

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 0277-01
Bill No.: HB 66
Subject: Health Care Services; Health and Senior Services Department; Children and Minors
Type: Original
Date: January 12, 2017

Bill Summary: This proposal expands the newborn screening requirements to include spinal muscular atrophy (SMA) and Hunter syndrome.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2018	FY 2019	FY 2020
Total Estimated Net Effect on General Revenue	\$0	\$0	\$0

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2018	FY 2019	FY 2020
MoPHS	\$0	(\$454,581)	\$16,113
Total Estimated Net Effect on <u>Other</u> State Funds	\$0	(\$454,581)	\$16,113

Numbers within parentheses: () indicate costs or losses.

This fiscal note contains 10 pages.

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

* Income and expenses beginning in FY 19 net to \$0.

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2018	FY 2019	FY 2020
MoPHS	0	2	2
Total Estimated Net Effect on FTE	0	2	2

☒ 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 2018	FY 2019	FY 2020
Local Government	\$0	\$0	\$0

FISCAL ANALYSIS

ASSUMPTION

§191.332 - Newborn screening requirements

Officials from the **Department of Health and Senior Services (DHSS)** provide the following assumptions for this proposal:

The proposed legislation would permit the DHSS to increase the newborn screening fee which would be deposited into the Missouri Public Health Services Fund (MoPHS) to cover costs associated with implementation of this bill. DHSS assumes the newborn screening fee will have to be increased by \$7.25. It is estimated the MoPHS fund will receive an additional **\$304,910** $[(80,265 \text{ newborn screens} \times \$7.25 = \$581,921) + (15,000 \text{ Medicaid screens} \times \$3 \times 62\% \text{ Federal match} = \$27,900) = \$609,821] / 2$ (effective January 1, 2019) in newborn screening fees in FY 19 and an additional **\$609,820** in screening fees in FY 20.

Oversight notes the DHSS used an estimated FMAP rate of 62% to calculate Medicaid payments received from the Department of Social Services (DSS) for newborn screenings. The actual FMAP rate used by DSS was 64.26%. Therefore, DHSS' estimated income from DSS is slightly less than the reimbursement estimated by DSS. For fiscal note purposes, Oversight will use the DSS calculated Medicaid reimbursement for newborn screenings.

Division of Community and Public Health (DCPH)

The incidence for Spinal Muscular Atrophy (SMA) is estimated to be one in 10,000 newborns. Based on this information, it is estimated that Missouri would have a total of 60-100 abnormal newborn screening results annually that would require follow-up with confirmatory testing to determine whether the newborn is affected with the disorder or not. There would be approximately 8 newborns each year diagnosed with SMA in Missouri, given an annual birth rate of around 78,000 in Missouri and 2,000 more screenings from bordering states. Newborns with SMA would need to be seen by a neurology specialist for confirmatory testing and diagnosis in a manner similar to what has been established for Severe Combined Immunodeficiency Disease (SCID) and immunology specialists. It is assumed that the tracking and follow-up of these cases could be coordinated by the current Public Health Senior Nurse; therefore, no additional personnel would be required for follow-up.

The incidence of MPS-II is estimated to be one in 100,000 newborns. Based on this information, it is estimated that Missouri would have a total of 30-50 abnormal newborn screening results annually that would require follow-up with confirmatory testing to determine whether the

ASSUMPTION (continued)

newborn is affected with the disorder or not. There could be approximately one (1) newborn every two years diagnosed with MPS-II in Missouri, given an annual birth rate of around 78,000 in Missouri and 2,000 more screenings from bordering states. Based on the assumption that there would be 30-50 abnormal newborn screening results annually that would require follow-up, each of the four (4) contracted genetic tertiary centers would potentially receive approximately 12 referrals per year, or one per month. Follow-up for these newborns will typically include DNA molecular analysis, which is not consistently covered or reimbursed adequately by third party insurance, private insurance, Medicaid, Tricare, etc. Therefore, the genetic tertiary centers will incur costs associated with ordering the confirmatory tests needed to provide a diagnosis for the newborns referred with abnormal newborn screening results for MPS-II. It is estimated that the cost of DNA molecular analysis will be \$2,000 per newborn. If there are 50 newborns referred per year, the total cost would be \$100,000 or \$25,000 per center. Therefore, the genetics and newborn screening program would need to increase each of the four genetic tertiary center contracts by \$25,000 annually.

The genetics and newborn screening program would require no additional FTEs as it is assumed that the current program staff will be able to absorb any additional duties associated with screening for MPS-II.

Missouri State Public Health Laboratory (MSPHL)

The Missouri State Public Health Laboratory (MSPHL) will need to hire two additional FTEs Senior Public Health Laboratory Scientists (\$42,780 each, annually), to oversee and maintain newborn screening for SMA and Hunter syndrome. Based on the January 1, 2019 implementation date, these staff will be hired at the beginning of Fiscal Year 2019 when the method validation begins.

