

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 1155-05
Bill No.: HCS for SCS for SB 266
Subject: Health Care; Health Care Professionals; Health Department; Health, Public;
Medical Procedures
Type: Original
Date: May 7, 2001

FISCAL SUMMARY

ESTIMATED NET EFFECT ON STATE FUNDS			
FUND AFFECTED	FY 2002	FY 2003	FY 2004
All funds	(Unknown)	(Unknown)	(Unknown)
General Revenue	(\$1,657,263)	(\$1,929,538)	(\$487,056)
Missouri Public Health Services	\$0	\$0	\$0
Highway	\$0 to (\$38,000)	\$0 to (\$38,000)	\$0 to (\$38,000)
Total Estimated Net Effect on <u>All</u> State Funds	(\$1,657,263 TO \$1,695,263)	(\$1,929,538 TO \$1,967,538)	(\$487,056 TO \$525,056)

***Subject to appropriation and does not include potential increased state contributions for state health plans.**

ESTIMATED NET EFFECT ON FEDERAL FUNDS			
FUND AFFECTED	FY 2002	FY 2003	FY 2004
None			
Total Estimated Net Effect on <u>All</u> Federal Funds	\$0	\$0	\$0

ESTIMATED NET EFFECT ON LOCAL FUNDS			
FUND AFFECTED	FY 2002	FY 2003	FY 2004
Local Government	(UNKNOWN)	(UNKNOWN)	(UNKNOWN)

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

FISCAL ANALYSIS

ASSUMPTION

Section 191.332

Officials from the **Department of Insurance** and the **Department of Conservation** assume this proposal would not fiscally impact their agencies.

Missouri Consolidated Health Care Plan (HCP) officials state since the cost of newborn screenings are covered under HCP health plans this proposal would have an impact on HCP. HCP states they have researched the tests listed and determined their usual and customary charges. HCP states the cost range from \$16 to \$176 for each screening listed. HCP states this cost represents the initial cost and the qualitative cost that would result if the results were positive. Positive results would require the providers to run even more tests. HCP states the health plans would try to recoup their costs by increasing premiums. HCP states the cost associated with this proposal, however, is too difficult to determine.

Officials from the **Department of Transportation (DHT)** state the corrected impact is a decrease from the previous fiscal impact. DHT states the difference is that DHT have been told by the Department of Health (DOH) what the fee would be for performing the newborn screenings. In the previous response DHT did not have the information from DOH and so DHT based the impact on the usual and customary rates for a provider to do the various additional screenings. DHT assumes that health care third party payers would be responsible for the cost of the newborn screenings listed in this proposal, there would be a fiscal impact to the Highway and Patrol Medical Plan. DOH provided a fee of \$38 for the expanded newborn screenings. Since the current the fee is \$13, the increased fee amount is \$25 per screening. The Medical Plan has had an average of 1,520 new births each year over the past three years. Assuming that DOH is going to charge \$38 for all the screenings listed in the proposal and the Medical Plan would be responsible for the cost of those screenings, there would be a fiscal impact of approximately \$38,000 per year (1,520 births x \$25 fee increase). DHT's percentage of total participants is 75% for a cost of \$28,500 and the Patrol's percentage of total participants is 25% for a cost of \$9,500. Historically, the department and the plan members have shared in any premium increases necessary because of increases in benefits. The costs may be shared in the long run (meaning

ASSUMPTION (continued)

shared between three categories: absorbed by the plan, state appropriated funds, and/or costs to individuals covered under the plan). However, the department (commission) must make a decision on what portion they will provide. Until the commission makes a decision, we can only provide the cost to the medical plan.

Office of Secretary of State (SOS) officials state this proposal would require the Department of Health to promulgate rules to implement new ambulance regulations. SOS states that based on experience with other divisions, the rules, regulations and forms issued by the Department of Health could require as many as 24 pages in the Code of State Regulations. For any given rule, roughly half again as many pages are published in the Missouri Register in the Code because cost statements, fiscal notes and the like are not repeated in Code. These costs are estimated. The estimated cost of a page in the Missouri Register is \$23.00. The estimated cost of a page in the Code of State Regulations is \$27.00. The actual cost could be more or less than the numbers given. The impact of this proposal in future years is unknown and depends upon the frequency and length of rules filed, amended, rescinded or withdrawn.

