

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 4902-03
Bill No.: SCS for HB 1682 with SA 1, SA 2, SA 4 & SA 5
Subject: Professional Registration and Licensing; Physicians; Dentists; Chiropractors;
Optometrists; Healthcare; Health Care Professionals; Medicaid; Insurance -
Health; Insurance, Financial Institutions & Professional Registration Department;
Pharmacy; Drugs and Controlled Substances
Type: Original
Date: April 26, 2016

Bill Summary: This proposal requires licensure of certain health care professionals to be granted based on skill and academic competence, modifies vision care insurance and physician examination requirements, allows pharmacists to dispense maintenance medication in varying quantities, expands the newborn screening requirements to include severe combined immunodeficiency (SCID), and allows physician assistants to determine the necessity of physical or chemical restraint of a patient in a mental health facility or program.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
General Revenue	Unknown, less than \$50,000	Unknown, less than \$100,000	Unknown, less than \$100,000
Total Estimated Net Effect on General Revenue	Unknown, less than \$50,000	Unknown, less than \$100,000	Unknown, less than \$100,000

Numbers within parentheses: () indicate costs or losses.
This fiscal note contains 14 pages.

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
MoPHS	Could exceed \$54,761	Could exceed \$60,645	Could exceed \$48,214
Total Estimated Net Effect on <u>Other</u> State Funds	Could exceed \$54,761	Could exceed \$60,645	Could exceed \$48,214

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

* Income and transfer-out nets to \$0.

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
MoPHS	2	2	2
Total Estimated Net Effect on FTE	2	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 2017	FY 2018	FY 2019
Local Government	\$0	\$0	\$0

FISCAL ANALYSIS

ASSUMPTION

Senate Amendment 1 (§191.332):

In response to similar legislation (HB 1387), officials from the **Department of Health and Senior Services (DHSS)** provided the following assumptions:

Division of Community and Public Health

Based on information from states that have implemented severe combined immunodeficiency (SCID) screening, it is predicted that by adding SCID to the newborn screening panel, Missouri would have a total of 120 - 267 abnormal screenings annually that would need to be followed up on for a repeat screen or to coordinate with the treatment centers for confirmation of the disorders. Thus, it is assumed that the tracking and follow-up of SCID would exceed the current capacity of the newborn screening program.

Due to the nature of SCID, it would not be appropriate to add funding to the existing genetic contracts because newborns referred for follow-up after an abnormal SCID newborn screen would not be seen or followed in the genetic clinics. These newborns would be seen by immunologists and, if necessary, transplant teams. Therefore, the newborn screening program would require one (1) Public Health Senior Nurse (\$49,788 annually) to conduct and coordinate all follow-up activities for SCID newborn screening.

ASSUMPTION (continued)

The Public Health Senior Nurse responsibilities would include:

- Coordinating and facilitating a SCID Newborn Screening Task Force to advise the Newborn Screening program in the implementation of adding SCID to the newborn screening panel;
- Coordinating directly with the primary care provider, the family, and the specialists to confirm or rule out the disorder and assure treatment as appropriate;
- Developing any necessary parent educational materials on SCID;
- Revising the newborn screening pamphlet to include information on SCID;
- Collaborating with the Missouri State Public Health Laboratory to develop procedures for calling out high risk SCID newborn screening results;
- Collaborating with physicians, nurses, and other medical professionals to ensure all newborns with a high risk SCID newborn screen are followed-up appropriately including all necessary evaluations and tests to confirm or rule out a disorder;
- Ensuring all confirmatory results and diagnoses are received and documented in order to close out the cases;
- Responding to calls from families that receive letters regarding SCID or are calling to find out more about newborn screening;

- Continually evaluate and monitor SCID newborn screening to ensure policies and procedures are in alignment with best practice and evidence-based standards of care; and
- Any additional tasks or duties related to SCID newborn screening.

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

State Public Health Laboratory (SPHL):

The State Public Health Laboratory (SPHL) will need to hire one (1) additional FTE Senior Public Health Laboratory Scientist (\$41,940 annually) to be 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.

