# LEGISLATIVE SERVICES AGENCY
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## FISCAL IMPACT STATEMENT

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

**NOTE PREPARED:** Feb 26, 2007
**BILL AMENDED:** Feb 26, 2007

**SUBJECT:** Medical Adverse Event Reporting.

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

**BILL STATUS:** 2nd Reading - 1st House

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

**IMPACT:** State

**Summary of Legislation:** (Amended) This bill requires the State Department of Health (ISDH), subject to appropriation by the General Assembly, to enter into an agreement with an agency to collect, analyze, interpret, and disseminate findings on a statewide basis until June 30, 2010, regarding patient safety. The bill makes it voluntary for certain persons to submit information to the agency and makes the reports and certain other information confidential and privileged.

The bill also requires the State Department of Health to: (1) study and develop quality indicators for infections; (2) publish the indicators; and (3) report to the Health Finance Commission before September 1, 2007, and September 1, 2008, concerning the implementation of the program.

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

**Explanation of State Expenditures:** *Summary:* The cost of the Medical Adverse Event Reporting program will depend on the General Assembly to appropriate funds and subsequent administrative actions taken by the Department of Health to select an agency 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 submitted a budget request for FY 2008 of $648,739.

*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. Subject to an appropriation by the General Assembly, the bill requires the Department to enter into an agreement with a federally certified patient safety organization or an academic institution to administer a confidential, voluntary 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 collect, analyze, interpret, and disseminate findings on a statewide basis regarding patient safety. The State Department is allowed to adopt rules to administer the chapter.

The bill also requires the Department to study and develop quality indicators for infections and publish the indicators for use by health care facilities before December 1, 2008. 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 would fall under the reporting requirements of this bill.

**Explanation of Local Revenues:**

**State Agencies Affected:** State Department of Health.

**Local Agencies Affected:**

**Information Sources:** Department of Health; *Indiana Register*, Volume 29, Number 4, January 1, 2006,

LSA Document #06-73(E).

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