

Creating a Culture of Safety:

Preliminary Guide to the Patient Safety Provisions of Act 13 of 2002



Pennsylvania
MEDICAL SOCIETY®



THE HOSPITAL & HEALTHSYSTEM
ASSOCIATION OF PENNSYLVANIA

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Introduction

The Medical Care Availability and Reduction of Error Act (Act 13) was signed into law on March 20, 2002. Act 13 begins to address the complex and difficult issue of medical professional liability reform through tort reform, CAT Fund reform, and patient safety. Key provisions of the act include:

- Privatization of the CAT Fund over the next seven years.
- Allocation of approximately one-half billion dollars in state subsidy from the Auto CAT Fund to provide immediate financial relief (2002–2004) by enabling discounts on the CAT Fund surcharge during 2002–2004 and assisting in paying down the CAT Fund liabilities.
- Tort reforms – including collateral source, periodic payment for future damages, criteria for expert witnesses, statute of repose.
- Patient safety provisions.

The legislative intent of the Medical Care Availability and Reduction of Error Act (Act 13) is to ensure that medical care is available through a comprehensive and high-quality health care system; to ensure access to a full spectrum of hospital services and physicians; to ensure medical professional liability insurance is obtainable at affordable and reasonable cost; and to reduce and eliminate medical errors by identifying problems and implementing solutions that promote patient safety.

Chapter 3 of Act 13 specifically relates to the reduction of medical errors and improvement of patient safety. The patient safety provisions of the act apply to ambulatory surgical facilities, birthing centers, and hospitals. Act 13:

- Establishes a Patient Safety Authority.
- Establishes a patient safety trust fund.
- Requires medical facilities to develop, implement, and comply with an internal patient safety plan.
- Requires reporting of serious events or incidents, as well as providing written notification to any patients affected by a serious event.
- Requires that each medical facility designate a patient safety officer, as well as create a patient safety committee.
- Includes confidentiality and compliance.
- Requires patient safety discounts under medical malpractice insurance.

This preliminary guidebook is designed to assist HAP member hospitals and health systems, as well as medical staff, to effectively implement and comply with the patient safety provisions of Act 13. The guidebook addresses reporting and notification requirements, patient safety plan development and implementation, and the role of the Patient Safety Authority. Where applicable, sample templates are included for consideration by member hospitals and health systems. Hospitals, health systems, and medical staff should use these preliminary guidelines in conjunction with legal counsel recommendations.

Key Definitions in Chapter 3 of Act 13:

- **Health Care Provider** – A primary health care center or person; including a corporation, university, or other educational institution licensed or approved by the commonwealth to provide health care or professional medical services as a physician, a certified nurse midwife, a podiatrist, hospital, nursing home, birth center, and an officer, employee, or agent of any of them acting in the course and scope of employment.
- **Patient** – A natural person who receives or should have received health care from a health care provider.
- **Health Care Worker** – An employee, independent contractor, licensee, or other individual authorized to provide services in a medical facility.
- **Medical Facility** – An ambulatory surgical facility, birth center, or hospital.
- **Patient Safety Officer** – An individual designated by a medical facility.
- **Incident** – An event, occurrence, or situation involving the clinical care of a patient which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a serious event.
- **Infrastructure** – Structures related to the physical plant and service delivery systems necessary for the provision of health care services in a medical facility.
- **Infrastructure failure** – An undesirable or unintended event, occurrence, or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety.
- **Serious event** – An event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an incident.

Reporting and Notification Requirements

Health care workers who reasonably believe that a serious event or incident has occurred must report the event or incident as prescribed by the medical facility's patient safety plan. The report must be made immediately or as soon as possible after the discovery of the event or incident, but no later than 24-hours after occurrence or discovery of the event or incident.

See Appendix 1 and 2 on pages 11 and 12 (Decision Tree/Categorization of Errors). You may wish to use the algorithm and the categorization of errors in Appendix 1 and 2 to aid you in developing a policy and process for determining whether the adverse occurrence was a serious event or an incident. While this tool was originally devised for medication errors, use of such a process can be applicable to the determination of what type of event to report. Categories B through D may be considered incidents, while categories E through I may be considered serious events.

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Health care workers who report the event or incident as prescribed by the patient safety plan cannot be subject to any retaliatory action for reporting the event or incident and have protections afforded under Pennsylvania's Whistleblower Law. However, a medical facility is able to take any necessary disciplinary action against a health care worker who fails to meet performance expectations, or take corrective action against a licensee for unprofessional conduct (which includes making false reports or failure to report a serious event or incident). It is important that all health care workers are held equally accountable for complying with reporting requirements. Facility human resource policies should be modified to incorporate responsibility for these reporting requirements.