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. Any decisions to raise fees to defray costs would likely be made in subsequent fiscal years.

Officials from the **Department of Social Services - Division of Medical Services (DMS)** do not anticipate a fiscal impact as a result of this proposal. DMS assumes that physicians would be checking for these potentially treatable or manageable disorders in the EPSDT screenings. DMS states the new screening requirements could be incorporated with the current newborn screenings required in Section 191.131.

Department of Health (DOH) officials assume the following:

State Public Health Lab

DOH states this proposal would add at least 17 new genetic conditions to the existing four conditions that the DOH's State Public Health Lab (SPHL) presently screens all newborns for. It would add a series of genetic diseases which are detected through the use of a new laboratory technology called Tandem Mass Spectrometry (TMS). Recent advances in Tandem Mass Spectrometry allow simultaneous detection of 20-30 genetic disorders. Most states, at least initially, use TMS to screen for 14 disorders that have been found to be more prevalent in the population and for which medical treatment is possible. DOH assumes, if this proposal would pass, Missouri would use TMS to initially screen for the 14 disorders the other states are also testing for.

ASSUMPTION (continued)

In addition to the disorders that can be detected with TMS, this proposal instructs DOH to screen for three other genetic conditions. These three are cystic fibrosis, biotinidase deficiency and glucose-6-phosphate dehydrogenase deficiency (G-6-PD). Laboratory techniques to screen newborns for these three conditions exist and a few states are testing for them. In determining costs, TMS and the separate costs to perform the three other conditions were examined.

DOH officials state the SPHL uses three phases to implement new newborn screening tests. The first phase would be to acquire new instrumentation, hiring and training staff, and learning how to perform the laboratory testing. The second phase would be what is termed a "pilot phase". In this phase a selected group of newborns would be tested. This would be a statistically significant percentage of the population to verify testing performance, establish DOH follow-up and case management procedures and determine baseline frequency/incidence of the genetic disorders. The final phase would be to provide statewide testing for the approximate 75,000 Missouri births per year. DOH states that phase one and two typically each last one year.

DOH officials state the SPHL funds newborn screening through a fee system. Birthing facilities are required to pay the actual laboratory costs of testing all births that occur in their facilities. This fee would not imposed until the SPHL is conducting statewide testing (phase 3). DOH assumes, for this fiscal note, that general revenue would be needed to cover the expenses for phase one and phase two, that could not be latter recovered through the fee system. After year two, all expenses would be covered by the fee system and all revenue placed within the Missouri Public Health Services Fund.

First Year Expenses

Personnel – in order to carry out the additional testing involves adding 17 new testing parameters on 100,000 samples per year (75,000 initial birth samples and 25, 000 follow-up samples) additional staffing would be required. Listed below are the classifications, number required, and brief job descriptions:

Computer Info Technology Specialist (1) – integrate testing data into existing data system for reporting and case management.

Senior Public Health Laboratory Scientist (2) – Method development, instrument calibration and performance, establish quality assurance, determine test interpretation standards.

Public Health Laboratory Scientist (7) – Instrument calibration, test performance, quality control, test result interpretation and reporting.

Medical Laboratory Technician II (3) – Specimen processing, test performance, and laboratory support functions.

ASSUMPTION (continued)

Clerk Typist II (3) –Specimen data entry, specimen result reporting, and data management

Equipment and Expense – Costs for the first year would consist of 1st year equipment leasing, computer and data handling equipment, facility modification, standard employee equipment costs, and a small amount of testing reagents (chemicals used to conduct the testing). Also would included one time laboratory support equipment which would be purchased and not leased.

