

HF17 - 2A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**  
 Committee: **Health Finance And Policy**  
 Date Completed: **3/3/2023 10:20:29 AM**  
 Lead Agency: **Health Dept**  
 Other Agencies:  
     Attorney General                      Commerce Dept  
     Governors Office                      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
<b>Attorney General</b>						
General Fund	-	476	476	476	476	476
<b>Commerce Dept</b>						
General Fund	-	717	682	645	645	645
<b>Governors Office</b>						
General Fund	-	-	-	-	-	-
<b>Health Dept</b>						
General Fund	-	69	51	51	51	51
<b>Pharmacy Board</b>						
Health Related Boards	-	278	280	280	280	280
<b>State Total</b>						
General Fund	-	1,262	1,209	1,172	1,172	1,172
Health Related Boards	-	278	280	280	280	280
	<b>Total</b>	<b>-</b>	<b>1,540</b>	<b>1,489</b>	<b>1,452</b>	<b>1,452</b>
			<b>Biennial Total</b>	<b>3,029</b>		<b>2,904</b>

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
<b>Attorney General</b>					
General Fund	-	2.34	2.34	2.34	2.34
<b>Commerce Dept</b>					
General Fund	-	4	4	4	4
<b>Governors Office</b>					
General Fund	-	-	-	-	-
<b>Health Dept</b>					
General Fund	-	.25	.25	.25	.25

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
Pharmacy Board					
Health Related Boards	-	1	1	1	1
<b>Total</b>	<b>-</b>	<b>7.59</b>	<b>7.59</b>	<b>7.59</b>	<b>7.59</b>

**Lead 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:** 3/3/2023 10:20:29 AM  
**Phone:** 651-296-6053    **Email:** shannon.zila@lbo.mn.gov

**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.

<b>State Cost (Savings) = 1-2</b>		<b>Biennium</b>			<b>Biennium</b>	
<b>Dollars in Thousands</b>		<b>FY2023</b>	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>
<b>Attorney General</b>						
General Fund	-	476	476	476	476	476
<b>Commerce Dept</b>						
General Fund	-	717	682	645	645	645
<b>Governors Office</b>						
General Fund	-	-	-	-	-	-
<b>Health Dept</b>						
General Fund	-	69	51	51	51	51
<b>Pharmacy Board</b>						
Health Related Boards	-	278	280	280	280	280
<b>Total</b>		<b>-</b>	<b>1,540</b>	<b>1,489</b>	<b>1,452</b>	<b>1,452</b>
<b>Biennial Total</b>				<b>3,029</b>		<b>2,904</b>
<b>1 - Expenditures, Absorbed Costs*, Transfers Out*</b>						
<b>Attorney General</b>						
General Fund	-	549	549	549	549	549
<b>Commerce Dept</b>						
General Fund	-	717	682	645	645	645
<b>Governors Office</b>						
General Fund	-	-	-	-	-	-
Expenditures	-	1	-	-	-	-
Absorbed Costs	-	(1)	-	-	-	-
<b>Health Dept</b>						
General Fund	-	69	51	51	51	51
<b>Pharmacy Board</b>						
Health Related Boards	-	278	280	280	280	280
<b>Total</b>		<b>-</b>	<b>1,613</b>	<b>1,562</b>	<b>1,525</b>	<b>1,525</b>
<b>Biennial Total</b>				<b>3,175</b>		<b>3,050</b>
<b>2 - Revenues, Transfers In*</b>						
<b>Attorney General</b>						
General Fund	-	73	73	73	73	73
<b>Commerce Dept</b>						
General Fund	-	-	-	-	-	-
<b>Governors Office</b>						
General Fund	-	-	-	-	-	-
<b>Health Dept</b>						
General Fund	-	-	-	-	-	-
<b>Pharmacy Board</b>						
Health Related Boards	-	-	-	-	-	-
<b>Total</b>		<b>-</b>	<b>73</b>	<b>73</b>	<b>73</b>	<b>73</b>
<b>Biennial Total</b>				<b>146</b>		<b>146</b>

