

SF1098 - 2CE - Prescription Drug Price Transparency Act

Chief Author: **Julie Rosen**
 Committee: **Finance**
 Date Completed: **2/28/2020 4:39:30 PM**
 Lead Agency: **Health Dept**
 Other Agencies:
 Commerce Dept Minn Management and Budget
 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	FY2019	FY2020	FY2021	FY2022	FY2023
Health Dept						
General Fund	-	(899)	244	98	68	
State Total						
General Fund	-	(899)	244	98	68	
Total	-	(899)	244	98	68	
Biennial Total			(655)			166

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2019	FY2020	FY2021	FY2022	FY2023
Health Dept					
General Fund	-	-	4	4	4
Total	-	-	4	4	4

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: Carlos Guereca **Date:** 2/28/2020 4:39:30 PM
Phone: 651-2846541 **Email:** carlos.guereca@lbo.leg.mn

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		FY2019	FY2020	FY2021	FY2022	FY2023
Health Dept						
General Fund		-	(899)	244	98	68
Total		-	(899)	244	98	68
Biennial Total				(655)		166
1 - Expenditures, Absorbed Costs*, Transfers Out*						
Health Dept						
General Fund						
Expenditures		-	-	965	789	759
Absorbed Costs		-	(899)	(721)	(691)	(691)
Total		-	(899)	244	98	68
Biennial Total				(655)		166
2 - Revenues, Transfers In*						
Health Dept						
General Fund						
Total		-	-	-	-	-
Biennial Total				-		-

SF1098 - 2CE - Prescription Drug Price Transparency Act

Chief Author: **Julie Rosen**
 Committee: **Finance**
 Date Completed: **2/28/2020 4:39:30 PM**
 Agency: **Health Dept**

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

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Total	-	(899)	244	98	68	68
Biennial Total			(655)			166

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2019	FY2020	FY2021	FY2022	FY2023
General Fund	-	-	4	4	4
Total	-	-	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: Carlos Guereca **Date:** 2/25/2020 4:11:56 PM
Phone: 651-2846541 **Email:** carlos.guereca@lbo.leg.mn

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.

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Total	-	(899)	244	98	68	
Biennial Total			(655)		166	
1 - Expenditures, Absorbed Costs*, Transfers Out*						
General Fund						
Expenditures	-	-	965	789	759	
Absorbed Costs	-	(899)	(721)	(691)	(691)	
Total	-	(899)	244	98	68	
Biennial Total			(655)		166	
2 - Revenues, Transfers In*						
General Fund						
Total	-	-	-	-	-	
Biennial Total			-		-	

Bill Description

This bill requires manufacturers to submit data on price increases for prescription drugs to the commissioner of health, including detailed financial and pricing data related to those drugs for categories of drugs identified in subdivisions 3, 4 and 5. The commissioner is required to make certain information available to the public and to submit an annual report to the legislature on the findings, implementation, and effectiveness of the Prescription Drug Transparency Act in supporting goals outlined in subdivision 9. The commissioner is also required to adopt a schedule of penalties and, as appropriate, impose these penalties on manufacturers subject to them under subdivision 8.

Assumptions

The department assumes that the requirements under this bill will extend to a substantial number of prescription drugs of the nearly 50,000 products with a National Drug Code that are developed or sold by dozens of pharmaceutical manufacturers. The resulting volume of effort and expertise required under this bill necessitates that the health department develop internal staff knowledge to lead the work; contract with experts; obtain input from key stakeholders, collect and validate data; post public data to a publicly accessible website; analyze the information and summarize findings; and report results, as required, in a report to the legislature. The department will incur annual costs for the four following full-time equivalent staff: pharmacist senior to lead all efforts under this bill, supported by a research scientist, planner, and research analyst specialist senior.