The duties of the two FTEs are designated to be:

Senior Public Health Laboratory Scientist – SMA

1) Responsible for the oversight, analytical testing, interpretation of results, and reporting of approximately 375 newborn screening samples per working day for the Spinal Muscular Atrophy (SMA) testing section. This involves:

- Opening daily samples received and assessing quality and suitability;
- Processing samples for the SMA testing platform;
- Comprising work lists, preparing reagents, maintaining appropriate inventory, and performing instrument operations and maintenance;
- Performing nucleic acid extractions and PCR amplification on dried blood spots to detect the presence or absence of SMA;
- 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.

ASSUMPTION (continued)

2) Responsible for continual quality assurance and quality improvement of the SMA testing section. This involves:

- Reviewing and approving daily instrument controls for accuracy;
- Monitoring quality control results for shifts and trends, and performing corrective and preventive actions;
- Overseeing instrument performance, performing maintenance, and troubleshooting;
- Conducting and overseeing regular proficiency testing to ensure accuracy and proficiency certifications;
- Training and cross-training new scientists to be proficient in the SMA 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 genetics and newborn screening program.
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Senior Public Health Laboratory Scientist – Hunter syndrome

1) Responsible for the oversight, analytical testing, interpretation of results, and reporting of approximately 375 newborn screening samples per working day for the Mucopolysaccharidosis Type II (Hunter Syndrome) testing section. Hunter syndrome is an X-Linked (runs in boys) Lysosomal Storage Disorder (LSD) caused by defects in the iduronate 2-sulfatase (IDS) gene. The duties of this Senior Scientist will involve:

- Opening daily samples received and assessing quality and suitability;
- Processing samples for the LSD testing platforms;
- Comprising work lists, making necessary solutions, and performing instrument preparations;
- Performing the enzyme assay and detection procedures for the enzyme activity levels that are markers for Hunter syndrome.
- Reviewing and interpreting test results, and conducting necessary re-testing of abnormal results; and,
- Assessing the risk of the final abnormal results and contacting appropriate genetic referral center for confirmation and follow-up testing.

2) Responsible for continual quality assurance and quality improvement of the Hunter testing section. This involves:

- Reviewing and approving daily instrument controls for accuracy;
- Monitoring quality control results for shifts and trends, and performing corrective and preventive actions;
- Overseeing instrument performance, performing maintenance, and troubleshooting;
- Conducting and overseeing regular proficiency testing to ensure accuracy and proficiency certifications;

ASSUMPTION (continued)

- Training and cross-training new scientists to be proficient in the Hunter testing 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.

All laboratory Equipment and Expense costs associated with these disorders are based upon vendor quotes for technology currently available.

Laboratory Supplies - Hunter syndrome	Quantity	Unit Cost	Total Cost
96 well microtiter plate (80/cs)	18.00	\$141.84	\$2,553
Finntip Flex 10 (20x96/refill)	64.00	\$111.69	\$7,148
Finntip 200 (20x96/refill)	1.50	\$108.73	\$163
Finntip Flex 1200 (16x96/refill)	6.00	\$142.11	\$853
Pipet basin, 50ml (100/cs)	7.00	\$60.30	\$422
IDS2-4MU Substrate	744.00	\$231.33	\$172,112
Extraction Solution	744.00	\$22.00	\$16,368
Stop Solution	744.00	\$32.00	\$23,808
4MU Dilution Set (A-H concentration)	744.00	\$48.00	\$35,712
Plate sealer	1,550.00	\$0.48	\$744
96-well plate (black)	1,550.00	\$7.00	\$10,850
Foil plate sealer	1,550.00	\$1.68	\$2,604
Quality Control Material	124.00	\$147.00	\$9,114
Laboratory Supplies - SMA			
Primers and probe for SMA test			\$20,000
Total Expense Costs			\$302,451
Laboratory Equipment			
BioMek NxP Liquid Handler	1.00	\$110,877	\$110,877
Computer for SMA lab	1.00	\$800	\$800
Total Equipment Costs			\$111,677
Equipment Maintenance			
Service agreement for second BioMek (The MSPHL estimates the cost of the maintenance agreement to be 20 percent of the cost to purchase the BioMek equipment.)			\$22,175

ASSUMPTION (continued)

Oversight assumes DHSS would not need additional rental space for two (2) new FTE for this single proposal. However, Oversight notes, depending on the number of proposals passed during the legislative session, that accumulatively, DHSS may need additional rental space or capital improvements as determined by the Office of Administration, Facilities Management, Design and Construction.

DHSS officials provided the response for the **Office of Administration (OA), Information Technology Services Division (ITSD)**. OA, ITSD state, there will be a one-time cost associated with this proposed legislation. ITSD needs to develop the programming that allows Spinal Muscular Atrophy (SMA) and Hunter Syndrome (MPS-II) newborn screening laboratory results to be loaded into the Missouri Health Strategic Architecture and Information Cooperative (MOHSAIC) data system for tracking and follow-up. For estimation purposes, the project has been projected to be a 3 month project utilizing a project team to include a project manager, business analyst and a developer.

ITSD assumes that every new IT project/system will be bid out because all ITSD resources are at full capacity. The current contract rate for IT consultants is \$75 per hour. ITSD estimates this proposal will require 1,036.8 contract hours for a total cost to the General Revenue Fund in FY 19 of \$77,760 (1,036.8 hours X \$75).

