

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 3696-03
Bill No.: HCS HB 1089
Subject: Hospitals; Insurance - Medical; Medical Procedures and Personnel
Type: Original
Date: April 14, 2006

FISCAL SUMMARY

| ESTIMATED NET EFFECT ON GENERAL REVENUE FUND | | | |
|---|-------------------------------------|-------------------------------------|-------------------------------------|
| FUND AFFECTED | FY 2007 | FY 2008 | FY 2009 |
| General Revenue | (Unknown exceeding \$33,370) | (Unknown exceeding \$66,740) | (Unknown exceeding \$66,740) |
| Total Estimated Net Effect on General Revenue Fund | (Unknown exceeding \$33,370) | (Unknown exceeding \$66,740) | (Unknown exceeding \$66,740) |

| ESTIMATED NET EFFECT ON OTHER STATE FUNDS | | | |
|---|--|---|---|
| FUND AFFECTED | FY 2007 | FY 2008 | FY 2009 |
| Insurance Dedicated | \$5,000 | \$0 | \$0 |
| Highway - Highway Patrol | (Unknown) | (Unknown) | (Unknown) |
| Road | (Unknown) | (Unknown) | (Unknown) |
| Conservation Commission | (Unknown expected to exceed \$50,000) | (Unknown expected to exceed \$100,000) | (Unknown expected to exceed \$100,000) |
| All Other | (Unknown exceeding \$6,030) | (Unknown exceeding \$12,060) | (Unknown exceeding \$12,060) |
| Total Estimated Net Effect on <u>Other</u> State Funds | (Unknown expected to exceed \$51,030) | (Unknown expected to exceed \$112,060) | (Unknown expected to exceed \$112,060) |

Numbers within parentheses: () indicate costs or losses.
This fiscal note contains 9 pages.

| ESTIMATED NET EFFECT ON FEDERAL FUNDS | | | |
|---|-------------------------------------|-------------------------------------|-------------------------------------|
| FUND AFFECTED | FY 2007 | FY 2008 | FY 2009 |
| Federal | (Unknown exceeding \$10,600) | (Unknown exceeding \$21,200) | (Unknown exceeding \$21,200) |
| | | | |
| Total Estimated Net Effect on <u>All</u> Federal Funds | (Unknown exceeding \$10,600) | (Unknown exceeding \$21,200) | (Unknown exceeding \$21,200) |

| ESTIMATED NET EFFECT ON LOCAL FUNDS | | | |
|--|------------------|------------------|------------------|
| FUND AFFECTED | FY 2007 | FY 2008 | FY 2009 |
| Local Government | (Unknown) | (Unknown) | (Unknown) |

FISCAL ANALYSIS

ASSUMPTION

Officials from the **Department of Public Safety (DPS) - Director's Office** and **Department of Social Services** assume the proposal will have no fiscal impact on their organizations.

Officials from the **Department of Public Safety - Missouri State Highway Patrol** defer to the Missouri Department of Transportation for response regarding the fiscal impact of the proposal on their organization.

Officials from the **Department of Insurance (INS)** state the INS estimates approximately 100 insurers would be required to submit amendments to their policies to comply with the legislation. Policy amendments must be submitted to the INS for review, along with a \$50 filing fee. One-time additional revenues to the Insurance Dedicated Fund are estimated to be \$5,000.

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

ASSUMPTION (continued)

Officials from the **Missouri Consolidated Health Care Plan (HCP)** state many insurers believe requiring the medical plan to cover clinical trials for cancer and other life threatening conditions could result in an increase in the plan's financial risk. Insurers believe due to varying treatments, more physician visits, more expensive test and more pathology reports compared to those of non-participants, participants in early phase trials have substantially higher treatment cost. To reduce this risk, the plan may transfer these additional costs to the members through an increase in the premium.

