PREPARED BY: Mikayla Findlay
DATE PREPARED: January 09, 2023
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LB 200

Revision: 00

FISCAL NOTE

LEGISLATIVE FISCAL ANALYST ESTIMATE

ESTIMATE OF FISCAL IMPACT – STATE AGENCIES (See narrative for political subdivision estimates)

	FY 2023-24		FY 2024-25	
	EXPENDITURES	REVENUE	EXPENDITURES	REVENUE
GENERAL FUNDS				
CASH FUNDS				
FEDERAL FUNDS				
OTHER FUNDS				
TOTAL FUNDS	See below		See below	

Any Fiscal Notes received from state agencies and political subdivisions are attached following the Legislative Fiscal Analyst Estimate.

This bill creates the Canadian Prescription Drug Importation Act (Act). Section 2 describes the necessity of the Act and Section 3 provides definitions. Section 4 creates the Canadian Prescription Drug Importation Program to be administered by the Department of Health and Human Services (DHHS) via contract with one or more vendors. Such a vendor will establish a wholesale prescription drug importation list identifying which drugs have highest potential cost savings, drugs for which there are shortages, specialty drugs, and high-volume drugs. DHHS will review such a list or lists at least quarterly. The vendor is responsible for identifying and facilitating contracts with lawfully compliant Canadian prescription drug suppliers willing to export prescription drugs at prices that will provide cost savings to the people of Nebraska and eligible importers. Each vendor is to assist DHHS in developing and administering a distribution program, producing annual reports, responding to information requests, and ensuring safety and quality of the drugs imported under the program as described by Section 4 Subsection 6 and 7. Section 4 also details fiduciary and legal responsibilities for any vendor.

Section 5 details the parameters for which drugs may be imported and the requirements for Canadian exporters under the Act. Section 5 also requires DHHS to set a maximum profit margin no greater than the profit margin that such person would have earned on the equivalent non-imported drug, comply with all pertinent US laws including patent laws pertaining to generic drugs, and determine a method for covering the administrative costs of the program which may include a fee not to significantly reduce consumer savings. Canadian suppliers must comply with US tracking and tracking requirements and are not allowed to distribute, dispense, or sell prescription drugs under the program outside of Nebraska. DHHS is to immediately suspend the importation of a specific drug or activity of a particular importer if it discovers that any drug or activity is in violation of this section or any federal or state law or regulation. Such a suspension may be lifted if, following an investigation, it determines the public is adequately protected from counterfeit or unsafe drug importation.

Section 6 requires DHHS to submit a request as outline in Subsection 1 to the federal Secretary of Health and Human Services for the approval of the program under 21 U.S.C. 384. DHHS is to start the program no later than six months after receiving approval. DHHS may expend funds for the purpose of requesting federal approval of the program but DHHS may not expend any other funds to implement the program until it received federal approval. Upon federal approval DHHS is to notify the Governor, Health and Human Services Committee of the Legislature, and the Appropriations Committee of the Legislature and submit a proposal for implementation to the Governor and such committees before the start of the next regular session of the Legislature. Section 7 sets report requirements for the program and Section 8 permits DHHS to adopt and promulgate rules and regulations as necessary to carry out the Act.

DHHS indicates implementation of this bill will require a significant initial infrastructure investment as well as additional staff for administration however the precise cost is unknown. At minimum, the initial development of the program would require $6 million: at least $2 million each for (1) development of a basic claims database, (2) interoperability with all Nebraska pharmacies and drug wholesalers, and (3) capability to capture the anticipated pricing for imported drugs and match that pricing to equivalent US manufactured drugs to calculate the maximum profit margin. The total costs of implementation could potentially be higher; a publicly available contract in another state pursuing such a program indicates first year costs of $10 million.

Startup costs for this program would need to be funded directly through state funded appropriations. The bill allows administrative costs to be covered by fees, as outlined in Section 5, but such fees will not be implemented until the program is established. A limited portion of the implementation costs could receive a higher federal match percentage due to usability of the claims portion by Medicaid. In order to utilize federal funds, federal approval must be obtained. To date, no states have received federal approval from the FDA for Canadian prescription drug importation programs and states have sought approval since as early as 2019.

