# HOUSE BILL 821

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By: **Delegates Summers, Howard, and V. Turner**
Introduced and read first time: February 11, 2011
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

**Hospitals – Medical Harm Disclosure Act**

FOR the purpose of altering certain requirements for hospital licensure; requiring hospitals to report certain medical harm events to the Department of Health and Mental Hygiene; requiring hospitals that have had no medical harm events to make a certain statement to the Department; requiring hospitals to establish a certain patient safety program for certain purposes and to provide an annual summary of the program to the Department; requiring hospitals to inform certain persons of medical harm events, interview certain persons about medical harm events, and include a medical harm event on a death certificate under certain circumstances; requiring the Secretary of Health and Mental Hygiene to appoint an advisory committee to assist the Department in carrying out certain requirements; providing for the composition of the advisory committee; requiring the Department to seek advice from the advisory committee on certain matters; requiring meetings of the advisory committee to be subject to the Open Meetings Act; requiring the Department, with the advice of the advisory committee, to develop certain guidelines and methodologies; requiring the Department to validate the accuracy of certain information with certain frequency; requiring the Department to conduct certain reviews of hospital medical records for a certain purpose; requiring certain methodologies to be disclosed to the public; requiring the Department to have a certain audit conducted with certain frequency by a State university without certain affiliation; requiring the Department to publish certain penalties on its Web site and to issue a certain news release with certain frequency; requiring the Department, on or before a certain date and annually thereafter, to report to the Governor and the General Assembly on medical harm events at each hospital and to publish the report on the Department's Web site; requiring the Department to publish information on its Web site on certain inspections; prohibiting a hospital report and a Department public disclosure from containing certain identifying information; prohibiting a hospital from taking certain actions against certain persons for certain reasons; requiring the

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
**[**Brackets**]** indicate matter deleted from existing law.

Department to assess a certain surcharge on hospitals for a certain purpose; requiring collections from the surcharge to be paid into a certain Fund; establishing the Patient Safety Trust Fund as a special, nonlapsing fund; establishing the contents and uses of the Fund; requiring the State Treasurer to invest the money in the Fund in a certain manner; providing that any investment earnings of the Fund shall be paid into the Fund; requiring expenditures from the Fund to be made only in accordance with the State budget; requiring the Department or its agent to conduct an on–site inspection and complete an investigation under certain circumstances; authorizing the Department to assess a certain penalty under certain circumstances; providing for certain appeals; requiring the Department to adopt certain regulations; establishing a certain short title; defining certain terms; and generally relating to hospitals and the Medical Harm Disclosure Act.

BY repealing and reenacting, with amendments,
Article – Health – General
Section 19–319(a)
Annotated Code of Maryland
(2009 Replacement Volume and 2010 Supplement)

BY adding to
Article – Health – General
Section 19–3C–01 through 19–3C–11 to be under the new subtitle "Subtitle 3C. Medical Harm Disclosure Act"
Annotated Code of Maryland
(2009 Replacement Volume and 2010 Supplement)

Preamble

WHEREAS, Recent research indicates that little progress has been made in reducing medical harm since "To Err Is Human" was published by the Institute of Medicine in 1999, estimating 98,000 deaths of hospital patients each year due to medical harm; and

WHEREAS, A November 2010 study by the U.S. Health and Human Services Office of the Inspector General (OIG) estimated that one in seven Medicare patients experienced serious or long–term medical harm, including infections, in the hospital, and that this harm contributed to the deaths of 15,000 patients each month; and

WHEREAS, A November 2010 New England Journal of Medicine study of general acute care hospitals in North Carolina found that one in four hospital patients are harmed, with little evidence that harm had decreased substantially over a period of 6 years, despite a high level of engagement in efforts to improve patient safety in that state during the same period; and

WHEREAS, The cost of medical harm in lives and dollars is significant, with an estimated $4.4 billion in extra hospital costs to Medicare patients alone, according to the OIG study; and

