HB5093

LRB093 15482 AMC 41085 b

93RD GENERAL ASSEMBLY

State of Illinois

2003 and 2004

Introduced 02/05/04, by Mary E. Flowers

SYNOPSIS AS INTRODUCED:

New Act

Creates the Medical Error Reporting Law. Requires a health care facility to develop and implement a patient safety plan for the purpose of improving the health and safety of patients at the facility. Requires a health care facility to report to the Department of Public Health every serious preventable adverse incident that occurs in that facility. Provides that a health care facility shall ensure that the patient affected by a serious preventable adverse incident is informed of the serious preventable adverse incident.

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FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning health care.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the Medical Error Reporting Law.

Section 5. Findings. The General Assembly finds and declares that:

(1) adverse incidents, some of which are the result of preventable errors, are inherent in all systems;

(2) well-designed systems have processes built in to minimize the occurrence of errors, as well as to detect those that do occur; they incorporate mechanisms to continually improve their performance;

(3) to enhance patient safety, the goal is to craft a health care delivery system that minimizes, to the greatest extent feasible, the harm to patients that results from the delivery system itself;

(4) an important component of a successful patient safety strategy is a feedback mechanism that allows detection and analysis not only of adverse incidents, but also of "near-misses";

(5) to encourage disclosure of these incidents so that they can be analyzed and used for improvement, it is critical to create a non-punitive culture that focuses on improving processes rather than assigning blame;

(6) under current Illinois law, hospitals are required to investigate any unusual incidents that occur at any time on a patient care unit and summarized reports of these unusual incidents are to be made available to the Department of Public Health;

(7) governing boards of hospitals are responsible for the establishment of policy for the investigation of

unusual incidents that may occur;

(8) hospitals are required to maintain accurate, current, and complete personnel records for each employee, including current and background information sufficient to justify the initial and continuing employment of the individual;

(9) hospitals are routinely denied information about prospective employees from their former employers with regard to patient error or unusual incidents because these former employers fear that their former employees may file defamation or other civil lawsuits; and

(10) by establishing an environment that both mandates the confidential disclosure of the most serious preventable adverse incidents and encourages the voluntary, anonymous and confidential disclosure of less serious adverse incidents, as well as preventable incidents and near-misses, the State seeks to increase the amount of information on systems failures, analyze the sources of these failures, and disseminate information on effective practices for reducing systems failures and improving the safety of patients.

Section 10. Definitions. As used in this Law:

"Adverse incident" means an unusual incident that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.

"Anonymous" means that information is presented in a form and manner that prevents the identification of the person filing the report.

"Department" means the Department of Public Health.

"Director" means the Director of Public Health.

"Incident" means a discrete, auditable, and clearly defined occurrence.

"Health care facility" means a facility or institution, whether public or private, engaged principally in providing services for health maintenance organizations or in diagnosis

of treatment of human disease, pain, injury, deformity, or physical condition, including, but not limited to, a general hospital, special hospital, mental hospital, public health center, diagnostic center, treatment center, rehabilitation center, extended care facility, skilled nursing home, nursing home, intermediate care facility, tuberculosis hospital, chronic disease hospital, maternity hospital, outpatient clinic, dispensary, home health care agency, residential health care facility, and bioanalytical laboratory (except as specifically excluded hereunder) or central services facility serving one or more such institutions but excluding institutions that provide healing solely by prayer and excluding such bioanalytical laboratories as are independently owned and operated, and are not owned, operated, managed or controlled, in whole or in part, directly or indirectly by any one or more health care facilities, and the predominant source of business of which is not by contract with health care facilities within the State.

"Health care professional" means an individual who, acting within the scope of his or her licensure or certification, provides health care services and includes, but is not limited to, a physician, dentist, nurse, pharmacist, or other health care professional whose professional practice is regulated pursuant to Chapter 225 of the Illinois Compiled Statutes.

"Near-miss" means an occurrence that could have resulted in an adverse incident but the adverse incident was prevented.

"Preventable incident" means an incident that could have been anticipated and prepared against, but occurs because of an error or other system failure.

"Serious preventable adverse incident" means an adverse incident that is a preventable incident and results in death or loss of a body part, or disability or loss of bodily function lasting more than 7 days or still present at the time of discharge from a health care facility.

Section 15. Patient safety plan.

(a) In accordance with the requirements established by the Director by rule, a health care facility shall develop and implement a patient safety plan for the purpose of improving the health and safety of patients at the facility.

(b) The patient safety plan shall, at a minimum, include all of the following:

(1) A patient safety committee, as prescribed by rule.

(2) A process for teams of facility staff, which teams are comprised of personnel who are representative of the facility's various disciplines and have appropriate competencies, to conduct ongoing analysis and application of evidence-based patient safety practices in order to reduce the probability of adverse incidents resulting from exposure to the health care system across a range of diseases and procedures.

(3) A process for teams of facility staff, which teams are comprised of personnel who are representative of the facility's various disciplines and have appropriate competencies, to conduct analyses of near-misses, with particular attention to serious preventable adverse incidents and adverse incidents.