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In addition to the implementation costs of between $6 million and $10 million, DHHS would need additional staff to maintain the program. The following chart shows the total personnel costs by area. For specific number and type of FTE, refer to the agency fiscal note. There would be additional costs for workspace and computer equipment.

	Year 1	Year 2	Year 3	Year 4+
IT Support	$998,800	$998,800	$998,800	$998,800
Health Data	$1,030,000	$1,030,000	$1,030,000	$900,000
Lifespan Health	$677,000	$677,000	$587,000	$587,000
Total Personnel Costs	$2,705,800	$2,705,800	$2,615,800	$2,485,800

The total implementation cost of between $8.7 million and $12 million in the first year of the program is an estimate. The actual costs of the Canadian Prescription Drug Importation program as well as the prescription drug cost savings to Nebraskans are indeterminate at this time.

ADMINISTRATIVE SERVICES STATE BUDGET DIVISION: REVIEW OF AGENCY & POLT. SUB. RESPONSE				
LB: 200	AM:	AGENCY/POLT. SUB: Nebraska Department of Health & Human Services		
REVIEWED BY: Ann Linneman		DATE: 1-23-2023		PHONE: (402) 471-4180
COMMENTS: The Nebraska Department of Health and Human Services' analysis and estimate of fiscal impact to the department appears reasonable.				

LB(1) 200 FISCAL NOTE 2023

ESTIMATE PROVIDED BY STATE AGENCY OR POLITICAL SUBDIVISION

State Agency or Political Subdivision Name:(2) Department of Health and Human Services

Prepared by: (3) John Meals | Date Prepared 1-23-2023 | Phone: (5) 471-6719

	FY 2023-2024		FY 2024-2025	
	EXPENDITURES	REVENUE	EXPENDITURES	REVENUE
GENERAL FUNDS				
CASH FUNDS				
FEDERAL FUNDS				
OTHER FUNDS				
TOTAL FUNDS	See below		See below	

Return by date specified or 72 hours prior to public hearing, whichever is earlier.

Explanation of Estimate:

LB200 is a bill to adopt the Canadian Prescription Drug Importation Act with the goal of allowing Nebraska to safely import prescription drugs from Canada at a lower cost to consumers. It is unknown at this time how significant that cost savings may be.

LB 200 will have a fiscal impact for the Department, albeit one that is difficult to project. A significant initial infrastructure investment and permanent additional staffing will be required to administer the program as outlined below. Procurement will be impacted with additional contracts for vendors under the program. IT will be impacted by developing a data system to maintain information for the program and provide reports to monitor program activity.

Other states have submitted proposals to the FDA for Canadian prescription drug importation programs. To date, no states have received federal approval. In a publicly available contract for the State of Florida, development and implementation costs are $10,000,000 for year 1, with subsequent years priced at $14,500,000 for providing Canadian prescription drug importation program services. It is unknown how costs in Nebraska would compare.

LB200 would require the development of a claims database necessary to set the maximum profit margin as described in Sec. 4 of LB 200. The claims database would need to include pharmacy or wholesaler purchasing price for US manufactured non-imported drugs along with claims reimbursement from payors for those US manufactured non-imported drugs. The purchasing data would need to be compared to the estimated purchase price from Canadian drug suppliers to set the maximum profit margin.

This would require several layers for full implementation. First is the development of the basic claims database. Second is interoperability with all Nebraska pharmacies and drug wholesalers. Third is the ability to capture the anticipated pricing for imported drugs and match that pricing to equivalent national drug code (NDC) identifiers used by the FDA for US manufactured drugs to calculate the maximum profit margin.

Publicly available information on a claims database in Nevada suggests an initial development cost of $2M in year one and ongoing maintenance and operational costs of $3M per year. The department could submit an APD request with CMS to potential receive 90/10 funding on the year one development and 75/25 funding for subsequent years maintenance and operations.

The interoperability and data capture aspects are more difficult to project. The department believes at a minimum, each phase would cost the same $2M for development with ongoing maintenance and operations costs. These phases, however, would receive a much lower federal match from CMS as possibly below 20% of these projects would be applicable to Medicaid.

