

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 2795-03
Bill No.: SB 827
Subject: Insurance - Medical; Health Care; Insurance Department
Type: Original
Date: February 11, 2002

FISCAL SUMMARY

ESTIMATED NET EFFECT ON STATE FUNDS			
FUND AFFECTED	FY 2003	FY 2004	FY 2005
All funds	(Unknown)	(Unknown)	(Unknown)
Conservation *	(Unknown)	(Unknown)	(Unknown)
Insurance Dedicated	\$9,850	\$0	\$0
Highway	(Unknown)	(Unknown)	(Unknown)
Total Estimated Net Effect on <u>All</u> State Funds	(Unknown)	(Unknown)	(Unknown)

*Not expected to exceed \$100,000 annually.

ESTIMATED NET EFFECT ON FEDERAL FUNDS			
FUND AFFECTED	FY 2003	FY 2004	FY 2005
Total Estimated Net Effect on <u>All</u> Federal Funds	\$0	\$0	\$0

ESTIMATED NET EFFECT ON LOCAL FUNDS			
FUND AFFECTED	FY 2003	FY 2004	FY 2005
Local Government	(Unknown)	(Unknown)	(Unknown)

Numbers within parentheses: () indicate costs or losses.

This fiscal note contains 6 pages.

FISCAL ANALYSIS

ASSUMPTION

Officials from the **Department of Insurance (INS)** assume insurers and HMOs would be required to amend their policies to comply with this legislation. Amendments must be filed with INS. INS estimates that 171 insurers and 26 HMOs would be required to file at least one amendment to their policy form with a filing fee of \$50, resulting in revenue of \$9,850 in FY 2003. INS has reached capacity in policy form reviews and the additional workload created by this legislation would cause delays in policy form reviews. Additional staff are not being requested with this single proposal, but if multiple proposals pass during the legislative session which require policy form amendments, the department would need to request additional staff to handle the increase in workload.

Officials from the **Department of Social Services - Division of Medical Services (DMS)** assume there will not be a fiscal impact to the DMS from this proposed legislation. Section 376.429.9 exempts Title XIX of the Social Security Act from the provisions of this legislation. However, Title XXI (States Children's Health Insurance Program - SCHIP) is not included in the programs that are exempt. DMS states in Missouri, the Title XXI program is administered through the Title XIX program therefore, the DMS assumes the Title XXI program is also exempt from this proposed legislation.

Officials from the **Missouri Department of Conservation (MDC)** state that this proposal mandates insurance coverage for clinical trials for treatment of cancer and other life-threatening illnesses. MDC assumes this proposed legislation has a fiscal impact on MDC funds that would not exceed \$100,000 annually.

Officials from **Missouri Consolidated Health Care Plan (HCP)** assume that requiring the medical plan to cover Phase I, Phase II, Phase III or Phase IV clinical trials for cancer and other life threatening conditions could result in an increase in the plan's financial risk. Since the treatments may vary and only a few providers would be able to administer the treatments, the cost could be significant. HCP states to reduce this risk, the plan may transfer these additional costs to the members through an increase of premiums. Since the type of treatments, the associated costs and the number of patients cannot be estimated, the overall cost is unknown but could be significant. **Oversight** assumes unknown costs to the Public Entities, also.

HCP states the proposal does include an exclusion for "items and services customarily provided by the research sponsors free of charge for any enrollee in the trial". However, if health plans are required to cover the routine patient care costs incurred for drugs and devices that have been approved by the FDA, the sponsors of such programs may cut the funding to these programs and rely on the health plans' reimbursement for funding. Again, should this occur, the plans may

transfer the additional costs to the members through increased premiums.

ASSUMPTION (continued)

Officials from the **Department of Public Safety - Missouri State Highway Patrol** defer their fiscal note response to the Department of Transportation.

Officials from the **Department of Transportation (DHT)** assume this legislation requires coverage for certain patient care costs for certain clinical trials. This legislation will have no fiscal impact on DHT. The Highway & Patrol Medical Plan is not expressly included in the new legislation, but section 104.801 RSMo. would require the Medical Plan to offer similar coverage.

However, 104.801 only requires similar coverage and the reporting requirements are not included in the mandates of 104.801. Currently, the Medical Plan does not cover costs for clinical trials. As a result, there would be a fiscal impact to the Highway & Patrol Medical Plan.

DHT assumes that if health carriers are required to cover the cost of services needed to administer the drugs or use the device under evaluation in the clinical trial, that manufacturers and distributors or providers of the drugs or devices would no longer pay for any of the related costs. Assuming that this is true, DHT assumes that the fiscal impact to the Medical Plan would be very significant.

