

REVISED FISCAL NOTE

(replaces fiscal note dated March 20, 2018)

Drafting Number: Prime Sponsors:

LLS 18-0504 Rep. Roberts

Sen. Donovan

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Bill Status: House Appropriations

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DIABETES DRUG PRICING TRANSPARENCY ACT 2018 **Bill Topic:**

Summary of **Fiscal Impact:** State Expenditure □ State Transfer

□ Local Government

□ Statutory Public Entity

This bill requires drug manufacturers, pharmacy benefit managers, health insurers, and pharmacies to submit information on insulin drug costs and price increases to the Department of Public Health and Environment, which will increase state

expenditures on an ongoing basis.

Appropriation Summary:

For FY 2018-19, the bill requires an appropriation of \$287,602 to the Department of

Public Health and Environment.

Fiscal Note Status:

This revised fiscal note reflects the introduced bill, as amended by the House Health,

Insurance, and Environment Committee.

Table 1 State Fiscal Impacts Under HB 18-1009

		FY 2018-19	FY 2019-20
Revenue	General Fund	less than \$20,000	less than \$20,000
		less than \$20,000	less than \$20,000
Expenditures	General Fund	\$287,602	\$251,361
	Centrally Appropriated	\$64,632	\$66,176
	Total	\$352,234	\$317,537
	Total FTE	2.5 FTE	2.7 FTE
Transfers		-	-
TABOR Refund	General Fund	less than \$20,000	less than \$20,000

Summary of Legislation

This bill requires drug manufacturers, pharmacy benefit managers, health insurers, and pharmacies to submit information to the Colorado Department of Public Health and Environment (CDPHE) concerning prescription insulin drugs used to treat diabetes. The CDPHE is required to compile a list of essential insulin drugs and to identify which of these drugs had an increase in wholesale acquisition cost that was greater than the medical inflation rate in the previous year or twice the medical inflation rate over the previous two years.

Drug manufacturers. For each insulin drug on the list, drug manufacturers are required to submit the following information starting on May 1, 2019, and continuing each May 1 thereafter:

- production costs:
- administrative costs, including advertising costs;
- profits attributable to the drug;
- financial assistance to patients;
- current and historical information on the drug's wholesale acquisition cost;
- rebates and coupons used by patients; and
- a specific explanation for the price increase, broken down by the various factors contributing to the increase.

Pharmacy benefit managers. Pharmacy benefit managers are required to submit information on rebates negotiated with insulin drug manufacturers, the percent of rebates retained by the pharmacy benefit managers, and the total amount of administrative fees received from drug manufacturers and insurers related to insulin drugs. Further, they must report the amount of rebates provided to patients on Medicare, Medicaid, and commercial insurance and the total annual payments paid to Colorado pharmacies for dispensing insulin drugs.

Pharmacy and insurance pricing reports. Insurance carriers and pharmacies are required to submit various pricing information to the CDPHE. Specifically, insurers must submit premium information, percent of premiums and cost increases attributable to insulin drugs, annual cost for insulin drugs paid by enrollees, and other information. Pharmacists must report total payments received from pharmacy benefit managers and insurers, and fees received for dispensing prescription insulin drugs.

Pricing analysis report. Under the bill, the CDPHE is required to analyze the data submitted by drug manufacturers and pharmacy benefit managers and prepare a pricing report by August 1, 2019, and each August 1 thereafter. This report is to be posted on the CDPHE website and submitted to the General Assembly.

Nonprofit organization reports. Starting May 1, 2019, and continuing each May 1 thereafter, a nonprofit organization that advocates on behalf of patients with diabetes or funds diabetes medical research in Colorado must report each payment, donation, subsidy, or thing of value it has received from a drug manufacturer with a drug on the list compiled by the CDPHE, if any. In addition, the nonprofit organization must specify the percentage of its total gross income attributable to drug manufacturers in the previous calendar year. The report must be posted on the nonprofit's website.

Other provisions. The CDPHE may accept gifts, grants, and donations to pay for the costs of implementing this bill. In addition, the CDPHE may impose a fine penalty on drug manufacturers and pharmacy benefit managers that do not comply with the requirements of the bill. The penalty may not exceed \$10,000 per day for each day that an entity fails to submit the required information.

State Revenue

The bill increases state General Fund revenue by less than \$20,000 per year starting in FY 2018-19. The revenue impacts of the bill are discussed below.

