

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 4188-01
Bill No.: SB 916
Subject: Health Care; Health Care Professionals; Health, Public; Physicians; Hospitals;
 Health Department
Type: Original
Date: March 3, 2008

Bill Summary: This legislation requires hospitals to report adverse health events to a patient safety organization for review.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2009	FY 2010	FY 2011
General Revenue	(Greater than \$100,000)	(Greater than \$100,000)	(Greater than \$100,000)
Total Estimated Net Effect on General Revenue Fund	(Greater than \$100,000)	(Greater than \$100,000)	(Greater than \$100,000)

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2009	FY 2010	FY 2011
Total Estimated Net Effect on <u>Other</u> State Funds	\$0	\$0	\$0

Numbers within parentheses: () indicate costs or losses.
 This fiscal note contains 7 pages.

ESTIMATED NET EFFECT ON FEDERAL FUNDS			
FUND AFFECTED	FY 2009	FY 2010	FY 2011
Total Estimated Net Effect on <u>All</u> Federal Funds	\$0	\$0	\$0

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2009	FY 2010	FY 2011
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 2009	FY 2010	FY 2011
Local Government	\$0	\$0	\$0

FISCAL ANALYSIS

ASSUMPTION

Officials from the **Office of the State Courts Administrator** assume the proposal would have no fiscal impact on their agency.

Officials from the **Office of the Attorney General** assume any potential costs arising from this proposal can be absorbed with existing resources.

In response to a similar proposal from last year (SB 578), officials from the **Office of Prosecution Services** assume this proposal would not have a significant direct fiscal impact on county prosecutors or the Office of Prosecution Services.

Officials from the **Office of the Secretary of State (SOS)** state 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 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. Any decisions to raise fees to defray costs would likely be made in subsequent fiscal years.

Officials from the **Department of Social Services** assume the proposal requires hospitals to report each reportable incident to a patient safety organization and to the Department of Health and Senior Services (DHSS). Since this primarily involves the hospital and the DHSS, it will not have a fiscal impact on the MO HealthNet Division.

ASSUMPTION (continued)

Officials from the **Department of Health and Senior Services** state Section 197.554.1. requires the Department to define the form and content of information submitted and promulgate related regulations. Section 197.563.1. requires the Department to promulgate regulations establishing criteria for defining cases in which reportable incidents have occurred in a hospital with a frequency or possible pattern of adverse outcomes that would necessitate Departmental intervention. Promulgation of these rules will require research by the Department and input from the patient safety organization and affected facilities.

Section 197.557.1. states the Department shall investigate each incident upon receiving notice. The extent of this investigation will be determined based on the findings and the proposed prevention plan prepared by the hospital. Some of these cases may be found to not require any further intervention. Other cases may require staff to go on-site. Many of the cases will likely be some of the most egregious and will require intense scrutiny by the Department. Additional nursing staff skilled at investigating and analyzing these events will be required. The state of Minnesota has enacted similar legislation. As a result of the reporting in Minnesota, they have experienced an average increase of 103 cases per year. The extent of any follow-up investigations on the Minnesota reports is unknown.

Section 197.557.3. requires the Department to, "periodically evaluate the performance of the patient safety organization regarding report submission processes and its reviews of reportable incident prevention plans and root cause analyses submitted by hospitals." The nursing staff mentioned previously would also need to review activities of the patient safety organization(s).

The assessment of a fee to cover the cost of investigations that is allowed by Section 197.557.2. (language says "may" charge a fee) would be a new activity for the Bureau of Health Services Regulation. Depending on the number of reports that need to be investigated and thus the number of fees assessed, there may be a need for additional staff to track the fee process from the initiation of a fee to the receipt of payment. Data would also need to be analyzed to determine the appropriate fee amount and the necessary rule(s) would have to be drafted and promulgated.

Due to the extent of the unknowns, an accurate estimate of the fiscal impact is not known at this time, but it is believed to exceed \$100,000. At the point that the impact can be determined, the Division of Regulation and Licensure would request additional staffing through the appropriations process.

<u>FISCAL IMPACT - State Government</u>	FY 2009 (10 Mo.)	FY 2010	FY 2011
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GENERAL REVENUE FUND

Income - Department of Health and Senior Services*

Investigation Fee	Unknown	Unknown	Unknown
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Costs - Department of Health and Senior Services*

Investigations and Reviews	<u>(Greater than \$100,000)</u>	<u>(Greater than \$100,000)</u>	<u>(Greater than \$100,000)</u>
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ESTIMATED NET EFFECT ON GENERAL REVENUE FUND	<u>(Greater than \$100,000)</u>	<u>(Greater than \$100,000)</u>	<u>(Greater than \$100,000)</u>
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*Oversight assumes costs will exceed incomes.

<u>FISCAL IMPACT - Local Government</u>	FY 2009 (10 Mo.)	FY 2010	FY 2011
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	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>
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FISCAL IMPACT - Small Business

No direct fiscal impact to small businesses would be expected as a result of this proposal.

FISCAL DESCRIPTION

The proposed legislation requires hospitals to report whenever they have a "serious reportable event in health care," as identified by the National Quality Forum. Such events include wrong-site surgery, retention of a foreign object in a patient after surgery, and death or serious disability associated with medication error.

FISCAL DESCRIPTION (continued)

The procedure for hospitals reporting such events to the Department of Health and Senior Services and to a patient safety organization are prescribed in the legislation. The requirements for a patient safety organization are also prescribed in the legislation. The patient-identifying data shall be redacted from information provided to the Department or patient safety organization. The initial report of the event shall be reported to the patient safety organization and include a description of immediate actions taken by the hospital to minimize the risk of harm to patients and prevent reoccurrence. Within 45 days after the event occurred, the hospital shall submit to the patient safety organization a root cause analysis and a prevention plan, which shall be forwarded to the Department.

The Department shall investigate the reportable incident and based on its findings, determine whether the hospital's response and proposed prevention plan is sufficient to reduce the risk of future occurrences of that type. The Department shall also periodically evaluate the performance of the patient safety organization regarding report submission processes and its reviews of prevention plans. The legislation also prescribes the procedure for the Department when taking action on insufficient prevention plans.

If a reportable incident is disclosed to the Department and patient safety organization and the prevention plan and root cause analysis is submitted and approved by the Department, the incident shall not be deemed grounds for a finding of a licensure deficiency. The Department shall promulgate rules establishing criteria for defining cases in which reportable incidents have occurred in a hospital with a frequency or possible pattern of adverse outcomes as to necessitate Departmental intervention.

The patient safety organization shall in collaboration with the Department publish an annual report to the public on reportable incidents. The report shall show the number and rate per patient encounter by region and by category of reportable incident and may identify reportable incidents by type of facility.

This legislation provides for certain legal protections of patient safety organization documents. The proceedings and records of the organization shall not be subject to discovery or introduction into evidence in any civil action against a provider. However, information otherwise available from original sources shall not be immune from discovery or use in any civil action if they were presented during a patient safety organization meeting. Patient safety work product shall be privileged and confidential and shall not be disclosed for any purpose.

Any hospital that reports a reportable incident shall not charge for or bill any entity for all

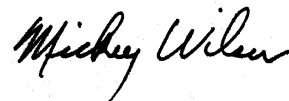
services related to the reportable incident.

FISCAL DESCRIPTION (continued)

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

Office of the Attorney General
Office of the State Courts Administrator
Department of Health and Senior Services
Department of Social Services
Office of Prosecution Services
Office of the Secretary of State



Mickey Wilson, CPA
Director
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