HB 821

Department of Legislative Services

Maryland General Assembly
2011 Session

FISCAL AND POLICY NOTE

House Bill 821 (Delegate Summers, *et al.*)
Health and Government Operations

Hospitals - Medical Harm Disclosure Act

This bill requires that hospitals, as a condition for licensure, satisfy certain reporting requirements regarding medical harm events. In addition, the bill creates a Patient Safety Trust Fund that may be used only for expenses directly related to carrying out the bill.

DHMH must adopt regulations to carry out the bill's provisions.

Fiscal Summary

State Effect: Patient Safety Trust Fund revenues increase in FY 2012 due to surcharges collected to approximate costs. Special fund expenditures increase by $247,000 in FY 2012 to hire additional staff to collect and analyze data and conduct additional inspections. Future year expenditures and revenues reflect annualization, inflation, and, beginning in FY 2014, expenditures associated with triennial audits to be completed by a State university. The bill's penalty provisions are not expected to materially affect governmental finances.

(in dollars)	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
SF Revenue	-	-	-	-	-
SF Expenditure	$247,000	$312,300	$428,100	$344,700	$362,400
Net Effect	(-)	(-)	(-)	(-)	(-)

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

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: "Medical harm event" means harm to a patient as a result of care in a hospital and includes each event of the list of serious reportable events published by the National Quality Forum; a surgical or anesthesia event; the unintentional retention of a foreign object in a patient after a procedure; a medication or device event; a care management event; an environmental death; or the death of a previously healthy person while undergoing care at the hospital. A hospital must report a medical harm event to the Department of Health and Mental Hygiene (DHMH) within five days after detection or – if the event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors – no later than 24 hours after detection. Also in accordance with this timeline, a hospital is required to inform the patient, the person legally responsible for the patient, or (in cases of death or serious bodily injury) an adult member of the patient's immediate family of a medical harm event.

A hospital must interview a patient, a patient's family members, and/or other persons legally responsible for the patient about a medical harm event and must include a detailed summary of the interview in the patient's medical record. If a medical harm event contributed to the patient's death, the hospital is required to include the event as a contributing cause on the patient's death certificate.

The report to DHMH must indicate the level of harm to the patient. In addition, a hospital that has had no such events to report is required to quarterly report this fact to DHMH. If DHMH receives a report of a medical harm event that indicates an ongoing threat of imminent danger of death or serious bodily harm, the department must conduct an on-site inspection within the greater of 48 hours or 2 business days and complete an investigation of the event within 45 days.

If a hospital fails to report a medical harm event, DHMH may assess a civil penalty on the hospital of up to $100 for each day that the medical harm event is not reported as required. A hospital may appeal to the Board of Review of the department and take any subsequent appeal allowed by the Administrative Procedure Act.

At least quarterly, DHMH must validate the accuracy of information reported by a hospital under the bill. DHMH must also conduct annual random reviews of hospital medical records to validate the information provided. In addition, DHMH is required to have an independent audit of hospital reporting conducted every three years by a State university not affiliated with any hospital required to report under the bill. Certain information regarding the review process, audit results, and penalties assessed must be made available to the public on DHMH's website as specified by the bill. DHMH must also report annually to the Governor and the General Assembly, beginning April 1, 2013, on the medical harm events reported at each hospital during the previous calendar year.

A hospital must establish a hospital-wide patient safety program to routinely review patient records for medical harm events, determine if the events were preventable, and implement changes to prevent similar events. In addition, each hospital must provide an annual summary of its patient safety program to DHMH.

The Secretary of Health and Mental Hygiene is required to appoint an advisory committee (with a majority of members who represent interests other than hospitals) to assist DHMH in carrying out the bill's requirements. With the committee's advice, DHMH must develop (1) guidelines for hospitals to identify medical harm events; and (2) a methodology for collecting and analyzing information from hospitals on medical harm events.

In addition, the bill creates a Patient Safety Trust Fund which may be used only for expenses directly related to carrying out the bill. DHMH must assess an annual patient safety surcharge on hospitals to offset costs; collections from the surcharge must be paid into the fund.

