H. B. 2942

(By Delegate Walker)

[Introduced January 31, 2011; referred to the Committee on Health and Human Resources then the Judiciary.]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article, designated §16-43-1, §16-43-2, §16-43-3, §16-43-4, §16-43-5, §16-43-6, §16-43-7, §16-43-8, §16-43-9, §16-43-10, §16-43-11 and §16-43-12; all relating to establishing the Medical Harm Disclosure Act where hospitals are required to report medical harm events and face possible sanctions if they do not report such events at its hospitals; establishing an advisory committee within the Department of Health and Human Resources; and establishing procedures for patients to report incidents of medical harm.

Be it enacted by the Legislature of West Virginia:

That the Code of West Virginia, 1931, as amended, be amended by adding thereto a new article, designated §16-43-1, §16-43-2, §16-43-3, §16-43-4, §16-43-5, §16-43-6, §16-43-7, §16-43-8,

§16-43-9, §16-43-10, §16-43-11 and §16-43-12, all to read as follows:

ARTICLE 43. MEDICAL HARM DISCLOSURE ACT.

§16-43-1. Legislative Findings.

The Legislature declares:

(a) 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 ninety-eight thousand deaths of hospital patients each year was due to medical harm.

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

(c) 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 six years despite a high level of engagement in efforts to improve patient safety in that state during the same period.

(d) The cost of medical harm in lives and dollars is significant, an estimated $4.4 billion in extra hospital costs to Medicare patients alone, according to the Office of Inspector General.

(e) Ninety-two percent of Americans believe that hospital should be required to report serious medical errors and sixty-three percent believe that these reports should be made public.

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

(g) Research and experience in states indicate signficant 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.

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

(i) 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 for improvement of patient safety.

(j) Every effort must be made to reduce and eliminate medical harm by identifying problems and implementing solutions that promote patient safety.

(k) Information to help prevent adverse events is widely available, however, 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.

(l) The State of West Virginia has a compelling and urgent need to require hospitals to account for medical harm to patients and issue public reports regarding the number and type of harm that occur at each hospital.

§16-43-2. Definitions.

As used in this article:

(a) "Department" means the Department of Health and Human Resources.

(b) "Hospital" means an acute care health care facility licensed under the Hospital Licensing Act, hospital affilitated and freestanding outpatient or "ambulatory" surgical centers, dialysis centers and nursing homes.

(c) "Medical harm event" is harm to a patient as a result of medical care or in a health care setting. It may include, but should not be limited to, the National Quality Forum's list of Serious Reportable Events and should include the following categories of events:

(1) Surgical and related anesthesia events including unexpected complications and deaths, surgery performed on a wrong body part, surgery performed on the wrong patient, the wrong surgical procedure performed on a patient, and retention of a foreign object in a patient after surgery or other procedure,

excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

(2) Medication events related to professional practice, or healthcare products, procedures and systems, including, but not limited to, prescribing, prescription order communications, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.

(3) Product or device events related to the use or function of a device in patient care in which the device is used or functions other than as intended, including, but not limited to, catheters, infusion pumps or ventilators.

(4) Care management events including, but not limited to, stage three or four pressure ulcers acquired after admission to a health facility, failure to rescue, IV injuries and maternal death or serious disability associated with labor or delivery, including events that occurs within forty-two days post-delivery.

(5) Environmental deaths including, but not limited to, unintended electric shock, delivery of the wrong gas or contaminated toxic substance, burns incurred from any source, patient falls, and harm associated with the use of restraints or bed rails.

(6) Death of a previously healthy person while undergoing medical care.

§16-43-3. Hospital requirements.

(a) A hospital shall report a medical harm event to the department not later than five days after the event has been detected, or, if that event is an ongoing urgent or emergency threat to the welfare, health, or safety of patients, personnel, or visitors, not later than twenty-four hours after the adverse event has been detected. The reports shall be made on a form prescribed by the department.

(b) The report shall indicate the level of medical harm to the patient, such as whether it resulted in serious injury or death, using the format developed by the department.

(c) On a quarterly basis, each hospital that has had no medical harm events to report during that quarter shall affirmatively declare this fact to the department, using a form developed by the department.

(d) Each hospital shall create facility-wide patient safety programs to routinely review patient records for medical harm, analyze these events to determine if they were preventable and implement changes to prevent similar harmful events. Each hospital shall provide an annual summary of its patient safety program to the department.

(e) Each hospital shall inform the patient, the party responsible for the patient, or an adult member of the immediate family in cases of death or serious bodily injury, of the medical

harm event by the time the report is made to the department.

(f) Each hospital shall interview patients, family members, or parties responsible for the patient about medical harm events and document a detailed summary of that interview in the patient's medical record.

(g) If the medical harm event contributed to the death of a patient, the hospital shall include that event as a contributing cause on the patient's death certificate.

(h) If the hospital is a division or subsidiary of another entity that owns or operates multiple hospitals or related organizations, a report shall be made for each specific division or subsidiary and not an aggregate report from multiple hospitals.

(i) Nothing in this section shall be interpreted to change or otherwise affect hospital reporting requirements regarding reportable diseases or unusual occurences, as provided in article five-b of this chapter.

§16-43-4. Advisory committee.

(a) The director of the department shall appoint an advisory committee, including representatives from public and private hospitals, direct care nursing staff, physicians, epidemiologists with expertise in patient safety, academic researchers, consumer organizations, health insurers, health maintenance organizations, organized labor and purchasers of health insurance, such as employers. The advisory committee shall have a majority of members

representing interests other than hospitals.

(b) The advisory committee shall assist the department in the development of all aspects of the department's methodology for collecting, analyzing and disclosing the information collected under this article, including collection methods, formatting, evaluation of methods used and the methods and means for release and dissemination.

