

Preliminary

Consolidated Fiscal Note

2023-2024 Legislative Session

HF17 - 1A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**
 Committee: **Commerce Finance And Policy**
 Date Completed:
 Lead Agency: **Health Dept**
 Other Agencies:
 Attorney General Commerce Dept
 Governors Office Legislature
 Medical Practice Board Minn Management and Budget
 MNsure Nursing Board
 Pharmacy Board Prescription Drug Affordability Board

State Fiscal Impact	Yes	No
Expenditures	X	
Fee/Departmental Earnings		X
Tax Revenue		X
Information Technology		X
Local Fiscal Impact		X

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions shown in the parentheses.

State Cost (Savings)	Biennium			Biennium		
	Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027
Attorney General						
General Fund	-	476	476	476	476	476
Governors Office						
General Fund	-	-	-	-	-	-
Health Dept						
General Fund	-	23	16	16	16	16
Legislature						
General Fund	-	-	-	-	-	-
Pharmacy Board						
Health Related Boards	-	278	280	280	280	280
Prescription Drug Affordability Board						
General Fund	-	450	700	700	700	700
State Total						
General Fund	-	949	1,192	1,192	1,192	1,192
Health Related Boards	-	278	280	280	280	280
Total	-	1,227	1,472	1,472	1,472	1,472
Biennial Total			2,699			2,944

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
Attorney General					
General Fund	-	2	2	2	2
Governors Office					
General Fund	-	-	-	-	-
Health Dept					
General Fund	-	.1	.1	.1	.1

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Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
Legislature	-	-	-	-	-
General Fund	-	-	-	-	-
Pharmacy Board					
Health Related Boards	-	1	1	1	1
Prescription Drug Affordability Board					
General Fund	-	1.02	3	3	3
Total	-	4.12	6.1	6.1	6.1

Lead LBO Analyst's Comment

LBO Signature: **Date:**
Phone: **Email:**

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State Cost (Savings) Calculation Details

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions are shown in parentheses.

*Transfers In/Out and Absorbed Costs are only displayed when reported.

State Cost (Savings) = 1-2		Biennium			Biennium	
Dollars in Thousands		FY2023	FY2024	FY2025	FY2026	FY2027
Attorney General						
General Fund	-	476	476	476	476	476
Governors Office						
General Fund	-	-	-	-	-	-
Health Dept						
General Fund	-	23	16	16	16	16
Legislature						
General Fund	-	-	-	-	-	-
Pharmacy Board						
Health Related Boards	-	278	280	280	280	280
Prescription Drug Affordability Board						
General Fund	-	450	700	700	700	700
Total		-	1,227	1,472	1,472	1,472
Biennial Total				2,699		2,944
1 - Expenditures, Absorbed Costs*, Transfers Out*						
Attorney General						
General Fund	-	476	476	476	476	476
Governors Office						
General Fund	-	-	-	-	-	-
Expenditures	-	1	-	-	-	-
Absorbed Costs	-	(1)	-	-	-	-
Health Dept						
General Fund	-	23	16	16	16	16
Legislature						
General Fund	-	-	-	-	-	-
Expenditures	-	7	-	-	-	-
Absorbed Costs	-	(7)	-	-	-	-
Pharmacy Board						
Health Related Boards	-	278	280	280	280	280
Prescription Drug Affordability Board						
General Fund	-	450	700	700	700	700
Total		-	1,227	1,472	1,472	1,472
Biennial Total				2,699		2,944
2 - Revenues, Transfers In*						
Attorney General						
General Fund	-	-	-	-	-	-
Governors Office						
General Fund	-	-	-	-	-	-
Health Dept						
General Fund	-	-	-	-	-	-
Legislature						
General Fund	-	-	-	-	-	-

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State Cost (Savings) = 1-2 Dollars in Thousands	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
Pharmacy Board					
Health Related Boards	-	-	-	-	-
Prescription Drug Affordability Board					
General Fund	-	-	-	-	-
	Total	-	-	-	-
	Biennial Total		-		-

Preliminary

Fiscal Note

2023-2024 Legislative Session

HF17 - 1A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**
 Committee: **Commerce Finance And Policy**
 Date Completed:
 Agency: Health Dept

State Fiscal Impact	Yes	No
Expenditures	X	
Fee/Departmental Earnings		X
Tax Revenue		X
Information Technology		X
Local Fiscal Impact		X

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions shown in the parentheses.

State Cost (Savings) Dollars in Thousands	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	23	16	16	16
Total	-	23	16	16	16
Biennial Total			39		32

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	.1	.1	.1	.1
Total	-	.1	.1	.1	.1

LBO Analyst's Comment

I have reviewed this fiscal note for reasonableness of content and consistency with the LBO's Uniform Standards and Procedures.

I have reviewed this fiscal note for reasonableness of content and consistency with LBO's Uniform Standards and Procedures.

LBO Signature: Shannon Zila **Date:** 1/25/2023 9:12:49 AM
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Preliminary

State Cost (Savings) Calculation Details

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions are shown in parentheses.

*Transfers In/Out and Absorbed Costs are only displayed when reported.

State Cost (Savings) = 1-2		Biennium			Biennium	
Dollars in Thousands		FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	23	16	16	16	16
Total		-	23	16	16	16
Biennial Total				39		32
1 - Expenditures, Absorbed Costs*, Transfers Out*						
General Fund	-	23	16	16	16	16
Total		-	23	16	16	16
Biennial Total				39		32
2 - Revenues, Transfers In*						
General Fund	-	-	-	-	-	-
Total		-	-	-	-	-
Biennial Total				-		-

Bill Description

The bill establishes a framework for prohibiting and enforcing the prohibition of excess price increases by manufacturers on generic or off-patent drugs and to establish upper payment limits for certain prescription drugs.

This bill requires MDH to make prescription drug price data collected under Minnesota Statutes, section 62J.84 available within 30 days of receipt to the board. The bill also calls for MDH representation with expertise in health economics on the newly formed Prescription Drug Affordability Advisory Council.

The bill provides a blank general fund appropriation for fiscal years 2024 and 2025 to the Prescription Drug Affordability Board (PDAB). The Department of Health will incur costs to implement the bill, however the bill currently does not include an appropriation for the department.

Assumptions

This bill requires one member of the advisory council representing the commissioner of health to have expertise in health economics. MDH assumes this quarterly meeting will be provided as part of normal work duties and will not result in substantial commitment of staff time.

This bill requires MDH to provide the Prescription Drug Affordability Board (PDAB) with information collected under the Prescription Drug Price Transparency Act (Minnesota Statutes, section 62J.84) within 30 days of receiving it (Sec. 12, Subd. 1 (a)). MDH assumes a one-time cost to develop an automated process for sharing data via a dashboard or similar method. MDH assumes that the data provided to the board, as close to within 30 days as possible while meeting manufacturer notification requirements, will be what manufacturers submitted initially without verification, potentially missing data, any data not initially submitted, without correction of errors, and subject to change per review of data submitted under Minnesota Statutes, section 62.84. If PDAB would need validated and corrected data from MDH, at least 90 days would be needed prior to sending to the PDAB. MDH will withhold all not public and trade secret data.

To implement this provision of HF17, MDH anticipates building a reporting mechanism into the current data collection tool. The program will build and update a data file and create a PDAB dashboard with the necessary information. Based on cost estimates provided by MDH's current vendor, the one-time cost in fiscal year 2024 to build this dashboard will be \$6,000. Additionally, MDH will require 0.1 FTE Research Analysis Specialist Senior beginning in fiscal year 2024 and ongoing to regularly update the dashboard and answer associated data questions from the PDAB Board staff.

MDH assumes no responsibility nor significant assistance to the board in the identification of certain prescription drug products.

The bill does not include an effective date, MDH assumes an effective date of July 1, 2023 but that data requirements

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provided to the PDAB would occur on the effective date of January 1, 2024.

