Consolidated Fiscal Note

2021-2022 Legislative Session

HF1183 - 1A - Excessive Drug Price Increase Prohibited

Chief Author: Commitee: Date Completed:	Zack Stephenson Commerce Finance and Policy
Lead Agency: Other Agencies:	Pharmacy Board
Attorney General Human Services De	Commerce Dept pt Minn Management and Budget

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

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)			Bienni	ium	Bienni	um
Dollars in Thousands		FY2021	FY2022	FY2023	FY2024	FY2025
Attorney General						
General Fund		-	456	296	296	296
State Total						
General Fund		-	456	296	296	296
	Total	-	456	296	296	296
	Bier	nnial Total		752		592

Full Time Equivalent Positions (FTE)			Bienni	um	Biennium	
		FY2021	FY2022	FY2023	FY2024	FY2025
Attorney General						
General Fund		-	2	2	2	2
-	Total	-	2	2	2	2

Lead LBO Analyst's Comment LBO Signature: Date:

Phone: Email:

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		FY2021	FY2022	FY2023	FY2024	FY2025
Attorney General						
Attorney General General Fund - Expenditures, Absorbed Costs*, Tran ttorney General General Fund - Revenues, Transfers In*		-	456	296	296	296
	Total	-	456	296	296	296
	Bier	nnial Total		752		592
1 - Expenditures, Absorbed Costs*, Tr	ansfers Out*					
Attorney General						
•		-	456	556	556	556
	Total	-	456	556	556	556
	Bier	nnial Total		1,012		1,112
2 - Revenues, Transfers In*						
Attorney General						
General Fund		-	-	260	260	260
	Total	-	-	260	260	260
	Bier	nnial Total		260	556 260	520

Fiscal Note

2021-2022 Legislative Session

HF1183 - 1A - Excessive Drug Price Increase Prohibited

Chief Author:Zack StephensonCommitee:Commerce Finance and PolicyDate Completed:Pharmacy Board

State Fiscal Impact	Yes	No
Expenditures		х
Fee/Departmental Earnings		х
Tax Revenue		х
Information Technology		х
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		Bienn	ium
Dollars in Thousands	FY2021	FY2022	FY2023	FY2024	FY2025
Total	-	-	-	-	-
Ві	ennial Total		-		-

Full Time Equivalent Positions (FTE)		Biennium		Biennium	
	FY2021	FY2022	FY2023	FY2024	FY2025
Tota	-	-	-	-	-

LBO Analyst's Comment

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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		FY2021	FY2022	FY2023	FY2024	FY2025
	Total	-	-	-	-	-
	Bier	nnial Total		-		-
1 - Expenditures, Absorbed Costs*, Tra	nsfers Out*					
	Total	-	-	-	-	-
	Bier	nnial Total		-		-
2 - Revenues, Transfers In*						
	Total	-	-	-	-	-
	Bier	nnial Total		-		-

Bill Description

Section 1 defines a number of terms used in the bill.

Section 2 prohibits excessive price increases for any generic or off-patent drugs sold, dispensed or delivered to consumers in this state. It also explains what constitutes an excessive price increase and creates an exemption.

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

Section 4 requires certain state agencies and entities under contract to those agencies to notify the manufacturer, the attorney general, and the Board of Pharmacy of any price increase imposed by the manufacturer that is in violation of the new law. It also requires a manufacturer receiving such notice to submit a drug cost statement to the attorney general. This section allows the Attorney General to petition a court to issue an order requiring a manufacturer to take certain actions.

Section 5 prohibits a manufacturer from withdrawing covered drugs from sale within Minnesota for the purpose of avoiding the excessive price prohibition. Any manufacturer that intends to withdraw a covered drug from sale or distribution within the state would have to provide a written notice of withdrawal to the Board of Pharmacy and the attorney general, at least 180 days prior to the withdrawal. The Attorney General would be allowed to assess a penalty of \$500,00 against any manufacturer violating the section.

Section 6 is a severability clause.

Section 7 would allow the Board of Pharmacy to take disciplinary action against a manufacturer violating this new law and Section 8 would allow the Board to impose a civil penalty of up to \$25,000 per violation.

