COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 5452-02
Bill No.: SB 875
Subject: Pharmacy; Drugs and Controlled Substances; Physicians; Boards, Commissions, Committees, and Councils; Health Care Professionals; Health Care
Type: Original
Date: January 27, 2016

Bill Summary: This proposal allows a pharmacist to select an interchangeable biological product when filling a biological product prescription.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
General Revenue	$0	$0 to $5,527,903	$0 to $12,161,386
Total Estimated Net Effect on General Revenue	**$0**	**$0 to $5,527,903**	**$0 to $12,161,386**

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
Total Estimated Net Effect on Other State Funds	**$0**	**$0**	**$0**

Numbers within parentheses: ( ) indicate costs or losses.
This fiscal note contains 6 pages.

ESTIMATED NET EFFECT ON FEDERAL FUNDS			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
Federal*	$0	$0	$0
Total Estimated Net Effect on All Federal Funds	**$0**	**$0**	**$0**

* Savings and losses exceed $20 million annually beginning in FY 2018 and net to $0.

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
Total Estimated Net Effect on FTE	**0**	**0**	**0**

☐ Estimated Net Effect (expenditures or reduced revenues) expected to exceed $100,000 in any of the three fiscal years after implementation of the act.

ESTIMATED NET EFFECT ON LOCAL FUNDS			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
Local Government	**$0**	**$0**	**$0**

FISCAL ANALYSIS

ASSUMPTION

Oversight was unable to receive some of the agency responses in a timely manner due to the short fiscal note request time. Oversight has presented this fiscal note on the best current information that we have or on prior year information regarding a similar bill. Upon the receipt of agency responses, Oversight will review to determine if an updated fiscal note should be prepared and seek the necessary approval of the chairperson of the Joint Committee on Legislative Research to publish a new fiscal note.

Oversight notes this proposal is similar to HB 1878 and HB 1366 from the current session. Agency responses to HB 1878 have been used to prepare this fiscal note and are provided as follows:

In response to HB 1878, officials from the **Department of Social Services (DSS), MO HealthNet Division (MHD)** stated this legislation amends Chapter 338 (Pharmacies and Pharmacists), RSMo, to authorize a pharmacist to substitute an interchangeable biological product if the product has been classified as an interchangeable biological product by the Food and Drug Administration (FDA) and the pharmacy informs the patient of the substitution.

Total MHD drug expenditures for FY 2015 were $1,254,938,930. MHD assumes a 10% increase in pharmaceutical expenditures each year. MHD also assumes that 30% of total drug spending is related to biologic pharmaceuticals.

Non-biological generic pharmaceuticals are made up of small molecule products and therefore easier to produce, whereas the biological pharmaceuticals are made up of large complex molecules that are harder to make. Therefore, there are fewer manufacturers that produce biological pharmaceutical products. MHD assumes there will be no savings in FY 2017 as there are no biologic generics anticipated to become available in the near future.

MHD assumes a potential 3% savings in FY 2018 and an additional 3% increase each year until reaching the max of 25% savings. This represents a lower level of savings than is generally experienced with generic drugs in the non-biological sector. This assumption is primarily attributed to the nature of the biological pharmaceuticals and the related complexities trying to make bio-similar pharmaceutical products.

The total projected savings for FY 2018 would be $0 to $15,032,913, of which the Federal portion (63.228%) for FY 2018 would be $9,505,011 and the State share (36.772%) would be $5,527,903.

ASSUMPTION (continued)

The total projected savings for FY 2019 would be $0 to $33,072,410, of which the Federal portion (63.228%) for FY 2019 would be $20,911,023 and the State share (36.772%) would be $12,161,386.

Long term projected annual savings are estimated to be $0 to $137,801,707 of which, the Federal portion (63.228%) would be $87,129,263 and the State share (36.772%) would be $50,672,444.

