

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 1815-01
Bill No.: SB 375
Subject: Health Care; Insurance - Medical; Medical Procedures and Personnel
Type: Original
Date: February 23, 2009

Bill Summary: Provides health insurance coverage for Phase I clinical trials for cancer treatment.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2010	FY 2011	FY 2012
General Revenue	(Unknown exceeding \$33,500)	(Unknown exceeding \$67,000)	(Unknown exceeding \$67,000)
Total Estimated Net Effect on General Revenue Fund	(Unknown exceeding \$33,500)	(Unknown exceeding \$67,000)	(Unknown exceeding \$67,000)

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2010	FY 2011	FY 2012
Insurance Dedicated	Up to \$5,600	\$0	\$0
Conservation Commission	(Unknown)	(Unknown)	(Unknown)
Road	(Unknown exceeding \$50,000)	(Unknown exceeding \$100,000)	(Unknown exceeding \$100,000)
Other	(Unknown exceeding \$6,000)	(Unknown exceeding \$12,000)	(Unknown exceeding \$12,000)
Total Estimated Net Effect on Other State Funds	(Unknown exceeding \$50,400)	(Unknown exceeding \$112,000)	(Unknown exceeding \$112,000)

Numbers within parentheses: () indicate costs or losses.

This fiscal note contains 7 pages.

ESTIMATED NET EFFECT ON FEDERAL FUNDS			
FUND AFFECTED	FY 2010	FY 2011	FY 2012
Federal	(Unknown exceeding \$10,500)	(Unknown exceeding \$21,000)	(Unknown exceeding \$21,000)
Total Estimated Net Effect on <u>All</u> Federal Funds	(Unknown exceeding \$10,500)	(Unknown exceeding \$21,000)	(Unknown exceeding \$21,000)

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2010	FY 2011	FY 2012
Total Estimated Net Effect on FTE	0	0	0

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

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

ESTIMATED NET EFFECT ON LOCAL FUNDS			
FUND AFFECTED	FY 2010	FY 2011	FY 2012
Local Government	(Unknown)	(Unknown)	(Unknown)

FISCAL ANALYSIS

ASSUMPTION

Officials from the **Department of Health and Senior Services** assume the proposal will not fiscally impact their organization.

Officials from the **Department of Social Services (DOS)** state the requirement for health insurers to cover routine patient care costs incurred as a result of a patient's participation in phase I clinical trials for cancer treatment will not result in an impact to the MO HealthNet Division because Section 376.429.8, RSMo, exempts any policy, plan, or contract paid under Title XVIII or Title XIX (Medicaid) of the Social Security Act.

Officials from the **Department of Public Safety (DPS) - Directors' Office** state they are unable to determine the fiscal impact of the proposal and defer to the Missouri Consolidated Health Care Plan for response regarding the potential fiscal impact.

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

Officials from the **Missouri Department of Conservation (MDC)** state the proposed legislation would have a significant impact to the medical insurance expenses of the MDC. However, since there is no accurate way to estimate the fiscal impact of this type of service, the exact amount of impact is unknown.

Officials from the **Department of Insurance, Financial Institutions and Professional Registration (DIFP)** estimate up to 90 insurers and 22 HMOs (from 2007 supplemental data reports) would be required to submit amendments to their policies to comply with the legislation. Policy amendments must be submitted to the department for review along with a \$50 filing fee. One-time additional revenues to the Insurance Dedicated Fund are estimated to be up to \$5,600.

Additional staff and expenses are not being requested with this single proposal, but if multiple proposals pass during the legislative session which require policy form reviews, the DIFP will need to request additional staff to handle the increase in workload.

Officials from the **Missouri Consolidated Health Care Plan (HCP)** state current state law requires coverage for costs incurred as a result of phase II, III, or IV of a clinical cancer trial. Coverage includes routine patient care costs incurred for drugs and devices that have been approved by the FDA; reasonable and medically necessary services needed to administer the drug or use the device under evaluation in the clinical trial.

ASSUMPTION (continued)

Due to varying treatments, more physician visits, more tests and more pathology reports of participants in a phase I clinical cancer trial compared to those of non-participants, phase I trials could have substantially higher treatment cost and may result in an increase in the plan's financial risk.

Predicting the financial impact of mandatory coverage of phase I cancer trials is extremely difficult, and therefore, unknown. However, mandated coverage, in general, ends up adding cost to the plan. The HCP assumes the proposal would result in unknown costs exceeding \$100,000 annually.

Officials from the **Missouri Department of Transportation (DOT)** assume an unknown fiscal impact from this legislation. The Highway and Patrol Medical Plan is not within the definition of health benefit plan but section 104.801 RSMo would require the medical plan to offer similar coverage. Currently the Medical Plan is mandated to cover phases II, III and IV of a clinical trial, but not phase I. As a result, this legislation will have a fiscal impact on the Highway and Patrol Medical Plan.

According to information from the American Cancer Society's website, the purpose of phase I of clinical trials are the first studies of a new treatment or drug that involve people as participants. The studies usually include small numbers of people and are usually reserved for individuals who do not have good treatment options left to them. Phase I is to determine a treatment's safety. If a new treatment is found to be reasonably safe in phase I of a clinical trial, the treatment can then be tested for effectiveness in a phase II clinical trial. Phase II clinical trials include a somewhat larger group of patients and are used to determine a treatment's effectiveness. Currently, phase I of clinical trials would be considered investigational under the Highway and Patrol Medical Plan and would not be a covered benefit.