Expenditure and/or Revenue Formula

Expenditure (Actual Dollars)	Amount	FY 2024	FY 2025	FY 2026	FY 2027
Salary & Fringe:		FTE	FTE	FTE	FTE
Research Analysis Spec Sr	129,602	0.10	0.10	0.10	0.10
	FTE	0.10	0.10	0.10	0.10
	Subtotal	12,960	12,960	12,960	12,960
Information Technology:					
	Subtotal	0	0	0	0
Other Operating Costs:					
Contract for Tableau dashboard development		6,000			
	Subtotal	6,000	0	0	0
Grants, Aids & Subsidies:					
	Subtotal	0	0	0	0
Indirect (20.3% Eligible Costs)	Subtotal	3,849	2,631	2,631	2,631
Expenditure	Total	22,809	15,591	15,591	15,591
Fiscal Tracking (Dollars in Thousands)		FY 2024	FY 2025	FY 2026	FY 2027
Health Improvement BACT 01		23	16	16	16
Administration		23	16	16	16
Grants		0	0	0	0

Long-Term Fiscal Considerations

Local Fiscal Impact

References/Sources

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Fiscal Note

2023-2024 Legislative Session

HF17 - 1A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**
 Committee: **Commerce Finance And Policy**
 Date Completed:
 Agency: **Attorney General**

State Fiscal Impact	Yes	No
Expenditures	X	
Fee/Departmental Earnings		X
Tax Revenue		X
Information Technology		X
Local Fiscal Impact		X

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions shown in the parentheses.

State Cost (Savings)	Biennium			Biennium		
	Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	476	476	476	476	476
Total	-	476	476	476	476	476
Biennial Total			952			952

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	2	2	2	2
Total	-	2	2	2	2

LBO Analyst's Comment

I have reviewed this fiscal note for reasonableness of content and consistency with the LBO's Uniform Standards and Procedures.

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State Cost (Savings) Calculation Details

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions are shown in parentheses.

*Transfers In/Out and Absorbed Costs are only displayed when reported.

State Cost (Savings) = 1-2		Biennium			Biennium	
Dollars in Thousands		FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	476	476	476	476	476
Total		-	476	476	476	476
Biennial Total				952		952
1 - Expenditures, Absorbed Costs*, Transfers Out*						
General Fund	-	476	476	476	476	476
Total		-	476	476	476	476
Biennial Total				952		952
2 - Revenues, Transfers In*						
General Fund	-	-	-	-	-	-
Total		-	-	-	-	-
Biennial Total				-		-

Bill Description

Sections 1 through 6 of the Bill prohibit drug manufacturers from imposing, or causing to be imposed, an excessive price increase, whether directly or through a wholesale distributor, pharmacy, or similar intermediary, on the sale of any generic or off-patent drug sold, dispensed, or delivered to any consumer in Minnesota.

Section 4 requires MMB and any other state agency (except DHS) that provides or purchases pharmacy benefits to notify the manufacturer of a generic or off-patent drug, the Office of the Attorney General (“OAG”) and the Board of Pharmacy of any price increase that violates the excessive price increase prohibition in the Bill. Upon such notice, the Bill requires the manufacturer to submit information about the price increase to the OAG within 45 days. The Bill authorizes the OAG to investigate such price increases in accordance with its investigative authority under Minn. Stat. § 8.31. The Bill further authorizes the OAG to bring an enforcement action and seek the following remedies from a court for violation of the Bill’s excessive price increase prohibition: (1) injunctive relief requiring the drug price be restored to a level that complies with the Bill; (2) an accounting from the manufacturer of all revenues that resulted from the violation; (3) restitution (or alternatively disgorgement to a special fund) for all consumers and third-party payers for which the manufacturer obtained as a result of an excessive price increase; (4) civil penalties of up to \$10,000 per day per violation; (5) costs and reasonable attorney’s fees; and (6) any other appropriate relief as determined by the court.

Sections 7 through 20 of the Act constitute the Prescription Drug Affordability Act.

Section 9 creates the Prescription Drug Affordability Board and directs that the Attorney General provide legal services to the board. The board must meet at least quarterly.

Section 10 creates a council to advise the board.

Section 13 gives the board the authority to review drug costs, assess whether a drug price creates an affordability challenge, and determine upper payment limits. A board’s decision is subject to an administrative appeal and then judicial review.

The Bill requires the Board to receive and review prescription drug pricing information from MDH and a prescription drug pricing subscription service and identify certain prescription drug products that may impose costs that create significant affordability challenges for the state’s health care system or patients. For prescription drug products that the Board identifies, the Board is authorized to conduct a cost- review of the drug and if it finds that it creates an affordability challenge, to establish an upper payment limit for all public and private purchases, payments, and payer reimbursements for the prescription drug product that is intended for individuals in the state in person, by mail, or by other means. If an entity is noncompliant with the upper payment limit established by the Board, the Bill authorizes the Board to refer the noncompliant entity to the AGO. The AGO may then investigate the noncompliance and pursue an enforcement action and remedies in accordance with Minnesota Statutes section 8.31. The Bill further directs the AGO to “provide guidance to

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stakeholders concerning activities that could be considered noncompliant.”

Section 19 empowers the Board of Pharmacy to impose disciplinary action against a manufacturer for violations of Section 2.

Assumptions

We assume that, in representing the board, an attorney would be needed to consult with the board regarding various legal issues, including the Open Meeting Law, the Minnesota Government Data Practices Act, and other common issues and responsibilities that boards encounter.

We assume that an attorney would attend the quarterly meetings or at least consult with board staff regarding each meeting.

We assume that, if the board creates a committee and delegates certain enforcement responsibilities, a separate attorney may be needed to advise the committee rather than the board.

We assume that the board will be involved in litigation as affected parties have the right to administrative and judicial review. Litigation costs are difficult to estimate, and we assume that the board will pay all costs (e.g., OAH costs, depositions, excerpt witnesses, court reporters, transcripts, etc.) and that the Attorney General’s Office would absorb the costs of any attorney or paralegal time incurred. We estimate that the board may see one or two appeals each year.

We assume the AGO will require additional staff in its Consumer, Wage, and Antitrust division devoted to the new investigatory and enforcement provisions in Sections 4 and 14 of the Bill. The AGO assumes 1.0 FTE attorney and 1.0 FTE investigator will be required. The AGO also assumes that it will require qualified vendors with expertise in pharmaceutical pricing, reimbursement, as well as public and private purchases, payments, and payer reimbursements for prescription drugs to assist the AGO in assessing and investigating whether violations of the Bill’s prohibitions have occurred, and to subsequently provide expert testimony in enforcement actions it brings for violations of these prohibitions in accordance with Minn. Stat. § 8.31. It should also be noted that there are potential secondary costs associated with this Bill, if it faces a pre-enforcement challenge to its constitutionality.

It is presently unknown how many cost reviews the Board will conduct in any given fiscal year, as well as how many price increases the Board will identify from the information it receives from the Commissioner of Health and its review of drug pricing data. There could, however, be a substantial number of notifications and cost reviews. For example, a report from California’s Office of Statewide Health Planning and Development (“OSHPD”), which reviewed the pricing trends for over 900 prescription drugs, and found that the overall 3-year median WAC experienced a 21.2% increase. (see reference below). Thus, for purposes of this fiscal note, the AGO will assume that beginning in fiscal year 2025, it will begin to receive at least 5 referrals from the Board for investigation and potential enforcement actions for violation of the upper payment limits established by the Board.

We assume the Board of Pharmacy would consult with an attorney on its new enforcement obligation and could potentially incur litigation costs in the event a manufacturer violates Section 2. Litigation costs are difficult to estimate and we assume litigation would not commonly occur.

Given the above assumptions, the Attorney General’s Office estimates that, it will expend approximately 410 hours of attorney time and 100 hours of legal assistant time per fiscal year relative to the creation of the new board. In addition, the Attorney General’s Office estimates that it will require a separate 1.0 FTE attorney and 1.0 FTE investigator in order to carry out the enforcement provisions in sections 4 and 14 of the Bill. The work for the new board and work for enforcement would be performed in separate divisions of the office and must be performed by separate attorneys and legal assistants.

