

Nebraska Coalition for Patient Safety

First Annual Report - March 2008

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TABLE OF CONTENTS

Background 4

Founding Legislation 5

Reporting is the Foundation of Learning in Cultures of Safety 6

Progress to Date 8

 Reporting Committee Activities 2006-2007 8

 Education Committee Activities 2006-2007 9

 Finance Committee Activities 2006-2007 9

Future Plans 10

Appendices

 A. Statutes 11

 B. Reportable List 16

 C. Members of the Board of Directors 18

 D. Financial Sponsors 19

 E. Member Hospitals 19

 F. Works Cited 20

BACKGROUND

The Institute of Medicine¹, in its 1999 report *To Err is Human - Building a Safer Healthcare System* identified preventable adverse events (medical errors resulting in injury) as a major cause of death and injury in the United States. “Total national costs (lost income, lost household production, disability and health care costs) of preventable adverse events were estimated to be between \$17 billion and \$29 billion, of which health care costs represent over one half.” The report laid out a four-tiered approach to a solution:

- Establish a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety;
- Identify and learn from errors through mandatory and voluntary reporting efforts;
- Raise standards and expectations for improvements in safety;
- Create safety systems within health care organizations by implementing safe practices at the site of health care delivery.

Despite much debate about the accuracy of the original studies cited in the Institute of Medicine report, the report focused the nation’s attention on the issue of medical errors. There can be little debate that even one patient who is harmed by the care that is intended to help them is one too many.

Nebraska’s health care community responded to the Institute of Medicine’s challenge to build a safer health care system by establishing an issue strategy group whose charge was to:

- Foster the sharing of knowledge and information about optimal patient safety practices and models,
- Convene stakeholders for an ongoing dialogue in support of patient safety improvements, and
- Encourage individual health care providers to identify causes and influence changes in their health care delivery systems to prevent medical errors.

The issue strategy group proposed legislation that would encourage a culture of safety and quality by providing for the legal protection of information reported for the purposes of quality and safety; to provide for the reporting of aggregate information about patient safety events; and to provide for the reporting and sharing of information designed to improve health care delivery systems and reduce the incidence of adverse health events and near misses. Legal protection from discovery of the information reported is key to the success of the initiative. This protection allows individual providers and facilities the opportunity to openly discuss issues so that others may learn from them. The ultimate goal of the legislation is to facilitate a learning environment in which health care providers and facilities work to ensure the safety of all individuals who seek health care in Nebraska.

This legislation, the Patient Safety Improvement Act, was signed into law by Governor Heineman in 2005, forming the Nebraska Coalition for Patient Safety.

FOUNDING LEGISLATION

In 2005, the Nebraska Hospital Association, the Nebraska Medical Association, the Nebraska Academy of Physician Assistants, the Nebraska Pharmacists Association and the Nebraska Nurses Association developed legislation titled the Patient Safety Improvement Act. This legislation was the result of the efforts of many individuals who participated in the Patient Safety Issue Strategy Group. This legislation was signed into law by Governor Heineman in April 2005. (Neb.Rev.Stat. Sections 71-8701 to 71-8721)

The goal of the Act is to increase the likelihood that all people who seek health care in Nebraska are not harmed by the care that is intended to help them. To achieve this goal, the Act provides for and promotes the establishment of a private, nonprofit patient safety organization, which is independent of state agencies—The Nebraska Coalition for Patient Safety. The Act seeks to create a culture of safety in Nebraska health care by providing for the following: (1) legal protection for information about patient safety events that are reported to a patient safety organization for the purposes of quality improvement and patient safety—this legal protection is essential for establishing the transparency necessary for a culture of safety within a health care organization, (2) the reporting of aggregate information by providers and organizations about patient safety events to a patient safety organization, and (3) the public reporting of aggregate patient safety events and sharing of information by a patient safety organization to improve the systems used to deliver health care in Nebraska. This shared information includes evidence-based practices, protocols, identification of system sources of errors, and methods of implementing and sustaining organizational change.

The Nebraska Coalition for Patient Safety is comprised of the five founding organizations that are committed to ensuring the safety and quality of health care in Nebraska. These organizations are: the Nebraska Academy of Physician Assistants, the Nebraska Hospital Association, the Nebraska Medical Association, the Nebraska Nurses Association, and the Nebraska Pharmacists Association. The Coalition is governed by a 12 to 15 member board of directors that includes representation from each of the founding organizations plus at least one consumer member.

