COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 0277-03
Bill No.: SCS for HCS for HB 66
Subject: Children and Minors; Fees; Health Care; Health and Senior Services Department; Medical Procedures and Personnel
Type: Original
Date: April 3, 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
General Revenue	($1,004,579)	($1,168,017)	($1,185,205)
Total Estimated Net Effect on General Revenue	**($1,004,579)**	**($1,168,017)**	**($1,185,205)**

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2018	FY 2019	FY 2020
MoPHS	$0	(Up to $469,040)	(Up to $12,804)
Total Estimated Net Effect on Other State Funds	**$0**	**(Up to $469,040)**	**(Up to $12,804)**

Numbers within parentheses: ( ) indicate costs or losses.
This fiscal note contains 15 pages.

ESTIMATED NET EFFECT ON FEDERAL FUNDS			
FUND AFFECTED	FY 2018	FY 2019	FY 2020
Federal*	$0	$0	$0
Total Estimated Net Effect on All 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
General Revenue	12	12	12
MoPHS	0	2	2
Total Estimated Net Effect on FTE	**12**	**14**	**14**

☒ 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

§191.331 -Specimens to be collected and submitted do DHSS within 24 hours

Officials from the **Department of Health and Senior Services (DHSS), Missouri State Public Health Laboratory (MSPHL)** provide the following assumptions:

Section 191.331 will require the MSPHL to increase the frequency of newborn screening testing to seven days per week.

Historically, Saturday testing and Sunday courier costs have been funded with General Revenue.

The MSPHL will need to hire the following additional FTE:
- Four (4) Senior Public Health Laboratory Scientists ($42,780 annually, each)
- Six (6) Public Health Laboratory Scientists ($38,304 annually, each)
- Two (2) Senior Office Support Assistants ($26,340 annually, each)

Senior Public Health Laboratory Scientist (SPHLS):
Responsible for the oversight, analytical testing, interpreting of results, and reporting of approximately 375 newborn screening samples per working day. This involves:

- Supervising one to two Associate/Public Health Laboratory Scientists (PHLS) working in their testing section while fully overseeing the testing area for which they are responsible. This involves:
  - Opening daily samples (average of 300 per day received) and assessing quality and suitability;
  - Processing samples for the testing platforms;
  - Comprising work lists, making necessary solutions, and performing instrument preparations;
  - Performing the assay and detection procedures for the analyte levels that are markers for the screening disorders that they are overseeing.
  - 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.

ASSUMPTION (continued)

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

- Quality Control (QC) new reagent lots, perform instrument comparisons as part of the Quality Assurance (QA) plan, maintain and update procedure manuals when necessary.
- 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 their 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.

Public Health Laboratory Scientist (PHLS):

- Daily assess specimen quality and necessary demographic information that is necessary for sample to be tested.
- Daily punch specimens into specified microtiter plates.
- Be familiar with the dried blood spot (DBS) punchers and perform daily, weekly and monthly maintenance.
- Prepare instruments for testing (i.e. preparing reagents and loading reagents, specimen extraction, loading tips, discarding waste).
- Preparing sample maps and loading instruments with specimens for testing.
- Preparing daily worklist and presumptive positive reports for the senior scientist.
- Ensuring and performing preventative measures in the lab, such as equipment (daily, weekly, monthly).
- Participating in QA programs with Centers for Disease Control (CDC) for Clinical Laboratory Improvement Amendments (CLIA) compliance.
- Checking patient assays and QC.
- Perform inventory and alert supervisor of a shortage to ensure reagent and consumables have been ordered already.
- Fill out temperature charts daily.
- Analyze new reagent lot number changes and perform instrument comparisons per the request of the supervisor.

ASSUMPTION (continued)

- Provide back up to other Scientist when that person is absent.
- Assist with validation on new platforms and instrumentation on new tests per the request of the supervisor.
- Assist with training new scientist.
- Assist in troubleshooting in the laboratory
- Familiar with the following software: Specimen Gate, Natus MSDS and the MS Office Suite, and DELTA.