Expenditure and/or Revenue Formula

	Hourly Billing Rate	Hours	Total Amount	Partner Agency
Attorney, (Board)	\$163	410	\$66,830	<i>Prescription Drug Affordability Board</i>
Legal assistant, (Board)	\$103	100	\$10,300	<i>Prescription Drug Affordability Board</i>

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Attorney, Consumer, Wage Theft, & Antitrust Division (enforcement)	\$163	1500 (1 FTE)	\$244,500	N/A
Legal Assistant, Consumer, Wage Theft, & Antitrust Division (enforcement)	\$103	1500 (1 FTE)	\$154,500	N/A

Long-Term Fiscal Considerations

It is assumed that the increased AGO staff (referenced above) as well as litigation expenses (including expert costs) will be needed on an ongoing basis, into fiscal years 2026, 2027, and beyond. Staffing, expert, and revenue assumptions on a long-term basis outside the three year period will depend on reevaluation of the need for this work on a continuing basis.

Local Fiscal Impact

References/Sources

OSHPD Report, *Wholesale Acquisition Cost (WAC) Increase Report Data*, available at <https://hcai.ca.gov/visualizations/wholesale-acquisition-cost-wac-increase-report-data-current-year/> (last visited Feb. 1, 2023).

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Preliminary

Fiscal Note

2023-2024 Legislative Session

HF17 - 1A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**
 Committee: **Commerce Finance And Policy**
 Date Completed:
 Agency: **Commerce Dept**

State Fiscal Impact	Yes	No
Expenditures		X
Fee/Departmental Earnings		X
Tax Revenue		X
Information Technology		X
Local Fiscal Impact		X

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions shown in the parentheses.

State Cost (Savings) Dollars in Thousands	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
Total	-	-	-	-	-
Biennial Total			-		-

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
Total	-	-	-	-	-

LBO Analyst's Comment

I have reviewed this fiscal note for reasonableness of content and consistency with the LBO's Uniform Standards and Procedures.

I have reviewed this fiscal note for reasonableness of content and consistency with LBO's Uniform Standards and Procedures.

LBO Signature: Shannon Zila **Date:** 1/24/2023 8:57:14 AM
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Preliminary

State Cost (Savings) Calculation Details

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions are shown in parentheses.

*Transfers In/Out and Absorbed Costs are only displayed when reported.

State Cost (Savings) = 1-2 Dollars in Thousands	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
Total	-	-	-	-	-
Biennial Total			-		-
1 - Expenditures, Absorbed Costs*, Transfers Out*					
Total	-	-	-	-	-
Biennial Total			-		-
2 - Revenues, Transfers In*					
Total	-	-	-	-	-
Biennial Total			-		-

Bill Description

House File 17-1A proposes to prohibit drug manufacturers from excessively increasing the prices of generic or off-patent drugs. Utilizing the consumer price index (adjusted for inflation) the bill identifies a price increase as excessive when it exceeds 15 percent of the wholesale acquisition cost over the immediately preceding calendar year, or 40 percent of the wholesale acquisition cost over the immediately preceding three calendar years. The bill also identifies a price increase as excessive when it exceeds \$30 for a 30-day supply of the drug or a course of treatment lasting fewer than 30 days.

The bill requires drug manufacturers selling, distributing, delivering, or offering sale of any generic or off-patent drug in the state to maintain a registered agent and office while in the state.

The bill requires any manufacturer that has excessively increased the price of a generic or off-patent drug must submit a drug cost statement itemizing cost components related to the production of the drug as well as any circumstances and other information justifying a price increase. The bill authorizes the attorney general to enforce its provisions and assess penalties of up to \$10,000 per day for each violation.

The bill requires a written notice to the Board of Pharmacy and the attorney general 180 days prior to withdrawal of a generic or off-patent drug from sale or distribution in the state and prohibits withdrawal for purposes of avoiding the prohibition on excessive price increases. The bill authorizes the attorney general to assess penalties of up to \$500,000 for failure to comply.

The bill requires the Legislative Coordinating Commission to establish a Prescription Drug Affordability Board. The Prescription Drug Affordability Board consists of seven voting members appointed by the governor and two nonvoting members appointed by legislative leadership, that must have knowledge and demonstrated expertise in pharmaceutical or health care economics and finance. The bill requires the board to meet publicly at least every three months.

The bill establishes that the governor shall appoint twelve members, representing multiple areas of the health care system, to a Prescription Drug Affordability Advisory Council to represent stakeholder views on prescription drug affordability. The bill requires the advisory council to meet publicly at least every three months.

The bill establishes several prescription drug products to be reviewed by the board and council, with a focus on prescription drugs with significant increases in wholesale acquisition costs and other potentially high-cost drugs. The bill establishes requirements for conducting a prescription drug price cost review. Initial information for the cost review is to be provided by the Commissioner of Health and other sources. Initial information provided to the advisory council will come from data collected under Minn. Stat. § 62J.84, Subd. 3, 4, and 5. The board and advisory council must make their findings publicly available minus any drug pricing information determined to be proprietary. A cost review of a specific prescription drug under this section may be pursued with board consensus.

The bill includes factors to consider if a prescription drug product is being reviewed. Factors to be considered include pricing information of the drug; rebates; the cost of the drug to group purchasers, measures of patient access, including cost-sharing, and the extent to which a price increase was determined to be excessive.

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The bill also establishes compliance remedies when a prescription drug product has been reviewed and found to create an affordability challenge. The board may establish an upper payment limit for the drug reviewed, which will apply to all state-regulated entity purchases, payments, billing, and payer reimbursements. The Attorney General is tasked enforcing compliance in this area. The bill establishes requirements for implementing and administering the upper payment limit and requires health plan companies and pharmacy benefit managers to report annually on how cost savings resulting from an upper payment limit have been used to benefit enrollees.

The bill establishes reporting requirements of the board beginning March 1, 2024. The report must include general information on prescription drug pricing as well as the specific drugs reviewed by the board.

Finally, the bill establishes blank appropriations from the general fund for the Prescription Drug Affordability Board.

Assumptions

Commerce assumes that HF 17 will not have a fiscal impact on the agency as it does not include any specific responsibilities for the department. Commerce may be consulted by the proposed board on certain drug pricing items given its work with implementing transparency reporting requirements for PBMs under Minn. Stat. § 62W.06. Any requests for information or assistance would not substantially increase existing staff workload.

Expenditure and/or Revenue Formula

N/A

Long-Term Fiscal Considerations

Local Fiscal Impact

References/Sources

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Preliminary

Fiscal Note

2023-2024 Legislative Session

HF17 - 1A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**
 Committee: **Commerce Finance And Policy**
 Date Completed:
 Agency: **Governors Office**

State Fiscal Impact	Yes	No
Expenditures	X	
Fee/Departmental Earnings		X
Tax Revenue		X
Information Technology		X
Local Fiscal Impact		X

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions shown in the parentheses.

State Cost (Savings)	Biennium			Biennium		
	Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	-	-	-	-	-
Total	-	-	-	-	-	-
Biennial Total			-			-

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	-	-	-	-
Total	-	-	-	-	-

LBO Analyst's Comment

I have reviewed this fiscal note for reasonableness of content and consistency with the LBO's Uniform Standards and Procedures.

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State Cost (Savings) Calculation Details

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions are shown in parentheses.

*Transfers In/Out and Absorbed Costs are only displayed when reported.

State Cost (Savings) = 1-2		Biennium			Biennium	
Dollars in Thousands		FY2023	FY2024	FY2025	FY2026	FY2027
General Fund		-	-	-	-	-
Total		-	-	-	-	-
Biennial Total				-		-
1 - Expenditures, Absorbed Costs*, Transfers Out*						
General Fund						
Expenditures		-	1	-	-	-
Absorbed Costs		-	(1)	-	-	-
Total		-	-	-	-	-
Biennial Total				-		-
2 - Revenues, Transfers In*						
General Fund						
Total		-	-	-	-	-
Biennial Total				-		-

Bill Description

This bill provides for the creation of a prescription drug advisory council and other regulatory provisions around prescription drug affordability.