(4) A process for the provision of ongoing patient safety training for facility personnel.

(c) Any documents, materials, or information developed by a health care facility as part of a process of self-critical analysis conducted pursuant to this Section concerning preventable incidents, near-misses, and adverse incidents, including serious preventable adverse incidents, and any document or oral statement that constitutes the disclosure provided to a patient or the patient's family member or guardian pursuant to subsection (b) of Section 20, shall not be (i) subject to discovery or admissible as evidence or otherwise disclosed in any civil, criminal, or administrative action or proceeding or (ii) used in an adverse employment action or in the evaluation of decisions made in relation to accreditation, certification, credentialing, or licensing of an individual,

which is based on the individual's participation in the development, collection, reporting, or storage of information in accordance with this Section. The provisions of this subsection shall not be construed to limit a health care facility from taking disciplinary action against a health care professional in a case in which the professional has displayed recklessness, gross negligence, or willful misconduct or in which there is evidence, based on other similar cases known to the facility, of a pattern of significant substandard performance that resulted in serious preventable adverse incidents.

Section 20. Reports; use of information.

(a) A health care facility must report to the Department in a form and manner established by the Director every serious preventable adverse incident that occurs in that facility.

(b) A health care facility shall ensure that the patient affected by a serious preventable adverse incident, or, in the case of a minor or a patient who is incapacitated, the patient's parent or guardian or other family member, as appropriate, is informed of the serious preventable adverse incident, no later than the end of the episode of care, or, if discovery occurs after the end of the episode of care, in a timely fashion as established by the Director by rule. If the patient's physician determines, in accordance with criteria established by the Director by rule, that the disclosure would seriously and adversely affect the patient's health, then the facility shall notify the family member, if available. In the event that an adult patient is not informed of the serious preventable adverse incident, the facility shall ensure that the physician includes a statement in the patient's medical record that provides the reason for not informing the patient pursuant to this Section.

(c) A health care professional or other employee of a health care facility is encouraged to make anonymous reports to the Department in a form and manner established by the Director

regarding near-misses, preventable incidents, and adverse incidents that are otherwise not subject to mandatory reporting pursuant to subsection (a) of this Section. The Director shall establish procedures for and a system to collect, store, and analyze information voluntarily reported pursuant to this subsection. The repository shall function as a clearinghouse for trend analysis of the information collected pursuant to this subsection.

(d) Any documents, materials, or information received by the Department pursuant to the provisions of subsections (a) and (c) of this Section concerning serious preventable adverse incidents, near-misses, preventable incidents, and adverse incidents that are otherwise not subject to mandatory reporting pursuant to subsection (a) of this Section shall not be (i) subject to discovery or admissible as evidence or otherwise disclosed in any civil, criminal, or administrative action or proceeding, (ii) considered a public record under the Freedom of Information Act, or (iii) used in an adverse employment action or in the evaluation of decisions made in relation to accreditation, certification, credentialing, or licensing of an individual, which is based on the individual's participation in the development, collection, reporting, or storage of information in accordance with this Section. The provisions of this subsection shall not be construed to limit a health care facility from taking disciplinary action against a health care professional in a case in which the professional has displayed recklessness, gross negligence, or willful misconduct or in which there is evidence, based on other similar cases known to the facility, of a pattern of significant substandard performance that resulted in serious preventable adverse incidents.

The information received by the Department may be used by the Department and the Attorney General for the purposes of this Law and for oversight of facilities and health care professionals. The Department and the Attorney General shall not use the information for any other purpose. In using the

information to exercise oversight, the Department and the Attorney General shall place primary emphasis on ensuring effective corrective action by the facility or health care professional, reserving punitive enforcement or disciplinary action for those cases in which the facility or the professional has displayed recklessness, gross negligence, or willful misconduct or in which there is evidence, based on other similar cases known to the Department or the Attorney General, of a pattern of significant substandard performance that has the potential for or actually results in harm to patients.

Section 25. Rules. The Director shall adopt any rules necessary to carry out the provisions of this Law. The regulations shall establish: criteria for a health care facility's patient safety plan and patient safety committee; the time frame and format for mandatory reporting of serious preventable adverse incidents at a health care facility; the types of incidents that qualify as serious preventable adverse incidents; and the circumstances under which a health care facility is not required to inform a patient or the patient's family about a serious preventable adverse incident. In establishing the criteria for reporting serious preventable adverse incidents, the Director shall, to the extent feasible, use criteria for these incidents that have been or are developed by organizations engaged in the development of nationally recognized standards.

Section 30. Report to General Assembly. The Director of Public Health shall issue an annual report to the General Assembly, which is also available to the general public, no later than 18 months after the effective date of this Law on the status of patient safety plans established by health care facilities subject to this Law and information reported to the Department as required by this Law or which is voluntarily reported as permitted by this Law regarding serious preventable

adverse incidents that occur in health care facilities subject to this Law.