Senior Office Support Assistant (SOSA):

- Process and prepare Newborn Screening results for dissemination.
- Enter "Poor Quality" specimens into Laboratory Information System (LIMS) and conduct quality assurance checks to validate proper entry of sample demographic and medical information.
- Generate Newborn laboratory results and fax to physician of record and submitting facility.
- Generate Poor Quality Specimen Proofing Report and send to testing laboratory.
- Conduct demographic entry on initial Newborn Screen specimens and entered into LIMS.
- Conduct demographic entry on repeat Newborn Screen specimens and entered into LIMS.
- Perform Quality Assurance checks on all of Newborn Screen specimens entered that day.
- Generate Initial and Repeat Proofing Report and send to testing laboratory.
- Respond to submitters, providers and customers questions regarding results. Handle all incoming calls for Newborn Screening information. Provide verbal and written results to appropriate facilities.
- Scan all Initial and Repeat Newborn Screening forms for retrieval and retention. Complete Quality Assurance checks on scanned form images. Complete validation examinations on all Quality Assurance checked scanned forms.
- Document and record all incoming samples delivered by courier. Provide quality assurance and safety checks on all incoming samples to assure proper handling while maintaining the integrity of the sample.
- Accession all incoming samples and deliver to appropriate testing unit for processing.
- Verify accurate and timely pick-up and delivery of samples from courier stops through the reconciliation of courier route sheets.
- Provide technical support to customers and stakeholders with regards to courier issues.

The state public health courier system that is coordinated by the MSPHL will have to be expanded to include a Saturday courier pick up at selected birthing hospitals to support testing taking place on Sunday. Based upon current courier costs to conduct the Sunday courier pick up that was added in 2015, approximately $78,161 will be required to adjust the contract to provide this service.

ASSUMPTION (continued)

All laboratory E&E costs associated are based upon current contracts or vendor quotes.

Courier Expansion	Unit Cost	Quantity	Total Cost
Expand to seven days per week at the existing 50 hospitals	$78,161	1	$78,161
Equipment Maintenance			
Weekend service agreement	$97,271	2	$194,542
Quantstudio priority service	$9,613	5	$48,067

§191.332 - Newborn screening requirements

MSPHL states this section will require the MSPHL to add Spinal Muscular Atrophy (SMA) and Mucopolysaccharidosis Type II (MSP 11/Hunter Syndrome) to the newborn screening panel.

An assumption was made to fund this section from the Missouri Public Health Services Fund (MoPHS, Fund #0298) with the Newborn Screening Fee as new disorders have been in the past.

The MSPHL will need to hire two additional FTEs Senior Public Health Laboratory Scientists ($42,780 annually, each) 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 (SPHLS) – SMA
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)

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.

Senior Public Health Laboratory Scientist (SPHLS) – Hunter Syndrome

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 SPHLS 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.

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;
- Oversight of 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			**$22,175**

ASSUMPTION (continued)

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 newborn screens X $7.25 = $581,921) + (15,000 Medicaid screens X $3 X 62% 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.

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

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 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

ASSUMPTION (continued)

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.

DHSS officials provided the response for the **Office of Administration (OA), Information Technology Services Division (ITSD)**. OA, ITSD states, 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).

DHSS estimates the fiscal impact of this proposal (including ITSD costs) to be as follows: (negative = costs)/ positive

	FY18	FY19	FY20
General Revenue Fund	($1,020,679)	($1,187,820)	($1,205,503)
MoPHS	$0	($464,993)	$4,946

Oversight notes that in response to other proposals from the current session where agencies have indicated the need for additional rental space, officials from the **OA, Division of Facilities Management, Design and Construction (FMDC)** have stated additional space in leased facilities for new staff for agencies in the Cole County area is estimated at 230 sq. ft. per FTE

ASSUMPTION (continued)

times $17.50 per sq. ft., or $4,025 annually per FTE. This cost includes building lease costs, fuel and utilities, and janitorial services. If a larger space were needed, the space was needed in other regions of the state, or newly constructed space if required, the estimated costs would be higher cost per sq. ft. (estimated at $24.50 per sq. ft.).

