



Legislative  
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# REVISED FISCAL NOTE

(replaces fiscal note dated February 19, 2019)

**Drafting Number:** LLS 19-0406  
**Prime Sponsors:** Sen. Rodriguez; Ginal  
 Rep. Jaquez Lewis  
**Date:** April 25, 2019  
**Bill Status:** House Appropriations  
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**Bill Topic:** IMPORT PRESCRIPTION DRUGS FROM CANADA

**Summary of Fiscal Impact:**

- State Revenue (*conditional*)
- State Expenditure
- State Transfer
- TABOR Refund
- Local Government (*conditional*)
- Statutory Public Entity

This bill creates the Canadian Prescription Drug Importation Program in the Department of Health Care Policy and Financing (HCPF). This bill will increase state expenditures in FY 2019-20 and FY 2020-21 to design the program. Conditional upon federal approval, it will increase state expenditures in future fiscal years, with these expenditures potentially offset by savings in future years. Local governments may also realize future savings under the bill.

**Appropriation Summary:** This bill requires an appropriation of \$1.5 million to the Department of Health Care Policy and Financing in FY 2019-20.

**Fiscal Note Status:** The revised fiscal note reflects the reengrossed bill, as amended by the House Health and Insurance Committee.

**Table 1  
State Fiscal Impacts Under SB 19-005**

		FY 2019-20	FY 2020-21
<b>Revenue</b>		-	-
<b>Expenditures</b>	General Fund	\$1,479,777	\$1,677,169
	Federal Funds	(\$70,000)	(\$70,000)
	Centrally Appropriated	\$71,612	\$86,623
	<b>Total</b>	<b>\$1,481,389</b>	<b>\$1,693,792</b>
	<b>Total FTE</b>	<b>5.1 FTE</b>	<b>5.5 FTE</b>
<b>Transfers</b>		-	-
<b>TABOR Refund</b>		-	-

## **Summary of Legislation**

This bill creates the Canadian Prescription Drug Importation Program in the Department of Health Care Policy and Financing (HCPF).

**Vendor requirements.** HCPF is required to contract with one or more vendors by February 1, 2020, to facilitate program design; vendor selection is exempt from the state procurement process for the first three years. Vendors, in consultation with HCPF and other vendors, must annually establish a wholesale prescription drug importation list that identifies the prescription drugs that have the highest potential for cost savings to the state. HCPF is required to ensure these lists meet program requirements every three months. Vendors must identify Canadian suppliers, verify the supplier meets all legal and program requirements, and contract with or facilitate contracts with suppliers to import prescription drugs under the program.

As outlined in the bill, vendors must follow specific requirements related to:

- developing and administering distribution programs;
- assisting HCPF with annual reporting;
- ensuring safety and quality of imported drugs through requirements for testing and certification;
- laboratory and documentation standards;
- financial reporting;
- surety bonds;
- required participation in applicable legal actions; and
- payments.

**Eligible drugs, importers, and suppliers.** A vendor may import a prescription drug from a Canadian supplier if the drug meets U.S. standards related to the drug's safety, effectiveness, misbranding, and adulteration; importing the drug would not violate federal patent laws; and importing the drug is expected to generate cost savings. Eligible importers include licensed Colorado pharmacists; pharmacists or wholesalers dispensing to Medicaid recipients; pharmacists or wholesalers dispensing to inmates in the custody of the Department of Corrections; and wholesalers approved by HCPF. An eligible Canadian supplier may only export prescription drugs into Colorado if the supplier is in full compliance with Canadian law and submits proof of a registered agent in the U.S.

Canadian suppliers and eligible importers participating under the program must comply with the tracking and tracing requirements of federal pharmaceutical distribution supply chain law; and may not distribute, dispense, or sell prescription drugs imported under the program outside of Colorado. In addition, both entities are required to submit certain information to the vendor related to drug type, quantity, point of origin and destination, price, and shipping information as applicable.

HCPF must immediately suspend the importation of specific drugs or the importation of drugs by specific eligible importers if it discovers that any drug or activity is in violation of any federal or state law or regulation. HCPF may revoke the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe drugs being imported into this state.