Consistent with the three purposes of the Patient Safety Improvement Act described above, the Nebraska Coalition for Patient Safety is developing a voluntary reporting system and provides educational programs specific to the needs of Nebraska's health care community. The reporting program will collect, analyze, and disseminate aggregate information about reported patient safety events from contracting organizations and providers. Aggregate information will be provided back to participating hospitals and health care providers, and made publicly available. The educational programs will seek to create a culture of learning about patient safety across the state by sharing critical alerts and notifications from the national quality and safety organizations. These organizations include The Joint Commission, the National Quality Forum, the National Patient Safety Foundation, and the Institute for Safe Medication Practices. The Coalition will disseminate evidence-based guidelines, establish benchmark goals for state quality initiatives, and partner with other Nebraska organizations to provide education about patient safety topics. These topics will include building an effective voluntary error reporting program, establishing a just culture, conducting root cause analysis, and improving communication/teamwork skills.

In summary, the Nebraska Coalition for Patient Safety was established in response to the growing evidence that patients are too often harmed by the care that is intended to help them. In Nebraska, a rural state served by large numbers of small hospitals, an independent patient safety organization can disseminate information and coordinate limited educational resources for all health care organizations and providers in the state. With appropriate resources, the Nebraska Coalition for Patient Safety can provide a focus for improving the safety and quality of health care in Nebraska.

This is the first annual report of the Nebraska Coalition for Patient Safety. The Patient Safety Improvement Act specifies that an annual report should be provided to the public. The Coalition has spent its time during these first two years developing the structure of the Coalition, identifying the members of the Board, refining the list of reportable adverse events, developing a template for reporting these events, identifying funding sources, and soliciting membership. We are proud of the accomplishments of the Coalition to this point, and look forward to next year's report, when we plan to share the results of information reported to the Coalition and the learning that has taken place throughout the year.

REPORTING IS THE FOUNDATION OF LEARNING IN CULTURES OF SAFETY

In *To Err is Human*, The Institute of Medicine¹ recommended mandatory and voluntary reporting of adverse events. The purpose of mandatory reporting is to hold organizations and providers accountable for their performance. State departments of health and professional licensure boards are charged with holding organizations and individual providers accountable for negligent behavior. The purpose of voluntary reporting is educational—sharing of information to improve systems of care. Voluntary reporting programs are particularly effective for large groups of small organizations because harmful incidents are relatively rare within individual organizations. By aggregating and sharing information about relatively rare events within a single organization, system improvements can be made to effectively decrease the risk to patients across multiple organizations.

Culture is the enduring and shared beliefs and practices of an organization. Safety culture is the enduring and shared beliefs and practices of an organization regarding the organization's willingness to detect and learn from errors. The Institute of Medicine states that a culture of safety in health care requires three elements: (1) the belief that although health care processes are high-risk, they can be designed to prevent failure, (2) a commitment at the organizational level to detect and learn from errors, and (3) an environment that is just because managers discipline only when an employee knowingly increases risk to patients and peers.²