**HF17 - 2A - Prescription Drug Affordability Act**

Chief Author: **Zack Stephenson**  
 Committee: **Health Finance And Policy**  
 Date Completed: **3/3/2023 10:20:29 AM**  
 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)	Biennium			Biennium		
	Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	69	51	51	51	51
<b>Total</b>	-	<b>69</b>	<b>51</b>	<b>51</b>	<b>51</b>	<b>51</b>
<b>Biennial Total</b>			<b>120</b>			<b>102</b>

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	.25	.25	.25	.25
<b>Total</b>	-	<b>.25</b>	<b>.25</b>	<b>.25</b>	<b>.25</b>

**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:** 3/2/2023 10:18:22 AM  
**Phone:** 651-296-6053    **Email:** shannon.zila@lbo.mn.gov

**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.

<b>State Cost (Savings) = 1-2</b>		<b>Biennium</b>			<b>Biennium</b>	
Dollars in Thousands		FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	69	51	51	51	51
<b>Total</b>		<b>-</b>	<b>69</b>	<b>51</b>	<b>51</b>	<b>51</b>
<b>Biennial Total</b>				<b>120</b>		<b>102</b>
<b>1 - Expenditures, Absorbed Costs*, Transfers Out*</b>						
General Fund	-	69	51	51	51	51
<b>Total</b>		<b>-</b>	<b>69</b>	<b>51</b>	<b>51</b>	<b>51</b>
<b>Biennial Total</b>				<b>120</b>		<b>102</b>
<b>2 - Revenues, Transfers In*</b>						
General Fund	-	-	-	-	-	-
<b>Total</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Biennial Total</b>				<b>-</b>		<b>-</b>

**Bill Description**

The bill establishes a prohibition of excessive price increases by manufacturers on generic or off-patent drugs, and it establishes a Prescription Drug Affordability Board (PDAB) 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. It calls for MDH representation with expertise in health economics on the newly formed Prescription Drug Affordability Advisory Council. The bill also includes several requirements for MDH to provide assistance to the PDAB.

**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 additionally requires MDH to identify prescription drugs that violate the excessive price increase prohibition and notify multiple entities (Sec. 4, Subd. 1). MDH must also provide technical assistance to the Prescription Drug Affordability Board (PDAB) (Sec. 9, Subd. 5 (b)). MDH is required to provide the PDAB with information collected under the Prescription Drug Price Transparency Act within 30 days of receiving it and MDH must consult with the PDAB to identify drugs with affordability challenges (Sec. 12, Subd. 2 (b)).

MDH assumes that technical assistance and consultation efforts would consist primarily of querying data MDH collects and analyzing reference data the agency licenses at the National Drug Code level. In addition, to supporting the PDAB in identifying drugs with affordability challenges, MDH assumes it will analyze claims data from the Minnesota All Payer Claims Database (MN APCD), focusing on utilization of prescription drugs and assessing cost sharing burden.

From the date MDH receives prescription drug price data, it takes at approximately 90 days to address reporting errors and to make data publicly available on its website. Because the bill requires MDH to share data within 30 days of receipt, MDH assumes that the data will be provided to the board as close to within 30 days as possible and will consist of information submitted by manufacturers initially without verification or data cleaning. To accomplish this data transfer, MDH assumes it will incur a one-time IT vendor cost of \$15,000 and one-time MNIT cost of \$5,000 in fiscal year 2024 to develop, implement, and support an automated process for sharing data with the PDAB via a dashboard or similar method. These costs relate to dashboard development, integration with MDH's IT infrastructure, and securing data access against unauthorized use. Ongoing MNIT support will amount to \$5,000 in fiscal year 2025 and ongoing.

MDH assumes this work will be supported by a 0.25 FTE Research Analysis Specialist Senior beginning in fiscal year 2024 and ongoing to execute monthly queries to identify drugs meeting the price increase prohibition criteria, regularly

update the dashboard with PDAB drug lists and Prescription Drug Price Transparency data, respond to data questions from the PDAB staff and board, and conduct an annual analysis to identify additional pharmaceuticals for PDAB review.