**Designated wholesaler.** HCPF must designate an office or division that must be a licensed pharmaceutical wholesaler or that must contract with a licensed pharmaceutical wholesaler to:

- set a maximum profit margin;
- exclude generic products if their importation would violate U.S. patent law;
- comply with federal laws regarding pharmaceutical distribution supply chains; and
- determine a method for covering the administrative costs of the program, which may include a fee imposed on each prescription drug sold through the program, as long as the fee amount does not significantly reduce consumer savings.

**Federal waiver application.** By September 1, 2020, HCPF must submit a request for federal approval of the program, following criteria outlined in the bill. HCPF is required to begin operating the program no later than 6 months after receiving federal approval.

**Reporting.** HCPF is required to report on program operations to the Governor and the General Assembly by December 1 of each year starting in 2021. The report must include information about participants, prescription drugs imported and dispensed, methodology, and estimated cost savings.

**Rulemaking.** HCPF is required to promulgate rules as necessary to implement the program.

## **Assumptions**

The fiscal note assumes the following implementation timeline; however, due to the program's complexity and conditionality, these dates may vary:

- vendors in place by February 1, 2020;
- request for federal program approval submitted by September 1, 2020;
- federal approval by January 1, 2021; and
- importation begins July 1, 2021.

If the program does not receive federal approval, importation will not occur in FY 2021-22. Staffing levels reflected in this fiscal note are required for FY 2019-20 and FY 2020-21, regardless of federal approval. Beginning in FY 2021-22, HCPF's costs may be offset by the use of a vendor to administer the program but may also increase due to contract management and enforcement requirements.

## **State Revenue**

Conditional upon federal approval, the bill may increase state revenue from fees assessed by HCPF related to the prescription importation program starting in FY 2021-22. This revenue amount cannot be estimated as the scope of the program and fee schedule are unknown. The bill does not specify a cash fund into which this revenue is deposited, so it is assumed that it will be deposited into the General Fund. In addition, the bill is expected to minimally increase pharmacy licensing fees to the Division of Professions and Occupations Cash Fund in the Department of Regulatory Agencies (DORA). Both revenue streams are subject to TABOR.

**State Expenditures**

To design and seek federal approval for the prescription drug importation program, the bill increases General Fund expenditures in HCPF by \$1.5 million and 4.1 FTE in FY 2019-20 and \$1.7 million and 5.0 FTE in FY 2020-21. An allocation of 1.0 FTE in FY 2019-20 and of 0.5 FTE in FY 2020-21 to the Department of Law is also required for legal services hours. These costs are summarized in Table 2 and discussed below. Future costs have not been estimated, such as purchasing or building information technology systems; it is assumed that these costs will be addressed through the annual budget process once the program design and likelihood of federal approval are known.

**Table 2  
 Expenditures Under SB 19-005**

	<b>FY 2019-20</b>	<b>FY 2020-21</b>
<b>Dept. of Health Care Policy and Financing</b>		
Personal Services	\$399,293	\$479,152
Operating Expenses and Capital Outlay Costs	\$27,790	\$4,750
Fund Source Adjustment	-	-
Vendor Contract	\$500,000	\$1,000,000
Information Technology Systems	\$296,160	<i>not estimated</i>
Legal Services	\$186,534	\$93,267
Public Hearings and Travel	-	\$30,000
Centrally Appropriated Costs*	\$71,612	\$86,623
FTE – Personal Services	4.1 FTE	5.0 FTE
FTE – Legal Services	1.0 FTE	0.5 FTE
<b>Total Cost</b>	<b>\$1,481,389</b>	<b>\$1,693,792</b>
<b>Total FTE</b>	<b>5.1 FTE</b>	<b>5.5 FTE</b>

\* Centrally appropriated costs are not included in the bill's appropriation.

**Department of Health Care Policy and Financing.** HCPF will require an additional 5.0 FTE to manage the program design process, compile required reports, hold public meetings, interact with the federal government, and oversee and work with contract consultants. This staff is prorated to 4.1 FTE in the first year to reflect an August effective date and the General Fund pay date shift. Standard operating and capital outlay expenses for these staff are included. Workload will also increase in the current fiscal year for existing HCPF staff to begin work on the RFP for the contract consultants and hiring in advance of the bill's effective date.

- *Fund source adjustment.* Because current senior executive staff will be responsible for supervising this program rather than federally funded operations, personal services costs from the General Fund will increase by \$70,000 to cover a decrease of the same amount in federal funds.