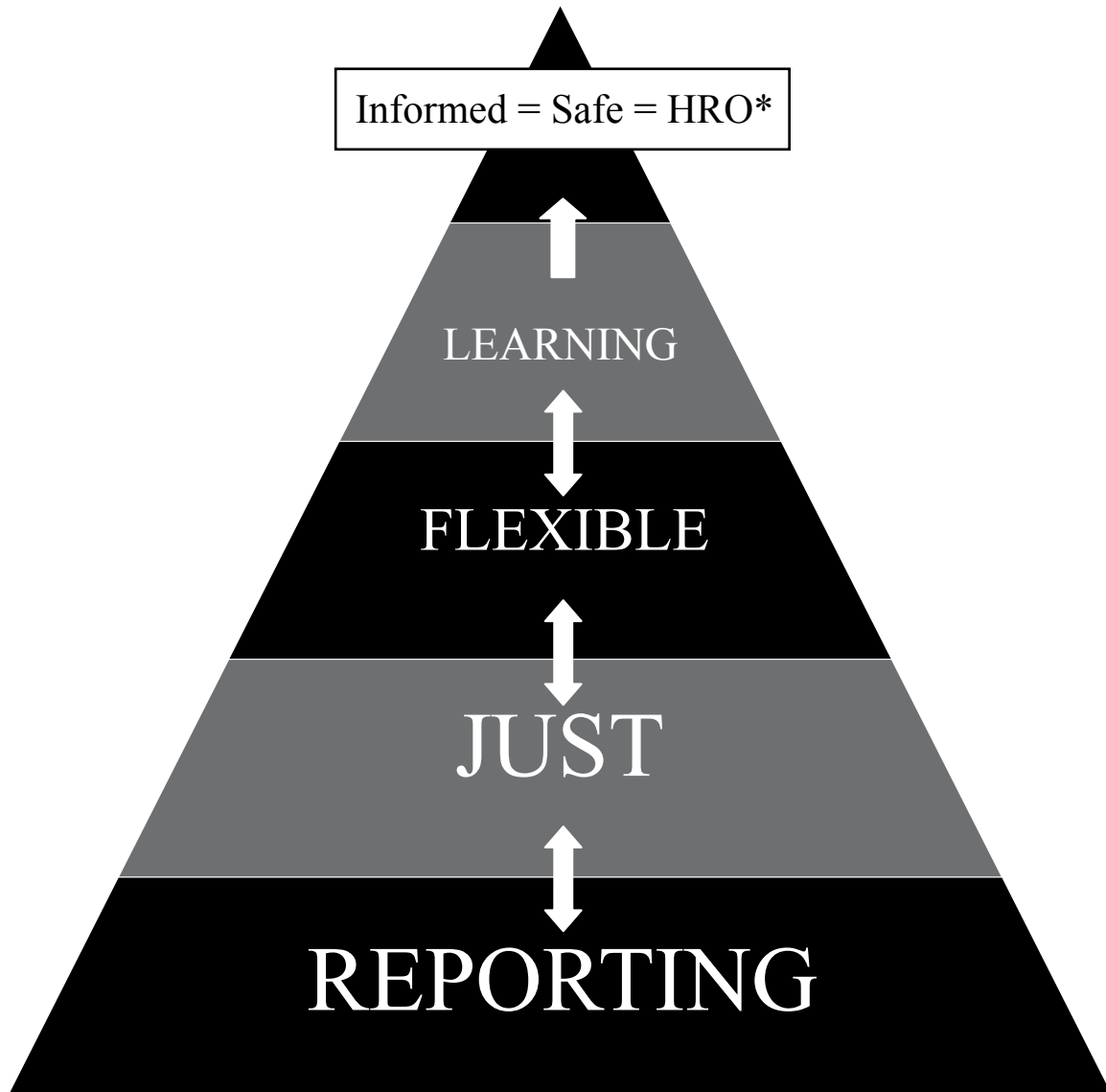
A culture of safety is present in high reliability organizations that are characterized by complex, risky processes but very low error rates. Such organizations achieve high reliability because they are preoccupied with failure, sensitive to how each team member affects a process, allow those who are most knowledgeable about a process to make decisions, and resist the temptation to blame individuals for errors within complex processes.³

Psychologist James Reason⁴ categorizes a culture of safety into four components, which reflect his assertion that an informed culture is a safe culture. These components identify the beliefs and practices present in an organization that is informed about risks and hazards and takes action to become safe.

Fundamentally, a safe health care organization is dependent on the willingness of health care professionals to voluntarily report their errors and near-misses because organizational practices support a *reporting culture*. This willingness of professionals to report depends on their belief that management will support and reward reporting and that discipline occurs based on risk-taking because organizational practices support a *just culture*. The willingness of professionals to report also depends on their belief that managers respect the knowledge of those delivering care because organizational practices support a *flexible culture*. Ultimately, the willingness of professionals to report depends on their belief that the organization will analyze reported information and implement appropriate change because organizational practices support a *learning culture*.

In summary, voluntary reporting and analysis of errors and near misses enables us to learn from our experience and decrease the risks and hazards that exist in complex systems of health care.

A culture of safety is informed.
It never forgets to be afraid...



*A high-reliability organization (HRO) is characterized by complex, risky processes but very low error rates. Such organizations achieve high reliability because they are preoccupied with failure, and sensitive to how each team member affects a process. They allow those who are most knowledgeable about a process to make decisions, and they resist the temptation to blame individuals for errors within complex processes.

PROGRESS TO DATE

Reporting Committee Activities 2006-07

In June and August 2006, the reporting committee of the board conducted telephone conference calls with the Oregon Patient Safety Commission, a voluntary state reporting program; and the Minnesota Hospital Association, a mandatory state reporting program. The purpose of the calls was to compare and contrast the history of each reporting program, the governing structure, reporting content, reporting structure, fee structure, nature of reporting, products, hospital perceptions of value, and lessons learned from these organizations. Given the voluntary nature of the Oregon Patient Safety Commission, the Board obtained specific “take home lessons” including: keep data collection simple and efficient, meet the educational needs of the reporting hospitals, and recognize that hospitals feel overwhelmed with existing demands to improve patient safety. A voluntary patient safety organization must establish relationships with reporting providers and hospitals through a field coordinator, and provide access to expertise and education.