WHEREAS, 92% of Americans believe that hospitals should be required to report serious medical errors, and 63% believe that these reports should be made public; and

WHEREAS, Most states rely solely on hospitals to report on medical harm voluntarily, without any oversight, despite repeated studies showing the inadequacy of voluntary reporting; and

WHEREAS, Research and the experience of states indicate significant underreporting of harmful events, due to overly narrow definitions of medical harm, failure to enforce existing laws and regulations, and failure to ensure accurate reporting; and

WHEREAS, Patients who have been harmed and their families have a right to know the details about medical harm when it occurs, and should be included in hospital assessments of harmful events and encouraged to report such events to State authorities; and

WHEREAS, It is in the public interest to have access to hospital–specific information about medical harm, and public reporting of medical harm is an essential component of improving of patient safety; and

WHEREAS, Every effort must be made to reduce and eliminate medical harm by identifying problems and implementing solutions that promote patient safety; and

WHEREAS, Information to help prevent adverse events is widely available, but many hospitals do not routinely apply recommended practices, such as basic electronic record keeping, computerized provider order entry, reasonable work hours, and compliance with simple interventions such as hand washing; and

WHEREAS, The State has a compelling and urgent need to require hospitals to account for medical harm to patients and issue public reports regarding the number of incidents and type of harm that occur at each hospital; now, therefore,

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

**Article – Health – General**

19–319.

(a) To qualify for a license**[**, an**]:**

**(1) AN** applicant and the hospital or related institution to be operated shall meet the requirements of this section**; AND**

**(2) A HOSPITAL SHALL MEET THE REQUIREMENTS OF SUBTITLE 3C OF THIS TITLE.**

**SUBTITLE 3C. MEDICAL HARM DISCLOSURE ACT.**

**19–3C–01.**

**(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.**

**(B) "FUND" MEANS THE PATIENT SAFETY TRUST FUND ESTABLISHED UNDER § 19–3C–08 OF THIS SUBTITLE.**

**(C) "HOSPITAL" HAS THE MEANING STATED IN § 19–301 OF THIS TITLE.**

**(D) (1) "MEDICAL HARM EVENT" MEANS HARM TO A PATIENT AS A RESULT OF CARE IN A HOSPITAL.**

**(2) "MEDICAL HARM EVENT" INCLUDES:**

**(I) EACH EVENT ON THE LIST OF SERIOUS REPORTABLE EVENTS PUBLISHED BY THE NATIONAL QUALITY FORUM;**

**(II) SURGICAL AND RELATED ANESTHESIA EVENTS, INCLUDING:**

**1. UNEXPECTED COMPLICATIONS AND DEATHS;**

**2. SURGERY PERFORMED ON A WRONG BODY PART;**

**3. SURGERY PERFORMED ON THE WRONG PATIENT;**

**4. THE WRONG SURGICAL PROCEDURE PERFORMED ON A PATIENT; AND**

**5. RETENTION OF A FOREIGN OBJECT IN A PATIENT AFTER SURGERY OR ANOTHER PROCEDURE, EXCLUDING:**

**A. OBJECTS INTENTIONALLY IMPLANTED AS PART OF A PLANNED INTERVENTION; AND**

**B. OBJECTS PRESENT BEFORE SURGERY THAT ARE INTENTIONALLY RETAINED;**

**(III) MEDICATION EVENTS RELATED TO PROFESSIONAL PRACTICE OR HEALTH CARE PRODUCTS, PROCEDURES, AND SYSTEMS, INCLUDING ERRORS IN:**

**1. PRESCRIBING;**

**2. PRESCRIPTION ORDER COMMUNICATIONS; AND**

**3. PRODUCT LABELING, PACKAGING AND NOMENCLATURE, COMPOUNDING, DISPENSING, DISTRIBUTION, ADMINISTRATION, EDUCATION, MONITORING, AND USE;**