Oversight further notes the DHSS used a lease cost for the additional rental space needed for 14 new FTE of $21 per square foot. This is an average of the lease rates for the various regions in the state. Oversight reduced the average cost to $17.50 per square foot (which includes utilities and janitorial services), the amount provided by OA, Facilities Management, Design and Construction.

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 $0 to $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 $0 to $14,459;
FY 2020: Total Federal Funds $0 to $28,917.

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

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.

ASSUMPTION (continued)

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.

In response to the previous version of this proposal, officials from the **University of Missouri Health Care (UMHC)** stated they had 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.

FISCAL IMPACT - State Government	FY 2018 (10 Mo.)	FY 2019	FY 2020
GENERAL REVENUE FUND			
Costs - DHSS (§191.331)			
Personal service	($378,020)	($458,160)	($462,742)
Fringe benefits	($215,654)	($260,136)	($261,501)
Equipment and expense	($143,597)	($120,931)	($123,953)
Weekend service agreement, courier expansion & priority service	($267,308)	($328,790)	($337,009)
Total Costs - DHSS	($1,004,579)	($1,168,017)	($1,185,205)
FTE Change - DHSS	12 FTE	12 FTE	12 FTE
ESTIMATED NET EFFECT ON THE GENERAL REVENUE FUND	**($1,004,579)**	**($1,168,017)**	**($1,185,205)**
Estimated Net FTE Change on the General Revenue Fund	12 FTE	12 FTE	12 FTE

FISCAL IMPACT - State Government	FY 2018 (10 Mo.)	FY 2019	FY 2020
MISSOURI PUBLIC HEALTH SERVICES (MoPHS) FUND (#0298)			
Income - DHSS (§191.332)	Up to...	Up to...	Up to...
Increase in newborn screening fees	$0	$290,961	$581,921
Transfer-In from DSS Federal Fund (§191.332)			
Reimbursement for screening costs	$0	$0 to $14,459	$0 to $28,917
Total Income & Transfers-In - DHSS	$0	Up to $305,420	Up to $610,838
Costs - DHSS (§191.332)	Up to...	Up to...	Up to...
Personal service	$0	($86,416)	($87,280)
Fringe benefits	$0	($46,351)	($46,608)
Equipment and expense	$0	($627,234)	($460,837)
Total Costs - DHSS	$0	($760,001)	($594,725)
FTE Change - DHSS	0 FTE	2 FTE	2 FTE
ESTIMATED NET EFFECT ON THE MoPHS FUND	**$0**	**(Up to $469,040)**	**(Up to $12,804)**
Estimated Net FTE Change on the MoPHS fund	0 FTE	2 FTE	2 FTE
FEDERAL FUNDS			
Income - DSS (§191.332)			
Increase in reimbursement for SMA & MPS-II newborn screenings	$0	$0 to $14,459	$0 to $28,917
Transfer-out - DSS (§191.332)			
Transfer-out to DHSS MoPHS Fund for SMA & MPS-II newborn screening expenses	$0	$0 to ($14,459)	$0 to ($28,917)
ESTIMATED NET EFFECT ON FEDERAL FUNDS	**$0**	**$0**	**$0**

FISCAL IMPACT - Local Government	FY 2018 (10 Mo.)	FY 2019	FY 2020
	$0	**$0**	**$0**

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

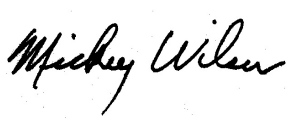
The proposed legislation will require the Missouri State Public Health Laboratory to increase the frequency of newborn screening testing to seven days per week. (Section 191.331)

This bill expands the newborn screening requirements to include spinal muscular atrophy (SMA) and Hunter syndrome (MPS-II). The department shall apply for available newborn screening grant funding specific to screening for SMA and MPS-II and shall have discretion in accepting the terms of such grants. (Section 191.332)

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



HWC:LR:OD

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