In August 2006, the reporting committee conducted an on-line survey of hospital CEOs in Nebraska to determine the educational needs of hospitals and priorities for patient safety event reporting. We received responses from 43 of 86 CEOs; 26 of the 43 respondents were from the state’s 65 Critical Access Hospitals. Findings from the survey included the following: (1) 100 percent of respondents reported that topical quarterly reports about a specific patient safety event such as medication errors, falls, or pressure ulcers with examples of root cause analyses, lessons learned, and references would be useful or very useful; (2) 73 percent reported that assistance to conduct, analyze, and benchmark results from the Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture would be useful or very useful; (3) 81 percent reported that learning how near miss and close call reports contribute to a culture of safety would be useful or very useful; (4) 100 percent reported that learning how to engage physicians in creating a culture of safety would be useful or very useful; (5) 81 percent reported that assistance to conduct a thorough, credible root cause analysis with appropriate follow-up action planning would be helpful or very helpful; and (6) 92 percent reported that learning about tools to improve communication and teamwork would be useful or very useful.

The board created a contract to be entered into between the Nebraska Coalition for Patient Safety and individual providers and hospitals. This contract specifies that any data, reports, records, or analyses that are exchanged between the Coalition and a provider are privileged and confidential pursuant to federal and state law.

The board finalized a list of adverse events and near misses that are reportable to the Coalition by health care providers and organizations. These events are based upon the work of the National Quality Forum and the Joint Commission on Accreditation of Healthcare Organizations. There are five broad categories of events: surgical events, product or device events, patient protection events, care management events and environmental events (see Appendices).

The board finalized a job description for the Executive Director of the Nebraska Coalition for Patient Safety.

In December 2006, the board laid the groundwork to invite interested hospitals to begin submitting reports in 2007 to develop a reporting history, products, and build trust with interested hospitals in the state. The Nebraska Coalition for Patient Safety completed a pilot study of voluntary reporting of patient safety events in July, 2007. Nine Nebraska hospitals (including three Critical Access Hospitals) submitted information about adverse patient safety events and their associated root cause analyses. The Coalition will use this information to: (1) provide examples of the range of patient safety events in Nebraska, (2) develop educational material for use by health care providers, and (3) demonstrate to all Nebraska hospitals the benefits of participating in the Coalition.

Education Committee Activities in 2006-07

Board member Katherine Jones, PhD, PT, created a presentation for use in educating hospital board members and front-line staff in patient safety principles. The presentation is based upon education Dr. Jones received at the Institute for Healthcare Improvement Patient Safety Officer, Executive Development Program, on September 6 – 13, 2006. The presentation is publicly available at: <http://www.unmc.edu/rural/patient-safety/Toolbox/Learning%20Culture/Learning.htm>.

With CIMRO of Nebraska, the Medicare Quality Improvement Organization for Nebraska, and the Nebraska Center for Rural Health Research, the Coalition sponsored the “SafetySkills Initiative” for rural hospital CEOs on February 28, 2006. This initiative promoted a culture of patient safety in Nebraska hospitals by assisting hospital senior leadership to establish an environment where patient safety is a top priority of all staff and a ‘just culture’ exists. To achieve these goals, the three organizations used a collaborative approach based on the Institute for Healthcare Improvement (IHI) experience in improving patient safety. This experience included the framework outlined in the IHI white paper, *Leadership Guide to Patient Safety*.⁵

The Nebraska Coalition for Patient Safety cosponsored an educational seminar with Creighton University Medical Center to bring the TeamSTEPPS teamwork training program to Nebraska hospitals. TeamSTEPPS⁶ stands for Team Strategies and Tools to Enhance Performance and Patient Safety. TeamSTEPPS is an evidence-based framework developed by the Department of Defense and the Agency for Healthcare Research and Quality (AHRQ). It builds on 25 years of research on teams and team performance in high-risk areas such as aviation, the military, nuclear power, and health care in which poor performance may lead to serious consequences or death. TeamSTEPPS is designed to optimize team performance across health care settings by focusing on four skills supporting team performance principles: leadership, situation monitoring, mutual support and communication. The seminar was held October 18-19, 2007 at Creighton University Medical Center.

The Nebraska Coalition for Patient Safety submitted an application to the Agency For Healthcare Research and Quality (AHRQ) to participate in their Patient Safety Improvement Corps (PSIC) education. The Coalition’s team was selected to participate and began this year-long educational journey in September 2007. The education these four individuals will gain will be useful to them in their hospitals of employment, as well as on the state level, as they share the expertise they gain with the Coalition and others in the state. The team completed a workshop for 16 Critical Access Hospitals from northeast Nebraska on February 28, 2008, entitled, *Root Cause Analysis - An Essential Tool for Learning Organizations*. These hospitals learned the five steps necessary to conduct a thorough, credible root cause analysis (RCA). Emphasis was placed on the skills needed to effectively facilitate the RCA and implement change that minimizes recurrence of similar errors.

