

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 5346-01
Bill No.: HB 1531
Subject: Children and Minors; Health Care; Medical Procedures and Personnel; Health Dept.
Type: Original
Date: February 15, 2012

Bill Summary: Adds Severe Combined Immune Deficiency Disease (SCID), also known as Bubble Boy Disease, to the newborn screening requirements.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2013	FY 2014	FY 2015
General Revenue	(\$571,572)	\$0	\$0
Total Estimated Net Effect on General Revenue Fund	(\$571,572)	\$0	\$0

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2013	FY 2014	FY 2015
MoPHS	\$0	(\$7,603)	(\$21,917)
Total Estimated Net Effect on <u>Other</u> State Funds	\$0	(\$7,603)	(\$21,917)

Numbers within parentheses: () indicate costs or losses.
This fiscal note contains 10 pages.

ESTIMATED NET EFFECT ON FEDERAL FUNDS			
FUND AFFECTED	FY 2013	FY 2014	FY 2015
Federal*	\$0	\$0	\$0
Total Estimated Net Effect on <u>All</u> Federal Funds	\$0	\$0	\$0

* Income and expenditures net to \$0.

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2013	FY 2014	FY 2015
General Revenue	2	0	0
MoPHS	0	2	2
Total Estimated Net Effect on FTE	2	2	2

Estimated Total Net Effect on All funds expected to exceed \$100,000 savings or (cost).

Estimated Net Effect on General Revenue Fund expected to exceed \$100,000 (cost).

ESTIMATED NET EFFECT ON LOCAL FUNDS			
FUND AFFECTED	FY 2013	FY 2014	FY 2015
Local Government	\$0	\$0	\$0

FISCAL ANALYSIS

ASSUMPTION

Officials from the **Missouri Department of Conservation** assume the proposal will have no fiscal impact on their organization.

Officials from the **Department of Public Safety - Missouri State Highway Patrol** defer to the Missouri Department of Transportation for response regarding the potential fiscal impact of this proposal on their organization.

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.

Officials from the **Office of Secretary of State (SOS)** state many bills considered by the General Assembly include provisions allowing or requiring agencies to submit rules and regulations to implement the act. The Secretary of State's office 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 this is a small amount and does not expect that additional funding would be required to meet these costs.** However, it is also recognized 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 within its 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.**

Officials from the **Missouri Consolidated Health Care Plan (MCHCP)** state they assume health carriers will be required to cover this screening on all newborns. Newborn screenings are bundled together on the newborn's hospital claim. The MCHCP assumes the fee for the bundled screenings will increase. The MCHCP currently adds approximately 1,006 newborns annually and estimates the cost to be approximately \$6 per SCID screening. The fiscal impact of this legislation is unknown, less than \$10,000 annually.

Oversight assumes the MCHCP and the health care plan for state employees can absorb an increase in costs of less than \$10,000 annually.

Officials from the **Missouri Department of Transportation (DOT)** state the plan would have increased costs by adding the screening to their newborn screening charges. The associated charges are unknown; therefore, the estimated impact is unknown, but would be less than \$100,000 annually.

ASSUMPTION (continued)

Oversight assumes the DOT's costs for this additional newborn screening test will be minimal and, therefore, assumes the DOT can absorb this cost.

Officials from the **Department of Social Services - MO HealthNet Division (MHD)** state currently, newborn screenings are reimbursed by the MHD for the federal portion only. The general revenue portion is included in the Department of Health and Senior Services (DHSS) budget.

In SFY 11, the MHD was billed for 14,673 newborn screenings by the State Health Lab. For this calculation it is assumed the same number of screenings would be billed for in SFY 13 as was billed for in SFY 11.

At this time, the rate for the additional newborn screenings is unknown. If the rate is increased by \$6.00 (estimate provided by DHSS), the result would be \$88,038 (\$6 increase x 14,673 newborn screenings).

Fiscal Impact: Unknown but at least:

FY13 (calculated for 10 months) Total \$73,365; Federal Funds \$45,024

FY14 (3.5% Trend) Total \$91,119; Federal Funds \$55,920

FY15 (3.5% Trend) Total \$94,308; Federal Funds \$57,877

Note: The MHD pays the federal portion only; the general revenue portion is included in the DHSS' budget.