Fine penalties. The CDPHE may impose fine penalties on drug manufacturers and pharmacy benefit managers that do not comply with the provisions of the bill. While this fine may be up to \$10,000 per day, it is assumed that the actual daily fine amount will be lower than the maximum allowable fine and that drug manufacturers and pharmacy benefit managers will have a high level of compliance with the bill. Therefore, revenue from fines is expected to be less than \$20,000 per year. It is assumed this revenue will be deposited into the General Fund.

Gifts, grants, and donations. The bill may potentially increase revenue to the CDPHE from gifts, grants, and donations. At this time, no source of such funding has been identified.

TABOR Refund

This bill increases state General Fund revenue from fines by up to \$20,000 per year, which will increase the amount of money required to be refunded under TABOR for FY 2018-19 and FY 2019-20. Since the bill increases revenue to the General Fund and the refund obligation by equal amounts, there is no net impact on the amount of money available in the General Fund for the budget. However, the bill will increase money for the General Fund budget in the future during years when the state does not collect revenue above the TABOR limit.

State Expenditures

This bill increases state General Fund expenditures in the CDPHE by \$352,234 and 2.5 FTE in FY 2018-19 and by \$317,537 and 2.7 FTE in FY 2019-20 and future years. These impacts are summarized in Table 2 and discussed below.

Table 2 Expenditures Under HB 18-1009

	FY 2018-19	FY 2019-20
Department of Public Health and Environment		
Personal Services	\$205,057	\$232,640
Operating Expenses and Capital Outlay Costs	\$16,389	\$2,565
Legal Services	\$10,656	\$10,656
Information Technology	\$54,000	\$4,000
Printing and Postage	\$1,500	\$1,500
Centrally Appropriated Costs*	\$64,632	\$66,176
FTE – Personal Services	2.5 FTE	2.7 FTE
Total Cost	\$352,234	\$317,537
Total FTE	2.5 FTE	2.7 FTE

^{*} Centrally appropriated costs are not included in the bill's appropriation.

Personal services. The CDPHE will require 2.7 FTE for rate and financial analyst staff who will review identify insulin drugs subject to the reporting requirement; review information submitted by drug manufacturers, pharmacy benefit mangers, health insurers, and pharmacies; analyze data; and write an annual report. Staff will also be responsible for promulgating rules in the first year and with pursing fine penalties against any manufacturer or pharmacy benefit manager that fails to submit the required information. Staff will also be required to conduct outreach with affected health entities to ensure that they submit information in the required form and in a timely manner. Cost and FTE amounts in the first year are prorated to reflect the General Fund paydate shift and a start date of August 8, 2018.

Operating and capital outlay expenses. Standard operating and capital outlay expenses for the new staff under the bill are shown in Table 2 above. In addition, the CDPHE will have costs for printing and postage.

Legal services. It is estimated that the CDPHE will require 100 hours of legal services provided by the Department of Law at a cost of \$10,656 per year. In the first year, legal services will address rulemaking, and in future years, enforcement actions against drug manufacturers and pharmacy benefit managers.

Information technology. The CDPHE will have costs of \$50,000 in the first year to develop an online data collection tool, plus an additional \$4,000 in the first and subsequent years for software licensing, maintenance, and subscriptions.

Administrative hearings. If a fine is levied against a drug manufacturer or pharmacy benefit manager and they appeal the decision of the CDPHE to impose the fine, workload will increase for the Office of Administrative Courts in the Department of Personnel and Administration to hear such cases. It is assumed this workload increase will be minimal. Should additional appropriations be required, it is assumed that they will be addressed through the annual budget process.

Centrally appropriated costs. Pursuant to a Joint Budget Committee policy, certain costs associated with this bill are addressed through the annual budget process and centrally appropriated in the Long Bill or supplemental appropriations bills, rather than in this bill. These costs, which include employee insurance, supplemental employee retirement payments, and indirect cost recoveries, are estimated to be \$64,632 in FY 2018-19 and \$66,176 in FY 2019-20.

Effective Date

The bill takes effect August 8, 2018, if the General Assembly adjourns on May 9, 2018, as scheduled, and no referendum petition is filed.

State Appropriations

For FY 2018-19, the bill requires an appropriation of \$287,602 to the CDPHE and an allocation of 2.5 FTE. Of this amount, \$10,656 is reappropriated to the Department of Law for legal services.

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State and Local Government Contacts

Health Care Policy and Financing Information Technology Law Public Health and Environment Regulatory Agencies Personnel