Oversight notes that MHD projected an increase in the potential savings of biologic drugs of 3% per year until the total savings reaches 25% of biologic drug costs. This 25% total savings would occur in FY 2026; however, MHD did not estimate the increase in the funds that would be spent on drugs each year past FY 2019 when their drug-spend estimate reached $1.837 billion. Therefore, Oversight is presenting only the potential savings though FY 2019 and will range the savings between $0 and the amount provided by MHD.

In response to HB 1878, officials from the **Office of the Secretary of State (SOS)** stated many bills considered by the General Assembly include provisions allowing or requiring agencies to submit rules and regulations to implement the act. The SOS is provided with core funding to handle a certain amount of normal activity resulting from each year's legislative session. The fiscal impact for this fiscal note to the SOS for Administrative Rules is less than $2,500. The SOS recognizes that this is a small amount and does not expect that additional funding would be required to meet these costs. However, the SOS also recognizes that many such bills may be passed by the General Assembly in a given year and that collectively the costs may be in excess of what the office can sustain with the core budget. Therefore, the SOS reserves the right to request funding for the cost of supporting administrative rules requirements should the need arise based on a review of the finally approved bills signed by the governor.

Oversight assumes the SOS could absorb the costs of printing and distributing regulations related to this proposal. If multiple bills pass which require the printing and distribution of regulations at substantial costs, the SOS could request funding through the appropriation process.

In response to HB 1878, officials from the **Joint Committee on Administrative Rules (JCAR)** stated the legislation is not anticipated to cause a fiscal impact to JCAR beyond its current appropriation.

In response to HB 1878, officials from the **Department of Health and Senior Services** and the **Department of Insurance, Financial Institutions and Professional Registration** each assumed the proposal would not fiscally impact their respective agencies.

FISCAL IMPACT - State Government	FY 2017 (10 Mo.)	FY 2018	FY 2019
GENERAL REVENUE FUND			
Savings - DSS (§338.056 & 338.085) Reduction in state share of MO HealthNet drug-spend	$0	$0 to... $5,527,903	$0 to... $12,161,386
ESTIMATED NET EFFECT ON THE GENERAL REVENUE FUND	**$0**	**$0 to $5,527,903**	**$0 to $12,161,386**

FISCAL IMPACT - State Government	FY 2017 (10 Mo.)	FY 2018	FY 2019
FEDERAL FUNDS			
Savings - DSS (§338.056 & 338.085) Reduction in MO HealthNet drug-spend	$0	$0 to... $9,505,011	$0 to... $20,911,023
Loss - DSS (§338.056 & 338.085) Reduction in reimbursements for MO HealthNet drug spend	$0	($9,505,011)	($20,911,023)
ESTIMATED NET EFFECT ON FEDERAL FUNDS	**$0**	**$0**	**$0**

FISCAL IMPACT - Local Government	FY 2017 (10 Mo.)	FY 2018	FY 2019
	$0	**$0**	**$0**

FISCAL IMPACT - Small Business

No direct fiscal impact to small businesses would be expected as a result of this proposal.

FISCAL DESCRIPTION

This act allows a pharmacist filling a prescription order for a brand name biological product to select a less expensive interchangeable biological product if the substitute has been approved by the FDA to be an interchangeable biological product, the prescriber has communicated that a interchangeable biological product may be substituted, and the pharmacist informs the patient. Within five days of dispensing a biological product, the pharmacist shall communicate the name and manufacturer of the product to the prescriber, unless there is no FDA approved interchangeable biological product or a refill prescription is not changed from the product dispensed on the prior filling.

The Board of Pharmacy shall maintain a link on its website to a current list of all biological products determined by the FDA to be interchangeable with a specific biological product.

This legislation is not federally mandated, would not duplicate any other program and would not require additional capital improvements or rental space.

SOURCES OF INFORMATION

Mickey Wilson, CPA
Director
January 27, 2016

Ross Strope
Assistant Director
January 27, 2016

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