One-time laboratory related equipment (centrifuges, refrigerators, specimen preparation machines)	\$ 85,000
One-time data handling equipment	\$ 45,000
One-time facility modification	\$ 25,000
Standard employee equipment cost	\$212,063
Equipment leasing cost (9 months)	\$230,000
Laboratory reagents	\$ 30,000

Second Year SPHL Expenses

Personnel – 2nd year would be the same as 1st year with the addition of inflation factors.

Equipment and Expense – 2nd year costs would consist of standard employee equipment cost that are not one-time expenditures, laboratory equipment leasing, and laboratory reagent cost to conduct pilot testing (approximately 50,000 samples).

Standard employee equipment cost	\$199,120
Equipment leasing cost	\$306,600
Laboratory reagents	\$210,000

ASSUMPTION (continued)

Third Year SPHL Expenses

Note: 3rd year expenses and beyond would not be General Revenue, but would be paid for with user fees. These would be deposited with the Missouri Public Health Services Fund.

Personnel – 3rd year would be the same as the 2nd year with the addition of inflation factors.

Standard DOH indirect rate is assessed on all non-General Revenue funds in accordance with agreement with the federal government @ 37.5% of salaries and fringe.

Equipment and Expense – 3rd year costs would consist of standard employee equipment cost that are not one-time expenditures, laboratory equipment leasing, and laboratory reagent cost to provide for state-wide testing (100,000 samples).

Standard employee equipment cost	\$205,094
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Equipment leasing cost	\$306,600
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Laboratory reagents	\$420,000
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Fee revenue is projected in year three as a total of \$38 per test. The current rate is \$13 to cover the four conditions the laboratory currently tests for. Through the rule-making process, action would be taken to increase this amount. For the purposes of this fiscal note, the estimated increase in fee to test for these additional conditions is \$20 per test.

Maternal Child and Family Health (MCFH)

The Division of Maternal Child and Family Health (MCFH) would need to hire a Health Program Representative III. This position would have the following job responsibilities: track and follow-up on those newborns who have an abnormal (borderline and presumptive positive) newborn screen results; ensure that either the infant has returned for a repeat newborn screen or has had a confirmatory test done; ensure those infants found to be positive are entered into a system of health care; research each of the 20 -30 conditions; develop informational material (pamphlets, fact sheets) on the 20 -30 conditions to distribute to parents, health care providers, local public health departments and the general public; provide educational programs to health care providers, birthing hospitals and local health departments about the expansion in the newborn screening program, and respond to questions from parents and health care professionals have about the condition or newborn screen results. In addition, the HPR III would refer abnormals to a treatment center for confirmatory testing, develop invitation for bids and monitor

ASSUMPTION (continued)

contracts that are awarded to four treatment centers, monitor state and federal legislation, collect baseline data on the incidence of the 20 -30 conditions screened for in Missouri, participate in research to determine the incidence of the 20 -30 conditions in the those state who screen using TMS on the incidence of those conditions which are screened. Because not only the incidence of the condition or how many infants would have the trait is unknown it is anticipated that there would be 30 trait carriers per 1 positive condition. This is based upon galactosemia in which the incidence is 1/50,000 resulting in 1 positive per year but 40 presumptive positives requiring follow-up, resulting in approximately 30 trait carriers per year.

Congenital Adrenal Hyperplasia 1/10,000	7 positives per year
Cystic Fibrosis 1/2,500	30 positives per year
Biotinidase deficiency 1/90,000	1 positive per 2 years
Maple Syrup Urine Disease 1/200,000 but 1/750 Mennonite Population	1 positive per year
Propionic Acidemia 1/100,000	1 positive per 2 years
Glutaric Acidemia Type I	Unknown
Glucose 6-phosphate dehydrogenase deficiency (G-6-PD)	Unknown
Fatty Acid Oxidation Disorders (7 disorders)	
Medium Chain Acyl-CoA Dehydrogenase Deficiency 1/10,000	7 positives per year
Long Chain 3-Hydroxyacyl CoA Dehydrogenase 1/50,000	1 positive per year
Very Long chain Acyl-CoA Dehydrogenase Deficiency	Unknown
Short Chain Acyl-CoA Dehydrogenase Deficiency	Unknown
Carinitine Palmitoyltransferase Deficiency Type II	Unknown
Glutaric Acidemia Type II	Unknown
2,4 Dienoyl-CoA Reductase Deficiency	Unknown
Organic Aciduria Disorders (7 Disorders)	
Glutaryl CoA Dehydrogenase Deficiency Type I 1/30,000	2 positives per year
Propionyl CoA Carboxylase Deficiency 1/50,000	1 positive per year
Methylmalonic Acidemia 1/50,000	1 positive per year
Isovaleryl CoA Dehydrogenase Deficiency 1/50,000	1 positive per year
3-Methylcrotonyl CoA Carboxylase Deficiency	Unknown
Mitochondrial Acetoacetyl CoA Thiolase Deficiency	Unknown
3-Hydroxy-3-Methylglutaryl-CoA Lyase Deficiency	Unknown