In contrast, some research, although now a few years old, suggests that the cost of clinical trials may not significantly differ from the cost for standard cancer treatment. A study by the Association of American Cancer Institutes found that charges for patients in clinical trials were about the same, or even a little lower, than those for patients receiving standard care. The study tracked 35 patients in phase II cancer clinical trials and 35 patients receiving standard care who were similar, or matched, to the clinical trials patients. As of June 2000, Medicare guidelines were revised to cover phase I and II clinical trials.

As is evidenced by the contradicting research, forecasting the consequential financial impact of mandatory coverage of phase II cancer trials is extremely difficult and therefore, unknown. However, mandated coverage in general, ends up adding some costs to the plan. An increase in costs is assumed to be greater than \$100,000 annually.

Officials from the **Missouri Department of Transportation (DOT)** state the proposal mandates coverage for phase II of a clinical trial when undertaken for the purposes of the prevention, early detection or treatment of cancer. The proposal will have no fiscal impact on the Missouri Highways and Transportation Commission (MHTC) or DOT. The Highway and Patrol Medical Plan is not within the definition of a 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 III and IV of a clinical trial and not phase II. As a result, the proposal will have a fiscal impact on the Highway and Patrol Medical Plan.

Based on information from the American Cancer Societies' website, DOT found that 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, 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, both phase I and II of clinical trials would be considered investigational under the Highway and Patrol Medical Plan and would not be a covered benefit.

ASSUMPTION (continued)

The DOT is assuming that if health carriers are required to cover the costs of services and drugs in phase II of 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 conduct the trials. Assuming this is true, DOT feels the 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 an exact fiscal impact to the Medical Plan, but the DOT assumes it would be over \$100,000 annually.

Historically, the DOT 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 Medical Plan, MHTC, DOT, and Patrol must make a decision on how to fund any increase.

Oversight is presenting unknown costs for General Revenue, Highway Fund - Highway Patrol, Road Fund and All Other State Funds. Total costs to all funds are unknown expected to exceed \$100,000 annually.

Officials from the **Missouri Department of Conservation (MDC)** state the proposed legislation would have a significant impact on MDC funds due to increased medical insurance expenses. The exact amount of the impact is unknown but is expected to exceed \$100,000 annually.

Oversight assumes changes in health plan coverage would be effective January 1, 2007.

This proposal will result in an increase total State Revenue.

| <u>FISCAL IMPACT - State Government</u> | FY 2007 (6 Mo.) | FY 2008 | FY 2009 |
|--|--|--|--|
| GENERAL REVENUE FUND | | | |
| <u>Costs - Missouri Department of Transportation</u> | | | |
| Increase in insurance contributions | (Unknown) | (Unknown) | (Unknown) |
| <u>Costs - Missouri Consolidated Health Care Plan</u> | | | |
| Increase in state contributions | <u>(Unknown exceeding \$33,370)</u> | <u>(Unknown exceeding \$66,740)</u> | <u>(Unknown exceeding \$66,740)</u> |
| ESTIMATED NET EFFECT ON GENERAL REVENUE FUND | <u>(Unknown exceeding \$33,370)</u> | <u>(Unknown exceeding \$66,740)</u> | <u>(Unknown exceeding \$66,740)</u> |
| INSURANCE DEDICATED FUND | | | |
| <u>Income - Department of Insurance</u> | | | |
| Policy form amendments | <u>\$5,000</u> | <u>\$0</u> | <u>\$0</u> |
| ESTIMATED NET EFFECT ON INSURANCE DEDICATED FUND | <u>\$5,000</u> | <u>\$0</u> | <u>\$0</u> |
| HIGHWAY FUND - HIGHWAY PATROL | | | |
| <u>Costs - Missouri Department of Transportation</u> | | | |
| Increase in insurance contributions | <u>(Unknown)</u> | <u>(Unknown)</u> | <u>(Unknown)</u> |
| ESTIMATED NET EFFECT ON HIGHWAY FUND - HIGHWAY PATROL | <u>(Unknown)</u> | <u>(Unknown)</u> | <u>(Unknown)</u> |

FISCAL IMPACT - State Government

FY 2007
(6 Mo.)