MDH assumes we will incur increased annual licensing costs in the amount of \$5,000 for its Walters Kluwer Medi-Span reference data to accommodate the use cases required under this bill.

The bill does not include an effective date, MDH assumes an effective date of July 1, 2023, but that data requirements provided to the PDAB would occur on the effective date of January 1, 2024 when it is established.

**Expenditure and/or Revenue Formula**

<b>Expenditure (Actual Dollars)</b>	<b>Amount</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
<b>Salary &amp; Fringe:</b>		FTE	FTE	FTE	FTE
Research Analysis Spec Sr	129,602	0.25	0.25	0.25	0.25
	<b>FTE</b>	<b>0.25</b>	<b>0.25</b>	<b>0.25</b>	<b>0.25</b>
	<b>Subtotal</b>	<b>32,401</b>	<b>32,401</b>	<b>32,401</b>	<b>32,401</b>
<b>Information Technology:</b>					
Contract for Tableau dashboard development and query		15,000			
MNIT support for dashboard deployment/data sharing process		5,000			
MNIT ongoing support of dashboard			5,000	5,000	5,000
	<b>Subtotal</b>	<b>20,000</b>	<b>5,000</b>	<b>5,000</b>	<b>5,000</b>
<b>Other Operating Costs:</b>					
Medi-Span annual license increase		5,000	5,000	5,000	5,000
	<b>Subtotal</b>	<b>5,000</b>	<b>5,000</b>	<b>5,000</b>	<b>5,000</b>
<b>Grants, Aids &amp; Subsidies:</b>					
	<b>Subtotal</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Indirect (20.3% Eligible Costs)</b>	<b>Subtotal</b>	<b>11,652</b>	<b>8,607</b>	<b>8,607</b>	<b>8,607</b>
<b>Expenditure</b>	<b>Total</b>	<b>69,053</b>	<b>51,008</b>	<b>51,008</b>	<b>51,008</b>
<b>Fiscal Tracking (Dollars in Thousands)</b>		<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
<b>Health Improvement BACT 01</b>		<b>69</b>	<b>51</b>	<b>51</b>	<b>51</b>
Administration		69	51	51	51
Grants		0	0	0	0

**Long-Term Fiscal Considerations**

**Local Fiscal Impact**

**References/Sources**

**Agency Contact:**

**Agency Fiscal Note Coordinator Signature:** Char Kimber

**Phone:** 651-201-4685

**Date:** 2/24/2023 5:59:47 PM

**Email:** health.fiscalnotes@state.mn.us

**HF17 - 2A - Prescription Drug Affordability Act**

Chief Author: **Zack Stephenson**  
 Committee: **Health Finance And Policy**  
 Date Completed: **3/3/2023 10:20:29 AM**  
 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
<b>Total</b>	<b>-</b>	<b>476</b>	<b>476</b>	<b>476</b>	<b>476</b>	<b>476</b>
<b>Biennial Total</b>			<b>952</b>			<b>952</b>

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	2.34	2.34	2.34	2.34
<b>Total</b>	<b>-</b>	<b>2.34</b>	<b>2.34</b>	<b>2.34</b>	<b>2.34</b>

**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:** 2/28/2023 3:48:36 PM  
**Phone:** 651-296-6054    **Email:** susan.nelson@lbo.mn.gov

**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.

<b>State Cost (Savings) = 1-2</b>		<b>Biennium</b>		<b>Biennium</b>	
<b>Dollars in Thousands</b>	<b>FY2023</b>	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>
General Fund	-	476	476	476	476
<b>Total</b>	<b>-</b>	<b>476</b>	<b>476</b>	<b>476</b>	<b>476</b>
<b>Biennial Total</b>			<b>952</b>		<b>952</b>
<b>1 - Expenditures, Absorbed Costs*, Transfers Out*</b>					
General Fund	-	549	549	549	549
<b>Total</b>	<b>-</b>	<b>549</b>	<b>549</b>	<b>549</b>	<b>549</b>
<b>Biennial Total</b>			<b>1,098</b>		<b>1,098</b>
<b>2 - Revenues, Transfers In*</b>					
General Fund	-	73	73	73	73
<b>Total</b>	<b>-</b>	<b>73</b>	<b>73</b>	<b>73</b>	<b>73</b>
<b>Biennial Total</b>			<b>146</b>		<b>146</b>

**Bill Description**

Section 19 empowers the Board of Pharmacy to impose disciplinary action for licensing violations against manufacturer, individuals, pharmacies, and other entities.