DOH states they would contract with four treatment centers at \$50,000 per center. Total General Revenue needed would be \$200,000. The centers would provide the following services: metabolic/genetic consultation to the DOH - State Public Health Laboratory and the Newborn Screening Program, birthing hospitals, local health departments and providers of health care to infants and children and parents on all abnormal newborn screen results; genetic counseling to those families whose infant is either positive (approximately 50) or has the trait for the condition (this number is unknown but extrapolating from the number of infants who have the trait for

ASSUMPTION (continued)

galactosemia, 1 positive per year and 30 trait carriers); and interpret results of confirmatory diagnosis.

DOH would also contract with an agency at \$75,000 to evaluate the Newborn Screening Program. Evaluation would include evaluating the program processes, procedures, and appropriateness of tracking and follow-up procedures, program goals, objectives and outcomes.

Section 191.714

Officials from the **Department of Elementary and Secondary Education**, the **Department of Mental Health**, the **Department of Public Safety - Capitol Police**, the **Department of Public Safety - Veterans' Commission**, and the **Department of Social Services** assume this proposal would not fiscally impact their agencies.

Officials from the **Department of Health (DOH)** state that one Consultant Community Health Nurse (CCHN) would be required to establish the DOH program, to develop for adoption a blood-borne pathogen standard governing occupational exposure of public employees to blood and other potentially infectious materials, and to develop the department's written exposure control plan. The CCHN would be responsible for collecting and recording the required data on exposure incidents in the sharps injury log, assessing engineering, administrative, or work practice controls to prevent such incidents/injuries, to train department staff, and lead the evaluation committee. The CCHN would develop additional measures to prevent sharps injuries or exposure incidents, compile and maintain a list of needleless systems and sharps with engineered sharps injury protection, and prepare the annual report on the use of needle safety technology as a means of reducing needlestick injuries and to place the report on the Department's internet site.

The **Department of Corrections (DOC)** and the **Department of Public Safety - Missouri State Highway Patrol (MHP)** officials did not respond to our fiscal impact request. However, in responding to a similar proposal from the current session DOC and MHP assumed no fiscal impact to their agencies.

Section 191.938

Officials from the **Office of Administration** assume this proposal would not fiscally impact their agency.

Department of Health (DOH) officials state there would be expenses for five committee

ASSUMPTION (continued)

members meeting four times a year. DOH stated this would be \$65 for lodging, \$45 for meals, and \$75 for travel per meeting per member. DOH assumes the administrative and technical support to the committee would be provided using existing resources with DOH's Bureau of Emergency Medical Services.

Section 192.729

Officials from the **Department of Health (DOH)** assume that at a minimum one additional staff person would be needed. A Health Educator I (\$30,204) would be responsible for planning, coordination of daily program operation, and integration of the lupus program in all seven Regional Arthritis Centers. In order to track and monitor the prevalence of lupus the existing surveillance system can be utilized, once modified. DOH anticipates that data collection and analysis would be conducted in-house. DOH states that regional arthritis centers would receive \$5,000 each for educational efforts to include materials and related expenses. When initial surveillance activities are completed and if prevalence is found to be higher in the urban areas, contracts would be adjusted.