The role of the research scientist will be to lead the analytic activities of this effort, including data specification, forms development, collection, analysis, synthesis and reporting consistent with requirements in this bill. The research scientist will be supported in these responsibilities by the research analyst specialist senior who will conduct data validation and quality control activities. As part of the quality control activities, the analytics staff will communicate with manufacturers subject to reporting concerning their submitted data and documentation. The planner will be responsible for contracting, facilitating stakeholder conversations, project planning, and corresponding, in partnership with the research scientist, with manufacturers subject to reporting under this bill.

To design the data collection content and format for reportable data required from pharmaceutical manufacturers under the bill in subdivisions 3, 4, and 5; to assess the quality, completeness and accuracy of the reported data; to help lead discussions with stakeholders; and to contribute to necessary analysis and reporting, the department will hire a vendor with expert knowledge in pharmacoeconomics, the market for prescription drugs, and price setting methods used by pharmaceutical manufacturers. We estimate the cost for this vendor would be \$75,000 in FY2021 and in FY2022 and \$45,000 annually thereafter. In addition, we assume a cost of \$58,000 annually for the purchase of secondary data to use

as validation tools.

The department anticipates incurring information technology costs for development of the (1) web-based data collection form, (2) database housing public and non-public information, and (3) external-facing website that permits users to search on a number of parameters (drugs, manufacturer, and increase in costs) to be organized in an easily consumable format. Costs for these activities are estimated at \$140,000. In addition, maintenance and ongoing IT support is \$15,221 annually, beginning in FY2022, to support to users of the data, and \$5,100 annually for server hosting.

Further, the department assumes it will seek legal advice on the public nature of price information and documentation submitted by manufacturers, including assertions that certain information is trade-secret information pursuant to the Defend Trade Secrets Act of 2016. This advice will be provided by in-house counsel and through contracting with the Attorney General's Office. The department of health estimates reimbursing the Attorney General \$20,000, based on previous consultation experience.

Under Subdivision 8, the department is authorized to impose civil penalties for a series of reporting failures by entities subject to data submission requirements. The department will develop and adopt a schedule of penalties and consistent reporting requirements, as appropriate, with the assistance of the Attorney General. Given the volume of drugs potentially subject to reporting under subdivision 8, and recognizing that compliance with the bill rests with manufacturers of prescription drugs, the department estimates it will seek to assess compliance for up to 30 drugs in each of the three categories of drugs in subdivisions 3, 4, and 5. The department will work, in partnership with the Minnesota Commissioner of Management and Budget on developing terms and conditions for remitting or mitigating civil penalties in ways that are proper and consistent with public health and safety, and on depositing civil penalties collected in the Health Care Access Fund; no revenues to the department are assumed related to Subdivision 8.

Technical comments:

Because subdivision 9 requires annual reporting, the department assumes all data submission requirements in subdivisions 3, 4 and 5 are ongoing requirements for manufacturers to submit data and for the commissioner of health to post information on a website.

Expenditure and/or Revenue Formula

Expenditure (Actual Dollars)	Amount	FY 2020	FY 2021	FY 2022	FY 2023
Salary & Fringe:		FTE	FTE	FTE	FTE
Research Scientist 3	116,697	0.00	1.00	1.00	1.00
Planner Principal State	104,016	0.00	1.00	1.00	1.00
Research Analysis Spec Sr	104,016	0.00	1.00	1.00	1.00
Pharmacist Senior	165,685	0.00	1.00	1.00	1.00
	FTE	0.00	4.00	4.00	4.00
	Subtotal	0	490,414	490,414	490,414
Information Technology:					
Computing & IT support per FTE	2,712	0	10,848	10,848	10,848
Prescription drug data reporting system development/implementation			140,000		
License for comparative secondary data			58,000	58,000	58,000
IT Support: Data reporting and web-based system maintenance				15,221	15,221
IT Support: Server hosting			5,100	5,100	5,100
	Subtotal	0	213,948	89,169	89,169
Other Operating Costs:					
Materials, supplies & training per FTE	600	0	2,400	2,400	2,400
Contract: pharmaceutical market expert		0	75,000	75,000	45,000
Attorney General reimbursement		0	20,000	0	0
	Subtotal	0	97,400	77,400	47,400
Grants, Aids & Subsidies:					