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 MDH 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 stakeholders concerning activities that could be considered noncompliant.”

### **Assumptions**

We assume that, in representing the board, an attorney would be needed to consult with the Prescription Drug Affordability 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 Prescription Drug Affordability Board staff regarding each meeting.

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

We assume that the Prescription Drug Affordability 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 Prescription Drug Affordability 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 Prescription Drug Affordability Board may see one or two appeals each year, based on past experience.

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, 5, 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 Prescription Drug Affordability Board will conduct in any given fiscal year, as well as how many price increases the Prescription Drug Affordability 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). 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 Prescription Drug Affordability Board for investigation and potential enforcement actions for violation of the upper payment limits established by the Prescription Drug Affordability 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.

We assume the Attorney General’s Office will recoup/recover costs incurred in bringing an action against a manufacturer found in violation under Section 4 “Enforcement”, Subdivision 3, number 7 (lines 4.11-4.13).

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 Prescription Drug Affordability Board. The cost for the 510 hours of work for the PDAB will be \$77,130 and those fees will be paid by PDAB by a partner agency agreement. The creation of the board will require the Attorney General’s Office to provide guidance on rulemaking, strategic plans, open meeting laws, and other issues that boards encounter. 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, 5 and 14 of the Bill.

**Expenditure and/or Revenue Formula**

The Office of the Attorney General uses billing rates to calculate revenue and costs. The billing rates effective from July 1, 2024-June 30, 2025 are \$163/hour for attorneys and \$103/hour for legal assistants (including investigators, paralegals, mediators, financial analysts, and support staff). The billable hour rate reflects the cost of providing legal services. One FTE is 1500 billable hours per year.

	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>
Total			\$77,130	

ATTORNEY GENERAL		FY2024	FY2025	FY2026	FY2027
	BoP Enforcement - Rev	\$(73,098.00)	\$(73,098.00)	\$(73,098.00)	\$(73,098.00)
	BoP Enforcement - Exp	\$73,098.00	\$73,098.00	\$73,098.00	\$73,098.00
	PDAB - Exp	\$77,103.00	\$77,103.00	\$77,103.00	\$77,103.00
	2 FTE Enforcement	\$399,000.00	\$399,000.00	\$399,000.00	\$399,000.00
<b>GENERAL FUND</b>	<b>Total</b>	<b>\$476,103.00</b>	<b>\$476,103.00</b>	<b>\$476,103.00</b>	<b>\$476,103.00</b>
			\$952,206.00		\$952,206.00

**Long-Term Fiscal Considerations**

n/a

**Local Fiscal Impact**

n/a

**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).

**Agency Contact:** Laura Sayles

**Agency Fiscal Note Coordinator Signature:** Laura Capuana

**Phone:** 651-402-2213

**Date:** 2/28/2023 3:30:09 PM

**Email:** laura.capuana@ag.state.mn.us

HF17 - 2A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**  
 Committee: **Health Finance And Policy**  
 Date Completed: **3/3/2023 10:20:29 AM**  
 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
<b>General Fund</b>	-	717	682	645	645
<b>Total</b>	-	717	682	645	645
<b>Biennial Total</b>			1,399		1,290

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
General Fund	-	4	4	4	4
<b>Total</b>	-	4	4	4	4

**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:** 3/3/2023 8:41:59 AM  
**Phone:** 651-296-6053    **Email:** shannon.zila@lbo.mn.gov

