

COMMITTEE ON LEGISLATIVE RESEARCH  
OVERSIGHT DIVISION

**FISCAL NOTE**

L.R. No.: 0213-01  
Bill No.: SB 174  
Subject: Children and Minors; Health Care; Health and Senior Services Department;  
Health, Public  
Type: Original  
Date: January 10, 2017

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Bill Summary: This proposal creates a voluntary replacement alternative program for children's vaccines which do not contain human DNA content.

**FISCAL SUMMARY**

<b>ESTIMATED NET EFFECT ON GENERAL REVENUE FUND</b>			
FUND AFFECTED	FY 2018	FY 2019	FY 2020
General Revenue	\$0 to (Could exceed \$100,000)	\$0 to (Could exceed \$143,008)	\$0 to (Could exceed \$616,098)
<b>Total Estimated Net Effect on General Revenue</b>	<b>\$0 to (Could exceed \$100,000)</b>	<b>\$0 to (Could exceed \$143,008)</b>	<b>\$0 to (Could exceed \$616,098)</b>

<b>ESTIMATED NET EFFECT ON OTHER STATE FUNDS</b>			
FUND AFFECTED	FY 2018	FY 2019	FY 2020
<b>Total Estimated Net Effect on <u>Other</u> State Funds</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>

Numbers within parentheses: ( ) indicate costs or losses.  
This fiscal note contains 8 pages.

<b>ESTIMATED NET EFFECT ON FEDERAL FUNDS</b>			
<b>FUND AFFECTED</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
Federal	\$0	\$0*	\$0*
<b>Total Estimated Net Effect on <u>All</u> Federal Funds</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>

\* Income and expenses \$0 to Could exceed \$100,000 beginning in FY 2019 net to \$0.

<b>ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)</b>			
<b>FUND AFFECTED</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
<b>Total Estimated Net Effect on FTE</b>	<b>0</b>	<b>0</b>	<b>0</b>

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

<b>ESTIMATED NET EFFECT ON LOCAL FUNDS</b>			
<b>FUND AFFECTED</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
<b>Local Government</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>

## **FISCAL ANALYSIS**

### **ASSUMPTION**

Officials from the **Department of Health and Senior Services (DHSS), Division of Community and Public Health (DCPH)** provide the following assumptions:

#### **Section 210.005.1**

This section prevents DHSS from mandating the public clinic use of children's vaccines containing human deoxyribonucleic acid (DNA). This would include vaccines for measles, mumps and rubella, varicella and hepatitis A. Currently, immunizations for measles, mumps and rubella and varicella vaccines are mandated for school and/or child care entry by DHSS per Section 210.003, RSMo. The only vaccinations available for these diseases are those that contain human DNA content. For fiscal note purposes, DHSS interprets this provision of the bill to mean that DHSS could not require these vaccinations because there are no alternative vaccinations without human DNA content. This would lead to a lower rate of children being vaccinated for diseases, increase the likelihood of disease outbreaks, and therefore, result in an unknown amount of state healthcare costs greater than \$100,000.

**Oversight** assumes an outbreak of measles, mumps and rubella, and varicella to be speculative and will range DHSS's projected costs as \$0 to could exceed \$100,000 annually if such an outbreak does occur.

DHSS is required to develop a voluntary replacement alternative program, which shall include, at the earliest date of availability, replacement vaccines that do not contain human DNA content and have been approved by the Centers for Disease Control and Prevention (CDC) and the Federal Drug Administration (FDA). However, there are no replacement options for vaccines containing human DNA content for the vaccines affected by the proposed legislation, nor is DHSS aware of plans for vaccine manufacturers to develop any replacement vaccines.

#### **Section 210.005.2**

This section requires DHSS to include in its annual budget request details for a statewide registry for children enrolled in the alternative replacement program. This request shall be within the fiscal year prior to including any replacement vaccines in the voluntary replacement alternative program.

Most vaccines take at least five to seven years to develop. If replacement vaccines are developed, DHSS would be required to develop and maintain a registry to track the children enrolled in the voluntary replacement program. The cost of developing and maintaining a registry is unknown, but estimated to be greater than \$2,000,000. However, because there are no

ASSUMPTION (continued)

replacement options for vaccines containing human DNA content for the vaccines affected by the proposed legislation, and DHSS is not aware of plans for vaccine manufacturers to develop any replacement vaccines, the costs for this registry and the staff needed to operate a voluntary replacement alternative program are not projected in this fiscal note estimate.

Officials from the **Department of Social Services (DSS), MO HealthNet Division (MHD)** state the provisions of the proposal provide beginning June 1, 2019, the state of Missouri and the Missouri Department of Health and Senior Services (DHSS) shall not mandate the public to use children's vaccines containing human DNA. DHSS shall develop a voluntary replacement program that will include replacement vaccines that do not contain human DNA and are approved by the Centers for Disease Control (CDC) and Food and Drug Administration (FDA).