The DOT assumes if health carriers are required to cover the costs of services and drugs in phase I clinical trials that pharmaceutical and biotechnology companies and other cooperative groups that conduct and sponsor these studies would no longer pay for any of the related costs to phase I trials. Assuming this is true, the DOT feels the fiscal impact to the Medical Plan would be very significant. Without knowing the types of drugs, devices or services necessary to conduct the trials or how many individuals would participate, it is impossible to calculate a fiscal impact to the Medical Plan. The fiscal impact to the DOT/Missouri State Highway Patrol (MHP) Medical Plan would be greater than \$100,000.

Oversight assumes the health benefit coverage for state employees would become effective January 1, 2010.

<u>FISCAL IMPACT - State Government</u>	FY 2010 (6 Mo.)	FY 2011	FY 2012
GENERAL REVENUE			
<u>Costs - HCP</u>			
Increase in state employee insurance costs	<u>(Unknown exceeding \$33,500)</u>	<u>(Unknown exceeding \$67,000)</u>	<u>(Unknown exceeding \$67,000)</u>
ESTIMATED NET EFFECT ON GENERAL REVENUE FUND	<u>(Unknown exceeding \$33,500)</u>	<u>(Unknown exceeding \$67,000)</u>	<u>(Unknown exceeding \$67,000)</u>
INSURANCE DEDICATED FUND			
<u>Income - DIFP</u>			
Form filing fees	<u>Up to \$5,600</u>	<u>\$0</u>	<u>\$0</u>
ESTIMATED NET EFFECT ON INSURANCE DEDICATED FUND	<u>Up to \$5,600</u>	<u>\$0</u>	<u>\$0</u>
CONSERVATION COMMISSION FUND			
<u>Cost - MDC</u>			
Increase in health insurance costs	<u>(Unknown)</u>	<u>(Unknown)</u>	<u>(Unknown)</u>
ESTIMATED NET EFFECT ON CONSERVATION COMMISSION FUND	<u>(Unknown)</u>	<u>(Unknown)</u>	<u>(Unknown)</u>
ROAD FUND			
<u>Cost - DOT</u>			
Increase in health insurance costs	<u>(Unknown exceeding \$50,000)</u>	<u>(Unknown exceeding \$100,000)</u>	<u>(Unknown exceeding \$100,000)</u>
ESTIMATED NET EFFECT ON ROAD FUND	<u>(Unknown exceeding \$50,000)</u>	<u>(Unknown exceeding \$100,000)</u>	<u>(Unknown exceeding \$100,000)</u>

<u>FISCAL IMPACT - State Government</u>	FY 2010 (6 Mo.)	FY 2011	FY 2012
OTHER STATE FUNDS			
<u>Costs - HCP</u>			
Increase in state employee insurance costs	<u>(Unknown exceeding \$6,000)</u>	<u>(Unknown exceeding \$12,000)</u>	<u>(Unknown exceeding \$12,000)</u>
ESTIMATED NET EFFECT ON OTHER STATE FUNDS	<u>(Unknown exceeding \$6,000)</u>	<u>(Unknown exceeding \$12,000)</u>	<u>(Unknown exceeding \$12,000)</u>
FEDERAL FUNDS			
<u>Costs - HCP</u>			
Increase in state employee health insurance costs	<u>(Unknown exceeding \$10,500)</u>	<u>(Unknown exceeding \$21,000)</u>	<u>(Unknown exceeding \$21,000)</u>
ESTIMATED NET EFFECT ON FEDERAL FUNDS	<u>(Unknown exceeding \$10,500)</u>	<u>(Unknown exceeding \$21,000)</u>	<u>(Unknown exceeding \$21,000)</u>
<u>FISCAL IMPACT - Local Government</u>	FY 2010 (6 Mo.)	FY 2011	FY 2012
ALL LOCAL GOVERNMENTS			
<u>Costs - All Local Governments</u>			
Increase in employee health insurance costs	<u>(Unknown)</u>	<u>(Unknown)</u>	<u>(Unknown)</u>
ESTIMATED NET EFFECT ON ALL LOCAL GOVERNMENTS	<u>(Unknown)</u>	<u>(Unknown)</u>	<u>(Unknown)</u>

FISCAL IMPACT - Small Business

The proposal would directly impact small business that provide health insurance for employees if insurers increase insurance premiums.

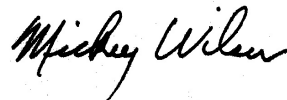
FISCAL DESCRIPTION

This proposal requires health insurance companies to provide coverage for routine patient care costs incurred as the result of phase I clinical trials undertaken to treat cancer. Currently, Section 376.429, RSMo, requires coverage for phases II, III, or IV only. This proposal also removes any of the additional prerequisites for coverage for phase II trials that do not apply to phase III of IV trials.

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 Insurance, Financial Institutions and Professional Registration
Department of Health and Senior Services
Department of Social Services
Missouri Department of Transportation
Department of Public Safety -
 Director's Office
 Missouri State Highway Patrol
Missouri Consolidated Health Care Plan
Missouri Department of Conservation



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