Assumptions

The Appointments team and members of the Policy team will prepare appointments for the 7 members listed in the bill.

The impact to the Governor's Office will be 15 hours of work for the Director of Appointments, 8 hours of work for the Jr Appointments Coordinator and 4 hours of work for the relevant Policy Advisor in the first year. The future appointments will be absorbed as part of the work of the Appointments team.

Expenditure and/or Revenue Formula

The Governor's Office will absorb the costs of the appointments in this bill.

Long-Term Fiscal Considerations

Local Fiscal Impact

References/Sources

Agency Contact: Alyssa Haugen (651-201-3416)

Agency Fiscal Note Coordinator Signature: Alyssa Haugen

Date: 1/23/2023 2:28:44 PM

Preliminary

Phone: 651-201-3416

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Preliminary

Fiscal Note

2023-2024 Legislative Session

HF17 - 1A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**
 Committee: **Commerce Finance And Policy**
 Date Completed:
 Agency: **Legislature**

State Fiscal Impact	Yes	No
Expenditures	X	
Fee/Departmental Earnings		X
Tax Revenue		X
Information Technology		X
Local Fiscal Impact		X

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions shown in the parentheses.

State Cost (Savings)	Biennium			Biennium		
	Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	-	-	-	-	-
Total	-	-	-	-	-	-
Biennial Total			-			-

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	-	-	-	-
Total	-	-	-	-	-

LBO Analyst's Comment

I have reviewed this fiscal note for reasonableness of content and consistency with the LBO's Uniform Standards and Procedures.

LBO Signature: Chloe Burns **Date:** 1/24/2023 2:39:52 PM
Phone: 651-297-1423 **Email:** chloe.burns@lbo.mn.gov

Preliminary

State Cost (Savings) Calculation Details

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions are shown in parentheses.

*Transfers In/Out and Absorbed Costs are only displayed when reported.

State Cost (Savings) = 1-2		Biennium			Biennium	
Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027	
General Fund	-	-	-	-	-	-
Total	-	-	-	-	-	-
Biennial Total			-			-
1 - Expenditures, Absorbed Costs*, Transfers Out*						
General Fund						
Expenditures	-	7	-	-	-	-
Absorbed Costs	-	(7)	-	-	-	-
Total	-	-	-	-	-	-
Biennial Total			-			-
2 - Revenues, Transfers In*						
General Fund	-	-	-	-	-	-
Total	-	-	-	-	-	-
Biennial Total			-			-

Bill Description

The bill, in part, creates a Prescription Drug Affordability Board in the executive branch under MS 15.012 (a) and a Prescription Drug Affordability Advisory Council to support the board's work with providing review and analysis of prescription drug cost. The board must submit a report to the governor and the legislature annually beginning March 1, 2024.

The Prescription Drug Affordability Board (PDAB) will consist of nine members with seven voting members appointed by the governor and two non-voting members appointed by the legislature with initial appointments to be done by January 1, 2024. The board must meet at a minimum once every three months. Members shall not receive compensation but may be reimbursed for expenses as provided by MS 15.059, Subd. 3.

The Prescription Drug Affordability Advisory Council (PDAAC) will consist of 12 members appointed by the governor. Initial appointments are to be made by January 1, 2024. Council members may be compensated as provided by MS 15.059. The council must meet at a minimum once every three months and does not expire.

The Legislative Coordinating Commission (LCC) shall establish the PDAB. An executive director and other staff are to be hired to support the board and the council. The board may also contract for professional and technical assistance as determined by the board. The attorney general shall provide legal services to the board.

General fund appropriations are to be appropriated to the board in FY24 and FY25.

Assumptions

1. The LCC is charged with the initial establishment of the PDAB. The executive director of the LCC will spend four hours per week from December 11, 2023, through February 29, 2024, for the limited responsibility of the LCC for establishment of the board and work with the board to coordinate the hiring of an executive director (FY24 .03 FTE, 60 hours). For this fiscal note we assume existing LCC staff will be utilized and costs may be absorbed, although that will depend on the priorities of the legislature and staff time required for competing projects.
2. House Research Department and Fiscal Analysis Department will follow the work of the PDAB. For this fiscal note we assume existing House staff will be utilized and costs may be absorbed, although that will depend on the priorities of the legislature and staff time required for competing projects.
- 3.

Preliminary

Senate Counsel, Research and Fiscal Analysis will follow the work of the PDAB and associated nominal cost will be absorbed. For this fiscal note we assume existing Senate staff will be utilized and costs may be absorbed, although that will depend on the priorities of the legislature and staff time required for competing projects.

4. This note does not project the cost for the member meeting participating participation and board operational cost, including staff compensation and consultant cost. Nor does this note project the member meeting participation cost of the advisory council or any cost of state agencies that may assistance to the board or advisory council.

Expenditure and/or Revenue Formula

Cost Category	FY24	FY25	FY26	FY27
LCC Executive Director (.03 FTE, approx. 60 hours total during FY24)	6,750	0	0	0
Total LCC Cost (rounded)	7,000	0	0	0
Total LCC Cost Absorbed (rounded)	(7,000)	0	0	0
Net Total Cost (rounded)	0	0	0	0

Long-Term Fiscal Considerations

N/A

Local Fiscal Impact

N/A

References/Sources

Emily Adriaens, House of Representatives

Patrick McCormack, House of Representatives

Eric Nauman, Minnesota Senate

Alexis Stangl, Minnesota Senate

Michelle Weber, Legislative Coordinating Commission

Agency Contact: Diane Henry-Wangenstein

Agency Fiscal Note Coordinator Signature: Diane Henry-Wangenstein

Phone: 651-296-1121

Date: 1/23/2023 2:48:22 PM

Email: diane.henry@lcc.leg.mn

Preliminary

Fiscal Note

2023-2024 Legislative Session

HF17 - 1A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**
 Committee: **Commerce Finance And Policy**
 Date Completed:
 Agency: **Medical Practice Board**

State Fiscal Impact	Yes	No
Expenditures		X
Fee/Departmental Earnings		X
Tax Revenue		X
Information Technology		X
Local Fiscal Impact		X

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions shown in the parentheses.

State Cost (Savings)	Biennium			Biennium		
	Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027
Total	-	-	-	-	-	-
Biennial Total				-		-

Full Time Equivalent Positions (FTE)	Biennium			Biennium		
		FY2023	FY2024	FY2025	FY2026	FY2027
Total	-	-	-	-	-	-

LBO Analyst's Comment

I have reviewed this fiscal note for reasonableness of content and consistency with the LBO's Uniform Standards and Procedures.

I have reviewed this fiscal note for reasonableness of content and consistency with LBO's Uniform Standards and Procedures.

LBO Signature: Shannon Zila **Date:** 1/23/2023 5:29:26 PM
Phone: 651-296-6053 **Email:** shannon.zila@lbo.mn.gov

Preliminary

State Cost (Savings) Calculation Details

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions are shown in parentheses.

*Transfers In/Out and Absorbed Costs are only displayed when reported.

State Cost (Savings) = 1-2		Biennium			Biennium	
Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027	
Total		-	-	-	-	-
Biennial Total				-		-
1 - Expenditures, Absorbed Costs*, Transfers Out*						
Total		-	-	-	-	-
Biennial Total				-		-
2 - Revenues, Transfers In*						
Total		-	-	-	-	-
Biennial Total				-		-

Bill Description

Makes changes to prescription drug pricing.

Assumptions

The bill has no impact on statutes or rules that the Board of Medical Practice is empowered to enforce. Therefore, there is no fiscal impact.

Expenditure and/or Revenue Formula

N/A

Long-Term Fiscal Considerations

N/A

Local Fiscal Impact

N/A

References/Sources

Agency Contact: Ruth Martinez (612-548-2150)

Agency Fiscal Note Coordinator Signature: Ruth Martinez

Phone: 612-548-2150

Date: 1/23/2023 2:29:24 PM

Email: ruth.martinez@state.mn.us

Preliminary

Fiscal Note

2023-2024 Legislative Session

HF17 - 1A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**
 Committee: **Commerce Finance And Policy**
 Date Completed:
 Agency: **Minn Management and Budget**

State Fiscal Impact	Yes	No
Expenditures		X
Fee/Departmental Earnings		X
Tax Revenue		X
Information Technology		X
Local Fiscal Impact		X

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions shown in the parentheses.