Future education for Coalition member hospitals will include training for additional hospitals to conduct RCA and implementing TeamSTEPPS. In addition, in collaboration with the University of Nebraska Medical Center, the Coalition will assist hospitals to measure the staff’s perception of the culture of patient safety using the AHRQ Hospital Survey on Patient Safety Culture. This survey allows hospitals to measure their progress in patient safety and prioritize efforts to address areas identified as a concern.

Finance Committee Activities 2006-07

The primary task of the finance committee has been to create a sustainable financial infrastructure for the Coalition. This task required obtaining appropriate designation as a tax-exempt organization under section 501(c)(3) of the Internal Revenue Code. Since obtaining this status in July 2007, we have developed a budget and determined sources of funding. These sources include soliciting financial sponsorship from our five founding associations and selected insurance companies.

In addition, a fee structure for hospital membership and a financial sponsorship structure for corporations were developed. Finally, applications for two grants were submitted and the Coalition is currently writing additional grant applications.

Future Plans

As a member of the Nebraska Coalition for Patient Safety, providers are asked to provide a summary of the RCA for reportable patient safety events within 75 days of their occurrence. The RCA should be completed within 45 days of the occurrence of the event and the RCA summary forwarded to the Coalition within 30 days of its completion. A root cause analysis is a process where the event is studied and causal factors identified. These causal factors include communication issues; issues related to rules, policies and procedures; staffing issues; education/training issues; environmental/equipment issues; and issues related to the culture of the facility. Educational material about these events, and the steps facilities take to reduce the potential of the event occurring again, will be shared with the members of the Coalition. The calendar year 2008 will be our first complete year of reporting. It is not known how many events will be reported to the Coalition. Some states, such as Minnesota, which is a state with mandatory reporting, received less than 200 reports of adverse patient safety events. Oregon, a state like Nebraska with voluntary reporting, received less than 100 reports in 2007.

An educational seminar is being planned for April of 2009. Content of the seminar will be determined by the Nebraska events that are reported to the Coalition.

While we are initially working with hospitals, the Coalition plans to also work with pharmacies, physician offices, nursing facilities and emergency medical personnel to study the patient safety events that occur in those settings, share information to help reduce their occurrence, and help assure that health care in Nebraska, across the continuum of care, is of high quality.

APPENDICES

A. Statute

71-8701. Act, how cited.

Sections 71-8701 to 71-8721 shall be known and may be cited as the Patient Safety Improvement Act.

71-8702. Legislative findings and intent.

(1) The Legislature finds that:

- (a) In 1999, the Institute of Medicine released a report entitled *To Err is Human* that described medical errors as the eighth leading cause of death in the United States;
- (b) To address these errors, the health care system must be able to create a learning environment in which health care providers and facilities will feel safe reporting adverse health events and near misses in order to improve patient safety;
- (c) To facilitate the learning environment, health care providers and facilities must have legal protections that will allow them to review protected health information so that they may collaborate in the development and implementation of patient safety improvement strategies;
- (d) To carry out a program to promote patient safety, a policy should be established which provides for and promotes patient safety organizations; and
- (e) There are advantages to having private nonprofit corporations act as patient safety organizations rather than a state agency, including the enhanced ability to obtain grants and donations to carry out patient safety improvement programs.

(2) It is the intent of the Legislature to encourage the establishment of broad-based patient safety organizations.

71-8703. Purposes of act.

The purposes of the Patient Safety Improvement Act are to (1) encourage a culture of safety and quality by providing for legal protection of information reported for the purposes of quality improvement and patient safety, to (2) provide for the reporting of aggregate information about occurrences, and to (3) provide for the reporting and sharing of information designed to improve health care delivery systems and reduce the incidence of adverse health events and near misses. The ultimate goal of the act is to ensure the safety of all individuals who seek health care in Nebraska's health care facilities or from Nebraska's health care professionals.

71-8704. Definitions, where found.

For purposes of the Patient Safety Improvement Act, unless the context otherwise requires, the definitions found in sections 71-8705 to 71-8709 apply.

71-8705. Identifiable information, defined.

Identifiable information means information that is presented in a form and manner that allows the identification of any provider, patient, or reporter of patient safety work product. With respect to patients, such information includes any individually identifiable health information as that term is defined in the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as such regulations existed on April 28, 2005.

71-8706. Non-identifiable information, defined.

Non-identifiable information means information presented in a form and manner that prevents the identification of any provider, patient, or reporter of patient safety work product. With respect to patients, such information must be de-identified consistent with the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as such regulations existed on April 28, 2005.