	Subtotal	0	0	0	0
Indirect (21.78% Eligible Costs)	Subtotal	0	163,734	132,201	132,201
Expenditure	Total	0	965,496	789,184	759,184
Fiscal Tracking (Dollars in Thousands)	BACT	FY 2020	FY 2021	FY 2022	FY 2023
Health		0	965	789	759
Administration		0	965	789	759
Grants		0	0	0	0

Note:

Absorbed costs reflect the appropriation levels for prescription drug price transparency embedded in the Laws of 2019, First Special Session, chapter 9, section 3, subdivision 2.

Long-Term Fiscal Considerations

Local Fiscal Impact

References/Sources

Agency Contact:

Agency Fiscal Note Coordinator Signature: Brian Awsumb

Phone: 651-201-5235

Date: 2/25/2020 3:26:45 PM

Email: brian.awsumb@state.mn.us

SF1098 - 2CE - Prescription Drug Price Transparency Act

Chief Author: **Julie Rosen**
 Committee: **Finance**
 Date Completed: **2/28/2020 4:39:30 PM**
 Agency: **Commerce Dept**

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

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State Cost (Savings)	Biennium			Biennium		
	Dollars in Thousands	FY2019	FY2020	FY2021	FY2022	FY2023
Total	-	-	-	-	-	-
Biennial Total			-			-

Full Time Equivalent Positions (FTE)	Biennium			Biennium		
		FY2019	FY2020	FY2021	FY2022	FY2023
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: Christian Larson **Date:** 2/28/2020 3:33:54 PM
Phone: 651-284-6436 **Email:** christian.larson@lbo.leg.mn

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.

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Dollars in Thousands	FY2019	FY2020	FY2021	FY2022	FY2023	
Total	-	-	-	-	-	-
Biennial Total			-			-
1 - Expenditures, Absorbed Costs*, Transfers Out*						
Total	-	-	-	-	-	-
Biennial Total			-			-
2 - Revenues, Transfers In*						
Total	-	-	-	-	-	-
Biennial Total			-			-

Bill Description

Senate File 1098 proposes creating the Prescription Drug Price Transparency Act. The bill requires the Commissioner of Health to report on increases in drug prices when certain conditions are met, including:

- When the prescription drug price is \$100 or greater for a 30 day supply;
- When there has been a 10 percent increase in a brand name drug price in the previous 12 months, or 16 percent increase over 24 months;
- When there has been an increase of 50 percent for a generic drug in the previous 12 months.

The information regarding drug pricing is to be supplied by drug manufacturers and requires disclosure of agreements between the manufacturer and other entities, total direct costs associated with reported prescription drugs, and the total amount of revenue and/or financial assistance associated with the prescription drug being reported on.

The Commissioner of Health is required to post the collected prescription drug pricing information on its web site, and may also consult Commerce utilizing standards under Minn Stat. §62U.04, Subd. 6. Minn Stat. §62U.04, Subd. 6 pertains to the collection of encounter and claims data from health plan companies for the purpose of payment reform on health care costs. The Commissioner of Health is also responsible for reporting to the chairs and ranking members of legislative committees with authority over Commerce and Health with proposals to that help promote prescription drug transparency and lowered costs.

Assumptions

Subdivision 7 of the bill allows the Health Department to consult with the Commerce Department, as well as other entities, regarding the form and format of public posting of prescription drug pricing information. Commerce assumes no fiscal impact from this requirement.

