

HF4 - 4A - Prohibit Rx Drug Price Gouging; Notify AG

Chief Author: **John Lesch**
 Committee: **Health & Human Services Finance Division**
 Date Completed: **2/26/2020 5:03:47 PM**
 Lead Agency: **Attorney General**
 Other Agencies:
 Human Services Dept 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
Attorney General						
General Fund	-	-	427	267	267	
Human Services Dept						
General Fund	-	-	31	36	36	
State Total						
General Fund	-	-	458	303	303	
	Total	-	-	458	303	303
				458		606

Full Time Equivalent Positions (FTE)	Biennium			Biennium		
	FY2019	FY2020	FY2021	FY2022	FY2023	
Attorney General						
General Fund	-	-	2	2	2	
Human Services Dept						
General Fund	-	-	.5	.5	.5	
	Total	-	-	2.5	2.5	2.5

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.

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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	FY2019	FY2020	FY2021	FY2022	FY2023
Attorney General					
General Fund	-	-	427	267	267
Human Services Dept					
General Fund	-	-	31	36	36
Total	-	-	458	303	303
Biennial Total			458		606
1 - Expenditures, Absorbed Costs*, Transfers Out*					
Attorney General					
General Fund	-	-	427	527	527
Human Services Dept					
General Fund	-	-	31	36	36
Total	-	-	458	563	563
Biennial Total			458		1,126
2 - Revenues, Transfers In*					
Attorney General					
General Fund	-	-	-	260	260
Human Services Dept					
General Fund	-	-	-	-	-
Total	-	-	-	260	260
Biennial Total			-		520

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 Date Completed: **2/26/2020 5:03:47 PM**
 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	FY2019	FY2020	FY2021	FY2022	FY2023
General Fund	-	-	427	267	267	
Total	-	-	427	267	267	
Biennial Total			427			534

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2019	FY2020	FY2021	FY2022	FY2023
General Fund	-	-	2	2	2
Total	-	-	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 Dollars in Thousands	Biennium			Biennium	
	FY2019	FY2020	FY2021	FY2022	FY2023
General Fund	-	-	427	267	267
Total	-	-	427	267	267
Biennial Total			427		534
1 - Expenditures, Absorbed Costs*, Transfers Out*					
General Fund	-	-	427	527	527
Total	-	-	427	527	527
Biennial Total			427		1,054
2 - Revenues, Transfers In*					
General Fund	-	-	-	260	260
Total	-	-	-	260	260
Biennial Total			-		520

Bill Description

H. F. No. 4 (Second Engrossment-4A) (“Bill”) prohibits drug manufacturers and wholesale drug distributors from charging unconscionable prices for certain essential prescription drugs in Minnesota. The Bill amends Minnesota Statutes section 8.31 to provide the Office of the Attorney General (“OAG”) with the investigative and enforcement powers in that section for these matters. The Minnesota Board of Pharmacy, the commissioner of human services, and health plan companies are required to report certain price increases for designated prescription drugs to the OAG. The OAG is also required to engage in a meet and confer process with drug manufacturers or distributors prior to bringing any enforcement action.

Assumptions

1. The OAG will require additional staff in its Consumer Protection Section devoted to the new investigatory and enforcement provisions in this Bill. The OAG assumes 1.0 FTE attorney (\$199,500) and 1.0 FTE investigator (\$127,500) will be required.
2. The OAG will also require qualified vendors with expertise in evaluating the clinical and economic value of pharmaceuticals and with access to appropriate data to assess whether violations of the Bill’s prohibitions have occurred, to assist in the OAG’s investigation, and to subsequently provide expert testimony in enforcement actions it brings for violations of section 151.462 in accordance with Minn. Stat. § 8.31.
3. It should be noted there are potential secondary costs with this bill, which are not specified in the above tables. The Fourth Circuit Court of Appeals found Maryland statutes prohibiting price gouging in the sale of prescription drugs unconstitutional in violation of the dormant commerce clause, *Brian E. Frosh, Attorney General of Maryland, et al v. Association for Accessible Medicines*, 887 F.3d 664 (4th Cir., 2018) (2018 WL 5307744). Although there are important differences between the invalidated Maryland statutes and the provisions of this Bill, there may be similar pre-enforcement challenge in federal district court, with any decision appealed to the 8th Circuit Court of Appeals and to the U.S. Supreme Court. Legal costs can be expected to be at least \$200,000, which could be borne by Human Services or the Board of Pharmacy, unless other parties such as the Attorney General are named.