**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.

<b>State Cost (Savings) = 1-2</b>		<b>Biennium</b>			<b>Biennium</b>	
<b>Dollars in Thousands</b>	<b>FY2023</b>	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	
General Fund	-	717	682	645	645	
<b>Total</b>	<b>-</b>	<b>717</b>	<b>682</b>	<b>645</b>	<b>645</b>	
<b>Biennial Total</b>			<b>1,399</b>			<b>1,290</b>
<b>1 - Expenditures, Absorbed Costs*, Transfers Out*</b>						
General Fund	-	717	682	645	645	
<b>Total</b>	<b>-</b>	<b>717</b>	<b>682</b>	<b>645</b>	<b>645</b>	
<b>Biennial Total</b>			<b>1,399</b>			<b>1,290</b>
<b>2 - Revenues, Transfers In*</b>						
General Fund	-	-	-	-	-	
<b>Total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	
<b>Biennial Total</b>			<b>-</b>			<b>-</b>

**Bill Description**

House File 17-2A 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 commissioner of commerce 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.

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 HF17-2A will have a fiscal impact on the department related to the proposed Prescription Drug Affordability Board. The commissioner of commerce is charged with establishing the board and 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.

Commerce assumes that there will be an initial investment of staff time to help establish the board. Commerce assumes that this work will consist of a total of 2 FTE for FY24 to help with the logistics and legal questions to support the establishment of the board. This includes working with the Governor's office to develop the necessary board recruitment materials, providing logistical and administrative support until the board and staff are in place, and providing legal counsel.

Commerce assumes that once the board is established and staff have been hired that the costs to the agency will be minimal and can be accommodated by existing staff. This assumes that the PDAB, once established, will handle all necessary administrative, logistical, reporting, and analytical work.

Commerce assumes that there will be an ongoing appropriation to fund the staff costs associated with running the board. Commerce assumes that staff members will include one executive director and three additional staff. One staff member will focus on data collection procedures, including the implementation, data organization, publication, and confidentiality considerations. One staff member will analyze drug cost data and provide support in developing methodology for and conducting the affordability reviews. Another staff member will primarily support the board and advisory council with logistics, administration, and annual reporting.

Commerce also assumes that the board will hire a consultant to establish the upper payment limits. Commerce assumes that this work will take 300 hours at the cost of \$250/hr. Commerce assumes this is a one time cost split between FY24 and FY25.

Commerce assumes \$3,200 each meeting for Council expenses for 11 members, including per diem (\$55), mileage (150 miles), meals (\$42) and lodging (\$175/6 members). Two meetings in FY24 and 4 meetings each FY thereafter.

Commerce assumes reimbursement costs for Board members will be immaterial, or covered in the current assumptions for Council reimbursements

### **Expenditure and/or Revenue Formula**

#### **FY24 Commerce costs for establishment of the Board:**

1 FTEAnalyst SPA, Coordinator

1 FTEAttorney 3

			FY24
--	--	--	------

Salary			220,013
Fringe			66,004
Other Personnel Related Costs			71,659
			357,676

**Board Expenses ½ of FY24, and ongoing:**

4 FTE (one manager, one SPA, Coord, SPA, Prin, one Management Analyst 2; consultant costs

			FY24	FY25	FY26
Salary			191,022	382,044	382,044
Fringe			57,307	114,613	114,613
Other Personnel Related Costs			67,664	135,328	135,328
			315,993	631,985	631,985

\$250 x 300 hours - \$75,000, split between FY24 and FY25, \$37,500 each year.

Other Personnel Related Costs includes estimates for rent, supplies, IT related expenses, etc. for each FTE.

Council Member expenses: \$3,200 each meeting (2 meetings FY24-\$6,400 total; 4 meetings FY25-\$12,800 total - ongoing);

\$55 per diem x 11 members=\$605; \$100 mileage x 11 members=\$1,100; \$42 meals x 11 members=\$462; \$175 x 6 members=\$1,050

**Long-Term Fiscal Considerations**

Commerce assumes costs for the Board will be ongoing.