**(IV) DEVICE EVENTS RELATED TO THE USE OR FUNCTION OF A DEVICE IN PATIENT CARE IN WHICH THE DEVICE, INCLUDING A CATHETER, AN INFUSION PUMP, OR A VENTILATOR, IS USED OR FUNCTIONS OTHER THAN INTENDED;**

**(V) CARE MANAGEMENT EVENTS, INCLUDING:**

**1. STAGE 3 OR 4 PRESSURE ULCERS ACQUIRED AFTER ADMISSION TO THE HOSPITAL;**

**2. FAILURE TO RESCUE;**

**3. IV INJURIES; AND**

**4. MATERNAL DEATH OR SERIOUS DISABILITY ASSOCIATED WITH LABOR OR DELIVERY, INCLUDING EVENTS THAT OCCUR WITHIN 42 DAYS POST–DELIVERY;**

**(VI) ENVIRONMENTAL DEATHS, INCLUDING:**

**1. UNINTENDED ELECTRIC SHOCK;**

**2. DELIVERY OF THE WRONG GAS OR CONTAMINATED TOXIC SUBSTANCE;**

**3. BURNS RECEIVED FROM ANY SOURCE;**

**4. PATIENT FALLS; AND**

**5. HARM ASSOCIATED WITH THE USE OF RESTRAINTS OR BEDRAILS; AND**

**(VII) DEATH OF A PREVIOUSLY HEALTHY PERSON WHILE UNDERGOING CARE AT THE HOSPITAL.**

**19–3C–02.**

**(A) A HOSPITAL SHALL REPORT A MEDICAL HARM EVENT TO THE DEPARTMENT:**

**(1) NO LATER THAN 5 DAYS AFTER THE MEDICAL HARM EVENT HAS BEEN DETECTED; OR**

**(2) IF THE MEDICAL HARM 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 THE MEDICAL HARM EVENT HAS BEEN DETECTED.**

**(B) THE REPORT REQUIRED UNDER SUBSECTION (A) OF THIS SECTION SHALL INDICATE THE LEVEL OF HARM TO THE PATIENT, SUCH AS WHETHER THE MEDICAL HARM EVENT RESULTED IN SERIOUS INJURY OR DEATH.**

**(C) AT THE END OF A QUARTER, EACH HOSPITAL THAT HAS HAD NO MEDICAL HARM EVENTS TO REPORT DURING THE QUARTER SHALL AFFIRMATIVELY STATE THIS FACT TO THE DEPARTMENT.**

**(D) (1) EACH HOSPITAL SHALL ESTABLISH A HOSPITAL–WIDE PATIENT SAFETY PROGRAM TO ROUTINELY REVIEW PATIENT RECORDS FOR MEDICAL HARM EVENTS, ANALYZE THE MEDICAL HARM EVENTS TO DETERMINE IF THEY WERE PREVENTABLE, AND IMPLEMENT CHANGES TO PREVENT SIMILAR MEDICAL HARM EVENTS.**

**(2) EACH HOSPITAL SHALL PROVIDE AN ANNUAL SUMMARY OF ITS PATIENT SAFETY PROGRAM TO THE DEPARTMENT.**

**(E) EACH HOSPITAL SHALL INFORM THE PATIENT, THE PERSON LEGALLY RESPONSIBLE FOR THE PATIENT, OR, IN CASES OF DEATH OR SERIOUS BODILY INJURY, AN ADULT MEMBER OF THE IMMEDIATE FAMILY, OF A MEDICAL HARM EVENT NO LATER THAN THE TIME AT WHICH THE REPORT REQUIRED UNDER SUBSECTION (A) OF THIS SECTION MUST BE MADE TO THE DEPARTMENT.**

**(F) EACH HOSPITAL SHALL:**

**(1) INTERVIEW PATIENTS, FAMILY MEMBERS, AND OTHER PERSONS LEGALLY RESPONSIBLE FOR THE PATIENT ABOUT MEDICAL HARM EVENTS; AND**