Expenditure and/or Revenue Formula

N/A

Long-Term Fiscal Considerations

N/A

Local Fiscal Impact

N/A

References/Sources

Agency Contact:

Agency Fiscal Note Coordinator Signature: Amy Trumper

Phone: 651-539-1517

Date: 2/27/2020 1:10:31 PM

Email: amy.trumper@state.mn.us

SF1098 - 2CE - Prescription Drug Price Transparency Act

Chief Author: **Julie Rosen**
 Committee: **Finance**
 Date Completed: **2/28/2020 4:39:30 PM**
 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

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Total	-	-	-	-	-	-
Biennial Total			-			-

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2019	FY2020	FY2021	FY2022	FY2023
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: Joe Harney **Date:** 2/28/2020 1:24:22 PM
Phone: 651-284-6438 **Email:** joe.harney@lbo.leg.mn

State Cost (Savings) Calculation Details

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Total	-	-	-	-	-	-
Biennial Total			-			-
1 - Expenditures, Absorbed Costs*, Transfers Out*						
Total	-	-	-	-	-	-
Biennial Total			-			-
2 - Revenues, Transfers In*						
Total	-	-	-	-	-	-
Biennial Total			-			-

Bill Description

This bill would establish cost reporting requirements for drug manufacturers, public posting of drug price information, and penalties for failing to submit timely reports.

Assumptions

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 other groups including quasi-state agencies under the legislative authority provided in Minnesota Statutes 43A. Health benefits are provided through the self-funded Minnesota Advantage Health Plan.

Section 62J.84 establishes reporting requirements for drug manufacturers covering drug price increases, pricing of new prescription drugs, and the acquisition of a drug by a drug manufacturer and other supporting requirements.

MMB expects the bill will impact drug manufacturer’s processes for reporting drug price changes but does not expect a fiscal impact for itself from this legislation.

Expenditure and/or Revenue Formula

Not applicable.

Long-Term Fiscal Considerations

Not applicable.

Local Fiscal Impact

Not applicable.

References/Sources

Not applicable.

Agency Contact: Lorna Smith 651-259-3604

Agency Fiscal Note Coordinator Signature: Ruth McGlynn

Phone: 651-259-3787

Date: 2/26/2020 3:54:05 PM

Email: ruth.mcglynn@state.mn.us

SF1098 - 2CE - Prescription Drug Price Transparency Act

Chief Author: **Julie Rosen**
 Committee: **Finance**
 Date Completed: **2/28/2020 4:39:30 PM**
 Agency: **Pharmacy Board**

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

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Biennial Total			-			-

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2019	FY2020	FY2021	FY2022	FY2023
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: Carlos Guereca **Date:** 2/28/2020 4:37:38 PM
Phone: 651-2846541 **Email:** carlos.guereca@lbo.leg.mn

State Cost (Savings) Calculation Details

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Total	-	-	-	-	-	-
Biennial Total			-			-
1 - Expenditures, Absorbed Costs*, Transfers Out*						
Total	-	-	-	-	-	-
Biennial Total			-			-
2 - Revenues, Transfers In*						
Total	-	-	-	-	-	-
Biennial Total			-			-

Bill Description

This bill requires pharmaceutical manufacturers that are licensed by the Board to annually report to the Minnesota Department of Health (MDH) certain data about drugs, including sales and pricing data. MDH would have to make some of that data publicly available. Manufacturers would be subject to civil penalties levied by MDH for: failing to submit timely reports; failing to provide data; or providing inaccurate or incomplete data.

The bill does not require the Board of Pharmacy to do anything new or to collect any revenues.

Assumptions

As noted above, other than continuing to license manufacturers, the Board is not required to do anything. Nothing in the bill would change the way that we do license manufacturers. Nor does the bill require the Board to collect any new revenues.

Under current law, the Board can discipline a licensee and assess a civil penalty if a licensee violates a statute or rule that it is required to follow. (Up to \$10,000 per violation). However, this bill empowers MDH to assess civil penalties for the reasons stated above. That being the case, the Board probably will not be assessing civil penalties for violations of the reporting requirements.

Expenditure and/or Revenue Formula

None

Long-Term Fiscal Considerations

None

Local Fiscal Impact

None

References/Sources

Agency Contact: Cody Wiberg (651-201-8098)

Agency Fiscal Note Coordinator Signature: Cody Wiberg
Phone: 651-201-8098

Date: 2/28/2020 3:54:46 PM
Email: cody.wiberg@state.mn.us