Expenditure and/or Revenue Formula

FTE Positions. The OAG anticipates 1.0 FTE attorney (\$199,500) and 1.0 FTE Investigator (\$127,500) in order to investigate and enforce the provisions of this Bill. [1]

Expert Costs. The OAG anticipates additional expert costs starting in FY21 and increasing in FY22. In FY21, recognizing

it is the first year of the assumptions and that related work will build over time, the expert costs are assumed to be \$100,000 (increasing to the full amount of \$200,000 per year starting in FY22).

The OAG estimates that after enactment and for the foreseeable future, it will receive notification, and subsequently investigate, the price increases (of 15% or more) of approximately 15 brand name "essential prescription drugs" each year. [2] The OAG estimates that it will incur \$5,000 in expert expenses in each investigation (*i.e.*, expert expends 25 hours at a rate of \$200 per hour) it conducts. Thus, the AGO anticipates that it will incur approximately \$75,000 in expert expenses when investigating whether violations of sections 8.31 and 151.462 have occurred in FY21 and beyond.

The OAG anticipates that it will incur approximately \$25,000 in additional expert litigation expenses in FY21 for cases that reach litigation (*i.e.*, expert expends 125 hours at a rate of \$200 per hour during one enforcement action), but that these expert expenses will increase in FY22 as other investigations started in FY21 conclude and additional investigations begin. Accordingly, the AGO anticipates that in FY22, it will incur \$125,000 of investigatory expert expenses (*i.e.*, expert expends 125 hours at a rate of \$200 per hour in five enforcement actions).

Recovery of Costs and Civil Penalties. The OAG can recover attorney's fees and costs of investigation if successful in proving violations of the law, as well as civil penalties of up to \$25,000 per violation (and restitution for injured persons or entities). See Minn. Stat. § 8.31, subds. 3, 3a. Recoveries for the State of attorney's fees, costs of investigation, and civil penalties must be deposited in the general fund pursuant to Minnesota Statutes section 16A.151. Recognizing the uncertainties inherent in any litigation and the uncertainties of predicting the fiscal year of recovery of such funds (which necessarily is at the end of litigation), the OAG assumes that recovery of fees and civil penalties will begin in FY22, and therefore does not project revenue in FY21. Starting in FY22, the OAG assumes it will bring and successfully litigate or settle at least two cases each year that provide revenue to the State, in addition to addressing pricing of the product. The OAG assumes it will recover its experts costs on each of these two matters (\$5,000 for investigation each, plus \$25,000 for litigation expenses each, totaling \$60,000 for two matters), plus civil penalties on each matter of \$25,000 per violation estimated to be \$100,000 total per case (totaling \$200,000). Thus, revenue of \$260,000 per year is projected started in FY22.

In any given enforcement action the OAG successfully brings, it can recover its staff costs and vendor/expert witness costs, in addition to civil penalties of up to \$25,000 per violation (*i.e.*, each time the manufacturer or wholesale distributor charged an unconscionable price to a Minnesota patient). See, *e.g.*, Minn. Stat. § 645.24 ("When a penalty or forfeiture is provided for the violation of a law, such penalty or forfeiture shall be construed to be for each such violation.") Thus, for example, in any single enforcement action, which would likely involve many violations of sections 8.31 and 151.462, an award of civil penalties alone could amount to hundreds of thousands of dollars, or more. The OAG would also seek to recover the same type of remedial relief in any settlement it reaches prior to initiating litigation. In practice, the OAG typically obtains substantial civil penalties where allowed by law; for purposes of preparing this fiscal note, the revenue projections are measured.

[1] Attorney billing rate of \$133/hour at 1,500 hours and investigator billing rate of \$85/hour at 1,500 hours.

[2] This estimate is based on a recent report, which found that in 2017 the retail price of 30 brand name drugs increased by 15% or more. Stephen W. Schondelmeyer & Leigh Purvis, *Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans*, AARP Public Policy Institute, September 2018.

Long-Term Fiscal Considerations

Yes, as noted above, FY22 and beyond will include increased staff costs at the same level as FY21, and expert witness costs of \$200,000.00 per year. 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

None.

References/Sources

Stephen W. Schondelmeyer & Leigh Purvis, *Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by*

Older Americans, AARP Public Policy Institute, September 2018.