The job description for Senior Public Health Laboratory Scientist includes:

- Opening daily samples received and assessing for quality and suitability;
- Processing samples into split samples for the SCID testing platforms;

ASSUMPTION (continued)

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;
- Assessing the risk of abnormal results and contacting appropriate genetic referral center for confirmation and follow-up testing.
- 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.

All laboratory equipment and expense costs associated with SCID testing are based upon vendor quotes for technology currently available. The DHSS assumes the proposal will have a cost to the MoPHS Fund of \$657,801 for FY 2017; \$761,285 for FY 2018 and \$777,560 for FY 2019.

DHSS currently has the authority to set the fee per 191.331, RSMo. It will be necessary to raise the newborn screening fee to add SCID testing. These fund would be deposited into the Missouri Public Health Services (MoPHS) Fund. DHSS estimates that the fee will increase by \$9.00 when testing is begun.

Based on previous years, it is estimated the DHSS will perform 95,640 screens annually - 80,640 will be billed to the submitters (hospitals) and approximately 15,000 will be submitted to Medicaid. $15,000 \times \$9$ (can only claim Medicaid for the lab portion) $\times 60\%$ (Federal Medical Assistance Percentage rate) = \$81,000; $80,640 \times \$9 = \$725,760$; total annual income \$806,760 ($\$81,000 + \$725,760$).

The net estimated fiscal impact to the MoPHS Fund is expected to be \$148,959 for FY 2017; \$45,475 for FY 2018; and \$29,200 for FY 2019.

Oversight assumes the DHSS does not need additional space for 2 FTE.

ASSUMPTION (continued)

Oversight assumes the provisions of this proposal will take effect on January 1, 2017 when the state employee health insurance plan year goes into effect. In addition, Oversight assumes, based on the Department of Social Services, MO HealthNet response a 3.0% growth rate in Medicaid reimbursements for newborn screening expenses.

In response to similar legislation (HB 1387), officials from the **Department of Social Services (DSS), MO HealthNet Division (MHD)** stated by January 1, 2017, the Department of Health and Senior Services (DHSS) shall, subject to appropriations, expand the newborn screening requirements in section 191.331 to include severe combined immunodeficiency (SCID), also known as bubble boy disease.

Currently, newborn screenings are reimbursed by the MHD for the federal portion only. The general revenue portion is included in the DHSS budget.

In State Fiscal Year (SFY) 2014, the MHD was billed for approximately 15,000 newborn screenings by the State Health Lab. For this calculation, it is assumed the same number of screenings would be billed in SFY 2017 as billed in SFY 2014.

At this time the rate for the additional newborn screenings is unknown. Using DHSS' estimates that the rate will be \$9.00, the result would be \$135,000 (\$9 increase X 15,000 newborn screenings).

Fiscal Impact: Unknown, but at least:

FY 2017 (calculated for 6 months): Total Federal Funds \$42,679;
FY 2017 (3.0% trend factor): Total Federal Funds \$87,919; and,
FY 2018 (3.0% trend factor): Total Federal Funds \$90,556.

There is no fiscal impact on the Division of Legal Services.

In response to similar legislation (HB 1387), 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

ASSUMPTION (continued)

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 similar legislation (HB 1387), officials from the **University of Missouri Health Care** stated the proposed legislation has been reviewed and it has been determined that, as written, it should not result in a net loss in excess of \$100,000 based on the proposed revenue offset.

Oversight assumes this is an amount which the University assumes is an absorbable loss within current resource levels.

In response to similar legislation (HB 1387), 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 similar legislation (HB 1387), officials from the **Missouri Consolidated Health Care Plan** and the **Missouri Department of Transportation** each assumed the proposal would not fiscally impact their respective agencies.

In response to similar legislation (HB 1387), officials from the **Department of Public Safety, Missouri State Highway Patrol** deferred 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.

Senate Amendment 2 (§§191.1075, 191.1080, &191.1085):

In response to similar legislation (SB 635), officials from the **Department of Health and Senior Services (DHSS)** stated section 191.1080 creates the Missouri Palliative Care and Quality of Life Interdisciplinary Council and directs the DHSS to coordinate meeting logistics. These activities will be accomplished through the use of current staff.