FY 2008

FY 2009

ROAD FUND

Costs - Missouri Department of
Transportation

Increase in insurance contributions

(Unknown)

(Unknown)

(Unknown)

**ESTIMATED NET EFFECT ON
ROAD FUND**

(Unknown)

(Unknown)

(Unknown)

**CONSERVATION COMMISSION
FUND**

Costs - Missouri Department of
Conservation

Increase in insurance contributions

(Unknown
expected to
exceed \$50,000)

(Unknown
expected to
exceed
\$100,000)

(Unknown
expected to
exceed
\$100,000)

**ESTIMATED NET EFFECT ON
CONSERVATION COMMISSION
FUND**

(Unknown
expected to
exceed \$50,000)

(Unknown
expected to
exceed
\$100,000)

(Unknown
expected to
exceed
\$100,000)

| <u>FISCAL IMPACT - State Government</u> | FY 2007 (6 Mo.) | FY 2008 | FY 2009 |
|---|--|--|--|
| ALL OTHER STATE FUNDS | | | |
| <u>Costs - Missouri Department of Transportation</u> | | | |
| Increase in insurance contributions | (Unknown) | (Unknown) | (Unknown) |
| <u>Costs - Missouri Consolidated Health Care Plan</u> | | | |
| Increase in state contributions | <u>(Unknown exceeding \$6,030)</u> | <u>(Unknown exceeding \$12,060)</u> | <u>(Unknown exceeding \$12,060)</u> |
| ESTIMATED NET EFFECT ON ALL OTHER STATE FUNDS | <u><u>(Unknown exceeding \$6,030)</u></u> | <u><u>(Unknown exceeding \$12,060)</u></u> | <u><u>(Unknown exceeding \$12,060)</u></u> |
| FEDERAL FUNDS | | | |
| <u>Costs - Missouri Consolidated Health Care Plan</u> | | | |
| Increase in state contributions | <u>(Unknown exceeding \$10,600)</u> | <u>(Unknown exceeding \$21,200)</u> | <u>(Unknown exceeding \$21,200)</u> |
| ESTIMATED NET EFFECT ON FEDERAL FUNDS | <u><u>(Unknown exceeding \$10,600)</u></u> | <u><u>(Unknown exceeding \$21,200)</u></u> | <u><u>(Unknown exceeding \$21,200)</u></u> |

| <u>FISCAL IMPACT - Local Government</u> | FY 2007 (6 Mo.) | FY 2008 | FY 2009 |
|---|-------------------------|-------------------------|-------------------------|
| ALL POLITICAL SUBDIVISIONS | | | |
| <u>Costs - All Political Subdivisions</u> | | | |
| Increase in insurance premium contributions | <u>(Unknown)</u> | <u>(Unknown)</u> | <u>(Unknown)</u> |
| ESTIMATED NET EFFECT ON ALL POLITICAL SUBDIVISIONS | <u>(Unknown)</u> | <u>(Unknown)</u> | <u>(Unknown)</u> |

FISCAL IMPACT - Small Business

Small businesses could be expected to be fiscally impacted to the extent they incur increased health insurance premiums as a result of the requirements of this proposal.

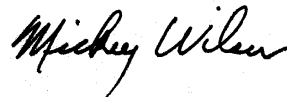
DESCRIPTION

This proposal requires health insurers to cover routine patient care costs incurred as a result of phase II clinical trials for cancer treatment. Currently, coverage is only required for phase III and IV of these trials. Health benefit plans may limit coverage for routine medical care of patients in a Phase II trial to those treating facilities within the benefit plans' provider network. These provisions apply if the Phase II trial is sanctioned by the National Cancer Institute and conducted at an academic or National Cancer Institute center. The person covered under these provisions must be enrolled in the clinical trial; the provisions do not apply to persons who are only following the protocol of phase II of a clinical trial, but not actually enrolled.

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

A handwritten signature in black ink that reads "Mickey Wilson". The signature is written in a cursive, flowing style.

Mickey Wilson, CPA
Director
April 14, 2006