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HF4 - 4A - Prohibit Rx Drug Price Gouging; Notify AG

Chief Author: **John Lesch**
 Committee: **Health & Human Services Finance Division**
 Date Completed: **2/26/2020 5:03:47 PM**
 Agency: **Human Services 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	
	FY2019	FY2020	FY2021	FY2022	FY2023
Dollars in Thousands					
General Fund	-	-	31	36	36
Total	-	-	31	36	36
Biennial Total			31		72

Full Time Equivalent Positions (FTE)	Biennium			Biennium	
	FY2019	FY2020	FY2021	FY2022	FY2023
General Fund	-	-	.5	.5	.5
Total	-	-	.5	.5	.5

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		FY2019	FY2020	FY2021	FY2022	FY2023
General Fund		-	-	31	36	36
Total		-	-	31	36	36
Biennial Total				31		72
1 - Expenditures, Absorbed Costs*, Transfers Out*						
General Fund		-	-	31	36	36
Total		-	-	31	36	36
Biennial Total				31		72
2 - Revenues, Transfers In*						
General Fund		-	-	-	-	-
Total		-	-	-	-	-
Biennial Total				-		-

Bill Description

Section 1 provides the attorney general authority to investigate instances of price gouging for generic drugs.

Section 2 grants the Board of Pharmacy the ability to fine manufacturers for each instance of price gouging.

Section 3 grants the Board of Pharmacy the ability to take disciplinary action against a manufacturer or distributor if price gouging occurs.

Section 4 defines what price gouging is with regards to generic drugs, what drugs are subject to the bill language, and what the thresholds to report price gouging to the Attorney General’s office. This section also grants the Attorney General the authority to request information from manufacturers.

Section 4 requires the commissioner of human services to designate essential off-patient or generic drugs as essential medicine due to its efficacy in treating a life-threatening or substantially impairing health condition or chronic condition. The Department of Human Services (DHS) must report to the Attorney General if the price of any designated drugs increase by 15 percent or more in a one year period.

Assumptions

This bill requires an additional 0.5 FTE (MAPE 11) beginning September 2020 to identify and establish a list of all essential prescription drugs and monitor price changes. In addition to salary costs of \$ 46,000 in FY2021 and \$52,000 ongoing, this fiscal note assumes fringe benefits at 30% of salary costs and overhead of \$14,000 upfront costs and \$1,300 per month per FTE ongoing. This fiscal note assumes an administrative FFP of 32 percent.

Expenditure and/or Revenue Formula

Fiscal Tracking Summary (\$000's)						
Fund	BACT	Description	FY2020	FY2021	FY2022	FY2023
GF	13	HCA Admin (PSD 0.5 FTE)		46	52	52
GF	REV1	FFP@ 32%		(15)	(17)	(17)

		Total Net Fiscal Impact		31	36	36
		Full Time Equivalents		0.5	0.5	0.5

Long-Term Fiscal Considerations

Local Fiscal Impact

References/Sources

MAPE Compensation Grid

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HF4 - 4A - Prohibit Rx Drug Price Gouging; Notify AG

Chief Author: **John Lesch**
 Committee: **Health & Human Services Finance Division**
 Date Completed: **2/26/2020 5:03:47 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

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
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.

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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	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

If enacted, this bill would prohibit drug manufacturers and wholesalers from charging an unconscionable price for essential prescription drugs. The terms “unconscionable price” and “essential prescription drug” are defined in the bill. The department of human services would be required to develop a list of essential prescription drugs, in consultation with that agency’s Drug Formulary Committee. Both DHS and the Board of Pharmacy would be required to notify the Attorney General of any increase in price of an essential drug of 15% or more during a one-year period.

The bill would make it grounds for disciplinary action, on the part of the Board of Pharmacy, for a drug manufacturer to charge an unconscionable price. The Board would be allowed to assess a civil penalty of up to \$25,000 for each separate violation related to the charging of an unconscionable price.

The Attorney General would be specifically empowered to investigate violations of the unconscionable price provisions.

Assumptions

Currently, in regards to drug manufacturers and wholesalers, the Board is empowered to “inspect and make copies of any and all records of shipment, purchase, manufacture, quality control, and sale of” drugs “provided, however, that such inspection shall not extend to financial data, sales data, or pricing data.” Therefore, the Board has no historical data concerning price increases that it can use to estimate how often unconscionable price increases (as defined in the bill) have occurred. In addition, the Board doesn’t know what drugs DHS might add to the required list of essential drugs.

There have been recent, highly publicized examples of drug price increases that might have been unconscionable, as defined in the bill. But for the reasons given above, the Board can’t accurately predict how many complaints it might need to pursue. Also, the bill allows manufacturers to justify price increases by providing information about the “actual cost of inventing, producing, selling, and distributing the essential prescription drug.” The Board is unable to predict the number of complaints, and therefore unable to predict the number of complaints that would result in disciplinary action.

Given that the Board is unable to predict how many complaints it might receive, we are unable to determine if increased staffing (and other resources) would be required to handle an increased volume of complaints. The Attorney General’s fiscal note addresses the impact on civil penalties. Therefore, the Board has not assigned costs or revenues.

Expenditure and/or Revenue Formula

None

Long-Term Fiscal Considerations

Unknown

Local Fiscal Impact

Unknown

References/Sources

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