**Local Fiscal Impact**

**References/Sources**

State of Colorado

**Agency Contact:**

**Agency Fiscal Note Coordinator Signature:** Amy Trumper

**Phone:** 651-539-1517

**Date:** 3/2/2023 9:25:45 PM

**Email:** amy.trumper@state.mn.us

HF17 - 2A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**  
 Committee: **Health Finance And Policy**  
 Date Completed: **3/3/2023 10:20:29 AM**  
 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	-	-	-	-	-	-
<b>Total</b>	-	-	-	-	-	-
<b>Biennial Total</b>			-			-

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

**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:** 2/10/2023 7:19:54 AM  
**Phone:** 651-296-6054    **Email:** susan.nelson@lbo.mn.gov

**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.

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

**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:** 2/8/2023 2:39:31 PM

**Phone:** 651-201-3416

**Email:** [alyssa.haugen01@state.mn.us](mailto:alyssa.haugen01@state.mn.us)

**HF17 - 2A - Prescription Drug Affordability Act**

Chief Author: **Zack Stephenson**  
 Committee: **Health Finance And Policy**  
 Date Completed: **3/3/2023 10:20:29 AM**  
 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
<b>Total</b>	-	-	-	-	-	-
<b>Biennial Total</b>			-			-

Full Time Equivalent Positions (FTE)	Biennium			Biennium		
		FY2023	FY2024	FY2025	FY2026	FY2027
<b>Total</b>	-	-	-	-	-	-

**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:** 2/9/2023 12:43:47 PM  
**Phone:** 651-296-6053    **Email:** shannon.zila@lbo.mn.gov

**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.

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

**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:** Elizabeth Huntley (612-548-2168)

**Agency Fiscal Note Coordinator Signature:** Elizabeth Huntley

**Phone:** 612-548-2168

**Date:** 2/7/2023 12:21:44 PM

**Email:** elizabeth.huntley@state.mn.us

**HF17 - 2A - Prescription Drug Affordability Act**

Chief Author: **Zack Stephenson**  
 Committee: **Health Finance And Policy**  
 Date Completed: **3/3/2023 10:20:29 AM**  
 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
<b>Total</b>	-	-	-	-	-	-
<b>Biennial Total</b>			-			-

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
<b>Total</b>	-	-	-	-	-

**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:** 2/10/2023 9:17:42 AM  
**Phone:** 651-296-6054    **Email:** susan.nelson@lbo.mn.gov

**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.

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

**Bill Description**

House File 17-2A 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 may notify the pharmaceutical manufacturer, Attorney General, and Board of Pharmacy of generic drug price increases that potentially violate the standards established in the legislation. This is a change from HF17-1A, which made mandatory rather than optional the reporting of potential price increase violations by the commissioner of Management and Budget.

**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 HF17-2A. MMB may 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 this legislation. We do not anticipate additional administrative fees or costs to perform monitoring or reporting under this bill.

**Expenditure and/or Revenue Formula**

**Long-Term Fiscal Considerations**

**Local Fiscal Impact**

**References/Sources**

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

**Agency Contact:**

**Agency Fiscal Note Coordinator Signature:** Ronika Rampadarat

**Date:** 2/10/2023 9:14:01 AM

**Phone:** 612-659-6873

**Email:** ronika.rampadarat@state.mn.us

**HF17 - 2A - Prescription Drug Affordability Act**

Chief Author: **Zack Stephenson**  
 Committee: **Health Finance And Policy**  
 Date Completed: **3/3/2023 10:20:29 AM**  
 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
<b>Total</b>	-	-	-	-	-	-
<b>Biennial Total</b>			-			-

Full Time Equivalent Positions (FTE)	Biennium			Biennium		
		FY2023	FY2024	FY2025	FY2026	FY2027
<b>Total</b>	-	-	-	-	-	-

**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:** 2/9/2023 2:40:13 PM  
**Phone:** 651-296-6053    **Email:** shannon.zila@lbo.mn.gov

**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.

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

**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 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  
**Phone:** 651-247-0247