Assumptions

Currently, in regards to drug manufacturers, 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 excessive price increases (as defined in the bill) have occurred.

Once a manufacturer has been notified about what appears to be an excessive price increase, it is required to provide data to the Attorney General, to be used to determine if a violation did occur. It is possible that the Attorney General might sometimes find violations, but sometimes find that violations had not occurred. The Board has no way to predict how often violations will occur.

Given that the Board can't predict how many violations might occur, it would not be prudent to assume that increased staffing (and other resources) would be required to handle an increased volume of complaints. Nor would it be prudent to assume that the Board will pursue disciplinary actions that will result in the assessment of civil penalties. Consequently, the Board can't assign costs or revenues

Expenditure and/or Revenue Formula

None

Long-Term Fiscal Considerations

Unknown

Local Fiscal Impact

References/Sources

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Fiscal Note

2021-2022 Legislative Session

HF1183 - 1A - Excessive Drug Price Increase Prohibited

Chief Author:Zack StephensonCommitee:Commerce Finance and PolicyDate Completed:Attorney General

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

		Bienni	ium	Bienni	um
	FY2021	FY2022	FY2023	FY2024	FY2025
	-	456	296	296	296
Total	-	456	296	296	296
Bien	nial Total		752		592
			FY2021 FY2022 - 456 Total - 456	- 456 296 Total - 456 296	FY2021 FY2022 FY2023 FY2024 - 456 296 296 Total - 456 296 296

Full Time Equivalent Positions (FTE)			Biennium		Biennium	
		FY2021	FY2022	FY2023	FY2024	FY2025
General Fund		-	2	2	2	2
	Total	-	2	2	2	2

LBO Analyst's Comment

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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		Bienni	um	Biennium		
Dollars in Thousands		FY2021	FY2022	FY2023	FY2024	FY2025
General Fund		-	456	296	296	296
	Total	-	456	296	296	296
	Bier	nnial Total		752		592
1 - Expenditures, Absorbed Costs*, Tra	ansfers Out*					
General Fund		-	456	556	556	556
	Total	-	456	556	556	556
	Bier	nnial Total		1,012		1,112
2 - Revenues, Transfers In*						
General Fund		-	-	260	260	260
	Total	-	-	260	260	260
	Bier	nial Total		260		520

Bill Description

HF 1183 (First Engrossment) ("Bill") prohibits 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. The Bill provides that a price increase is excessive when a 30-day supply or course of treatment for the drug exceeds \$30 and: (1) the price increase (adjusted for inflation) exceeds 15% of the wholesale acquisition cost ("WAC") over the immediately preceding calendar year; or (2) the price increase (adjusted for inflation) exceeds 40% of the WAC over the immediately preceding three calendar years. The Bill exempts price increases by wholesaler distributors or pharmacies that are directly attributable to additional costs for the drug imposed on the distributor or pharmacy by the manufacturer.

The Bill requires manufacturers that sell, distribute, deliver, or offer for sale any generic or off-patent drug in Minnesota to maintain a registered agent and office in Minnesota. The Bill further prohibits manufacturers of generic prescription drugs from withdrawing that drug from sale or distribution in Minnesota for the purpose of avoiding the excessive price increase prohibition of the Bill.

The Bill requires MMB, DHS, and any other state agency 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.

The Bill also provides for a private right of action for violations under Minn. Stat. § 8.31, subd. 3a, as well as establishes that violation of the Bill's excessive price prohibition is grounds for discipline by the Board of Pharmacy against a manufacturer's license under Minnesota Statutes chapter 151.

Assumptions

1. The OAG will require additional staff in its Consumer, Wage, and Antitrust Division devoted to the new investigatory and enforcement provisions in this Bill. The OAG assumes 1.0 FTE attorney and 1.0 FTE investigator will be required.

2. The OAG will also require qualified vendors with expertise in evaluating the clinical and economic value of generic or off-patent 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 provide expert testimony in enforcement actions it brings for violations of the Bill's prohibitions 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). Although there are important differences between the invalidated Maryland statute and the provisions of this Bill, there may be a 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 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 and 1.0 FTE investigator in order to investigate and enforce the provisions of this Bill. 1.0 FTE attorney is \$222,000 and 1.0 FTE investigator is \$133,500.

