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**FISCAL IMPACT STATEMENT**

**LS 6515**  
**BILL NUMBER: SB 207**

**NOTE PREPARED: Feb 1, 2007**  
**BILL AMENDED:**

**SUBJECT:** Medical adverse event reporting.

**FIRST AUTHOR:** Sen. Dillon  
**FIRST SPONSOR:**

**BILL STATUS:** As Introduced

**FUNDS AFFECTED:**  **GENERAL**  
 **DEDICATED**  
 **FEDERAL**

**IMPACT:** State

**Summary of Legislation:** This bill requires a health care facility to file, with an agency selected by the Indiana State Department of Health (ISDH), patient safety incident reports concerning certain acts that have caused or could have caused harm to a patient. The bill allows other persons to file the reports. It also requires the agency to receive, process, and summarize the reports. The bill makes the reports and certain other information confidential.

The bill also requires the Indiana State Department of Health to study and develop quality indicators for infections and establish infection monitoring systems as part of the Health Care Quality Indicator Data Program.

**Effective Date:** July 1, 2007.

**Explanation of State Expenditures:** *Summary:* The cost of the Medical Adverse Event Reporting program will be dependent upon administrative actions taken by the Department of Health to select an agency or organization to administer the program, the events required to be reported, the associated information required to be included in the report, and the amount of preparation and analysis required to produce the reports. As a point of reference, the cancer registry, a similar type of data reporting and analysis program run by the Department, has four employees and an annual appropriation for FY 2007 of \$237,224. The state of Missouri appropriated \$200,000 to implement a similar program.

*Background:* The Department of Health promulgated adverse event reporting regulations, effective April 1, 2006, in response to an executive order requiring the establishment of a Medical Error Reporting and Quality System (MERS). These rules require hospitals and ambulatory outpatient surgical centers to include reporting

of serious adverse events for the quality assessment and improvement programs of these two types of licensed providers. Rules are also being promulgated that will include licensed birthing centers and abortion clinics in the reporting requirements as well. The reporting requirements implemented are for 27 events based on National Quality Forum standards. The requirements for reporting include more narrowly defined terminology for adverse drug event or what constitutes a reportable event than those defined in the bill. The ISDH has established an on-line reporting system to accept reports on an event-by-event basis. The first preliminary annual report of the information collected for CY 2006 is expected to be released in March 2007; because not all reportable events may have been received, the final report is expected to be completed in August 2007. This reporting system was implemented with resources currently available to the Department.

The bill would not allow the ISDH to operate the Medical Adverse Event Reporting system. The bill requires the Department to enter into an agreement with a governmental agency or a private nongovernmental organization that does not have regulatory control over health care facilities to administer the reporting system. This provision would require a funded contract rather than the use of existing personnel and resources within the ISDH for the project. The contracting agency is to develop incident reporting forms, receive reports of patient safety incidents, analyze the reports, and prepare and distribute quarterly summary patient safety reports to the Department of Health. The agency is also to make findings and recommendations based on the reported information. The bill provides that the affected health care providers are not required to report adverse events to a contractor before July 1, 2008, allowing time for ISDH to amend existing rules, develop rules that comply with the provisions of the bill, and identify a contractor.

The bill would expand the number of providers that are required to report, expand the definition of the events and incidents that are to be reported, and require more reports than the system implemented by the ISDH. The bill would require abortion clinics, ambulatory outpatient surgical centers, birthing centers, community mental health centers, community mental retardation and other developmental disabilities centers, community or migrant health centers, nursing facilities, home health agencies, hospice programs, hospitals, maternal and child health clinics, methadone clinics, and psychiatric hospitals to report events to be defined by rules. The ISDH reporting system currently requires only hospitals and outpatient ambulatory surgery centers to report. The bill also requires the contracting agency to prepare quarterly as opposed to annual summary reports planned by the ISDH.

The Department of Health is to distribute the patient safety information to health care facilities, health care organizations, or governmental agencies as necessary. The ISDH is also to determine the information required to be reported to the agency and promulgate necessary rules. An incident report of an occurrence that caused or could have caused a patient harm is to contain information required by the ISDH rules.

The bill also requires the Department to study and develop quality indicators for infections and, where the Department deems appropriate, to establish infection monitoring programs before December 1, 2007. The fiscal impact of this activity will depend on administrative actions taken by the Department and the availability of definitions and quality indicators for infection reporting.

Ultimately, the source of funds and resources required to satisfy the requirements of this bill will depend upon legislative and administrative actions.

The funds and resources required above could be supplied through a variety of sources, including the following: (1) existing staff and resources not currently being used to capacity; (2) existing staff and resources currently being used in another program; (3) authorized, but vacant, staff positions, including those positions that would need to be reclassified; (4) funds that, otherwise, would be reverted; or (5) new

appropriations. In FY 2006, the Department of Health administration account reverted \$2,912,557 to the General Fund.

*Appropriation Background:* The ISDH administrative appropriations were made from the dedicated Tobacco Master Settlement Agreement Fund for FY 2006 and FY 2007. The funding source of the FY 2008 and FY 2009 ISDH administrative appropriations will be determined by the General Assembly.

**Explanation of State Revenues:**

**Explanation of Local Expenditures:** Local government-owned hospitals, nursing facilities, and clinics would fall under the reporting requirements of this bill.

**Explanation of Local Revenues:**

**State Agencies Affected:** State Department of Health and potentially another state agency with no health care regulatory oversight.

**Local Agencies Affected:** Local departments of health that may operate maternal and child health clinics or other clinics that might be required to report.

**Information Sources:** Department of Health; *Indiana Register*, Volume 29, Number 4, January 1, 2006, LSA Document #06-73(E).

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