71-8707. Patient safety organization, defined.

Patient safety organization means an organization described in section 71-8714 that contracts with one or more providers subject to the Patient Safety Improvement Act and that performs the following activities:

- (1) The conduct, as the organization's primary activity, of efforts to improve patient safety and the quality of health care delivery;
- (2) The collection and analysis of patient safety work product that is submitted by providers;
- (3) The development and dissemination of evidence-based information to providers with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
- (4) The utilization of patient safety work product to carry out activities limited to those described under this section and for the purposes of encouraging a culture of safety and of providing direct feedback and assistance to providers to effectively minimize patient risk;
- (5) The maintenance of confidentiality with respect to identifiable information;
- (6) The provision of appropriate security measures with respect to patient safety work product; and
- (7) The possible submission, if authorized by federal law, of non-identifiable information to a national patient safety data base.

71-8708. Patient safety work product, defined.

- (1) Patient safety work product means any data, reports, records, memoranda, analyses, deliberative work, statements, root cause analyses, or quality improvement processes that are:
 - (a) Created or developed by a provider solely for the purposes of reporting to a patient safety organization;
 - (b) Reported to a patient safety organization for patient safety or quality improvement processes;
 - (c) Requested by a patient safety organization, including the contents of such request;
 - (d) Reported to a provider by a patient safety organization;
 - (e) Created by a provider to evaluate corrective actions following a report by or to a patient safety organization;
 - (f) Created or developed by a patient safety organization; or
 - (g) Reported among patient safety organizations after obtaining authorization.
- (2) Patient safety work product does not include information, documents, or records otherwise available from original sources merely because they were collected for or submitted to a patient safety organization. Patient safety work product also does not include documents, investigations, records, or reports otherwise required by law.
- (3) Patient safety work product does not include reports and information disclosed pursuant to sections 71-8719 and 71-8720.

71-8709. Provider, defined.

Provider means a person that is either:

- (1) A facility licensed under the Health Care Facility Licensure Act; or
- (2) A health care professional licensed under the Uniform Credentialing Act.

71-8710. Patient safety work product; confidentiality; use; restrictions.

- (1) Patient safety work product shall be privileged and confidential.
- (2) Patient safety work product shall not be:
 - (a) Subject to a civil, criminal, or administrative subpoena or order;
 - (b) Subject to discovery in connection with a civil, criminal, or administrative proceeding;
 - (c) Subject to disclosure pursuant to the Freedom of Information Act, 5 U.S.C. 552, as such act existed on April 28, 2005, or any other similar federal or state law, including sections 84-712 to 84-712.09;
 - (d) Offered in the presence of the jury or other factfinder or received into evidence in any civil, criminal, or administrative proceeding before any local, state, or federal tribunal; or
 - (e) If the patient safety work product is identifiable information and is received by a national accreditation organization in its capacity:

- (i) Used by a national accreditation organization in an accreditation action against the provider that reported the information; (ii) Shared by such organization with its survey team; or (iii) Required as a condition of accreditation by a national accreditation organization.

71-8711. Patient safety organization; proceedings and records; restrictions on use; violation; penalty.

No person shall disclose the actions, decisions, proceedings, discussions, or deliberations occurring at a meeting of a patient safety organization except to the extent necessary to carry out one or more of the purposes of a patient safety organization. The proceedings and records of a patient safety organization shall not be subject to discovery or introduction into evidence in any civil action against a provider arising out of the matter or matters that are the subject of consideration by a patient safety organization. Information, documents, or records otherwise available from original sources shall not be immune from discovery or use in any civil action merely because they were presented during proceedings of a patient safety organization. This section shall not be construed to prevent a person from testifying to or reporting information obtained independently of the activities of a patient safety organization or which is public information. A person who knowingly violates this section shall be guilty of a Class IV misdemeanor.

71-8712. Patient safety work product; unlawful use; effect.

Any reference to, or offer into evidence in the presence of the jury or other factfinder or admission into evidence of, patient safety work product during any proceeding contrary to the Patient Safety Improvement Act shall constitute grounds for a mistrial or a similar termination of the proceeding and reversible error on appeal from any judgment or order entered in favor of any party who discloses or offers into evidence patient safety work product in violation of the act.

71-8713. Act; cumulative to other law.

The prohibition in the Patient Safety Improvement Act against discovery, disclosure, or admission into evidence of patient safety work product is in addition to any other protections provided by law.

71-8714. Patient safety organization; conditions.