(c) Meetings of the advisory committee shall be open to the public.

§16-43-5. Methodologies for collecting, analyzing and validating data.

(a) The department shall, with the advice of the advisory committee created in section four of this article, develop guidelines for hospitals in identifying medical harm events.

(b) The department shall create standardized reporting formats for hospitals to use to comply with all provisions of this article.

(c) In developing the methodology for collecting the data on medical harm events, the department and advisory committee shall use the forms developed by the Agency for Healthcare Research and Quality as "Common Formats," or a similar standardized collection method.

(d) In developing the methodology for analyzing the date, the department shall include a standardized method of categorizing the level of harm experienced by the patient, such as the National

Coordinating Council for Medication Errors Reporting and Prevention.

(e) The department shall at least quarterly check the accuracy of information reported by hospitals under this act by comparing the information with other available data such as patient safety indicators from hospitals patient discharge data, complaints filed with the licensing division, death certificates, inspection and survey reports, and medical malpractice information. The department shall annually conduct random reviews of hospital medical records.

(f) The data collection, analysis and validation methodologies shall be disclosed to the public.

(g) Every three years, the department shall have an independent audit conducted by a state university not affiliated with any hospital required to report under this article. The audit shall:

(1) Assess the accuracy of reporting by hospitals, especially seeking to identify under-reporting;

(2) Be funded by Patient Safety Trust Fund created in section nine of this article; and

(3) Be available to the public on the department's website within one month of receiving the final report.

(h) The department shall adopt regulations to carry out the provisions of this article.

§16-43-6. Public reports.

(a) Each quarter, the department shall publish details of the fines assessed to hospitals for failure to report medical harm events under section ten of this article, and shall issue a news release about that publication.

(b) The department shall annually submit a report to the Legislature detailing medical harm events reported at each hospital required to report under this article. The report may include policy recommendations, as appropriate. The report shall:

(1) Be published on the department's website at the same time it is submitted to the Legislature;

(2) Include hospital-specific information on the number and type of medical harm events reported, the level of harm to patients, fines assessed and enforcement actions take, and the quarterly affirmation by hospital in which no medical harm events have occurred;

(3) Provide information in a manner that stratifies the data based on characteristics of the hospitals, such as number of patient admissions and patient days in each hospital; and

(4) Contain text written in plain language that includes a discussion of findings, conclusions and trends concerning the overall patient safety in the state, including a comparison to prior years, and the methods the department used to check for the accuracy of hospital reports.

(c) Each quarter, the department shall make information

regarding outcomes of inspections and investigations conducted pursuant to its regulatory duties readily accessible to the public on the department website.

(d) No hospital report or department public disclosure may contain information identifying a patient, employee or licensed health care professional in connection with a specific infection incident.

(e) The first report required under subsection (b) of this section shall be submitted and published no later than January 1, 2012. Following the initial report, the department shall publish these reports annually.

§16-43-7. Privacy.

It is the expressed intent of the Legislature that a patient's right of confidentiality shall not be violated in any manner. Patient social security numbers or any other information that could be used to identify an individual patient shall not be released notwithstanding any other provision of law.

§16-43-8. Protection for taking action.

No hospital shall 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 such employee, applicant for employment or health care provider takes or has taken any action in furtherance of the enforcement of the provisions of this article.

§16-43-9. Funding.

(a) A Patient Safety Trust Fund is created independent of the general fund. Moneys in the trust fund shall come from an annual patient safety surcharge on licensing fees charged to those medical facilities required to report under this article.

(b) All penalties assessed under section ten of this article shall be deposited into the patient safety trust fund.

(c) Spending from the fund shall be used for regulatory oversight and public accountability for safe health care, including the audit specified under section five of this article.

§16-43-10. Department actions and penalties.

(a) In any case in which the department receives a report from a hospital pursuant to section three of this article, that indicates an ongoing threat or imminent danger of death or serious bodily harm, the department shall make an onsite inspection or investigation within forty-eight hours or two business days, whichever is greater, of the receipt of the report and shall complete that investigation within forty-five days.

(b) If a hospital fails to report a medical harm event pursuant to section three of this article, the department may assess the licensee a civil penalty in an amount not to exceed $100 for each day the adverse event is not reported following the initial five-day period or twenty-four hour period, as applicable. If the licensee disputes a determination by the department

regarding alleged failure to report an adverse event, the licensee may, within ten days, request a hearing. Penalties shall be paid when appeals pursuant to those provisions have been exhausted.

(c) The department shall be responsible for ensuring compliance with this article as a condition of licensure under article five-b of this chapter and shall enforce such compliance according to the provisions of article five-b of this chapter.

(d) A violation of this act may lead to license termination, sanctions or fines according to rules promulgated by the Director of the Department Health and Human Resources in accordance with article three of chapter twenty-nine-a.

§16-43-11. Oversight information.

The department's hospital licensing division and the division collecting the information required by this article shall share data regarding medical harm events in hospitals, with patient confidentially maintained by both divisions.

§16-43-12. Public awareness.

The department shall promote public awareness regarding where and how consumers can file complaints about hospitals, including a requirement that information about filing complaints be posted in a visible manner:

(1) On the department licensing website;

(2) On each hospital's website;

(3) In public areas in hospital facilities;

(4) On all hospital correspondence and billing documents; and

(5) On all correspondence by the department's hospital licensing division and the division collecting data on medical harm events under this article.

NOTE: The purpose of this bill is to establish the Medical Harm Disclosure Act where hospitals are required to report and face possible sanctions if they do not report medical harm events at its hospitals.

This article is new; therefore, it has been completely underscored.