Hospitals and health systems will need to revise personnel policies to include non-retaliation clauses as well as to indicate that reporting of events and incidents is mandatory and a condition of employment.

Language must also be incorporated into medical or hospital bylaws regarding medical staff requirements to report events or incidents.

Patient Written Notification

In addition to reporting requirements, the act requires medical facilities to provide written notice of serious events to the patient or an adult family member within seven days of the occurrence or discovery of the occurrence of a serious event. The medical facility may designate who handles the disclosure and provides written notice, as well as the process to be used to fulfill this obligation.

See Appendix 3 on pages 13–19 for a sample disclosure policy. In developing a policy, the following are provider considerations:

- This notification requirement does not constitute an acknowledgment or admission of liability. It is important to acknowledge the occurrence was not expected, and to offer empathy and even an apology as appropriate.
- The patient safety plan should clearly specify which person/persons will be designated to disclose the occurrence of a serious event and provide the written notification. As a starting point, hospitals should review current policies to comply with the Joint Commission notification requirements and to modify that process accordingly. Training on how to communicate with patients should be given to anyone designated to provide the notice.
- It is important to note that any documentation in the medical record is **not** protected under the confidentiality provisions of the act. The medical record is an original source document, and as such hospitals need to develop a policy regarding what information (i.e., details regarding the serious event) is documented in the medical record.

See Appendix 3 for a sample written notification acknowledgment.

Medical Facility Filing of Reports and Notification

The act states that medical facilities will have to begin reporting serious events and incidents to the Patient Safety Authority and serious events and infrastructure failures to the Department of Health **30 days** after a notice is published in the *Pennsylvania Bulletin*.

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The state has 120 days from the effective date of the act to establish the Patient Safety Authority and also requires the authority to work with the Department of Health in implementing the act.

The earliest reports are likely to have to be submitted under this act are late summer/early fall. Hospitals must continue reporting under the Department of Health's current Chapter 51 reporting until such time as the requirements are terminated. Failure to continue making Chapter 51 reports could result in licensure sanctions.

Failure to Report

If a medical facility determines that a licensee providing health care services in the medical facility during a serious event fails to report the event as required, the medical facility is required to notify the licensee's licensing board of the failure to report. *The board's have not yet established a preferred reporting process.*

Failure to report a serious event or infrastructure failure or to develop and comply with a patient safety plan as required by the act will constitute as a violation of the Health Care Facilities Act which permits penalties to be imposed. Failure to report a serious event or infrastructure failure or to notify a licensure board may result in an administrative penalty of \$1,000 per day being imposed by the Department of Health.

Repeal of Chapter 51 Serious Event Reporting Requirements

The Department of Health's current chapter 51 reporting requirements continue until 30 days after the notice on filing reports with the authority is published in the *Pennsylvania Bulletin*.

Patient Safety Plans

Act 13 requires that medical facilities develop, implement, and comply with an internal patient safety plan for the purpose of improving the health and safety of patients. Medical facilities must consult with licensees providing health care services in the medical facility when developing the internal patient safety plan. Medical facilities must submit their patient safety plan to the Department of Health by **July 18, 2002**.

Required components of the patient safety plan include:

- Designation of a patient safety officer.
- Establishment of a patient safety committee.
- Establishment of a system (accessible 24/7) for health care workers to report serious events and incidents.
- Non-retaliatory language for health care workers who report events or incidents (according to Pennsylvania's Whistleblower Law).
- Definition of the process by which written notification of serious events will be provided to patients.

The Department of Health has **60 days** after a medical facility submits a patient safety plan to approve or reject the plan. *If the department does not act during that time, the plan is deemed approved.*

Once the Department of Health approves the plan, and assuming that the Patient Safety Authority has published the reporting notice in the *Pennsylvania Bulletin*, medical facilities must affirmatively notify health care workers and medical staff of the patient safety plan, and that as a condition of employment or

credentialing at the medical facility, all health care workers and medical staff must comply with the patient safety plan regarding the serious event and incident reporting requirements. Health care workers and medical staff are required to report serious events and incidents within 24-hours of occurrence or discovery. The failure of licensed health care workers to report serious events and incidents can, in and of itself, become reportable to the relevant licensure board.

Provider Considerations:

A sample patient safety plan is included in this guidebook (*See Appendix 4 on pages 20–32*).