**(2) INCLUDE A DETAILED SUMMARY OF THE INTERVIEW IN THE PATIENT'S MEDICAL RECORD.**

**(G) IF A MEDICAL HARM EVENT CONTRIBUTED TO THE DEATH OF A PATIENT, A HOSPITAL SHALL INCLUDE THE MEDICAL HARM EVENT AS A CONTRIBUTING CAUSE ON THE PATIENT'S DEATH CERTIFICATE.**

**19–3C–03.**

**(A) THE SECRETARY SHALL APPOINT AN ADVISORY COMMITTEE TO ASSIST THE DEPARTMENT IN CARRYING OUT THE REQUIREMENTS OF THIS SUBTITLE.**

**(B) (1) THE ADVISORY COMMITTEE SHALL INCLUDE REPRESENTATIVES OF:**

**(I) PUBLIC AND PRIVATE HOSPITALS;**

**(II) DIRECT CARE NURSING STAFF;**

**(III) PHYSICIANS;**

**(IV) EPIDEMIOLOGISTS WITH EXPERTISE IN PATIENT SAFETY;**

**(V) ACADEMIC RESEARCHERS;**

**(VI) CONSUMER ORGANIZATIONS;**

**(VII) HEALTH INSURERS, NONPROFIT HEALTH SERVICE PLANS, AND HEALTH MAINTENANCE ORGANIZATIONS;**

**(VIII) ORGANIZED LABOR; AND**

**(IX) PURCHASERS OF HEALTH CARE BENEFITS, INCLUDING EMPLOYERS.**

**(2) THE ADVISORY COMMITTEE SHALL HAVE A MAJORITY OF MEMBERS WHO REPRESENT INTERESTS OTHER THAN HOSPITALS.**

**(C) THE DEPARTMENT SHALL SEEK ADVICE FROM THE ADVISORY COMMITTEE ON:**

**(1) METHODS OF COLLECTING INFORMATION;**

**(2) FORMATTING OF FORMS AND REPORTS;**

**(3) EVALUATION OF METHODS USED; AND**

**(4) METHODS AND MEANS FOR THE RELEASE AND DISSEMINATION OF INFORMATION.**

**(D) MEETINGS OF THE ADVISORY COMMITTEE SHALL BE SUBJECT TO THE OPEN MEETINGS ACT.**

**19–3C–04.**

**(A) WITH THE ADVICE OF THE ADVISORY COMMITTEE APPOINTED UNDER § 19–3C–03 OF THIS SUBTITLE, THE DEPARTMENT SHALL DEVELOP:**

**(1) GUIDELINES FOR HOSPITALS TO IDENTIFY MEDICAL HARM EVENTS;**

**(2) A METHODOLOGY FOR COLLECTING INFORMATION FROM HOSPITALS ON MEDICAL HARM EVENTS, INCLUDING FORMS AND STANDARDIZED FORMATS FOR HOSPITALS TO SUBMIT THE REPORTS REQUIRED UNDER THIS SUBTITLE; AND**

**(3) A METHODOLOGY FOR ANALYZING THE INFORMATION REPORTED BY HOSPITALS UNDER THIS SUBTITLE.**

**(B) IN DEVELOPING THE METHODOLOGY REQUIRED UNDER SUBSECTION (A)(2) OF THIS SECTION, THE DEPARTMENT SHALL USE:**

**(1) THE FORMS DEVELOPED BY THE FEDERAL AGENCY FOR HEALTHCARE RESEARCH AND QUALITY AS "COMMON FORMATS"; OR**

**(2) A SIMILAR STANDARDIZED COLLECTION METHOD.**

**(C) IN DEVELOPING THE METHODOLOGY REQUIRED UNDER SUBSECTION (A)(3) OF THIS SECTION, THE DEPARTMENT SHALL USE A STANDARDIZED METHOD OF CATEGORIZING THE LEVEL OF HARM EXPERIENCED BY A PATIENT, SUCH AS THE NATIONAL COORDINATING COUNCIL FOR**