Oversight assumes that DOH could use the existing resources of the Office of Women's Health, the Office of Minority Health, and the State Arthritis Program to track and monitor the prevalence of lupus.

<u>FISCAL IMPACT - State Government</u>	FY 2002 (10 Mo.)	FY 2003	FY 2004
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ALL FUNDS

Cost - All Funds

Increased state contributions	(Unknown)	(Unknown)	(Unknown)
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ESTIMATED NET EFFECT ON ALL FUNDS

<u>(UNKNOWN)</u>	<u>(UNKNOWN)</u>	<u>(UNKNOWN)</u>
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<u>FISCAL IMPACT - State Government</u>	FY 2002 (10 Mo.)	FY 2003	FY 2004
GENERAL REVENUE FUND			
<u>Costs - Department of Health (section 191.332)</u>			
Personal services (17 FTE)	(\$487,131)	(\$599,171)	(\$42,050)
Fringe benefits	(\$162,361)	(\$199,704)	(\$14,015)
Expense and equipment	(\$900,052)	(\$1,012,497)	(\$305,561)
Total <u>Costs</u> - Department of Health*	<u>(\$1,549,544)</u>	<u>(\$1,811,372)</u>	<u>(\$361,626)</u>
<u>Transfer Out - Department of Health (section 191.332)</u>			
Transfer to Missouri Public Health Services Fund*	\$0	\$0	(\$8,925)
<u>Costs - Department of Health (section 191.714)</u>			
Personal services (1 FTE)	(\$41,974)	(\$51,628)	(\$52,918)
Fringe benefits	(\$13,990)	(\$17,208)	(\$17,638)
Expense and equipment	(\$13,055)	(\$10,630)	(\$10,949)
Total <u>Costs</u> - Department of Health	<u>(\$69,019)</u>	<u>(\$79,466)</u>	<u>(\$81,505)</u>
<u>Costs - Department of Health (section 191.938)</u>			
Board meeting expenses	(\$3,700)	(\$3,700)	\$0
<u>Costs - Department of Health (section 192.729)</u>			
Expense and equipment	(\$35,000)	(\$35,000)	(\$35,000)
ESTIMATED NET EFFECT ON GENERAL REVENUE FUND	<u>(\$1,657,263)</u>	<u>(\$1,929,538)</u>	<u>(\$487,056)</u>

***Subject to appropriation.**

MISSOURI PUBLIC HEALTH SERVICES FUND

<u>Income - Department of Health</u>			
Testing fees	\$0	\$0	\$2,000,000

MW:LR:OD (12/00)

<u>FISCAL IMPACT - State Government</u>	FY 2002 (10 Mo.)	FY 2003	FY 2004
<u>Transfer In - Department of Health</u>			
Transfer from General Revenue Fund	\$0	\$0	\$8,925
<u>Costs - Department of Health</u>			
Personal services (16 FTE)	\$0	\$0	(\$572,100)
Fringe benefits	\$0	\$0	(\$190,681)
Expense and equipment	<u>\$0</u>	<u>\$0</u>	<u>(\$1,246,144)</u>
Total <u>Costs</u> - Department of Health	<u>\$0</u>	<u>\$0</u>	<u>(\$2,008,925)</u>
ESTIMATED NET EFFECT ON MISSOURI PUBLIC HEALTH SERVICES FUND	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

HIGHWAY FUND

<u>Cost - Department of Transportation</u>			
Increased contributions	\$0 to (\$28,500)	\$0 to (\$28,500)	\$0 to (\$28,500)
<u>Cost - Department of Public Safety - Missouri State Highway Patrol</u>			
Increased contributions	<u>\$0 to (\$9,500)</u>	<u>\$0 to (\$9,500)</u>	<u>\$0 to (\$9,500)</u>
ESTIMATED NET EFFECT ON HIGHWAY FUNDS*	<u>\$0 TO (\$38,000)</u>	<u>\$0 TO (\$38,000)</u>	<u>\$0 TO (\$38,000)</u>

***Could exceed \$100,000 annually.**

<u>FISCAL IMPACT - Local Government</u>	FY 2002 (10 Mo.)	FY 2003	FY 2004
LOCAL POLITICAL SUBDIVISIONS			
<u>Costs - Local Political Subdivisions</u>			
Increased contributions	<u>(Unknown)</u>	<u>(Unknown)</u>	<u>(Unknown)</u>

FISCAL IMPACT - Local Government

FY 2002
(10 Mo.)