Funds are requested for the reimbursement of travel expenses for the Council members to attend Council meetings. DHSS assumes the meetings will be held biannually. The cost per Council member to attend these meetings is calculated at \$180 per day for lodging, meals, and mileage.

ASSUMPTION (continued)

The total cost for the Council meetings in the first year is calculated at \$1,980 (11 members x 1 meeting x \$180). Subsequent years include a 2.5 percent cost of living increase and two meetings per year.

Total Cost:
FY 17: \$1,980 General Revenue (GR)
FY 18: \$4,059 GR
FY 19: \$4,160 GR

Section 191.1085 creates the Palliative Care Consumer and Professional Information and Education Program within DHSS. DHSS is to publish information and resources, including links to external resources, about palliative care on its website. Some resources are already identified on the DHSS website. The addition of further resources, links, etc. on the website will be accomplished through the use of current staff.

Oversight assumes DHSS appropriations are sufficient to cover the Council members' travel costs within current funding levels. If costs significantly exceed estimates, the DHSS may seek additional resources through the appropriations process.

In response to similar legislation (SB 635), officials from the **Office of the Governor (GOV)** stated section 191.1080 establishes the Missouri Palliative Care and Quality of Life Interdisciplinary Council which includes seven gubernatorial appointees. There should be no added cost to the GOV as a result of this measure. However, if additional duties are placed on the office related to appointments in other Truly Agreed To and Finally Passed (TAFP) legislation, there may be the need for additional staff resources in future years.

In response to similar legislation (SB 635), officials from the **University of Missouri (UM)** stated the proposal should not create additional expenses in excess of \$100,000.

Oversight assumes the UM's statement indicates any costs that may be incurred are absorbable within current funding levels.

In response to similar legislation (SB 635), officials from the **Joint Committee on Administrative Rules** assumed the proposal would not fiscally impact their agency.

In response to similar legislation (SB 635), 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

ASSUMPTION (continued)

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 similar legislation (SB 635), officials from the **Missouri Senate** assumed the proposal would not fiscally impact their agency.

Senate Amendment 4 (§630.175):

In response to similar legislation from 2014 (HB 1779), officials from the **Department of Mental Health (DMH)** stated it is anticipated that allowing the use of advanced practice registered nurses in the way described in the proposal, particularly during evenings and weekends, could result in savings compared to the cost of psychiatrists.

The number of occasions in which an advanced practice registered nurse might order restraints or seclusion in the place of a physician is unknown and unpredictable; therefore, the actual savings is unknown, but estimated to be less than \$100,000.

It should be noted that using advanced practice registered nurses for this purpose gives some facilities more timely access to mental health professionals capable of ordering seclusion and restraint, better ensuring facility compliance with national accreditation and certification standards.

In response to similar legislation from 2014 (HB1779), officials from the **Department of Insurance, Financial Institutions and Professional Registration** assumed the proposal would not fiscally impact their agency.

Oversight notes the provisions of the current proposal provides for physician assistants or assistant physicians, with a supervision agreement, to make the determination to use physical or chemical restraints when that chosen intervention is imminently necessary to protect the health and safety of the patient, resident, client or others. Since these provisions are very similar to the

ASSUMPTION (continued)

provisions provided for advanced practice registered nurses in TAFP'd HB 1779 (2014), Oversight assumes a similar fiscal impact - an Unknown, less than \$100,000 annual savings to the General Revenue Fund.

Senate Amendment 5 (§192.947):

Oversight notes the current provisions of the law at 192.945, RSMo, provide that the Department of Health and Senior Services (DHSS) shall issue a hemp extract registration care to a parent who, among other requirements, demonstrates that a minor in the parent's care suffers from intractable epilepsy and that this diagnosis is consistent with a record from the neurologist concerning the minor.