Expert Costs. The OAG anticipates expert costs starting in FY22 and increasing in FY23. In FY22, 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 FY23).

The OAG estimates that after enactment and for the foreseeable future, it will receive notification, and subsequently investigate, the price increases of approximately 15 generic or off-patent prescription drugs each year.*#_ftn1 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 FY22 and beyond.

The OAG anticipates that it will incur approximately \$25,000 in additional expert litigation expenses in FY22 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 FY23 as other investigations started in FY22 conclude and additional investigations begin. Accordingly, the AGO anticipates that in FY23, it will incur \$125,000 of investigatory expert expenses (*i.e.*, expert expends 125 hours at a rate of \$200 per hour of \$200 per hour stigatory 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 FY23, and therefore does not project revenue in FY22. Starting in FY23, 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 inFY23.

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 \$10,000 per day, per violation (*i.e.*, each time the manufacturer charged an excessive price). 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, 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.

Long-Term Fiscal Considerations

Yes, as noted above. FY23 and beyond will include increased staff costs at the same level as FY22, 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

N/A

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References/Sources

California's Office of Statewide Health Planning and Development (OSHPD) prescription drug transparency data

*This estimate is supported by the WAC increases disclosed by manufacturers pursuant to California's prescription drug cost transparency law, which requires manufacturers to report quarterly WAC increases of more than 16%. For example, California' data showed that generics with WAC's less than \$250 experienced the largest overall 3-year median percent increase (52.8%). See OSHPD, Wholesale Acquisition Cost (WAC) Increase Report Data Current Year (2020), available at https://oshpd.ca.gov/visualizations/wholesale-acquisition-cost-wac-increase-report-data-current-year/.

This data has further shown excessive price increases of numerous generic or off-patent prescription drugs including, for example, fluoxetine (667% increase in Q1 2019) and guanfacine (204% increase in Q1 2019). See, e.g., Barbara Feder Ostrov and Harriet Blair Rowan, *California's New Transparency Law Shows Staggering Rise in Wholesale Drug Prices*, LA Times (Oct. 11, 2019), *available at* https://www.latimes.com/business/story/2019-10-11/californias-new-transparency-law-shows-staggering-rise-in-wholesale-drug-prices#_ftnref1

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Fiscal Note

2021-2022 Legislative Session

HF1183 - 1A - Excessive Drug Price Increase Prohibited

Chief Author:Zack StephensonCommitee:Commerce Finance and PolicyDate Completed:Commerce Dept

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

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)		Bienn	ium	Bienn	ium
Dollars in Thousands	FY2021	FY2022	FY2023	FY2024	FY2025
Total	-	-	-	-	-
Ві	Biennial Total		-		-

Full Time Equivalent Positions (FTE)		Biennium		Biennium	
	FY2021	FY2022	FY2023	FY2024	FY2025
Tot	al -	-	-	-	-

LBO Analyst's Comment

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State Cost (Savings) Calculation Details

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

State Cost (Savings) = 1-2			Bienni	um	Bienni	um
Dollars in Thousands		FY2021	FY2022	FY2023	FY2024	FY2025
	Total	-	-	-	-	-
	Bier	nial Total		-		-
1 - Expenditures, Absorbed Costs*, Tra	ansfers Out*					
	Total	-	-	-	-	-
	Bier	nial Total		-		-
2 - Revenues, Transfers In*						
	Total	-	-	-	-	-
	Bier	nial Total		-		-

Bill Description

House File 1183-1A proposes a new law prohibiting 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 impose penalties of up to \$10,000 per day for each violation.

The bill also adds manufacturers and excessive price increases to the list of items subject to disciplinary action under the Pharmacy Practice Act in Minnesota.

