SB 19-005

Legislative Council Staff
Nonpartisan Services for Colorado's Legislature

REVISED FISCAL NOTE

(replaces fiscal note dated April 25, 2019)

Drafting Number:	LLS 19-0406	**Date:**	May 1, 2019
Prime Sponsors:	Sen. Rodriguez; Ginal Rep. Jaquez Lewis	**Bill Status:**	House Second Reading
		Fiscal Analyst:	Erin Reynolds | 303-866-4146 Erin.Reynolds@state.co.us

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. The bill will increase state expenditures in FY 2019-20 and FY 2020-21 to design the program and submit a federal waiver request. Conditional upon federal approval, it will increase state expenditures in future fiscal years. State and local governments that purchase prescription drugs may realize future savings under the bill.

Appropriation Summary: This bill requires an appropriation of $1.0 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 and the House Appropriations Committee.

Table 1
State Fiscal Impacts Under SB 19-005

		FY 2019-20	FY 2020-21
Revenue		-	-
Expenditures	General Fund	$1,041,802	$2,026,964
	Federal Funds	($70,000)	($70,000)
	Centrally Appropriated	$71,612	$86,623
	Total	**$1,043,414**	**$2,043,587**
	Total FTE	**4.8 FTE**	**5.8 FTE**
Transfers		-	-
TABOR Refund		-	-

Summary of Legislation

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

Federal waiver application and conditions of approval. By September 1, 2020, HCPF must submit a request for federal approval of the program, following criteria outlined in the bill. Initially, HCPF may expend money for the purpose of requesting federal program approval, but it may not spend any money on program implementation until the program receives federal approval. If the program is approved, HCPF is required to begin operating the program no later than six months after receiving federal approval.

Vendor requirements. HCPF is required to contract with one or more vendors when the program receives federal approval; 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.

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:

- request for federal program approval submitted by September 1, 2020;
- federal approval by January 1, 2021, followed by vendor selection; and
- importation of prescription drugs begins July 1, 2021, as required by the bill.

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. Beginning in FY 2020-21, staffing costs assume federal approval and the vendor contracts will cost approximately $1.0 million initially; however, these estimates are preliminary. Actual costs will be addressed through the annual budget process when program parameters are better outlined. It is assumed that HCPF will require ongoing resources related to vendor contract management and enforcement requirements in the bill.

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 $1.0 million and 4.1 FTE in FY 2019-20 and $2.0 million and 5.0 FTE in FY 2020-21. An allocation of 0.7 FTE in FY 2019-20 and of 0.8 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. Additional future year costs are expected but have not been estimated; 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

	FY 2019-20	FY 2020-21
Dept. of Health Care Policy and Financing		
Personal Services	$399,293	$479,152
Operating Expenses and Capital Outlay Costs	$27,790	$4,750
Fund Source Adjustment	-	-
Pharmaceutical Trade Consultant	$410,000	-
Vendor Contract*	-	$1,000,000
Information Technology Systems	-	$296,160
Legal Services	$134,719	$145,082
Public Hearings and Travel	-	$31,820
Centrally Appropriated Costs**	$71,612	$86,623
FTE – Personal Services	4.1 FTE	5.0 FTE
FTE – Legal Services	0.7 FTE	0.8 FTE
Total Cost	**$1,043,414**	**$2,043,587**
Total FTE	**4.8 FTE**	**5.8 FTE**

* *Vendor contracting costs are estimates only and are conditional upon federal program approval; actual costs will be established through the contract(s) once established.*
** *Centrally appropriated costs are not included in the bill's appropriation.*

Department of Health Care Policy and Financing. HCPF costs to implement the bill are presented below in two phases. Phase one reflects resources required for the federal waiver application process, while phase two reflects resources required if federal approval is received. Phase two costs are conditional.

Phase one — waiver application. For the first approximately 1.5 years of the program, the bill requires HCPF staff, consultants, and legal services, as discussed below.

- *Personal services and operating expenses.* HCPF will require 5.0 FTE to manage the program design process, interact with the federal government, and oversee and work with contract consultants. These costs will continue until the federal government approves or rejects the waiver, which the fiscal note assumes will occur around January 1, 2020. 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.

- *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.

- *Pharmaceutical and trade consultant.* To design the program, HCPF will use contract consultants with expertise in pharmaceuticals 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 pharmaceuticals. This cost is estimated at $410,000 in FY 2019-20 based on a consultant rate of $250 per hour and 1,640 hours of consultant time. Actual costs may vary depending on the rates for services obtained through the competitive bidding process.

- *Legal services.* HCPF will require legal services from the Department of Law for rulemaking and general counsel while applying for the federal waiver. These costs are estimated at $134,719 and an allocation of 0.7 FTE in FY 2019-20 for 1,300 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.

Phase two — program implementation and operation. Conditional upon federal approval, the bill requires ongoing HCPF staff, vendor contracting fees, information technology system costs, legal services, and public outreach, as discussed below. Phase two costs will not be incurred if federal approval is not granted. If the program does receive federal approval, these costs will be addressed through the annual budget process.

- *Personal services and operating expenses.* Staffing levels at HCPF will likely continue at 5.0 FTE in FY 2021-22 and ongoing to manage the program, the vendor contract, and vendor enforcement. It is assumed that these

- *Vendor.* HCPF will contract with one or more vendors that have expertise in pharmaceuticals and international trade. These experts will identify pharmaceutical products that are most promising for generating savings, then contract with wholesalers to import these drugs into Colorado. Contracting costs are estimated at $1,000,000 in FY 2020-21; however, actual costs will be established through the contracting process under the bill.

- *Information technology system costs.* HCPF will work with the Office of Information Technology to design data systems needed to support the drug importation program, including data collection, fee tracking, connectivity with contracted wholesalers, and other functions. 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. Additional maintenance and design costs have not been estimated.

- *Legal services.* HCPF will have costs for legal services from the Department of Law for the prevention of anti-competitive behavior by manufacturers, as specified in the bill. These costs are estimated at $51,815 and an allocation of 0.3 FTE in FY 2020-21 for 500 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 approximately $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

The bill requires and includes a net appropriation of appropriation $971,802 General Fund and an allocation of 4.1 FTE to the Department of Health Care Policy and Financing. This amount includes an increase in General Fund expenditures of $1,041,802, and a reduction in federal funds of $70,000 to account for the refinancing of certain personal services costs that are instead paid with General Fund. Of this appropriation, $134,719 is reappropriated to the Department of Law for legal services, with an allocation of 0.7 FTE.

State and Local Government Contacts

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