Officials from the **Department of Health and Senior Services (DHSS)** state Section 191.331, RSMo, broadly allows the DHSS to implement newborn screening for metabolic and genetic diseases. As such, the DHSS has begun planning for the process to implement screening for Severe Combined Immune Deficiency (SCID) Disease, as required by this proposal.

Section 191.332

Genetics Program Costs

Adding SCID to the newborn screening panel would result in approximately 20 or more cases per year that would require referral to the tertiary centers for follow-up and confirmation. These cases could be absorbed by the tertiary centers as it would add approximately five new cases per year per center to their current case load.

ASSUMPTION (continued)

The newborn screening pamphlet would need to be revised to include information on SCID. This would be a onetime cost of \$6,000 to revise and reprint the pamphlet: 100,000 pamphlets X \$.06 each = \$6,000.

Missouri State Public Health Laboratory (MSPHL) Costs

The Missouri State Public Health Laboratory (MSPHL) would need to hire two additional FTE's, one Senior Public Health Laboratory Scientist (\$40,212 annually) and one Public Health Laboratory Scientist (\$35,952 annually), to oversee and maintain newborn screening for SCID.

The duties of the two specified FTE's are designated to be:

Senior Public Health Laboratory Scientist

Responsible for the oversight, analytical testing, interpreting of results, and reporting of approximately 375 newborn screening samples per working day for the SCID testing section. This involves:

- Opening daily samples received and assessing for quality and suitability;
- Processing samples into split samples for the SCID testing platforms;
- Comprising work lists, making necessary solutions, and performing instrument preparations;
- Performing the molecular amplification and detection procedures for the presence of T-Cell Receptor Excision Circles (TRECs) to detect SCID;
- Reviewing and interpreting test results, and conducting necessary re-testing of abnormal results; and,
- Assessing the risk of abnormal results and contacting appropriate genetic referral center for confirmation and follow-up testing.

Responsible for continual quality assurance and quality improvement of the SCID testing section. This involves:

- Reviewing and approval of daily instrument controls for accuracy;
- Monitoring QC results for shifts and trends, and performing corrective and preventive actions;
- Oversight of instrument performance, maintenance, and troubleshooting;
- Conducting and oversight of regular proficiency testing to assure accuracy and proficiency certifications;
- Training and cross-training new scientists to be proficient in the SCID section;
- Ordering testing reagents and maintaining good inventory of items necessary for continuation of operations; and,
- Compiling monthly, annual, and as-needed reports for the newborn screening manager.

ASSUMPTION (continued)

Public Health Laboratory Scientist

Responsible for accurate and timely routine testing of newborn screening samples for the SCID testing section. This involves:

- Opening daily samples received and assessing for quality and suitability;
- Processing samples into split samples for the SCID testing platforms;
- Comprising work lists, making necessary solutions, and performing instrument preparations;
- Performing the molecular amplification and detection procedures for the presence of T-Cell Receptor Excision Circles (TRECs) to detect SCID;
- Assisting the Senior Scientist in instrument maintenance and troubleshooting; and,
- Assisting the Senior Scientist in interpreting and reporting of screening results.

It may be necessary to raise the newborn screening fee to add SCID testing. These funds would be deposited into the Missouri Public Health Services (MoPHS) Fund. Because the implementation date of the legislation is January 1, 2013, the rule change to increase the fee cannot be accomplished for first year funds. Thus, first year costs will be in General Revenue.

Nationally accepted cost estimates for public health laboratories to conduct SCID testing were used and are based upon information published in:

Newborn Screening for Severe Combined Immunodeficiencies (SCID) - A 2008 Wisconsin Perspective. University of Wisconsin and State Laboratory of Hygiene, Madison, WI and Medical college of WI and Children's Hospital of WI, Milwaukee, WI

Journal of American Medical Association. 2010;304(16):1771-1773. doi:
10.1001/jama.2010.1485

These references suggest that the current cost to conduct SCID testing is \$6.00 per test. These references indicate that this cost includes both total Personal Service (PS) and Expense and Equipment (EE) costs. The MSPHL conducts approximately 90,000 newborn screening tests annually: $90,000 \text{ tests} \times \$6.00/\text{test} = \$540,000$ PS and EE costs annually.