- Hospitals should review current policies and procedures for reporting sentinel events under the Joint Commission or serious events (Chapter 51) to the Department of Health and modify those policies to be consistent with this act. The plan should also be reviewed by legal counsel, to ensure that the confidentiality protections afforded by this act are fully recognized. Hospitals should develop a time line for submission of the plan to the Department of Health that enables input and action by the patient safety committee and hospital board.
- Because of the confidentiality provisions of Act 13, information that falls strictly under the purview of the patient safety committee should not be voluntarily shared with other groups external to the organization, including JCAHO and other patient safety organizations, particularly those documents produced within the committee that are prepared or created as part of the review, investigation, or evaluation of the event, such as a root cause analysis.
- Hospitals should develop training/education programs so that health care workers understand the facility’s policies and procedures for reporting, confidentiality, and written notification to patients. These programs should not be conducted until such time as the department approves the medical facility’s patient safety plan and the authority publishes the reporting requirements so that the facility can make final modifications to their policies and training programs, if necessary.

Patient Safety Officer

Each medical facility is required to designate a patient safety officer. The patient safety officer will serve on the patient safety committee, ensure investigation of serious events and incidents, report to the patient safety committee regarding actions to promote patient safety, and take action immediately necessary to improve patient safety.

A sample job description for the patient safety officer is attached in Appendix 5 on pages 33–35.

Provider Considerations:

- Medical facilities may determine who they want to designate as the patient safety officer. If your hospital has already identified a central point of control for existing Department of Health serious event reporting you may want to consider designating that individual as the patient safety officer. You also may want to consider a physician, such as the quality assurance director, the risk manager, or your corporate compliance officer as the patient safety officer.
- Consideration should be given to delegated authority to assure that facilities comply with the 24-hour reporting requirement.

Patient Safety Committee

The patient safety committee is to be comprised of at least three health care workers (including at least one nurse and one doctor), the patient safety officer, and two community residents who are not employed by the medical facility. You are only allowed to have one board member on the committee, otherwise there are no limits on the size of the committee.

The patient safety committee is responsible for:

- Receiving reports from the patient safety officer.
- Evaluating investigations and actions of the patient safety officer as it relates to the report.
- Reviewing and evaluating the quality of patient safety measures.
- Making recommendations to eliminate future serious events or incidents.
- Reporting to the administrative officer and governing body of the medical facility on a quarterly basis to include the number of serious events and incidents.

Provider Considerations:

- Since the confidentiality provisions of Act 13 are limited solely to the functions of this act, organizations need to consider seriously whether the patient safety committee should conduct other quality of care or peer review activities. Organizations may establish the patient safety committee separately as a hospital committee or as a subcommittee of the hospital's quality improvement committee or council. Organizations must be cautious to not include other business unrelated to patient safety in this committee, since it could risk jeopardizing the confidentiality and discoverability protections afforded under this act by including such business.
- The details of any specific incident or event should not be shared with other hospital or medical staff committees. Rather, the recommended actions may and should be shared with these other committees as a result of the lessons learned through the investigation of an event. Additionally, the organization may create comparable case studies based on the actual events reviewed by the patient safety committee to share as a learning experience with others in the organization and to reinforce the recommended actions.
- Each licensed hospital, ambulatory surgery facility, and birth center must have a designated safety officer, safety committee, and safety plan. If there are multiple licensed facilities that make up the health care system, each organization can have a separate plan, officer, and committee to be compliant with the provisions of Act 13. Or, there may be separate designated officers that report through the same patient safety committee utilizing the same plan. In this case, both hospitals would have a patient safety committee and plan that happens to be the same. If a health system determines that it will utilize the same officer, plan, and committee for each of its licensed organizations, it must be able to demonstrate that patient safety issues are adequately addressed in each organization through that structure.

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- There is no requirement in Act 13 that the patient safety officer needs to chair this committee. Organizations may determine whether the patient safety officer serves as staff or chair to the committee. If the patient safety officer serves as staff, the organization may elect to appoint another person as chair to the committee.
- Organizations may choose to appoint community residents who are familiar with the organization, such as former board members, volunteers, auxiliaries, or the spouse of an employee/medical staff member. An organization may also choose to appoint to this committee a patient or a family member of a patient who sustained an injury as a result of a serious event.

See Appendix 6 on page 36 for a suggested flow of information which is protected under Act 13 and has current peer review protection.

Confidentiality and Compliance

The confidentiality protections afforded in this act apply solely to documents, materials, or information prepared or created pursuant to the responsibilities of the patient safety committee or governing board of the medical facility.

Any documents, material, or information prepared or created for the purposes of complying with the patient safety plan, reporting, notification, and investigation which are reviewed by the patient safety committee or governing board of the medical facility are confidential and will not be discoverable or admissible as evidence in any civil or administrative action or proceeding.

Persons responsible for or participating in meetings of the patient safety committee or governing board will not be required to testify as to any matters within the knowledge gained by the person's responsibilities or participation on the patient safety committee or governing board of the medical facility.