**MEDICATION ERRORS REPORTING AND PREVENTION INDEX FOR CATEGORIZING ERRORS.**

**(D) (1) AT LEAST QUARTERLY, THE DEPARTMENT SHALL VALIDATE THE ACCURACY OF INFORMATION REPORTED BY HOSPITALS UNDER THIS SUBTITLE BY COMPARING THE INFORMATION WITH OTHER AVAILABLE DATA, INCLUDING:**

**(I) PATIENT SAFETY INDICATORS FROM HOSPITAL PATIENT DISCHARGE DATA;**

**(II) COMPLAINTS FILED WITH THE OFFICE OF HEALTH CARE QUALITY;**

**(III) DEATH CERTIFICATES;**

**(IV) INSPECTION AND SURVEY REPORTS; AND**

**(V) MEDICAL MALPRACTICE INFORMATION.**

**(2) THE DEPARTMENT SHALL CONDUCT ANNUAL RANDOM REVIEWS OF HOSPITAL MEDICAL RECORDS TO VALIDATE THE ACCURACY OF THE INFORMATION REPORTED BY HOSPITALS.**

**(E) THE DATA COLLECTION, ANALYSIS, AND VALIDATION METHODOLOGIES USED BY THE DEPARTMENT SHALL BE DISCLOSED TO THE PUBLIC.**

**(F) (1) EVERY 3 YEARS, THE DEPARTMENT SHALL HAVE AN INDEPENDENT AUDIT OF HOSPITAL REPORTING CONDUCTED BY A STATE UNIVERSITY NOT AFFILIATED WITH ANY HOSPITAL REQUIRED TO REPORT UNDER THIS SUBTITLE.**

**(2) THE AUDIT SHALL:**

**(I) ASSESS THE ACCURACY OF REPORTING BY HOSPITALS, INCLUDING, IN PARTICULAR, THE UNDERREPORTING OF MEDICAL HARM EVENTS; AND**

**(II) BE FUNDED BY THE FUND ESTABLISHED UNDER § 19–3C–08 OF THIS SUBTITLE.**

**(3) THE RESULTS OF THE AUDIT SHALL:**

**(I) BE REPORTED TO THE DEPARTMENT; AND**

**(II) BE MADE AVAILABLE TO THE PUBLIC ON THE DEPARTMENT'S WEB SITE WITHIN 1 MONTH AFTER THE DEPARTMENT RECEIVES THE AUDIT REPORT.**

**19–3C–05.**

**(A) EACH QUARTER, THE DEPARTMENT SHALL:**

**(1) PUBLISH ON ITS WEB SITE THE PENALTIES ASSESSED ON HOSPITALS UNDER § 19–3C–09 OF THIS SUBTITLE FOR FAILURE TO REPORT MEDICAL HARM EVENTS; AND**

**(2) ISSUE A NEWS RELEASE ABOUT THE PUBLICATION.**

**(B) (1) ON OR BEFORE APRIL 1, 2013, AND ANNUALLY THEREAFTER, THE DEPARTMENT SHALL REPORT TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2–1246 OF THE STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY ON THE MEDICAL HARM EVENTS REPORTED AT EACH HOSPITAL DURING THE PREVIOUS CALENDAR YEAR.**

**(2) THE REPORT MAY INCLUDE POLICY RECOMMENDATIONS RELATING TO MEDICAL HARM EVENTS, AS APPROPRIATE.**

**(3) THE REPORT SHALL:**

**(I) BE PUBLISHED ON THE DEPARTMENT'S WEB SITE AT THE SAME TIME IT IS SUBMITTED TO THE GOVERNOR AND THE GENERAL ASSEMBLY;**