A patient safety organization shall meet the following conditions:

- (1) It shall be a Nebraska nonprofit corporation described in section 501(c)(3) of the Internal Revenue Code as defined in section 49-801.01, contributions to which are deductible under section 170 of the code;
- (2) The purposes of the organization shall include carrying out the activities of a patient safety organization as described in the Patient Safety Improvement Act; and
- (3) It shall have a representative board of directors as described in section 71-8715.

71-8715. Patient safety organization; board of directors; membership.

The board of directors of a patient safety organization shall include at least one representative each from a statewide association of Nebraska hospitals, Nebraska physicians and surgeons, Nebraska nurses, Nebraska pharmacists, and Nebraska physician assistants as recommended by such associations. At least one consumer shall be a member of the board. The board shall consist of at least twelve but no more than fifteen members as established at the discretion of the board.

71-8716. Election to be subject to act; contract; requirements.

- (1) A patient safety organization shall contract with providers that elect to be subject to the Patient Safety Improvement Act. The patient safety organization shall establish a formula for determining fees and assessments uniformly within categories of providers.
- (2) A provider may elect to be subject to the Patient Safety Improvement Act by contracting with a patient safety organization to make reports as described in the act.

71-8717. Reportable patient safety events; provider; duties.

- (1) Every provider subject to the Patient Safety Improvement Act shall track and report pursuant to section 71-8718 the following occurrences of patient safety events:
 - (a) Surgery or procedures performed on the wrong patient or the wrong body part of a patient;
 - (b) Foreign object accidentally left in a patient during a procedure or surgery;
 - (c) Hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products with major blood group incompatibilities;
 - (d) Sexual assault of a patient during treatment or while the patient was on the premises of a facility;
 - (e) Abduction of a newborn infant patient from the hospital or the discharge of a newborn infant patient from the hospital into the custody of an individual in circumstances in which the hospital knew, or in the exercise of ordinary care should have known, that the individual did not have legal custody of the infant;
 - (f) Suicide of a patient in a setting in which the patient received care twenty-four hours a day;
 - (g) Medication error resulting in a patient's unanticipated death or permanent or temporary loss of bodily function, including (i) treatment intervention, temporary harm, (ii) initial-prolonged hospitalization, temporary harm, (iii) permanent patient harm, and (iv) near death event in circumstances unrelated to the natural course of the illness or underlying condition of the patient, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation or the wrong route of administration, but excluding reasonable differences in clinical judgment on drug selection and dose;
 - (h) Patient death or serious disability associated with the use of adulterated drugs, devices or biologics provided by the provider;
 - (i) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended; and
 - (j) Unanticipated death or major permanent loss of function associated with health care associated nosocomial infection.
- (2) A patient safety organization, based on a review of new indicators of patient safety events identified by the Joint Commission on Accreditation of Healthcare Organizations, shall recommend changes, additions or deletions to the list of reportable patient safety events, which changes, additions or deletions shall be binding on the providers. Providers may voluntarily report any other patient safety events not otherwise identified.

71-8718. Reporting requirements.

- (1) Every provider subject to the Patient Safety Improvement Act shall report aggregate numbers of occurrences for each patient safety event category listed in section 71-8717 to a patient safety organization. Reporting shall be done on an annual basis by March 31 for the prior calendar year.
- (2) For each occurrence listed in section 71-8717, a root cause analysis shall be completed and an action plan developed within forty-five days after such occurrence. The action plan shall (a) identify changes that can be implemented to reduce risk of the patient safety event occurring again or formulate a rationale for not implementing change and (b) if an improvement action is planned, identify who is responsible for implementation, when the action will be implemented, and how the effectiveness of the action will be evaluated. The provider shall, within thirty days after the development of an action plan, provide a summary report to a patient safety organization which includes a brief description of the patient safety event, a brief description of the root cause analysis, and a description of the action plan steps.
- (3) The facility where a reportable event occurred shall be responsible for coordinating the reporting of information required under the Patient Safety Improvement Act and ensuring that the required reporting is completed, and such coordination satisfies the obligation of reporting imposed on each individual provider under the act.

71-8719. Non-identifiable information; disclosure.

A patient safety organization may disclose non-identifiable information, including non-identifiable aggregate trend data and educational material developed as a result of the patient safety work product reported to it.

71-8720. Public disclosure of data and information.

A patient safety organization shall release to the public non-identifiable aggregate trend data identifying the number and types of patient safety events that occur. A patient safety organization shall publish educational and evidenced-based information from the summary reports, which shall be available to the public, that can be used by all providers to improve the care they provide.

71-8721. Immunity from liability.