Note – the confidentiality provisions do not apply to original source documents (i.e., medical records).

Time Line and Effective Dates

The patient safety chapter (Chapter 3) of The Medical Care Availability and Reduction of Error Act (Act 13) has the following effective dates for purposes of implementation. Please refer to applicable chapters within this guidebook for more detailed information on the specific provisions.

60 Days – May 19, 2002

- Designation of a patient safety officer
- Establishment of a patient safety committee
- Written Notice of Serious Events

120 Days – July 18, 2002

- Patient Safety Plan Submission

Other Dates

- **Licensure Surcharge**—July 2002.
- **Department of Health Approval of Patient Safety Plans**—60 days after submission of plan.

- **Notification of Health Care Workers about Reporting Requirement**—Upon approval of patient safety plan.
- **Begin Filing Reports with the Patient Safety Authority and the Department of Health**—30 days after a notice is published in the *Pennsylvania Bulletin*.
- **Repeal of Chapter 51 Serious Event Reporting Requirements**—30 days after a notice is published in the *Pennsylvania Bulletin*.
- **Patient Safety Discount**—This program would begin no sooner than policies issued or renewed after December 31, 2002. This program expires on December 31, 2007.

Patient Safety Authority

Act 13 establishes the Patient Safety Authority, whose primary responsibilities will include the management of the patient safety trust fund; contracting with an appropriate entity or entities to collect and analyze data regarding reports of serious events and incidents; issuing recommendations on how to reduce serious events and incidents; receiving and investigating anonymous reports; and reporting to the General Assembly annually on the authority's activities the preceding year.

The Patient Safety Authority will be an eleven-member board, which includes:

- Physician General (Chairperson)
- 4 residents of the commonwealth (Appointed by the legislature)
- 6 persons appointed by the governor:
 - Physician
 - Nurse
 - Pharmacist
 - Health care worker employed by a hospital
 - 2 residents (one a health care worker and one a non-health care worker)

The physician, nurse, and pharmacist also must meet the definition of a health care worker.

Patient Safety Trust Fund

Act 13 establishes a separate account in the State Treasury. The Patient Safety Trust Fund will be administered by the Patient Safety Authority. All funds deposited into the account will not be considered general revenue nor may they be used for any other purpose.

Beginning July 1, 2002, each medical facility will be required to pay the first annual licensure surcharge to provide funding to operate the Patient Safety Authority.

The Department of Health will develop a formula for purposes of levying the surcharge on hospitals, birthing centers, and ambulatory surgery centers and inform medical facilities of the surcharge requirement.

The total assessment for all medical facilities may not exceed \$5,000,000. This licensure surcharge must be paid within 30 days after receiving notice of payment due. If a medical facility fails to make payment, the Department of Health may assess an administrative penalty of \$1,000 per day until the surcharge is paid.

Department of Health Responsibilities

The Department of Health is responsible for reviewing and approving patient safety plans (See Chapter 7), receiving serious event reports and infrastructure failure reports, and investigating those reports. The Department of Health will also work in collaboration with the Patient Safety Authority in evaluating existing health care procedures and approving recommendations issued by the Patient Safety Authority to reduce medical errors and ensure patient safety.