**(II) INCLUDE HOSPITAL–SPECIFIC INFORMATION ON:**

**1. THE NUMBER AND TYPE OF MEDICAL HARM EVENTS REPORTED;**

**2. THE LEVEL OF HARM TO PATIENTS;**

**3. PENALTIES ASSESSED AND ENFORCEMENT ACTIONS TAKEN; AND**

**4. THE QUARTERLY AFFIRMATION BY HOSPITALS IN WHICH NO MEDICAL HARM EVENTS HAVE OCCURRED REQUIRED UNDER § 19–3C–02(C) OF THIS SUBTITLE;**

**(III) PROVIDE INFORMATION IN A MANNER THAT STRATIFIES THE DATA BASED ON CHARACTERISTICS OF THE HOSPITALS REPORTING, SUCH AS NUMBER OF PATIENT ADMISSIONS AND PATIENT DAYS IN THE HOSPITAL; AND**

**(IV) CONTAIN TEXT WRITTEN IN PLAIN LANGUAGE THAT INCLUDES A DISCUSSION OF:**

**1. FINDINGS, CONCLUSIONS, AND TRENDS CONCERNING OVERALL PATIENT SAFETY IN THE STATE, INCLUDING A COMPARISON TO PRIOR YEARS; AND**

**2. THE METHODS THE DEPARTMENT USED TO CHECK FOR THE ACCURACY OF HOSPITAL REPORTS OF MEDICAL HARM EVENTS.**

**(C) EACH QUARTER, THE DEPARTMENT SHALL PUBLISH ON ITS WEB SITE INFORMATION ON THE FINDINGS RESULTING FROM HOSPITAL INSPECTIONS CONDUCTED UNDER § 19–308 OF THIS TITLE.**

**(D) A HOSPITAL REPORT AND A DEPARTMENT PUBLIC DISCLOSURE MAY NOT CONTAIN INFORMATION IDENTIFYING A PATIENT, HOSPITAL EMPLOYEE, OR HEALTH CARE PROVIDER.**

**19–3C–06.**

**A HOSPITAL MAY NOT DISCHARGE, REFUSE TO HIRE, REFUSE TO SERVE, RETALIATE IN ANY MANNER, OR TAKE ANY ADVERSE ACTION AGAINST ANY EMPLOYEE, APPLICANT FOR EMPLOYMENT, OR HEALTH CARE PROVIDER BECAUSE THE EMPLOYEE, APPLICANT, OR HEALTH CARE PROVIDER TAKES OR HAS TAKEN ANY ACTION TO PROMOTE THE ENFORCEMENT OF THIS SUBTITLE.**

**19–3C–07.**

**(A) THE DEPARTMENT SHALL ASSESS AN ANNUAL PATIENT SAFETY SURCHARGE ON HOSPITALS TO OFFSET THE COSTS OF CARRYING OUT THIS SUBTITLE.**

**(B) COLLECTIONS FROM THE ANNUAL PATIENT SAFETY SURCHARGE SHALL BE PAID INTO THE FUND.**

**19–3C–08.**

**(A) THERE IS A PATIENT SAFETY TRUST FUND.**

**(B) THE PURPOSE OF THE FUND IS TO SUPPORT REGULATORY OVERSIGHT AND PUBLIC ACCOUNTABILITY FOR SAFE CARE IN HOSPITALS.**

**(C) THE DEPARTMENT SHALL ADMINISTER THE FUND.**

**(D) (1) THE FUND IS A SPECIAL, NONLAPSING FUND THAT IS NOT SUBJECT TO § 7–302 OF THE STATE FINANCE AND PROCUREMENT ARTICLE.**

