HB 1518

Department of Legislative Services

Maryland General Assembly
2004 Session

FISCAL AND POLICY NOTE

House Bill 1518 (Delegate Hurson)
Health and Government Operations

Health Care - Adverse Patient Safety Events - Reporting and Attorney's Fees for Civil Action

This bill requires each health care facility licensed and regulated by the Department of Health and Mental Hygiene (DHMH) to establish a patient safety program.

Fiscal Summary

State Effect: DHMH general fund expenditures could increase by $87,100 in FY 2005. Future year estimates reflect annualization and inflation. The bill's administrative penalty provisions are not expected to materially affect State finances or operations.

(in dollars)	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Revenues	$0	$0	$0	$0	$0
GF Expenditure	87,100	105,400	111,200	117,400	124,100
Net Effect	($87,100)	($105,400)	($111,200)	($117,400)	($124,100)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: None.

Small Business Effect: Minimal.

Analysis

Bill Summary: The patient safety program at each health care facility must have: (1) a designated patient safety coordinator; (2) patient safety education programs for all staff; (3) a process to review and evaluate the effectiveness of the health care facility's patient safety program; (4) a well-defined process for identifying and reporting "near-misses"

and "adverse events;" (5) procedures for determining which reported near-misses or adverse events require a "root cause analysis;" (6) procedures for conducting a root cause analysis investigation; (7) specific time frames for the reporting to DHMH of "near-misses" or "adverse events" that caused a serious disability; (8) a documentation and record keeping system; (9) an information sharing system among appropriate internal and external entities; and (10) a patient complaint program.

DHMH may impose penalties on a health care facility that violates these provisions. Penalties include revocation of the facility's license or a $500 fine for each day the facility is in violation.

An "adverse event" is an unexpected occurrence related to an individual's medical treatment and not related to the natural course of the individual's illness or underlying disease condition. A "near-miss" is an occurrence that could have resulted in an adverse event but did not, either by chance or through timely intervention.

In situations where a physician brings action against a hospital medical review committee or a member of the hospital review committee, the court must order the losing party to pay the prevailing party's reasonable attorneys' fees and costs. A physician who is aware of a "near-miss" or "adverse event" must report it to the Board of Physicians.

Current Law:

Patient Safety in Hospitals: On or before March 15, 2004, a hospital must have a patient safety program. A hospital must appoint an individual as patient safety coordinator who must: (1) coordinate patient safety activities; (2) facilitate assessment and determination of the appropriate response to reported "near-misses" and "adverse events" related to patient care; (3) monitor "root cause analyses" and any actions resulting from a "root cause analysis;" and (4) provide for flow of information among quality assurance, credentialing, peer review, and any patient safety committee.

A hospital must establish: (1) patient safety education programs for all staff; and (2) an internal staff committee structure in accordance with medical review committee provisions of the Health Occupations Article to conduct a review and evaluation of patient safety activities. The governing board of a hospital shall develop a process to review the hospital's patient safety program and to determine the effectiveness of the hospital's patient safety program. Before a committee may operate or review patient safety activities under this chapter, a hospital shall require that the committee meet the requirements for a medical review committee under the Health Occupations Article.

A hospital must develop and encourage a supportive environment that permits spontaneous identification, open discussion, and timely and accurate reporting of near-misses and adverse events. A hospital must perform a "root-cause analysis" of an "adverse event" or "near miss." A hospital must report an adverse event to DHMH within five days of the hospital's knowledge that the event occurred. A hospital must submit the "root cause analysis" and action plan for the adverse event to DHMH within 60 days of the hospital's knowledge of the occurrence.

If a hospital fails to have in effect a patient safety program, DHMH may impose on the hospital the following penalties: (1) revocation of the hospital's license; or (2) a fine of $500 for each day that the hospital is in violation.

Medical Review Committee: A medical review committee: (1) evaluates and seeks to improve the quality of health care provided by health care providers; (2) evaluates the need for and the level of performance of health care provided by health care providers; (3) evaluates the qualification, competence, and performance of health care providers; or (4) evaluates and acts on matters that relate to the discipline of any health care provider. A medical review committee can be a State or federal entity, a health care provider professional association, a professional standard review organization, or other group permitted by law.

Generally, a medical review committee's proceedings, records, and files are confidential and not admissible or discoverable. If a civil action is brought by a party to a medical review committee's proceedings who claims to be aggrieved by the committee's decision, the records and files would be subject to discovery.

Background: Since 2001, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has required hospitals to meet specified patient safety standards and approved the first set of six national patient safety goals. In 2003, JCAHO, as part of its accreditation process, began surveying hospitals' efforts to achieve these goals. All hospitals in Maryland are JCAHO accredited.

The Maryland Patients' Safety Act of 2001 requires the Maryland Health Care Commission (MHCC), in consultation with DHMH, to study the feasibility of developing a system for reducing incidences of preventable adverse medical events. One of the resulting initiatives was the Patient Safety Coalition, comprised of legislators, the Delmarva Foundation, MedChi, Maryland Hospital Association, MHCC, and other health care provider and regulatory entities. The coalition reviewed and discussed definitions (including adverse event versus near misses), reporting systems (mandatory versus voluntary), systematic changes, and implementation issues. In the resulting report, MHCC recommended a three-pronged approach, which includes: (1) establishment of a

Maryland Patient Safety Center; (2) the adoption of regulations to promote system improvements; and (3) limited mandatory reporting.

Chapter 126 of 2003 permits MHCC to designate a Maryland Patient Safety Center, which has medical review committee status. The center may collect objective data on adverse events and near-misses and identify and educate providers on "better or best" practices. The scope of the center's authority is limited to hospitals and nursing homes.

MHCC also revised the State Health Plan to include consideration of patient safety in reviewing certificates of need for capital expenditures or new or expanded services. MHCC has also initiated hospital and nursing home report card workgroups on patient safety. The Health Services Cost Review Commission, which sets hospital rates in Maryland, may consider hospital rate allowances for technological improvements or possibly paying for quality initiatives.

DHMH recently revised and implemented risk management regulations in 2004 to make them patient safety focuses. The regulations strengthen accountability of hospitals for certain adverse events, as well as enhance the hospital's reporting and evaluation systems. Mandatory reporting is limited to adverse events resulting in death and serious disability.

State Fiscal Effect: Although DHMH's Office of Health Care Quality has issued patient safety regulations for hospitals and nursing homes, the bill would mandate the establishment of patient safety programs in *all* health care facilities licensed and regulated by DHMH. Accordingly, DHMH general fund expenditures could increase by $87,069 in fiscal 2005, which accounts for the bill's October 1, 2005 effective date. This estimate reflects the cost of hiring two health facility nurse surveyors to audit health care facilities to confirm compliance with the patient safety program requirements and to collect data on reported adverse events and near misses. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Salaries and Fringe Benefits	$67,329
Operating Expenses	19,740
Total FY 2005 State Expenditures	**$87,069**

Future year expenditures reflect: (1) full salaries with 4.6% annual increases and 3% employee turnover; and (2) 1% annual increases in ongoing operating expenses.

The collection of "near-miss" and "adverse event" information related to physicians and the development of appropriate responses to "adverse events" and "near-misses" could be

handled with existing Board of Physicians' budgeted resources. It is assumed that if the reporting requirement does not provide for anonymity, very few "adverse events" or "near-misses" would be reported to the board.

The penalty provisions of this bill are not expected to significantly affect State finances or operations.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene (Office of Health Care Quality, Board of Physicians), Department of Legislative Services

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ncs/jr

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