State Cost (Savings)	Biennium			Biennium		
	Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027
Total	-	-	-	-	-	-
Biennial Total				-		-

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
Total	-	-	-	-	-

LBO Analyst's Comment

I have reviewed this fiscal note for reasonableness of content and consistency with the LBO's Uniform Standards and Procedures.

LBO Signature: Susan Nelson **Date:** 1/24/2023 10:50:05 AM
Phone: 651-296-6054 **Email:** susan.nelson@lbo.mn.gov

Preliminary

State Cost (Savings) Calculation Details

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions are shown in parentheses.

*Transfers In/Out and Absorbed Costs are only displayed when reported.

State Cost (Savings) = 1-2		Biennium			Biennium	
Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027	
Total	-	-	-	-	-	-
Biennial Total			-			-
1 - Expenditures, Absorbed Costs*, Transfers Out*						
Total	-	-	-	-	-	-
Biennial Total			-			-
2 - Revenues, Transfers In*						
Total	-	-	-	-	-	-
Biennial Total			-			-

Bill Description

House File 17-1A prohibits excessive price increases to generic and off-patent pharmaceuticals by drug manufacturers and establishes a Prescription Drug Affordability Board and Advisory Council to review potential violations and determine disciplinary measures.

The State Employee Group Insurance Program (SEGIP) at MMB contracts with a Pharmacy Benefits Manager (PBM) for pharmaceutical services. As a result, Section 4 Subdivision 1 of this legislation stipulates that the commissioner of Management and Budget must notify the pharmaceutical manufacturer, Attorney General, and Board of Pharmacy of generic drug price increases that potentially violate the standards established in the legislation.

Assumptions

Minnesota Management and Budget (MMB) administers the State Employee Group Insurance Program (SEGIP) which provides health, dental, life, and other benefits to eligible State employees and their dependents, and quasi-state agencies defined in Minnesota Statute. Health benefits are provided through the self-funded Minnesota Advantage Health Plan (Advantage). SEGIP contracts with three health plan administrators to provide medical benefits and a Pharmacy Benefit Manager (PBM) to provide its prescription drug benefit.

MMB does not expect a fiscal impact from this legislation. MMB's responsibility is to report potential drug price increase violations to the relevant authorities outlined in this legislation. We assume that ongoing monitoring for drug price violations would be performed by our PBM as part of their routine formulary maintenance process. The PBM negotiates confidential drug price and rebate amounts with drug manufacturers, and as a result is the only entity that can identify instances where a manufacturer's proposed drug price increase would be in violation of the legislation.

We assume that our PBM would also report price violations on MMB's behalf, however, SEGIP staff could also fulfill this role if desired. We do not anticipate additional administrative fees or costs to perform this monitoring or reporting.

Expenditure and/or Revenue Formula

Long-Term Fiscal Considerations

Local Fiscal Impact

Preliminary

References/Sources

Program Information and claims data from SEGIP, administered by MMB.

I have reviewed the content of this fiscal note and believe it is a reasonable estimate of the expenditures and revenues associated with this proposed legislation.

If Information Technology costs are included, my agency's Chief Information Officer has reviewed the estimate

Agency Contact: Galen Benshoof 651-207-8224

Agency Fiscal Note Coordinator Signature: Ronika Rampadarat

Date: 1/24/2023 9:48:02 AM

Phone: 612-659-6873

Email: ronika.rampadarat@state.mn.us

Preliminary

Fiscal Note

2023-2024 Legislative Session

HF17 - 1A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**
 Committee: **Commerce Finance And Policy**
 Date Completed:
 Agency: **MNsure**

State Fiscal Impact	Yes	No
Expenditures		X
Fee/Departmental Earnings		X
Tax Revenue		X
Information Technology		X
Local Fiscal Impact		X

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions shown in the parentheses.

State Cost (Savings)	Biennium			Biennium		
	Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027
Total	-	-	-	-	-	-
Biennial Total			-			-

Full Time Equivalent Positions (FTE)	Biennium			Biennium		
		FY2023	FY2024	FY2025	FY2026	FY2027
Total	-	-	-	-	-	-

LBO Analyst's Comment

I have reviewed this fiscal note for reasonableness of content and consistency with the LBO's Uniform Standards and Procedures.

I have reviewed this fiscal note for the reasonableness of content and consistency with LBO's Uniform Standards and Procedures. MNsure will need to complete an actuarial study to assess the fiscal impact should premium withhold amounts differ as the duties of the board, council, and Prescription Drug Affordability Act are implemented.

LBO Signature: Shannon Zila **Date:** 1/24/2023 11:13:42 AM
Phone: 651-296-6053 **Email:** shannon.zila@lbo.mn.gov

Preliminary

State Cost (Savings) Calculation Details

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions are shown in parentheses.

*Transfers In/Out and Absorbed Costs are only displayed when reported.

State Cost (Savings) = 1-2		Biennium			Biennium	
Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027	
Total	-	-	-	-	-	-
Biennial Total			-			-
1 - Expenditures, Absorbed Costs*, Transfers Out*						
Total	-	-	-	-	-	-
Biennial Total			-			-
2 - Revenues, Transfers In*						
Total	-	-	-	-	-	-
Biennial Total			-			-

Bill Description

This bill prohibits excessive price increases by manufacturers to generic or off-patent drugs. It authorizes the attorney general to take action against manufacturers for price increases, prohibits the withdrawal of generic or off-patent drug sales, establishes a prescription drug affordability board and prescription drug affordability advisory council, provides for prescription drug cost reviews and remedies, and imposes civil penalties. The bill also requires a report of prescription price trends to the legislature on March 1, 2024 and each following year.

Assumptions

This bill would result in no direct fiscal impact to MNsure; however, changes in plan premiums, plan choice, or plan demand could have an effect on the amount of revenue MNsure generates through its premium withhold.

The cost to provide prescription drug coverage is one of many factors health plans consider each year when setting their rates for plans sold on the individual market. Because the affordability board established in HF17 can establish an upper payment limit on any prescription drugs that it identifies as presenting an affordability challenge for the state health care system or for patients, this could impact rates and therefore plan premiums and plan design in the individual market.

An actuarial study would need to be conducted to determine the impact to health insurance premiums, plan choice, or plan demand caused by the effects of HF17. Further, MNsure does not know which prescription drugs will be reviewed by the affordability board nor whether any of those reviews will result in the establishment of an upper payment limit on a particular drug.

Expenditure and/or Revenue Formula

Long-Term Fiscal Considerations

Local Fiscal Impact

References/Sources

Agency Contact:

Agency Fiscal Note Coordinator Signature: Pete Engler

Date: 1/24/2023 10:42:26 AM

Phone: 651-247-0247

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Preliminary

Preliminary

Fiscal Note

2023-2024 Legislative Session

HF17 - 1A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**
 Committee: **Commerce Finance And Policy**
 Date Completed:
 Agency: **Nursing Board**

State Fiscal Impact	Yes	No
Expenditures		X
Fee/Departmental Earnings		X
Tax Revenue		X
Information Technology		X
Local Fiscal Impact		X

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions shown in the parentheses.

State Cost (Savings) Dollars in Thousands	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
Total	-	-	-	-	-
Biennial Total			-		-

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
Total	-	-	-	-	-

LBO Analyst's Comment

I have reviewed this fiscal note for reasonableness of content and consistency with the LBO's Uniform Standards and Procedures.

I have reviewed this fiscal note for reasonableness of content and consistency with LBO's Uniform Standards and Procedures.

LBO Signature: Shannon Zila **Date:** 1/23/2023 5:31:42 PM
Phone: 651-296-6053 **Email:** shannon.zila@lbo.mn.gov

Preliminary

State Cost (Savings) Calculation Details

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions are shown in parentheses.

*Transfers In/Out and Absorbed Costs are only displayed when reported.