**(2) THE STATE TREASURER SHALL HOLD THE FUND SEPARATELY, AND THE COMPTROLLER SHALL ACCOUNT FOR THE FUND.**

**(E) THE FUND CONSISTS OF:**

**(1) REVENUE DISTRIBUTED TO THE FUND UNDER §§ 19–3C–07 AND 19–3C–09 OF THIS SUBTITLE;**

**(2) MONEY APPROPRIATED IN THE STATE BUDGET TO THE FUND;**

**(3) INVESTMENT EARNINGS; AND**

**(4) ANY OTHER MONEY FROM ANY OTHER SOURCE ACCEPTED FOR THE BENEFIT OF THE FUND.**

**(F) THE FUND MAY BE USED ONLY FOR EXPENSES DIRECTLY RELATED TO CARRYING OUT THIS SUBTITLE, INCLUDING EXPENSES RELATED TO:**

**(1) THE ADVISORY COMMITTEE APPOINTED UNDER § 19–3C–03 OF THIS SUBTITLE; AND**

**(2) THE AUDIT REQUIRED UNDER § 19–3C–04 OF THIS SUBTITLE.**

**(G) (1) THE STATE TREASURER SHALL INVEST THE MONEY OF THE FUND IN THE SAME MANNER AS OTHER STATE MONEY MAY BE INVESTED.**

**(2) ANY INVESTMENT EARNINGS OF THE FUND SHALL BE PAID INTO THE FUND.**

**(H) EXPENDITURES FROM THE FUND MAY BE MADE ONLY IN ACCORDANCE WITH THE STATE BUDGET.**

**19–3C–09.**

**(A) IF THE DEPARTMENT RECEIVES A REPORT OF A MEDICAL HARM EVENT UNDER § 19–3C–02(A) OF THIS SUBTITLE THAT INDICATES AN ONGOING**

**THREAT OR IMMINENT DANGER OF DEATH OR SERIOUS BODILY HARM, THE DEPARTMENT OR ITS AGENT SHALL:**

**(1) CONDUCT AN ON–SITE INSPECTION WITHIN 48 HOURS OR 2 BUSINESS DAYS, WHICHEVER IS GREATER, AFTER RECEIVING THE REPORT; AND**

**(2) COMPLETE AN INVESTIGATION OF THE EVENT WITHIN 45 DAYS AFTER RECEIVING THE REPORT.**

**(B) (1) IF A HOSPITAL FAILS TO REPORT A MEDICAL HARM EVENT UNDER § 19–3C–02(A) OF THIS SUBTITLE, THE DEPARTMENT MAY ASSESS A CIVIL PENALTY ON THE HOSPITAL IN AN AMOUNT NOT EXCEEDING $100 FOR EACH DAY THAT THE MEDICAL HARM EVENT IS NOT REPORTED FOLLOWING THE INITIAL 5–DAY PERIOD OR 24–HOUR PERIOD, AS APPLICABLE UNDER § 19–3C–02(A) OF THIS SUBTITLE.**

**(2) IF A HOSPITAL DISPUTES A FAILURE TO REPORT A MEDICAL HARM EVENT UNDER § 19–3C–02(A) OF THIS SUBTITLE, THE HOSPITAL MAY:**

**(I) APPEAL TO THE BOARD OF REVIEW OF THE DEPARTMENT; AND**

**(II) AFTER AN APPEAL TO THE BOARD OF REVIEW, TAKE ANY FURTHER APPEAL ALLOWED BY THE ADMINISTRATIVE PROCEDURE ACT.**

**(3) A PENALTY ASSESSED UNDER THIS SECTION IS NOT PAYABLE UNTIL ANY APPEALS TAKEN UNDER PARAGRAPH (2) OF THIS SUBSECTION HAVE BEEN EXHAUSTED.**

**(C) A HOSPITAL SHALL COMPLY WITH THE REQUIREMENTS OF THIS SUBTITLE AS A CONDITION OF LICENSURE.**

**19–3C–10.**

**THE DEPARTMENT SHALL ADOPT REGULATIONS TO CARRY OUT THIS SUBTITLE.**

**19–3C–11.**

**THIS SUBTITLE MAY BE CITED AS THE "MEDICAL HARM DISCLOSURE ACT".**

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2011.