In the fiscal year prior to including any replacement vaccines in the voluntary replacement alternative program, DHSS shall include in its annual budget request details for a state-wide registry for children enrolled in the program.

The voluntary replacement alternative program shall automatically expire on August 28, 2029, unless reauthorized.

In FY16, MHD spent \$2,063,154 for State Children's Health Insurance Program (CHIP) children's vaccines. MHD is not aware of any alternative children's vaccines that are currently available on the market that do not contain human protein or DNA content. MHD assumes the cost for an alternative vaccine would differ from current vaccine costs. If the costs of these alternative vaccines are up to twice as much as current vaccines, MHD estimates the potential cost of this legislation to range from \$0-\$2,063,154 for the first full year alternative vaccines are available. MHD assumes 1/12th of this estimate for FY19 using a June implementation.

FY18: \$0;

FY19: (1 month – June 1, 2019) \$0 - \$171,929 (\$0 - \$43,008 GR; \$0 - \$128,921 Fed);

FY20: \$0 - \$2,063,154 (\$0 - \$516,098 GR; \$0 - \$1,547,056 Fed).

Officials from the DSS, Division of Legal Services assume the proposal would not fiscally impact their division.

Officials from the **Joint Committee on Administrative Rules (JCAR)** state the legislation is not anticipated to cause a fiscal impact to JCAR beyond its current appropriation.

ASSUMPTION (continued)

Officials from the **Office of Secretary of State (SOS)** did not respond to **Oversight's** request for a statement of fiscal impact. However, in response to previous year's legislation containing similar rules language, the SOS provided the following response:

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.

<u>FISCAL IMPACT - State Government</u>	FY 2018 (10 Mo.)	FY 2019	FY 2020
<b>GENERAL REVENUE FUND</b>			
<u>Costs - DHSS (§210.005)</u>			
Additional healthcare-related costs	\$0 to (Could exceed \$100,000)	\$0 to (Could exceed \$100,000)	\$0 to (Could exceed \$100,000)
<u>Costs - DSS (§210.005)</u>			
Increase in vaccine costs	<u>\$0</u>	<u>\$0 to (\$43,008)</u>	<u>\$0 to (\$516,098)</u>
<b>ESTIMATED NET EFFECT ON THE GENERAL REVENUE FUND</b>	<b><u>\$0 to (Could exceed \$100,000)</u></b>	<b><u>\$0 to (Could exceed \$143,008)</u></b>	<b><u>\$0 to (Could exceed \$616,098)</u></b>
<b>FEDERAL FUNDS</b>			
<u>Income - DSS (§210.005)</u>			
Increase in program reimbursements	\$0	\$0 to Could exceed \$128,921	\$0 to Could exceed \$1,547,056
<u>Costs - DSS (§210.005)</u>			
Increase in program distributions	<u>\$0</u>	<u>\$0 to (Could exceed \$128,921)</u>	<u>\$0 to (Could exceed \$1,547,056)</u>
<b>ESTIMATED NET EFFECT ON FEDERAL FUNDS</b>	<b><u>\$0</u></b>	<b><u>\$0</u></b>	<b><u>\$0</u></b>

FISCAL IMPACT - Local Government

FY 2018  
(10 Mo.)

FY 2019

FY 2020

\$0

\$0

\$0

FISCAL IMPACT - Small Business

This proposal may have a direct impact on small business health care providers.

FISCAL DESCRIPTION

Beginning June 1, 2019, the Missouri Department of Health and Senior Services shall not mandate the public clinic use of those children's vaccines containing human deoxyribonucleic acid (DNA), including those vaccines for such diseases as measles, mumps and rubella, varicella, and hepatitis A. Instead, the Department shall develop a voluntary replacement alternative program, which shall include, at the earliest date of availability, replacement vaccines that have been approved by the Centers for Disease Control (CDC) and the Federal Drug Administration (FDA), and which contain no human DNA content.

In the fiscal year prior to the inclusion of any such replacement vaccines in the voluntary replacement alternative program, the Department shall include in its annual budget request details for a state-wide registry for children enrolled in the program, a new schedule of delayed and separated vaccines, a periodic biennial individual screening survey with actual examination of those children with health or functional changes as noted by parents, a waiver of state liability for the replacement vaccines, and estimated annual costs of the program's operation for ten years.

The voluntary replacement alternative program shall automatically expire on August 28, 2029, unless reauthorized.

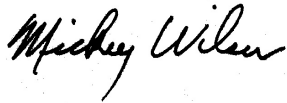
This legislation is not federally mandated, would not duplicate any other program and would not require additional capital improvements or rental space.

SOURCES OF INFORMATION

Department of Health and Senior Services  
Department of Social Services -  
    MO HealthNet Division  
    Division of Legal Services  
Joint Committee on Administrative Rules

NOT RESPONDING

Office of Secretary of State



Mickey Wilson, CPA  
Director  
January 10, 2017

Ross Strobe  
Assistant Director  
January 10, 2017