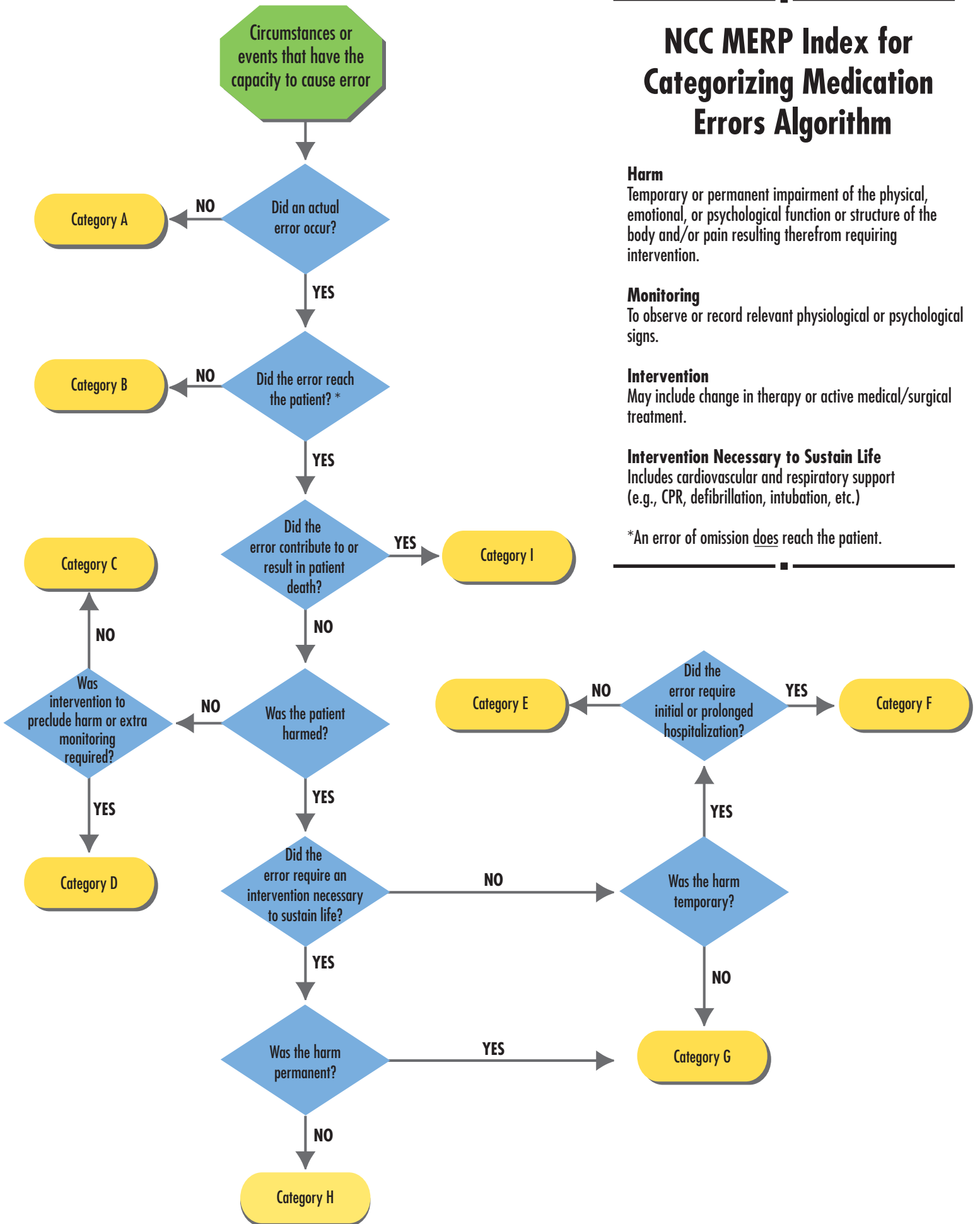
Provider Considerations:

- It is important to note that recommendations issued by the Patient Safety Authority may be considered by the Department of Health for licensure purposes under the Health Care Facilities Act of 1979. However, recommendations issued cannot be considered mandatory unless the Department of Health promulgates regulations pursuant to the Regulatory Review Act.
- Hospitals and health systems should closely monitor and review their Department of Health licensure survey results to ensure that any citations have a regulatory basis and are not merely based on recommendations from the authority. Any citations that the hospital or health system feels do not have a regulatory basis can be appealed.

Patient Safety Discount

The Department of Health, in consultation with the Insurance Department, is required to establish criteria for certification that would enable a patient safety discount to be applied to the mandated basic coverage. This program would begin no sooner than policies issued or renewed after December 31, 2002. This program expires on December 31, 2007.

NCC MERP Index for Categorizing Medication Errors Algorithm



Harm

Temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom requiring intervention.

Monitoring

To observe or record relevant physiological or psychological signs.