Assumptions

Commerce assumes that HF1183-1A will not have a fiscal impact on the agency. There are no provisions in the bill that are required to be enforced by Commerce. Given the agency's role in regulation of pharmacy benefit managers and its collection of prescription drug pricing information under Minn. Stat. § 62W.06, Commerce assumes that the agency may receive requests from the Attorney General's office if it undertakes investigations under this new law. Requests from the Attorney General's office would be incorporated into the workload of existing staff without an increase in cost to the agency.

Expenditure and/or Revenue Formula

None.

Long-Term Fiscal Considerations

Local Fiscal Impact

References/Sources

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Fiscal Note

2021-2022 Legislative Session

HF1183 - 1A - Excessive Drug Price Increase Prohibited

Chief Author:Zack StephensonCommitee:Commerce Finance and PolicyDate Completed:Minn Management and Budget

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

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)		Bienn	ium	Bienn	ium
Dollars in Thousands	FY2021	FY2022	FY2023	FY2024	FY2025
Total	-	-	-	-	-
Ві	Biennial Total		-		-

Full Time Equivalent Positions (FTE)		Biennium		Biennium	
	FY2021	FY2022	FY2023	FY2024	FY2025
Tot	al -	-	-	-	-

LBO Analyst's Comment

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State Cost (Savings) Calculation Details

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

State Cost (Savings) = 1-2			Biennium		Biennium	
Dollars in Thousands		FY2021	FY2022	FY2023	FY2024	FY2025
	Total	-	-	-	-	-
	Bier	nnial Total		-		-
1 - Expenditures, Absorbed Costs*, Tra	ansfers Out*					
	Total	-	-	-	-	-
	Bier	nnial Total		-		-
2 - Revenues, Transfers In*						
	Total	-	-	-	-	-
	Bier	nnial Total		-		-

Bill Description

This bill prohibits manufacturers from imposing excessive price increases directly or through a wholesale distributer, pharmacy, or intermediary on generic or off-patent drugs sold or dispensed in Minnesota.

Section 2 defines excessive prices increase, as adjusted for inflation, exceeds: 15% of the wholesale acquisition cost over the past calendar year, 40% of the wholesale acquisition cost over the past three calendar years, or exceeds \$30 for a 30 day supply of the drug or a course of treatment that is less than 30 days.

Section 4 of this bill would require the require the Commissioner of Management and Budget, the Commissioner of Human Services, and other state agencies that provide pharmacy benefits to notify the manufacturer of the drug, attorney general, and the Board of Pharmacy of any manufacturer price increase violation outlined in Section 2. Manufacturers in violation of excessive price increases would be required to provide a drug cost statement to the attorney general. The attorney general may petition the court to order manufacturers to: provide drug cost and revenue statements, repay consumers and third-party payers money as a result of a violation of excessive price increases, impose civil penalties, and/or recover attorney general costs of manufacturer investigation.

Section 5 prohibits manufacturers of a generic or off-patent drug from withdrawing the sale or distribution of a drug in Minnesota to avoid an excessive price increase. Manufacturers of generic or off-patent drugs are required to provide 180 day written notice to Board of Pharmacy and the attorney general prior to removal of a drug in the state.

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 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. SEGIP contracts with three health plan administrators to administer medical benefits and a Pharmacy Benefit Manager (PBM) to administer its prescription drug benefit.

This bill prohibits manufacturers from imposing excessive prices increases on generic and off-brand drugs in Minnesota based on wholesale acquisition costs as defined in Section 2. Section 4, Subdivision 1, of this legislation requires the Commissioner of Management and Budget, the Commissioner of Human Services, and other state agencies who provide a pharmacy benefit to notify the state attorney general, the Board of Pharmacy, and manufacturers of excessive price increase violations as defined in section 2.

SEGIP assumes no fiscal impact from this legislation. SEGIP's pharmacy benefit manager is able to track and report excessive manufacturer prices increases to the attorney general, the Board of Pharmacy, and the manufacturers in violation on SEGIP's behalf. Although this legislation would require more labor hours on SEGIP's PBM, SEGIP does not expect a fiscal impact based on claims and its PBM administrative fee.

Expenditure and/or Revenue Formula

Not applicable.

Long-Term Fiscal Considerations

Not applicable.

Local Fiscal Impact

References/Sources

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

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