State Cost (Savings) = 1-2 Dollars in Thousands	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
Total	-	-	-	-	-
Biennial Total			-		-
1 - Expenditures, Absorbed Costs*, Transfers Out*					
Total	-	-	-	-	-
Biennial Total			-		-
2 - Revenues, Transfers In*					
Total	-	-	-	-	-
Biennial Total			-		-

Bill Description

This bill establishes a board for the oversight of a process for affordable pricing of prescription medications.

Assumptions

The bill does not assign responsibility to the Board of Nursing for any portion of this process. There is no fiscal impact for the Board of Nursing.

Expenditure and/or Revenue Formula

Long-Term Fiscal Considerations

Local Fiscal Impact

References/Sources

Agency Contact: Kimberly Miller (612-317-3025)

Agency Fiscal Note Coordinator Signature: Kimberly Miller

Phone: 612-317-3025

Date: 1/23/2023 2:27:37 PM

Email: kimberly.miller@state.mn.us

Preliminary

Fiscal Note

2023-2024 Legislative Session

HF17 - 1A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**
 Committee: **Commerce Finance And Policy**
 Date Completed:
 Agency: **Pharmacy Board**

State Fiscal Impact	Yes	No
Expenditures	X	
Fee/Departmental Earnings		X
Tax Revenue		X
Information Technology		X
Local Fiscal Impact		X

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions shown in the parentheses.

State Cost (Savings) Dollars in Thousands	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
Health Related Boards	-	278	280	280	280
Total	-	278	280	280	280
Biennial Total			558		560

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
Health Related Boards	-	1	1	1	1
Total	-	1	1	1	1

LBO Analyst's Comment

I have reviewed this fiscal note for reasonableness of content and consistency with the LBO's Uniform Standards and Procedures.

LBO Signature: Shannon Zila **Date:** 2/1/2023 7:23:54 PM
Phone: 651-296-6053 **Email:** shannon.zila@lbo.mn.gov

Preliminary

State Cost (Savings) Calculation Details

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions are shown in parentheses.

*Transfers In/Out and Absorbed Costs are only displayed when reported.

State Cost (Savings) = 1-2 Dollars in Thousands	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
Health Related Boards	-	278	280	280	280
Total	-	278	280	280	280
Biennial Total			558		560
1 - Expenditures, Absorbed Costs*, Transfers Out*					
Health Related Boards	-	278	280	280	280
Total	-	278	280	280	280
Biennial Total			558		560
2 - Revenues, Transfers In*					
Health Related Boards	-	-	-	-	-
Total	-	-	-	-	-
Biennial Total			-		-

Bill Description

This bill prohibits excessive price increases by manufacturers to generic or off-patent drugs, prohibits the withdrawal of certain generic or off-patent drug sales to avoid the prohibition on excessive price increases, establishes a Prescription Drug Affordability Board and Advisory Counsel, and imposes civil penalties. This bill further amends MN Stat. 151.071, Subd. 1 and 2, such that a manufacturer's noncompliance with the aforementioned is grounds for disciplinary action by the Board of Pharmacy.

Assumptions

This bill requires manufacturers to report to the Board of Pharmacy, written notice of a company's withdrawal of generic or off-patent drug from the sale or distribution in Minnesota, 180 days prior to the withdrawal. Board staff will need to establish a repository for this information. Furthermore, this bill creates language in Chapter 151.071 Subd. 2 which the Board of Pharmacy has jurisdiction over. If enacted, the Board anticipates an increase in complaints, enforcement action, collaboration with the attorney general's office, and the cataloging of data based on previous year's percentage of non-complaint manufacturers. The Board licenses roughly 960 manufacturers. While it is unknown how many allegations of noncompliance or withdrawal reports the Board will receive, the assumption is that it will be greater than zero. Using the Board's licensing compliance data as a possible point of reference, manufacturers are required to renew their license by June 1st of every calendar year. This is required under Minnesota statutes and rules. Each year, prior to the renewal, the Board sends mass communications to licensees, reminding them of the renewal requirements and deadline. There are companies that fail to renew by the designated deadline and are subject to a late fee. An analysis of manufacturer renewals throughout time reveals that 92.25% are compliant with submitting the required renewal paperwork in time. However, 7.75% are not compliant and must pay a late fee. If these percentages are extrapolated to the anticipated compliance rate with this bill, roughly 74 manufacturers could require enforcement action by the Board. The Board receives roughly 160 complaints per year. Therefore, this bill could result in a 46% increase in the number of complaints received annually. Time required to investigate a complaint can vary significantly depending upon the type of complaint. Complaints related to this bill would take on average approximately 24 hours of work to complete times 74 complaints per year = 1776 hours or approximately 44 weeks. The life cycle of a Board complaint consists of an investigation conducted by a pharmacist surveyor, the surveyor's compilation of a complaint packet, the review of the complaint packet by the Board's Complaint Review Panel, and, if the complaint is not dismissed, the matter is referred to the Board's Committee on Professional Standards for further consideration of disciplinary action. Of note, complaints that are not dismissed require the legal assistance and counsel of the attorney general's office. **To account for the anticipated increase in workload, the Board is requesting one full-time employee pharmacist surveyor.**

In August, the AGO informed the health licensing boards that rates for legal services in FY24-FY25 will increase. Specifically, there will be a 9% increase for attorneys and a 15% increase for legal assistants. As the volume of complex

Preliminary

disciplinary matters and contested cases rise, so does the Board's utilization of the AGO for legal services. In FY21, the Board spent \$207,076 on AGO fees. In FY22, the Board spent \$110,745 on AGO fees. The average for the two years is \$158,910. If there is a 46% increase in complaints related to this bill, using the average expense of the AGO as a benchmark, the Board could conceivably expect an increase of \$73,098 due to this language. **Therefore, the Board is requesting an increase of \$73,098 for anticipated legal fees.**

Expenditure and/or Revenue Formula

1 FTE pharmacist surveyor:

	Job Classification:	
Expenditure Category	Pharmacist Surveyor	FY24 Total
# FTE in classification	1	1.00
# positions (for Insurance calculation)	1	1.00
http://mn.gov/mmb/employee-relations/labor-relations/Labor/	157,393.00	157,393.00
Total Base (# FTE x Base Salary)	157,393.00	157,393.00
Fringe Costs (calculate on Total Base):		
FICA - 6.2%	9,758.37	9,758.37
Medicare - 1.45%	2,282.20	2,282.20
Retirement - 6.25%	9,837.06	9,837.06
Insurance - FY23 - \$25,050, FY24 - \$25,946, FY25 - \$27,577, FY26-27 - \$27,577	25946.00	25,946.00
Total Salary & Fringe	205,216.63	205,216.63

Increase in attorney general legal expenses:

	YTD AG Expenses
FY 2021	\$ 207,076.00
FY 2022	\$ 110,745.00
Average	\$ 158,910.50

If there is a 46% increase in complaints related to this bill, using the average expense of the AGO as a benchmark, the Board could conceivably expect an increase of \$73,098 due to this language.

$$\text{\$158,910} * 0.46 = \text{\$73,098}$$

Preliminary

Long-Term Fiscal Considerations

The Board expects to incur these expenses annually if this bill's language remains enacted.

Local Fiscal Impact

N/A

References/Sources

Commissioner's Plan

Agency Contact: Jill Phillips (651-201-2834)

Agency Fiscal Note Coordinator Signature: Jill Phillips

Phone: 651-201-2834

Date: 2/1/2023 4:25:30 PM

Email: jill.phillips@state.mn.us

Preliminary

Fiscal Note

2023-2024 Legislative Session

HF17 - 1A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**
 Committee: **Commerce Finance And Policy**
 Date Completed:
 Agency: Prescription Drug Affordability Board

State Fiscal Impact	Yes	No
Expenditures	X	
Fee/Departmental Earnings		X
Tax Revenue		X
Information Technology		X
Local Fiscal Impact		X

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions shown in the parentheses.