Intervention

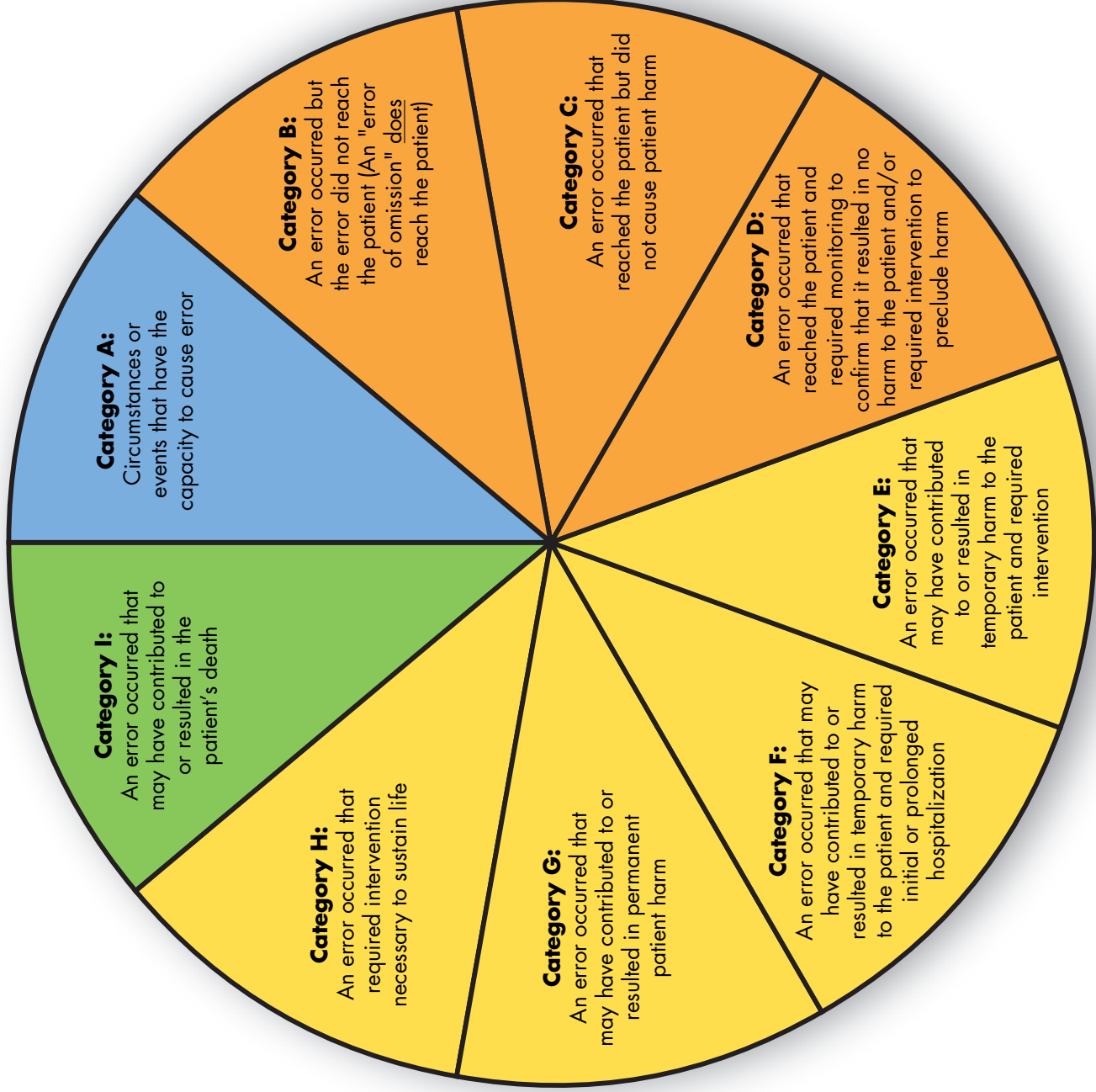
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life

Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

*An error of omission does reach the patient.

NCC MERP Index for Categorizing Medication Errors



- No Error
- Error, No Harm
- Error, Harm
- Error, Death

Definitions

Harm

Temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom requiring intervention.

Monitoring

To observe or record relevant physiological or psychological signs.

Intervention

May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life

Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

3. Sample Disclosure and Written Notification Policy

Policy – The Patient Safety Plan requires that disclosure of the unanticipated event and written notification be provided to a patient and/or their families when affected by a serious event.

Disclosure and written notification must be made within seven days of the occurrence or discovery of a serious event.

Purpose – The purpose of this policy is to provide guidelines for disclosure and written notification to patients and/or their families who have been affected by a serious event.

Procedures – The following procedures will provide specific guidelines for disclosing information and written notification to a patient and/or their families regarding a serious event.

1. Upon occurrence or discovery of occurrence of a serious event, the health care worker shall report the serious event according to the established system as defined in the patient safety plan. This includes notification to the patient safety officer of the occurrence of a serious event.
2. Depending on the circumstances, the registered nurse caring for the patient, the department supervisor, or the most appropriate staff person will immediately contact the attending physician (if not present at the time the serious event occurred), and relay the facts of the situation.
3. The Patient Safety Officer shall confirm that all necessary measures have been taken to provide the appropriate level of care to the patient and that any involved equipment, procedures, and personnel (as applicable) were immediately taken out of service.
4. Patient/Family Disclosure and Written Notification – The primary channel of communications with the patient/family regarding the occurrence of a serious event shall be through the attending physician, patient safety officer, or other designated staff.
5. Prior to initiating discussions, the attending physician and the patient safety officer will decide whether the patient is competent. If the patient is not competent, then disclosure and written notification must be provided to the patient's family. All efforts to contact family members or authorized representatives must be documented in the patient's medical record.
6. The attending physician, the patient safety officer, or other designated staff shall meet with the patient/family to discuss the serious event and its impact on the patient's care plan.
(See Attachments – (1) Talking points, (2) Guiding principles).
7. The patient safety officer (or other designated person) shall be responsible for discussing any issues related to billing or potential claims that may be raised by the patient/family.
8. Disclosure and written notification shall be based on the following premises:
 - (a) The patient safety plan requires that a patient/family affected by the occurrence of a serious event be notified of the event and such disclosure shall be accompanied with written notification. Disclosure of the occurrence of a serious event is for the benefit of the patient/family and should provide accurate and factual clinical information that will inform the patient/family of the serious event while ensuring that patient safety and confidentiality remain key priorities.