**Date:** 2/8/2023 6:44:53 PM  
**Email:** [pete.engler@state.mn.us](mailto:pete.engler@state.mn.us)

**HF17 - 2A - Prescription Drug Affordability Act**

Chief Author: **Zack Stephenson**  
 Committee: **Health Finance And Policy**  
 Date Completed: **3/3/2023 10:20:29 AM**  
 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)	Biennium			Biennium		
	Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027
<b>Total</b>	-	-	-	-	-	-
<b>Biennial Total</b>			-			-

Full Time Equivalent Positions (FTE)	Biennium			Biennium		
		FY2023	FY2024	FY2025	FY2026	FY2027
<b>Total</b>	-	-	-	-	-	-

**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:** 2/9/2023 12:43:57 PM  
**Phone:** 651-296-6053    **Email:** shannon.zila@lbo.mn.gov

**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.

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

**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:** 2/7/2023 12:21:00 PM

**Email:** kimberly.miller@state.mn.us

HF17 - 2A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**  
 Committee: **Health Finance And Policy**  
 Date Completed: **3/3/2023 10:20:29 AM**  
 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)	Biennium			Biennium		
	Dollars in Thousands	FY2023	FY2024	FY2025	FY2026	FY2027
Health Related Boards	-	278	280	280	280	280
<b>Total</b>	-	<b>278</b>	<b>280</b>	<b>280</b>	<b>280</b>	<b>280</b>
<b>Biennial Total</b>			<b>558</b>			<b>560</b>

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

**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:** 2/9/2023 2:40:27 PM  
**Phone:** 651-296-6053    **Email:** shannon.zila@lbo.mn.gov

**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.

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

**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 1<sup>st</sup> 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

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. In Section 18, subdivision 6 under Forms of Disciplinary Action, the Pharmacy Board is required to pay for the cost of the investigation, fees provided by the Office of Administrative Hearings, legal and investigative services provided by the Office of the Attorney General, court reporters, witnesses, reproduction of records, board member's per diem compensation, board staff time, and travel costs and expenses incurred by board staff and board members. The Pharmacy could potentially recoup none, some, or all costs associated here within from the penalties assessed.

**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
<a href="http://mn.gov/mmb/employee-relations/labor-relations/Labor/">http://mn.gov/mmb/employee-relations/labor-relations/Labor/</a>	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	25,946.00	25,946.00
<b>Total Salary &amp; Fringe</b>	<b>205,216.63</b>	<b>205,216.63</b>
<b>AGO Expenses</b>	<b>73,098</b>	<b>73,098</b>
<b>Total Expenses</b>	<b>278,314.63</b>	<b>278,314.63</b>

Increase in attorney general legal expenses:

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

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

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

**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:** 2/8/2023 2:39:13 PM

**Email:** [jill.phillips@state.mn.us](mailto:jill.phillips@state.mn.us)

HF17 - 2A - Prescription Drug Affordability Act

Chief Author: **Zack Stephenson**  
 Committee: **Health Finance And Policy**  
 Date Completed: **3/3/2023 10:20:29 AM**  
 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
<b>Total</b>	-	-	-	-	-	-
<b>Biennial Total</b>			-			-

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2023	FY2024	FY2025	FY2026	FY2027
<b>Total</b>	-	-	-	-	-

**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:** 2/17/2023 5:03:32 PM  
**Phone:** 651-284-6436    **Email:** christian.larson@lbo.mn.gov

**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.

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

**Bill Description**

H. F. No. 17-2A, **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."

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.

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**

- It is assumed that since the Board does not yet exist, the Department of Commerce will be responsible for estimating costs related to the establishment and ongoing administrative operations of the board and council, including staff, technical assistance, and all corresponding administrative costs.

### **Expenditure and/or Revenue Formula**

#### **Long-Term Fiscal Considerations**

Not applicable.

#### **Local Fiscal Impact**

Not applicable.

### **References/Sources**

#### **Agency Contact:**

**Agency Fiscal Note Coordinator Signature:** Shannon Zila  
**Phone:** 651-296-6053

**Date:** 2/17/2023 10:24:11 AM  
**Email:** shannon.zila@lbo.mn.gov