Without knowing the types of drugs, procedures, illnesses or how many individuals would participate, DHT finds it is impossible to calculate what a fiscal impact to the Medical Plan would be. Historically, the DHT 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 shared between three categories: absorbed by the plan, state appropriated funds, and/or costs to individuals covered under the plan). However, the DHT must make a decision on what portion they will provide. Until the commission makes a decision, DHT can only provide the cost to the medical plan.

<u>FISCAL IMPACT - State Government</u>	FY 2003 (10 Mo.)	FY 2004	FY 2005
---	---------------------	---------	---------

ALL FUNDS

Costs - Missouri Consolidated Health
Care Plan

Increased state contributions	<u>(Unknown)</u>	<u>(Unknown)</u>	<u>(Unknown)</u>
-------------------------------	------------------	------------------	------------------

ESTIMATED NET EFFECT ON ALL

CM:LR:OD (12/01)

<u>FISCAL IMPACT - State Government</u>	FY 2003 (10 Mo.)	FY 2004	FY 2005
FUNDS	<u>(UNKNOWN)</u>	<u>(UNKNOWN)</u>	<u>(UNKNOWN)</u>

CONSERVATION FUND

Costs - Missouri Department of Conservation

Increased state contributions	(Unknown)	(Unknown)	(Unknown)
-------------------------------	-----------	-----------	-----------

ESTIMATED NET EFFECT ON CONSERVATION FUND*	<u>(UNKNOWN)</u>	<u>(UNKNOWN)</u>	<u>(UNKNOWN)</u>
---	-------------------------	-------------------------	-------------------------

*Not expected to exceed \$100,000 annually

INSURANCE DEDICATED FUND

Revenue - Department of Insurance

Form filing fees	\$9,850	\$0	\$0
------------------	---------	-----	-----

ESTIMATED NET EFFECT ON INSURANCE DEDICATED FUND	<u>\$9,850</u>	<u>\$0</u>	<u>\$0</u>
---	-----------------------	-------------------	-------------------

HIGHWAY FUND

Costs - Department of Transportation

Increased state contribution	(Unknown)	(Unknown)	(Unknown)
------------------------------	-----------	-----------	-----------

Costs - Department of Public Safety-
Missouri State Highway Patrol

Increased state contribution	(Unknown)	(Unknown)	(Unknown)
------------------------------	-----------	-----------	-----------

ESTIMATED NET EFFECT ON HIGHWAY FUND	<u>(UNKNOWN)</u>	<u>(UNKNOWN)</u>	<u>(UNKNOWN)</u>
---	-------------------------	-------------------------	-------------------------

<u>FISCAL IMPACT - Local Government</u>	FY 2003 (10 Mo.)	FY 2004	FY 2005
---	---------------------	---------	---------

POLITICAL SUBDIVISION

Cost - Political Subdivision

Increased local contributions	<u>(Unknown)</u>	<u>(Unknown)</u>	<u>(Unknown)</u>
-------------------------------	------------------	------------------	------------------

ESTIMATED NET EFFECT ON POLITICAL SUBDIVISIONS	<u>(UNKNOWN)</u>	<u>(UNKNOWN)</u>	<u>(UNKNOWN)</u>
---	-------------------------	-------------------------	-------------------------

FISCAL IMPACT - Small Business

Small business could be affected by this proposal which could result in higher health insurance premiums.

DESCRIPTION

This proposal requires health insurance companies to provide coverage for routine patient care costs incurred as the result of clinical trials undertaken to treat cancer or other life-threatening illnesses. Entities providing clinical trial treatment must have sufficient expertise and training to treat a sufficient number of patients. There must be equal to or superior non-investigational treatments alternatives available before providing clinical trial treatment. Clinical trial coverage shall include coverage for drugs and devices approved by the FDA, whether or not the FDA has approved the drug or device for the patient's particular condition.

The clinical trials will only be covered if they are approved or funded by the following entities:

1) One of the National Institutes of Health (NIH); 2) An NIH Cooperative Group of Center; 3) The FDA in the form of an investigational new drug application; 4) The federal Department of Veteran's Affairs of Defense; 5) A Missouri institutional review board which has a multiple project assurance contract approved by the Office of Protection for the Research Risks of the NIH; 6) Research entities that meet the criteria for NIH Center support grant eligibility; or 7) A panel of qualified experts in clinical research.

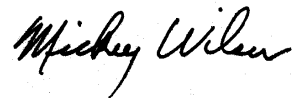
Every June 1st, health insurers must submit reports on its coverage of clinical trials during the previous year to the Director of Insurance. The Director shall submit an annual summary report

to the Speaker of the House and the Pro Tem of the Senate. Reports shall be available to the public upon request.

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 Transportation
Department of Social Services
Missouri Consolidated Health Care Plan
Department of Insurance
Missouri Department of Conservation
Department of Public Safety -
Missouri State Highway Patrol



Mickey Wilson, CPA
Acting Director
February 11, 2002