State Cost (Savings)	Biennium			Biennium		
	Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	450	700	700	700	700
Total	-	450	700	700	700	700
Biennial Total			1,150			1,400

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	1.02	3	3	3
Total	-	1.02	3	3	3

LBO Analyst's Comment

I have reviewed this fiscal note for reasonableness of content and consistency with the LBO's Uniform Standards and Procedures.

LBO Signature: Christian Larson **Date:** 1/24/2023 4:37:39 PM
Phone: 651-284-6436 **Email:** christian.larson@lbo.mn.gov

Preliminary

State Cost (Savings) Calculation Details

This table shows direct impact to state government only. Local government impact, if any, is discussed in the narrative. Reductions are shown in parentheses.

*Transfers In/Out and Absorbed Costs are only displayed when reported.

State Cost (Savings) = 1-2		Biennium			Biennium	
Dollars in Thousands		FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	450	700	700	700	700
Total		-	450	700	700	700
Biennial Total				1,150		1,400
1 - Expenditures, Absorbed Costs*, Transfers Out*						
General Fund	-	450	700	700	700	700
Total		-	450	700	700	700
Biennial Total				1,150		1,400
2 - Revenues, Transfers In*						
General Fund	-	-	-	-	-	-
Total		-	-	-	-	-
Biennial Total				-		-

Bill Description

H. F. No. 17-1A, **A bill for an act relating to health; prohibiting excessive price increases by manufacturers to generic or off-patent drugs; authorizing the attorney general to take action against manufacturers for certain price increases; prohibiting withdrawal of certain generic or off-patent drug sales; establishing a prescription drug affordability board and prescription board advisory council; providing for prescription drug cost reviews and remedies; providing appointments; imposing civil penalties; requiring a report; appropriating money; amending Minnesota Statutes 2022, section 151.071, subdivisions 1, 2; proposing coding for new law in Minnesota Statutes, chapter 62J.**

Section. 1 Subd. 1-7 defines the scope and terms as stated in the bill.

Section. 2 establishes the prohibition on excessive price increases that outlines the definition of excessive price increases and exemptions.

Section. 3 states the **any manufacturer that sells, distributes, delivers, or offers for sale any generic or off-patent drug in the state must maintain a registered agent and office within the state.**

Section. 4 outlines details for enforcement. Subdivisions 1 and 2 describe the protocol for notification to manufacturers of generic or off-patent drugs, the attorney general, and the Board of Pharmacy of price increases that are believed to violate section 62J.842 and the submission of information pertaining to the investigation of the previous notification of violation of section 62J.842. Subdivision 3 outlines the role of the courts, on petition from the attorney general, to respond and remediate, if necessary, to notification of violation of section 62J.842. Subdivision 4 states that **any action brought pursuant to section 8.31, subdivision 3a, by a person injured by a violation of section 62J.842 is for the benefit of the public.**

Section. 5 details the prohibition on withdrawal of generic or off-patent drugs for sale through Subdivisions 1-3. If a manufacturer does intend to withdraw a generic or off-patent drug from sale or distribution, a notice is required to the Prescription Drug Affordability Board and the attorney general and financial penalties may be assessed if the manufacturer has failed to comply with the requirements in Section 5.

Section. 6 outlines severability. **If any provision of sections 62J.841 to 62J.845 or the application thereof to any person or circumstance is held invalid for any reason in a court of competent jurisdiction, the invalidity does not affect other provisions or any other application of sections 62J.841 to 62J.845 that can be given effect without the invalid provision or application.**

Section. 7 cites the "Prescription Drug Affordability Act."

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Section. 8 provides definitions in relation to the “Prescription Drug Affordability Act.”

Section. 9 subdivisions 1-7 establishes the Prescription Drug Affordability board, sets membership rules, terms, chair and vice-chair appointments, the hiring of unclassified staff to serve the board, compensation (statute 15.059), and the scheduling of meetings that are subject to chapter 13D and section 62J.90 and 62J.91, and the terms on the appointments. The board will comprise of 7 members appointed by the governor and 2 non-voting members of the legislature (as stated in the amendment) whom must be named by January 1, 2024. These members must have knowledge and expertise in areas related to pharmaceuticals, health economics and finance, and must not be an employee of, board member of, or consultant to a manufacturer or trade association for manufacturers or a pharmacy benefit manager or trade association for pharmacy benefit managers.

Section 10 subdivisions 1-6 establishes the Prescription Drug Affordability Advisory Council. The council will consist of 12 governor appointed members who will provide guidance to the board on drug cost issues and represent stakeholders’ views. The membership must consist of the following: two members representing patients and health care consumers; two members representing health care providers, one member representing health plan companies; two members representing employers (one large employer and one small employer); one member representing government employee benefit plans; one member representing pharmaceutical manufacturers; one member who is a health services clinical researcher; one member who is a pharmacologist; and one member representing the commissioner of health with expertise in health economics. This section and subdivisions also set forth terms, compensation, meetings, and applicable exemptions.

Section 11 subdivisions 1-3 outlines conflicts of interest, definitions thereof, and prohibitions.

Section 12 and 13 outlines cost reviews and product reviews. Detailed in the subdivisions are reports from the commissioner of health from the manufacturers that are required in section 62J.84 subdivisions 3, 4, and 5. These sections outline the identification of prescription drug products resulting from the consultation between the board and the council. Review considerations are detailed in these sections including further review factors and publishing data.

Section 14 provides guidelines for determinations, compliance, and remediation. Subdivision 1 outlines the establishment of upper payment limits. Subdivision 2 outline noncompliance and the roles of the attorney general, board, and others in this process including notification, investigation and review, and guidance to the stakeholders on what could be considered noncompliant. Subdivision 3 details the request of appeals, judicial review (chapter 14).

Section 15 outlines reports required to the governor and legislature.

Section 16 details ERISA and Medicare drug plans are excluded from the requirements of the bill.

Section 17 defines severability from 62J.85 to 62J.94.

Section 18 outlines disciplinary action which includes: licensing and / or registration reparations and civil penalties details.

Section 19 outlines 1-25 grounds for disciplinary action.

Section 20 appropriates funds in fiscal years 2024 and 2025 from the general fund for the establishment of the Prescription Drug Affordability Board (PDAB) for the implementation of the Prescription Drug Affordability Act.

Assumptions

The Prescription Drug Affordability Board and Council’s appointments must be in place by January 1, 2024.

It is assumed that since the Board does not yet exist, the Legislative Coordinating Commission (LCC) in conjunction with the Legislative Budget Office (LBO) will be responsible for estimating costs related to the establishment and ongoing administrative operations of the board, council, and the implementation of the act outline in the Prescription Drug Affordability Act.

It is assumed that the board will consist of seven members appointment by the governor along two non-voting members of the legislature appointed by the Speaker of the House and the Majority Leader of the House.

It is assumed that the council will consist of twelve members of which one member will be representative of the Commissioner of Health.

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The LBO note represents the portions of the cost estimates to administer the bill that are not already included in the other agency estimated costs. These costs are as outlined in the fiscal note for any services provided by the LCC (establishing the PDAB), MNsure, the Medical Practices Board, the Nursing Board, the Pharmacy Board, MN Legislature, the Department of Commerce, the Attorney General, Minnesota Management and Budget, and the Governor's Office.

The costs included in the note are based on the timing within the language of the bill. The first report from the Board is required by March 1, 2024 and may be minimal in nature due to the timing of the creation of the board and the ability to meet before the first required report is due to the legislature.

It is assumed that the Board and the Council will meet within the State Office Building or in the MN Health Regulatory Boards Complex two times in FY2024 and four times each fiscal year thereafter beginning in FY25. Two of these meetings are assumed to occur during session with the other two meetings to occur during the interim. Costs are based on advisory council compensation terms specified in MS 15.059 Subd. 3.