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- (b) The occurrence of a serious event shall be conveyed to the patient/family in laymen's terms.
 - (c) Disclose only objective clinical facts – NOT beliefs or assumptions.
 - (d) Unless the cause has been clearly determined, there shall be no mention, assumption, or discussion of cause and effect.
 - (e) There shall be no assignment of blame or discussion of any actions taken or to be taken against any of the caregivers involved.
 - (f) The patient/family shall be assured that the hospital and physician are taking the appropriate steps to remedy the situation and reduce the likelihood of recurrence.
 - (g) After disclosing the occurrence of the serious event, the physician shall then focus on how the serious event affects the patient's care plan. If applicable, the physician shall involve the patient in the care plan by identifying any new symptoms or reactions that should be reported to the registered nurse or other appropriate staff member.
 - (h) Written notification shall be provided to the patient/family utilizing the disclosure form. This disclosure form indicates that a serious event occurred and that the hospital staff have notified the patient/family of the occurrence of the serious event and discussed with them pertinent clinical information, the effect the event has had on the patient's plan of care, and that the hospital and physician are taking the appropriate steps to remedy the situation and reduce the likelihood of recurrence. (*See Attachment 3 – Sample Written Disclosure Form*).
 - (i) The disclosure form in no way constitutes an acknowledgment or admission of liability. The disclosure is required per the patient safety plan (as required by Act 13) and is meant to ensure that the patient and family are notified of the occurrence of a serious event.
9. Chart documentation should indicate efforts to identify a family member or authorized representative that the physician and/or patient safety officer notified, in writing, of the occurrence of a serious event. Under no circumstances should chart documentation assign blame or responsibility.
 10. Chart documentation shall clearly state that the patient/family verbalized their understanding of the occurrence. This documentation will substantiate the disclosure and notification and informs subsequent caregivers who may need to have further discussions with the patient.
 11. A copy of the written notification of the disclosure shall be kept in the medical record. The original notification shall be provided to the patient/family.
 12. Any reports required by state or federal law shall be completed and submitted in accordance with the patient safety plan and hospital policy.
 13. At no time shall information regarding the occurrence of a serious event be communicated to the public or representatives of the media without prior approval by Public Affairs, Risk Management, Legal Affairs, and the CEO. The attending physician shall also be informed prior to communicating to the public or media representatives.

Attachment 1

Disclosure and Written Notification Policy Talking Points

When the physician and patient safety officer discuss the occurrence of the serious event with the patient/family, they should strive to provide informed notification. This means that the notification to the patient/family will be based on the facts that are known at the time of disclosure. It does not mean that they will speculate about why the serious event occurred or assign blame to any caregiver. The question of “why” can only be answered if causation is clear at the time of the disclosure. In most cases, the question of “why” can only be answered after a thorough internal review. The disclosure and written notification should not be delayed because the patient/family needs this information to make informed decisions about the updated plan of care. Consistent with state law, disclosure and written notification must be made within seven days of the occurrence of or discovery of the serious event.

These talking points are designed to focus discussions on the areas that are most important to the patient/family. Every situation is different, and the physician/patient safety officer should consult the “Guiding Principles” (*See attachment 2*) for additional assistance.

Talking Points:

1. Start with an apology and acknowledgment of the event and offer empathy to the patient and family.
2. Explain the patient’s status now. Discuss only pertinent clinical facts.
3. Explain the plan of action (i.e., what we have done and are continuing to do to provide for the patient’s immediate safety and comfort).
4. Explain the patient’s current prognosis.
5. Explain the updated plan of care.
6. Explain that the hospital has taken appropriate steps to reduce the risk that this type of occurrence could happen again. These steps include an internal review of the situation.
7. Rarely will causation be known at the time of the initial disclosure with the patient/family. For example, in a wrong site surgery caused by marking the wrong site, causation may be discussed with the patient/family without speculation. However, in most cases, causation will not become clear until after a thorough internal review has been conducted. In these cases, the physician and patient safety officer shall disclose the occurrence of the serious event and explain that causation is not clear but that an internal review is being conducted. The patient/family shall be advised that they may contact the facility for more information after the review is complete. If the patient/family contacts the facility, causation shall be discussed with the patient/family. In no event shall the hospital speculate about causation.
8. Provide written notification indicating that disclosure of the occurrence of the serious event has been made to the patient/family. A copy of the written notification should be kept in the patient’s medical record. (*See Attachment 3*)
9. Document in the patient’s medical record that disclosure and written notification was provided to the

patient/family. The discussion must be documented, as well as the fact that the patient/family verbalized their understanding of the occurrence. This documentation will substantiate the disclosure and notification and informs subsequent caregivers who may need to have further discussions with the patient.