For all three phases, this would amount to a minimum of $6M, with the potential to be significantly higher and only one phase receiving significant federal funding.

IT will be impacted because the Department will need to develop a data system for maintaining information to include in the annual report to the Governor, the Health and Human Services Committee of the Legislature, and the Appropriations Committee of the Legislature. Examples of data required include, but are not limited to, the prescription drugs imported under the program; Canadian suppliers and eligible importers involved in the program; prescriptions dispensed through the program; and estimated cost savings during each fiscal year and to date. There may also be an IT impact for monitoring the program to ensure compliance with state and federal law.

IT cost estimates include data ingestion from manufacturers and wholesalers into data nexus, development support to public health staff for building statistical models, and ongoing production support of models and reports post development.

Role	Allocation (%)	Rate (Hourly)	Duration (Bus Days)	Cost
Project Manager	1.00	$ 120	70	$ 67,200
Business Analyst	0.30	$ 80	70	$ 13,440
Data Architect	1.00	$ 150	70	$ 84,000
Data Integration Lead	1.00	$ 120	70	$ 67,200
Data Developer	6.00	$ 120	70	$ 403,200
Quality Assurance Tester	0.80	$ 120	70	$ 53,760
Total			420	$ 688,800

Other IT costs include development of a website to allow manufacturers and wholesalers to send files and/or enter drug information, as well as, to interface to Data Nexus.

Role	Allocation (%)	Rate (Hourly)	Hours	Cost
IT Supervisor	1.00	$ 100	300	$ 30,000
Application Developer	1.00	$ 100	2000	$ 200,000
Business Analyst	1.00	$ 80	1000	$ 80,000
Total			3300	$ 310,000

LB200 implementation will also include a significant staffing increase for the department.

Staffing (costs estimated including benefits & IDCR):

Health Data Section:

Years 1-3: 7 FTE @ $1,030,000/yr

Epidemiologist (1 FTE) $190,000/yr

Data Analyst (4 FTE)

- contractor with fees would be $680,000 /year (4 employees)
- if we can hire an FTE, this would be approximately $145,000/yr/FTE

Informatician (2 FTE)

- contractor with fees would be approximately $130,000/person/year (there is not currently a state classification matching the work done, therefore, a contractor is required)

Years 4 on: 4 FTE @ $900,000/yr

Epidemiologist (1 FTE) $190,000/yr

Data Analyst (4 FTE)

- contractor with fees would be $680,000 /year (4 employees)

- if we can hire an FTE, this would be approximately $145,000/yr/FTE

Informatician (FTE)

- contractor with fees would be approximately $130,000 /year

Lifespan Health Section:

Years 1-2: 6 FTE @ $677,000/yr

1 FTE Program Manager II – overall contract supervision $110,000/yr/FTE
1 FTE Pharmacist – drug SME $150,000/yr/FTE
2 FTE Program Coordinator – program support $90,000/yr/FTE
1 FTE Office Specialist – invoicing, payment, admin support $57,000/yr/FTE
1 FTE PhD-level laboratory specialist – SME for FDA importation standards, lab purity testing, etc. $180,000/yr/FTE

Years 3 onward: 5 FTE @ $587,000/yr

1 FTE Program Manager II $110,000/yr/FTE
1 FTE Pharmacist $150,000/yr/FTE
1 FTE Program Coordinator $90,000/yr/FTE
1 FTE Office Specialist $57,000/yr/FTE
1 FTE PhD-level laboratory specialist $180,000/yr/FTE

Additional workspace and IT equipment for the additional FTEs is required.

LB 200 allows a fee to be added to the prescription drugs sold through the program to cover administrative costs, but the fee cannot be set at an amount that will significantly reduce consumer savings. During the initial implementation, no fees would be charged, as no drugs would be sold. Startup costs for this program would need to be funded directly through appropriations.

MAJOR OBJECTS OF EXPENDITURE

PERSONAL SERVICES:				
	NUMBER OF POSITIONS		2023-2024	2024-2025
POSITION TITLE	23-24	24-25	EXPENDITURES	EXPENDITURES

Benefits	
Operating	
Travel	
Capital Outlay	
Aid	
Capital Improvements	
TOTAL	