- \$55 per diem (*the 2022 rate is for council members only, per subd. 6 of the bill language, board members are not eligible for compensation*)
- \$99.56/152 miles round trip mileage reimbursement
- \$42 meal reimbursement (2022 rate)
- \$175 lodging reimbursement for half of the members
- One member of the council, representing the Department of Health's Commissioner, is not eligible for any reimbursement in this section

It is assumed that the Executive Director will be hired at a managerial level 25M consistent with an Assistant Commissioner at the Department of Health in consideration of Section 9 Subdivision 5: **The executive director must have knowledge and demonstrated expertise in pharmaeconomics, pharmacology, health policy, health services research, medicine, or a related field or discipline.**

It is assumed that the executive director will be hired beginning February 2024 (.42 FTE / 874 hours in FY24, 1.0 FTE / 2088 hours in FY25 and beyond). The executive director will be responsible for hiring additional support staff alongside the Prescription Drug Affordability Board.

It is assumed that two additional managerial staff will be hired beginning March 2024. Total compensation estimate includes salary, FICA, and employer contribution for health insurance and unclassified retirement plan. This estimate is based on the following provisions taken from MMB:

- It is assumed that the staff employed for the purpose of service to the Board and Council need a certain level of expertise and experience in the field of pharmaceuticals and or medicine to be effective in their roles.
- It is assumed that the two additional support staff are necessary to both support the board and council and to ensure that administrative tasks such as fiscal analysis, communication, and research is complete. These staff will also need knowledge of pharmaceuticals, pharmaeconomics, and health policy.
 - A Health Program Manager/Fiscal Analyst is assumed at a managerial level 15M (.30 FTE / 624 hours in FY24; 1.0 FTE / 2088 hours in FY25 and beyond)
 - A Business Manager 2/ Researcher is assumed at a managerial level 13M (.30 FTE / 624 hours in FY24; 1.0 FTE / 2088 hours in FY25 and beyond)

It is assumed for the purposes of this note that consultant costs of \$200,000 will be incurred annually for actuarial services and specialized consultant services in assistance with the duties of the board and council as directed by Sec. 9 Subd. 5. This amount may need to be reassessed periodically as the Board and Council develops a strategic plan and refines the types and scope of studies needed to meet the statutory purposes of the Board and Council.

It is assumed that the build-out of rented state office space will need to be arranged and office equipment will need to be procured in fiscal year 2024. Rented space will include meeting space for the Board and additional rented space for the Council.

It is assumed that ancillary operating costs will include:

- Office supplies
- Computer hardware and software
- General office equipment and maintenance (phones, copier, etc.)

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- Professional development training and travel cost for staff and members

It is assumed that this fiscal note does not include any additional costs that other State agencies may incur for support and/or interaction with the Council.

Estimates in this fiscal note should be considered preliminary in nature and subject to change as several aspects of the bill depend on future decisions of the board. The current estimates support the analysis of the initial needs to establish a board and the duties as outlined in the bill.

It is assumed the effective date of the bill is January 1, 2024.

Expenditure and/or Revenue Formula

Board Member Meeting Participation Cost Summary

Board Members	FY23	FY24	FY25	FY26	FY27
Board Member Per Diem	0	0	0	0	0
Board Member Mileage Reimbursement	0	1,792	3,584	3,584	3,584
Board Member Lodging Reimbursement	0	1,750	3,500	3,500	3,500
Board Member Meal Reimbursement	0	756	1,512	1,512	1,512
Total	0	4,298	8,596	8,596	8,596

Per diem formula: The Board is not eligible for per diem

Mileage reimbursement formula: 0.655 mileage rate x 152 miles round trip x 9 members x 2 meetings in FY24 for \$1,792 and 4 meetings/year in FY25 and thereafter for \$3,584/year

Lodging reimbursement formula: \$175 room cost x 5 members x 2 meetings per year in FY24 for \$1,750 and 4 meetings/year in FY25 and thereafter for \$3,500/year

Meal reimbursement formula: \$42/day meal cost x 9 members x 2 meeting in FY24 for \$756 and 4 meetings/year in FY25 and thereafter for \$1,512/year

Council Member Meeting Participation Cost Summary

Council Members	FY23	FY24	FY25	FY26	FY27
Council Member Per Diem	0	1,210	2,420	2,420	2,420
Council Member Mileage Reimbursement	0	2,190	4,381	4,381	4,381
Council Member Lodging Reimbursement	0	2,100	4,200	4,200	4,200
Council Member Meal Reimbursement	0	924	1,848	1,848	1,848
Total	0	6,424	12,849	12,849	12,849

Per diem formula: \$55 per member x 11 members x 2 meetings in FY24 for \$1,210 and 4 meetings/year in FY25 and thereafter for \$2,420/year

Mileage reimbursement formula: 0.655 mileage rate x 152 miles round trip x 11 members x 2 meetings per year in FY24 for \$2,190 and 4 meetings/year in FY25 and thereafter for \$4,381/year

Lodging reimbursement formula: \$175 room cost x 6 members x 2 meetings per year in FY24 for \$2,100 and 4 meetings/year in FY25 and thereafter = \$4,200

Meal reimbursement formula: \$42/day meal cost x 11 members x 2 meetings in FY24 for \$924 and 4 meetings/year in

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FY25 and thereafter for \$1,848/year

Staff Support (Salary + Fringe) and Consultant Cost Summary (rounded)

Staff Position	FY23	FY24	FY25	FY26	FY27
Executive Director	0	80,000	190,000	190,000	190,000
Health Program Manager	0	39,000	130,000	130,000	130,000
Business Manager	0	36,000	120,000	120,000	120,000
Total Staff Support Costs	0	155,000	440,000	440,000	440,000
Est. Consultant Costs	0	200,000	200,000	200,000	200,000
Total Staff and Consultant Costs	0	355,000	640,000	640,000	640,000

Office Build-Out, Operation, and Support Costs Summary (rounded)

Cost Type	FY23	FY24	FY25	FY26	FY27
Office Space Rental (1,436 SF at \$17.70 per)	0	25,000	25,000	25,000	25,000
Office Space Build-Out (cubicles, conference room, office furniture, wiring)	0	29,000	0	0	0
Equipment (computers, phones, copiers)	0	18,000	0	0	0
Operations (software, general supplies, water, VoIP, copier maintenance, equipment repairs, staff travel)	0	12,000	12,000	12,000	12,000
Conference Room Rental	0	1,000	1,000	1,000	1,000
Total Build-Out, Operation, and Support Costs	0	85,000	38,000	38,000	38,000

Total Cost Summary (rounded)

Cost Category	FY23	FY24	FY25	FY26	FY27
Board Member Meeting Participation	0	4,000	9,000	9,000	9,000
Council Member Meeting Participation	0	6,000	13,000	13,000	13,000
Support Staff and Consultant Costs	0	355,000	640,000	640,000	640,000
Office Build-Out and Operation	0	85,000	38,000	38,000	38,000
Total Cost	0	450,000	700,000	700,000	700,000

Full Time Equivalents (FTE)

Year	FY23	FY24	FY25	FY26	FY27
New Total FTEs	0	1.02	3.00	3.00	3.00

Long-Term Fiscal Considerations

Costs will be ongoing. Staffing levels and consulting expenses may need to be reassessed in the future as the Board and

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Council establishes priorities and identifies the resources needed to meet statutory purposes.

Local Fiscal Impact

Not applicable.

References/Sources

2021-2023 MAPE Contract, https://mn.gov/mmb-stat/000/az/labor-relations/mape/2021-2023/2021-2023_MAPE_Contract.pdf

2021-2023 Managerial Plan, <https://mn.gov/mmb-stat/000/az/labor-relations/managerial-plan/contract/21-23/Managerial%20Plan%202021-23.pdf>

Real Estate Management Office, Department of Administration

Minnesota Statutes 15.059, Advisory Councils and Committees, <https://www.revisor.mn.gov/statutes/cite/15.059>

Legislative Coordinating Commission (LCC) costing data on office equipment, office build out, software, supplies, and ancillary items.

MN Department of Commerce on related information with consultant fees and PD's

Massachusetts Health Policy Commission: Public meeting information and materials, <https://www.mass.gov/hpc-public-meetings>

Massachusetts Health Policy Commission: BUSINESS REPORT AND FUNDS STATEMENT FY2013 FY2020, <https://www.mass.gov/doc/hpc-business-report-and-funds-sheet-fy13-fy20/download>

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