The MSPHL will be required to conduct a six month pilot study on samples prior to reporting SCID results. With these estimates, the pilot study will cost approximately \$270,000 and will be required six months prior to January 1, 2013. PS and EE costs were divided by subtracting Missouri specific PS costs from the base total of \$540,000, and the balance being EE. Subsequent fiscal years were adjusted with a 2.5 percent inflationary increase to the base total of \$540,000.

ASSUMPTION (continued)

All costs associated with SCID testing are based upon technology currently available. As the demand for this testing increases, new technology will drive the costs up or down.

The DHSS assumes the proposal will have a cost to the General Revenue Fund of \$571,572 for FY 13; costs to the MoPHS Fund are estimated to be \$7,603 for FY 14 and \$21,917 for FY 15.

<u>FISCAL IMPACT - State Government</u>	FY 2013 (10 Mo.)	FY 2014	FY 2015
GENERAL REVENUE FUND			
<u>Costs - Department of Health and Senior Services (\$191,332)</u>			
Personal service	(\$76,164)	\$0	\$0
Fringe benefits	(\$40,321)	\$0	\$0
Equipment and supplies	(\$39,097)	\$0	\$0
Pre-pilot costs	(\$207,995)	\$0	\$0
Testing costs	<u>(\$207,995)</u>	<u>\$0</u>	<u>\$0</u>
Total <u>Costs</u> - DHSS	<u>(\$571,572)</u>	<u>\$0</u>	<u>\$0</u>
FTE Change - DHSS	2 FTE	0 FTE	0 FTE
ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
	<u>(\$571,572)</u>	<u>\$0</u>	<u>\$0</u>
Estimated Net FTE Change on General Revenue Fund	2 FTE	0 FTE	0 FTE

<u>FISCAL IMPACT - State Government</u>	FY 2013 (10 Mo.)	FY 2014	FY 2015
MISSOURI PUBLIC HEALTH SERVICES FUND (MoPHS)			
<u>Income - Department of Health and Senior Services</u>			
Newborn screening income	\$0	\$565,000	\$565,000
<u>Costs - Department of Health and Senior Services (\$191.332)</u>			
Personal service	\$0	(\$76,926)	(\$77,695)
Fringe benefits	\$0	(\$40,725)	(\$41,132)
Equipment and supplies	\$0	(\$28,359)	(\$29,068)
Testing costs	\$0	(\$426,593)	(\$439,022)
Total <u>Costs</u> - DHSS	<u>\$0</u>	<u>(\$572,603)</u>	<u>(\$586,917)</u>
FTE Change - DHSS	0 FTE	2 FTE	2 FTE
ESTIMATED NET EFFECT ON MISSOURI PUBLIC HEALTH SERVICES FUND			
	<u>\$0</u>	<u>(\$7,603)</u>	<u>(\$21,917)</u>
Estimated Net FTE Change on Missouri Public Health Services Fund	0 FTE	2 FTE	2 FTE
FEDERAL FUNDS			
<u>Income - Department of Social Services</u>			
Newborn screening reimbursement	Unknown greater than \$45,024	Unknown greater than \$55,920	Unknown greater than \$57,877
<u>Costs - Department of Social Services</u>			
Newborn screening costs	<u>(Unknown greater than \$45,024)</u>	<u>(Unknown greater than \$55,920)</u>	<u>(Unknown greater than \$57,877)</u>
ESTIMATED NET EFFECT ON FEDERAL FUNDS			
	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

<u>FISCAL IMPACT - Local Government</u>	FY 2013 (10 Mo.)	FY 2014	FY 2015
	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

FISCAL IMPACT - Small Business

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

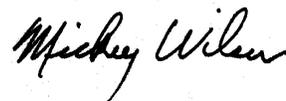
FISCAL DESCRIPTION

This proposal requires, by January 1, 2013, the Department of Health and Senior Services to expand, subject to appropriations, the newborn screening requirements to include severe combined immune deficiency disease (SCID), also known as bubble boy disease, prior to the newborn being discharged from a health care facility.

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
Missouri Department of Transportation
Department of Public Safety -
 Missouri State Highway Patrol
Missouri Consolidated Health Care Plan
Joint Committee on Administrative Rules
Missouri Department of Conservation
Office of Secretary of State



Mickey Wilson, CPA
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