031.

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BACKGROUND:

Approximately a third of pharmaceutical drugs purchased in the United States go unused, are considered hazardous wastes, and end up in water systems or landfills. Current disposal options are limited and inconsistent. In 2014, U.S. Drug Enforcement Administration (DEA) regulations expanded the types of locations allowed to accept unwanted medications on a routine basis. As of 2015, there are 615 authorized collectors nationwide that include drug manufacturers and distributors, narcotic treatment programs, retail pharmacies, and hospitals. Prior to this expansion, pharmacies and hospitals were banned from accepting unwanted prescription drugs, and the public's only legal option to discard unwanted medications safely was giving them to a law enforcement agency. Instead, many people flushed them down the toilet, resulting in contamination of the water supply, or kept them at home, leading to the theft and abuse of the prescription drugs

House Bill 3273 creates a drug take-back program to allow for the safe disposal of prescription drugs.