FY 2003

FY 2004

**ESTIMATED NET EFFECT ON
LOCAL POLITICAL SUBDIVISIONS**

(UNKNOWN)

(UNKNOWN)

(UNKNOWN)

FISCAL IMPACT - Small Business

Small businesses would expect to be fiscally impacted to the extent that they could have an increase in health insurance premiums, additional administrative expenses, and loss of revenue as a result of the requirements of this proposal.

DESCRIPTION

This proposal contains provisions pertaining to programs in the Department of Health.

Screening of newborns

This portion of the proposal would authorize the Department of Health to expand the newborn screening requirements of Section 191.331, RSMo, by including screening for various potentially treatable disorders, including cystic fibrosis, galactosemia, and congenital adrenal hyperplasia. The expansion of the screening would be subject to appropriations and would be required to be completed by January 1, 2002. The department would be required to promulgate rules to implement the provisions of this portion of the proposal.

Exposure control for blood-borne pathogens

This portion of the proposal would require the Department of Health to adopt a blood-borne pathogen standard governing the occupational exposure of public employees to blood and other potentially infectious materials. The portion of the proposal would:

- (1) require the department to develop a standard that would meet the standard developed by the Occupational Safety and Health Administration (OSHA). The standard would be adopted no later than February of 2002;
- (2) exempt the use of a drug or biologic that is pre-packaged or used in a pre-filled syringe from the blood-borne pathogen standard. This exemption would expire on June 1, 2004;
- (3) require the establishment of an evaluation committee and would specify the members, qualifications, and duties of the committee;

MW:LR:OD (12/00)

DESCRIPTION (continued)

(4) require the department to compile and maintain a list of needleless systems and sharps with engineered sharps injury protection;

(5) require the department to issue an annual report on the use of needle safety technology to the Governor, State Auditor, President Pro Tem of the Senate, Speaker of the House of Representatives, and the Technical Advisory Committee on the Quality of Patient Care and Nursing Practices by February 1 of each year. The report would be available to the public on the department's web site by February 15 of each year;

(6) require persons to report a suspected violation; and

(7) subject an employer to a reduction or loss in state funding for violating provisions of this portion of the proposal.

Automated External Defibrillator Advisory Committee

This portion of the proposal would establish an Automated External Defibrillator Advisory Committee within the Department of Health, subject to appropriations. The committee would advise the department, Office of Administration, and the General Assembly on the feasibility of placing automated external defibrillators in public buildings. The committee would issue a final report by December 31, 2002, and the committee would terminate on June 1, 2003.

Statewide Lupus Program

This portion of the proposal would establish a statewide Systemic Lupus Erythematosus Program in the Department of Health. Subject to appropriations, the program would be required to:

(1) track and monitor the prevalence of lupus;

(2) identify medical professionals and providers who specialize in the treatment of lupus and related diseases; and

(3) promote lupus research and public awareness through collaboration with academic researchers, local boards, and the Missouri Chapter of the Lupus Foundation.

The department can utilize or expand existing programs such as the state Arthritis Program, Office of Minority Health, and the Office of Women's Health to meet the requirements of this portion of the proposal.

DESCRIPTION (continued)

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

SOURCES OF INFORMATION

Department of Health
Department of Insurance
Missouri Consolidated Health Care Plan
Department of Transportation
Department of Social Services
Department of Conservation
Department of Public Safety
Missouri State Highway Patrol
Office of Secretary of State
Department of Mental Health
Department of Elementary and Secondary Education
Department of Public Safety - Capitol Police
Department of Public Safety - Veterans' Commission
Office of Administration
Department of Health

NOT RESPONDING: Department of Corrections



Jeanne Jarrett, CPA
Director

May 7, 2001