Section 192.947 provides that no individual or health care entity shall be subject to any adverse action by the state or any agency or board when acting in good faith upon or in furtherance of any order or recommendation by a neurologist authorized under section 192.945 relating to the medical use and administration of hemp extract with respect to an eligible patient. These provisions shall apply to the recommendation, possession, handling, storage, transfer, destruction, dispensing, or administration of hemp extract, including any act in preparation of such dispensing or administration.

Oversight assumes Senate Amendment 5 will have no fiscal impact.

In response to the previous version of SCS for HB 1682, officials from the **Department of Health and Senior Services**, the **Department of Insurance, Financial Institutions and Professional Registration**, the **Department of Mental Health**, the **Department of Social Services**, the **Missouri Consolidated Health Care Plan**, the **Missouri Department of Conservation** and the **Missouri Department of Transportation** each assumed the proposal would not fiscally impact their respective agencies.

Officials from the **Department of Public Safety, Missouri State Highway Patrol** deferred 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 2017 (6 Mo.)	FY 2018	FY 2019
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FEDERAL FUNDS
 (\$191.332)

Income - DSS - SA 1

Increase in reimbursement for SCID newborn screening expenses	At least \$42,679	At least \$87,919	At least \$90,556
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Transfer-out - DSS - SA 1

Transfer-out to DHSS MoPHS Fund for SCID newborn screening expenses	<u>(At least)</u> <u>\$42,679</u>	<u>(At least)</u> <u>\$87,919</u>	<u>(At least)</u> <u>\$90,556</u>
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**ESTIMATED NET EFFECT ON
 FEDERAL FUNDS**

	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>
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<u>FISCAL IMPACT - Local Government</u>	FY 2017 (6 Mo.)	FY 2018	FY 2019
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	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>
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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 requires the Department of Health and Senior Services, subject to appropriations, to add severe combined immunodeficiency (SCID), also known as the bubble boy disease to the list of newborn screening requirements. (\$191.332)

Under current law, physical or chemical restraints, isolation, or seclusion cannot be used on patients, residents or clients of a mental health facility or mental health program unless it is determined by the head of the facility or the attending licensed physician that it is necessary to protect the health and safety of the individual or others and that it provides the least restrictive

FISCAL DESCRIPTION (continued)

environment. This proposal allows such orders to also be made by an advanced practice registered nurse (APRN) in a collaborative practice arrangement with the attending licensed physician for certain patients in facilities or programs that only provide psychiatric care and in dedicated psychiatric units.

If the APRN orders the use of restraints, isolation or seclusion, it shall be reviewed in person by the attending licensed physician if the episode of restraint extends beyond 4 hours duration for a person under 18 years of age, or beyond 8 hours duration for a person 18 years of age or older, or for any total length of restraint lasting more than four hours duration in a 24 hour period in the case of a person under 18 years of age, or beyond eight hours duration in the case of a person over 18 years of age in a 24 hour period.

Depending on the circumstances under which an individual has been committed to the facility, security escort devices may be used when such individuals are transported outside a mental health facility based on the determination of the head of the facility or the attending licensed physician. This proposal allows such determinations to also be made by the attending advanced practice registered nurse in a collaborative practice arrangement with the attending licensed physician.

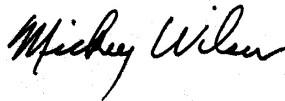
All orders made by the APRN under this proposal shall be reviewed in person by the attending licensed physician of the facility within 24 hours or the next regular working day of the order being issued, and such review shall be documented in the clinical record of the patient, resident, or client. The APRN shall also document the use of the restraint, isolation or seclusion.

Restraint or seclusion shall not be used in habilitation centers or community programs that serve persons with developmental disabilities that are operated or funded by the Division of Developmental Disabilities unless such procedure is part of an emergency intervention system approved by the Division and is identified in such person's individual support plan. (§630.175)

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 Insurance, Financial Institutions
and Professional Registration
Department of Mental Health
Department of Public Safety -
Missouri State Highway Patrol
Department of Social Services -
MO HealthNet Division
Office of the Governor
Joint Committee on Administrative Rules
Missouri Consolidated Health Care Plan
Missouri Department of Conservation
Missouri Department of Transportation
Missouri Senate
Office of Secretary of State
University of Missouri



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