- *Vendor.* HCPF will contract with vendors that have expertise in prescription drugs and international trade. These experts will identify pharmaceutical products that are most promising for generating savings through the importation program and will ensure that the process meets federal requirements for the importation of prescription drugs. These costs are estimated at \$500,000 in FY 2019-20 and \$1,000,000 in FY 2020-21.
- *Information technology system costs.* HCPF will work with the Office of Information Technology in the first year to design data systems needed to support the drug importation program, including data collection, fee tracking, connectivity with contracted wholesalers, and other functions. FY 2019-20 system design costs are estimated at \$296,160, based on 2,400 hours of contract services at a rate of \$123.40 per hour. Costs will be paid with reappropriated funds from HCPF. Future costs for system procurement and implementation will depend on the program design and will likely be incurred in FY 2020-21. It is assumed that these costs will be addressed through the annual budget process once the program design and likelihood of federal approval are known.
- *Legal services.* HCPF will have costs for legal services from the Department of Law for rulemaking, legal advice, and the prevention of anti-competitive behavior by manufacturers, as specified in the bill. These costs are estimated at \$186,534 and an allocation of 1.0 FTE in FY 2019-20 for 1,800 hours of legal services, and \$93,267 and an allocation of 0.5 FTE in FY 2020-21 for 900 hours of legal services. Costs are estimated based on the blended legal service rate of \$103.63 per hour and will be paid with reappropriated funds from HCPF.
- *Public hearings and travel.* HCPF will have costs to hold two public hearings. Each hearing is estimated to cost \$15,000, which includes costs for meeting space, materials, and necessary public accommodations. It is assumed that five HCPF employees will travel to the hearing on the Western Slope at an estimated cost of \$364 per person, including mileage, lodging, and meals.

**Department of Regulatory Agencies.** Conditional upon federal approval of the program, the Colorado Board of Pharmacy will have a minimal workload increase to approve any new wholesale licenses. The board may conduct rulemaking, education, and outreach, as well. These workload increases can be accomplished within existing appropriations.

**Potential state savings.** As discussed below, state programs may realize savings through lower prescription drug costs if the importation program is implemented. The extent of potential savings cannot be estimated at this time. It is assumed the annual budget process will address this as necessary.

*State employee group health insurance.* If the importation program allows state employees to purchase less expensive pharmaceuticals, costs for state employee group health insurance may decrease.

*HCPF pharmacy benefits.* Programs administered by HCPF, including Medicaid and the Children's Basic Health Plan (CHP+), may have savings from lower pharmaceutical costs if the importation program is implemented. The state Medicaid program currently receives rebates on pharmaceuticals that reduce costs by nearly 50 percent compared to the retail prices. It is unknown if wholesale importation from Canada will result in greater savings than from currently available rebates for domestically obtained pharmaceutical products.

*Other agencies.* The Departments of Corrections, Human Services, and Public Health and Environment, and any other state agency that purchases pharmaceuticals, may also see a decrease in costs.

**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 and supplemental employee retirement payments, are estimated to be \$71,612 in FY 2018-19 and \$86,623 in FY 2019-20.

### **Local Government**

Similar to the state, local governments that offer health insurance as an employee benefit or purchase pharmaceuticals may realize savings under the bill if the importation program is implemented. The extent of these savings cannot be estimated.

### **Effective Date**

The bill takes effect August 2, 2019, if the General Assembly adjourns on May 3, 2019, as scheduled, and no referendum petition is filed.

### **State Appropriations**

For FY 2019-20, the bill currently includes a General Fund appropriation of \$1,361,217 and an allocation of 4.1 FTE to the Department of Health Care Policy and Financing.

The bill requires an appropriation of \$1,409,777 General Fund and an allocation of 4.1 FTE to the Department of Health Care Policy and Financing. This amount includes a reduction in federal funds to HCPF of \$70,000 to account for the refinancing of certain personal services costs that are instead paid with General Fund. Of the General Fund appropriation, \$296,160 is reappropriated to the Office of Information Technology for information technology services and \$186,534 is reappropriated to the Department of Law for legal services, with an allocation of 1.0 FTE.

### **State and Local Government Contacts**

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