Any person who receives or releases information in the form and manner prescribed by the Patient Safety Improvement Act and the procedures established by a patient safety organization shall not be civilly or criminally liable for such receipt or release unless the receipt or release is done with actual malice, fraudulent intent, or bad faith. A patient safety organization shall not be liable civilly for the release of non-identifiable aggregate trend data identifying the number and types of patient safety events that occur. Because the candid and conscientious evaluation of patient safety events is essential to the improvement of medical care and to encourage improvements in patient safety, any provider furnishing services to a patient safety organization shall not be liable for civil damages as a result of such acts, omissions, decisions, or other such conduct in connection with the duties on behalf of a patient safety organization if done pursuant to the Patient Safety Improvement Act except for acts done with actual malice, fraudulent intent, or bad faith.

B. Reportable List

1. Surgical Events

- *A. Surgery performed on the wrong body part.
- *B. Surgery performed on the wrong patient.
- *C. Wrong surgical procedure performed on a patient.
- *D. Retention of a foreign object in a patient after surgery or other procedure.
- E. Intraoperative or immediate (first 24 hours) post-operative death or serious disability in an ASA Class I patient.

2. Product or Device Events

- *A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility.
- *B. Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used for functions other than as intended.
- C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility.

3. Patient Protection Events

- *A. Abduction of a newborn infant patient from the hospital or the discharge of a newborn infant patient from the hospital into the custody of an individual in circumstances in which the hospital knew, or in the exercise of ordinary care should have known, that the individual did not have legal custody of the infant.
- B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours.
- *C. Patient suicide or attempted suicide resulting in serious disability, while being cared for in a health care facility or if the institution becomes aware of such an event within 24 hours of dismissal.
- *D. Sexual assault of a patient during treatment or while the patient was on the premises of a facility.

4. Care Management Events

- *A. Medication error resulting in a patient's unanticipated death or permanent or temporary loss of bodily function, including (i) treatment intervention, temporary harm; (ii) initial prolonged hospitalization, temporary harm; (iii) permanent patient harm, and (iv) near death event in circumstances unrelated to the natural course of the illness or underlying condition of the patient, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, but excluding reasonable differences in clinical judgment on drug selection and dose.
- *B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
- C. Maternal death or serious disability associated with labor or delivery in a low risk pregnancy while being cared for in a health care facility.
- D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility.
- *E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates (bilirubin more than 30 milligrams/deciliter.)
- F. Stage 3 or 4 pressure ulcer acquired after admission to a health care facility in a patient who had no skin lesions on admission.
- G. Patient death or serious disability due to spinal manipulative therapy.

- *H. Unanticipated major permanent loss of function or death associated with health care associated nosocomial infections.
- *I. Prolonged fluoroscopy with cumulative dose greater than 1500 rads to a single field or any delivery of radiotherapy to the wrong region or greater than 25 percent above the planned dose.

5. Environmental Events

- A. Patient death or serious disability associated with an electric shock while being cared for in a health care facility.
- B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.
- C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility.
- D. Patient death or serious disability associated with a fall while being cared for in a health care facility.
- E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility.

Serious disability is defined as major permanent loss of body function lasting greater than two weeks.

* Joint Commission Defined Sentinel Event

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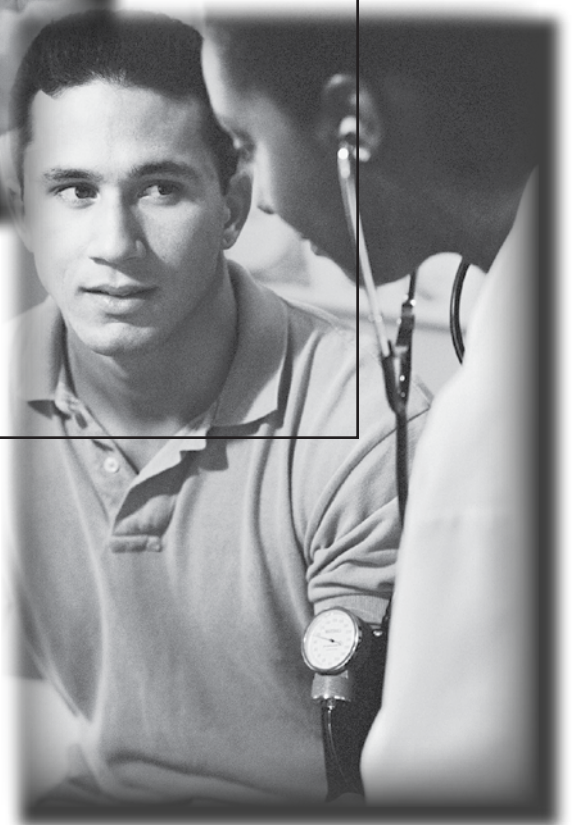
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