Current Law/Background: A hospital is required to report to DHMH, within five days of the hospital's knowledge of the occurrence, any unexpected occurrence related to an individual's medical treatment that results in death or serious disability that is not related to the natural course of the individual's illness or underlying condition. (DHMH advises that approximately 1,500 such occurrences have been reported in the last seven years.) A hospital may also report to DHMH an unexpected occurrence or other incident related to an individual's medical treatment that does not result in death or serious disability.

In addition, a hospital is required to conduct a root cause analysis of an occurrence required to be reported under the law and, unless DHMH approves a longer time period, to submit the root cause analysis to DHMH within 60 days of the hospital's knowledge of the occurrence.

If a hospital fails to comply with these requirements, the Secretary of Health and Mental Hygiene may impose a fine of $500 per day for each day the violation continues. (DHMH advises that it has fined two hospitals to date and may have identified an additional occurrence calling for a fine.) DHMH regulations also specify that a hospital's license may be revoked for failing to have a patient safety program as required.

DHMH regulations require a hospital to have a patient safety program and coordinator, as well as an internal staff committee structure to review and evaluate patient safety activities. The governing board of a hospital must develop a process to review and evaluate the effectiveness of the hospital's patient safety program. The patient safety coordinator must facilitate assessment and determination of the appropriate response to

reported "near-misses" and adverse events related to patient care; monitor root cause analyses and any actions resulting from such analyses; and provide for flow of information among quality assurance, credentialing, peer review, and any patient safety committee. A hospital must document in writing the operation of its patient safety program and any actions taken by the quality assurance and medical staff credentialing and peer review committees.

State Fiscal Effect: The bill requires that fees be collected to offset costs of implementing the bill. Accordingly, Patient Safety Trust Fund revenues are expected to increase in accordance with Patient Safety Trust Fund expenditures. In order for revenues to closely track expenditures, Legislative Services estimates that each of the approximately 50 hospitals in the State will have to pay a surcharge of between $6,000 and $9,000 to the fund annually. (Surcharges may vary from this estimate if they are set in accordance with hospital size.) Although the timing of revenues and expenditures may not align perfectly, it is assumed that revenues from surcharges collected will generally match the expenditures necessary to carry out the bill's requirements. For purposes of this estimate, it is assumed that surcharges will be assessed annually.

Because the bill requires significant additional reporting and may necessitate additional inspections, four additional full-time employees and one additional part-time employee are necessary to implement the bill. Accordingly, Patient Safety Trust Fund expenditures increase by $247,042 in fiscal 2012 to hire one part-time research statistician, three full-time health facility surveyors, and one full-time administrative aide. This estimate accounts for the bill's October 1, 2011 effective date and includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Positions (Full-time Equivalent)	4.5
Salaries and Fringe Benefits	$222,173
Operating Expenses	7,459
One-time Start-up Costs	17,410
Total FY State Expenditures	**$247,042**

Future year expenditures reflect full salaries with 4.4% annual increases, 3% employee turnover, and 1% annual increases in ongoing operating expenses.

In addition, future year revenues and expenditures reflect the cost of a triennial audit to be conducted by a State university. Because the audit is required to be conducted triennially, it is assumed for purposes of this estimate that Patient Safety Trust Fund expenditures first increase in fiscal 2014 by $100,000 to represent the cost of performing the audit. However, Legislative Services notes that this cost could, alternatively, be evenly distributed over a rolling three-year period. Future year expenditures would vary accordingly.

DHMH advises that it needs a new database to comply with the bill's requirements. However, the bill does not call for data to be collected that is more complex than or substantially dissimilar from data already collected by DHMH. Accordingly, Legislative Services believes that DHMH's current database is sufficient to enable the department to comply with the bill's requirements.

The bill lowers the maximum fine for reporting failures from $500 to $100. However, the bill also expands the category of occurrences that are required to be reported. Accordingly, the bill's penalty provisions are not expected to materially affect State finances. Any additional workload of the Office of Administrative Hearings or the Health Claims Alternative Dispute Resolution Office is expected to be minimal and can be handled with existing resources.

Additional Comments: Hospital expenditures may increase significantly under the bill. The University of Maryland Medical Center, for example, advises that its annual expenditures are likely to increase by $1.75 million, largely due to an increased volume of investigations.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Maryland Health Claims Alternative Dispute Resolution Office, Department of Health and Mental Hygiene, Office of Administrative Hearings, University of Maryland Medical System, Department of Legislative Services

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