Officials from the **Department of Social Services (DSS), MO HealthNet Division (MHD) and Division of Legal Services (DLS)** state section 191.332.3 requires the Department of Health and Senior Services (DHSS), by January 1, 2019 and subject to appropriations, expand the newborn screening requirements to include Spinal Muscular Atrophy (SMA) and Hunter Syndrome (MPSII). The department may increase the fee to cover the additional costs.

Currently, MO HealthNet reimburses DHSS the federal portion of the cost of the newborn screening fee for Medicaid eligible participants. The general revenue portion is included in the DHSS budget. MHD only reimburses DHSS for the portion of the fee that is attributed to the lab analysis.

DHSS estimates the lab portion of the newborn screening fee will need to be increased by \$3 to accommodate the additional tests for SMA and MPSII.

MHD provides reimbursement for 15,000 tests annually; therefore, this legislation is estimated to cost \$28,917 annually (15,000 tests X \$3 fee increase X 64.26% FMAP (Federal Medicaid Assistance Percentage)). The first year reflects only 6 months of costs due to delayed implementation.

FY 2019 (calculated for 6 months): Total Federal Funds \$14,459;
FY 2020: Total Federal Funds \$28,917.

Officials from the **DSS, DLS** assume the proposal would not fiscally impact their agency.

ASSUMPTION (continued)

Officials from the **University of Missouri Health Care (UMHC)** have reviewed the proposed legislation and determined that the fiscal impact should not exceed \$100,000 annually.

Oversight assumes the costs incurred by the UMHC related to this proposal can be absorbed within current resource levels.

Officials from the **Missouri Consolidated Health Care Plan**, the **Missouri Department of Conservation** and the **Missouri Department of Transportation** each assume the proposal would not fiscally impact their respective agencies.

Officials from the **Department of Public Safety, Missouri State Highway Patrol** defer to the Missouri Department of Transportation (MoDOT), Employee Benefits Section for response on behalf of the Highway Patrol. Please see MoDOT's fiscal note response for the potential fiscal impact of this proposal.

<u>FISCAL IMPACT - State Government</u>	FY 2018 (10 Mo.)	FY 2019	FY 2020
MoPHS FUND			
<u>Income - DHSS (\$191.332)</u>			
Increase in newborn screening fees	\$0	\$290,961	\$581,921
<u>Transfer-In from DSS Federal Fund (\$191.332)</u>			
Reimbursement for screening costs	<u>\$0</u>	<u>\$14,459</u>	<u>\$28,917</u>
Total <u>Income & Transfers-In - DHSS</u>	<u>\$0</u>	<u>\$305,420</u>	<u>\$610,838</u>
<u>Costs - DHSS (\$191.332)</u>			
Personal service	\$0	(\$86,416)	(\$87,280)
Fringe benefits	\$0	(\$46,351)	(\$46,608)
Equipment and expense	<u>\$0</u>	<u>(\$627,234)</u>	<u>(\$460,837)</u>
Total <u>Costs - DHSS</u>	<u>\$0</u>	<u>(\$760,001)</u>	<u>(\$594,725)</u>
FTE Change - DHSS	0 FTE	2 FTE	2 FTE
ESTIMATED NET EFFECT ON THE MoPHS FUND	<u>\$0</u>	<u>(\$454,581)</u>	<u>\$16,113</u>
Estimated Net FTE Change on the MoPHS fund	0 FTE	2 FTE	2 FTE

<u>FISCAL IMPACT - State Government</u>	FY 2018 (10 Mo.)	FY 2019	FY 2020
FEDERAL FUNDS			
<u>Income - DSS (§191.332)</u>			
Increase in reimbursement for SMA & MPS-II newborn screenings	\$0	\$14,459	\$28,917
<u>Transfer-out - DSS (§191.332)</u>			
Transfer-out to DHSS MoPHS Fund for SMA & MPS-II newborn screening expenses	<u>\$0</u>	<u>(\$14,459)</u>	<u>(\$28,917)</u>
ESTIMATED NET EFFECT ON FEDERAL FUNDS	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>
 <u>FISCAL IMPACT - Local Government</u>	 FY 2018 (10 Mo.)	 FY 2019	 FY 2020
	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

FISCAL IMPACT - Small Business

Small business birthing centers, midwives and any other entities that purchase newborn screening collection forms would have to pay an additional fee. However, this cost may be recovered by the fees charged. There would also be additional administrative costs. (§191.332)

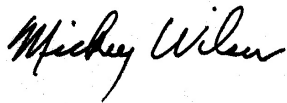
FISCAL DESCRIPTION

This bill expands the newborn screening requirements to include spinal muscular atrophy (SMA) and Hunter syndrome (MPS-II).

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 Public Safety -
 Missouri State Highway Patrol
Department of Social Services -
 MO HealthNet Division
 Division of Legal Services
Missouri Consolidated Health Care Plan
Missouri Department of Conservation
Missouri Department of Transportation
University of Missouri



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January 12, 2017

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