Consumers Union Safe Patient Project
Medical Harm Disclosure Act
February 15, 2010

Section 1. The Legislature/General Assembly finds:

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.

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 this harm contributed to the deaths of 15,000 patients each month.

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

Whereas, 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 OIG study.

Whereas, only ten states require disclosure of hospital-specific medical harm to the public; 15 states and DC keep hospital-specific information secret and 24 states do not require hospitals to report medical harm.

Whereas, 92 percent of Americans believe that hospitals should be required to report serious medical errors, and 63 percent believe that these reports should be made public.

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.

Whereas, research and experience in 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.

Whereas, 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.

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 for improvement of patient safety.

Whereas, every effort must be made to reduce and eliminate medical harm by identifying problems and implementing solutions that promote patient safety.

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.

Therefore, 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 and type of harm that occur at each hospital.

Section 2. This Act may be cited as the Medical Harm Disclosure Act

Section 3. Definitions.
For purposes of this Act:
(a) "Department" means the Department of _____ *[Note: your state may have several possible agencies to collect the data. These could be your state hospital licensing agency, your state health care data collection agency, or your state public health agency.]*

(b) "Hospital" means an acute care health care facility licensed under the Hospital Licensing Act *[Note: insert a cross-reference and/or citation to the definition of "acute care hospital" in your state hospital licensing law.* ***We recommend including other health facilities in this law, such as hospital-affiliated 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 health care 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 3 or 4 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 occur within 42 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 bedrails.

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

[Note: We do not recommend including hospital-acquired infections as medical harm events in this legislation, because the federal government and many states already require reporting of hospital-acquired infections using the Centers for Disease Control and Prevention's National Healthcare Safety Network.]
[Note: "Medical harm events" are often referred as "medical errors" or "preventable adverse events." The use of the term "medical harm event" in this Model Act is an attempt to allow states to assess all forms of preventable harm to hospital patients, rather than specific, narrowly defined events. The National Quality Forum has developed a list of "serious reportable events" that is often used by state reporting systems. Recent studies, however, have identified the need to seek broader definitions of harm because of significant underreporting in programs using very specific definitions. We recommend that states consider the NQF list but strive for a more comprehensive assessment of preventable medical harm. Information about the NQF list can be found at http://www.qualityforum.org/projects/hacs_and_sres.aspx]

Section 4. 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 emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 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 if 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 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. *[Note: Some states will have existing laws requiring hospitals to have a patient safety plan. This is not meant to duplicate those plans, but if the existing plans do not include the elements in this subsection, we recommend amending the existing law to do so.]*

(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, and/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 the each specific division or subsidiary and not aggregately for multiple hospitals. *[Note: The purpose of this section is to ensure that each facility's events are reported. When a hospital system or corporate parent of numerous hospitals uses a centralized data collection system to collect information on medical harm events, the system should not be permitted to report its system-wide rates aggregately, but should report each facility's rates individually.]*

(i) Nothing in this section shall be interpreted to change or otherwise affect hospital reporting requirements regarding reportable diseases or unusual occurrences, as provided in *[cite appropriate sections of the law]*.

Section 5. 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. *[Note: States with advisory committees on hospital-acquired infection reporting or some other type of health care reporting may decide to add the responsibilities created under the terms of this Act to those of existing committees.]*

(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 Act, 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. *[Note: The state's open meetings law should be cited.]*

Section 6. Methodologies for collecting, analyzing and validating data.
(a) The department shall, with the advice of the advisory committee created in Section 5 of this Act, 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 Act.

(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. *[Note: The AHRQ Common Formats were developed by committees of experts to identify and record medical harm events for "patient safety organizations" but the forms also provide clear standardized methods for collecting data for public reports – the forms are available at https://www.psoppc.org/web/patientsafety/version-1.1_documents.]*

(d) In developing the methodology for analyzing the data, 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 (NCC MERP) Index for Categorizing Errors. *[Note: The US HHS Office of Inspector General used the National Coordinating Council for Medication Errors Reporting and Prevention (NCC MERP) Index for Categorizing Errors to categorize all types of medical harm events in its November 2010 report. The OIG report can be found at http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf and NCC MERP can be found at http://www.nccmerp.org/medErrorCatIndex.html]*

(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 hospital 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. *[Note: The purpose of this section is to require the department to have a system in place to assure accuracy of self-reporting by hospitals. The federal Agency for Healthcare Research and Quality has available at no cost Patient Safety Indicators that states can be used by states to review the data for accuracy, See http://www.qualityindicators.ahrq.gov/psi_overview.htm . States with a large number of hospitals may have to focus the annual medical records reviews on selected hospitals that appear to be outliers – such as those reporting many events or those reporting none.]*

(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 Act. The audit shall:
(1) assess the accuracy of reporting by hospitals, especially seeking to identify underreporting;
(2) be funded by the Patient Safety Trust Fund created in Section 10 of this Act; 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 Act.

Section 7. 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 11 of this Act, 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 Act. 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 taken, and the quarterly affirmation by hospitals 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 under *[cite regulatory/licensing statute]*, readily accessible to the public on the department website. *[Note: The purpose of this subsection is to require the department to disclose hospital inspection reports to the public, including reports responding to complaints against the hospital or from routine inspections.]*

(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 *[set a specific date]*. Following the initial report, the department shall publish these reports annually.

Section 8. 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.

Section 9. 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 Act.

Section 10. 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 Act.

(b) All penalties assessed under Section 11 this Act 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 6 of this Act.

Section 11. Department actions and penalties.
(a) In any case in which the department receives a report from a hospital pursuant to Section 4 of this Act, that indicates an ongoing threat or imminent danger of death or serious bodily harm, the department shall make an onsite inspection or investigation within 48 hours or two business days, whichever is greater, of the receipt of the report and shall complete that investigation within 45 days.

(b) If a hospital fails to report a medical harm event pursuant to Section 4 of this Act, the department may assess the licensee a civil penalty in an amount not to exceed one hundred dollars ($100) for each day that the adverse event is not reported following the initial five-day period or 24-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 10 days, request a hearing. Penalties shall be paid when appeals pursuant to those provisions have been exhausted. *[Note: The method for hospitals to appeal these findings should follow the same procedures as those available in current law for contesting other regulatory penalties.]*

(c) The department shall be responsible for ensuring compliance with this Act as a condition of licensure under the Hospital Licensing Act and shall enforce such compliance according to the provisions of the Hospital Licensing Act. *[Note to advocates: insert the name and citation of your state hospital licensing act here].*

(d) The Hospital Licensing Act is amended as follows: *[Note to advocates: Amend your state hospital licensing act to add that a violation of this Act can lead to license termination, sanctions, or fines available under your state hospital licensing act.]*

Section 12. Oversight information.
The department's hospital licensing division and the division collecting the information required by this Act shall share data regarding medical harm events in hospitals, with patient confidentiality maintained by both divisions. *[Note: The intent of this section is to encourage those that oversee licensing standards to use information reported under this Act to enhance their ability to ensure safe medical care as well as to allow the division collecting medical harm events to use complaint information that the licensing division may have as a validation tool.]*

Section 13. 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 Act.

Section 14. Effective date. This Act is effective immediately. *[Note: Based on experience in other states with slow implementation of similar reporting laws, we recommend that the Act be effective immediately. The other date that should be specified in the law is the date for the publication of the initial report.]*

For additional information:
Consumers Union Safe Patient Project
Suzanne Henry
shenry@consumer.org
www.SafePatientProject.org