Example Dialogue (to be used as an educational tool)

Facts – The physician ordered heparin and insulin was given by mistake. It is unclear why the mistake was made but the order for the heparin was a verbal order. The patient became severely hypoglycemic and was transferred to ICU for treatment and stabilization.

Physician – You had a reaction to a medication that was given. You were given insulin instead of the heparin that was ordered. Upon discovery of the medication error, you were given Dextrose, a medication to reverse the effects of insulin. You were immediately transferred to ICU so that we could monitor your care more closely using the equipment you see next to you. You are responding well to the medication. All appropriate measures have been taken to alleviate the effects of the insulin. It appears that one or two additional days in the hospital will be required, but I expect you will fully recover without any ill effects. If you begin feeling dizzy, light headed, agitated, or have any other unusual feelings please tell your nurse immediately. I understand this may seem frightening to you. Do you have any questions about what we have discussed?

Patient's Husband – Yes. It sounds like the nurse made a mistake. Will the nurse be fired? Will she continue providing care to my wife?

Physician/Patient Safety Officer – At this point, we do not want to guess about why this happened. Instead, we have initiated a thorough internal review. The review will look at our policies, procedures, and other areas that may have been a factor. It would be premature at this time to discuss potential personnel actions that we may take. We can assure you that we will take any appropriate actions to reduce the risk that this type of occurrence happens again. If it makes you feel more comfortable, we can assign you to a new nurse.

Patient – May I obtain a copy of your report when it is complete?

Patient Safety Officer – We cannot share an actual copy of the report with you due to confidentiality; however, we would be happy to update you on the status of our review if you contact us.

Patient's Husband – Will we be required to pay for the additional two days in the ICU? Will my insurance company be billed?

Patient Safety Officer – Here is the business card of our Risk Manager. We have asked her to come and speak with you about your billing questions. She is the best person to answer those questions.

45 days later after the internal review is complete and the patient had been discharged:

Patient – I am calling to check on the status of the review you were conducting.

Patient Safety Officer – Our review is complete. All of the individuals involved met to discuss your case. We also searched the medical literature to identify best practices. We reviewed various records and data and ultimately determined to provide education to our physicians and nursing staff. The

education focused on the use of verbal orders for medications, and the education was completed last week. We also revised our medication administration policy to add some additional safety measures to reduce the risk that this happens again.

Patient – So why did this happen to me? It was a nursing error, wasn't it? She gave me the wrong medication, right?

Patient Safety Officer – The wrong medication was administered to you, and our review confirmed that. We ultimately determined that this happened because the physician verbally ordered your medication, and the nurse misunderstood the verbal order. Our policy has now been revised to limit the use of verbal orders to emergencies. As I mentioned, we have also provided education to our physicians and nursing staff on the use of verbal orders.

Patient – May I obtain a copy of the literature search and the revised policy?

Patient Safety Officer – Yes.

Attachment 2

Disclosure and Notification Policy Guiding Principles

1. Recognize that the patient is looking for an apology and information.
2. Recognize that all caregivers have the patient's best interest in mind so that they always endeavor to deliver quality, safe patient care.
3. Recognize that the hospital and physician are responsible for providing quality patient care.
4. Support the concept that physician performance should be reviewed by physician peers.
5. Promote appropriate disclosure and accountability in a non-punitive environment.
6. Recognize that performance improvement and patient safety are continuous tasks. Therefore, the hospital continually seeks to identify, develop, and share best practices.

Attachment 3

Disclosure and Written Notification Policy Sample Written Notification Form

_____ is committed to providing quality
(Hospital Name)

medical care to its patients and the communities it serves. Despite constant and committed efforts to provide and improve patient care, adverse events sometimes occur. While sometimes these outcomes of care are unavoidable, at other times they result from mistakes or errors in the provision of care.

While this notification does not constitute an admission of liability,

_____ is committed to respecting the rights
(Hospital Name)

of patients and their families to be informed about the occurrence of serious events, and to analyze such events to improve patient care and prevent recurrence. This notification provides relevant information concerning the occurrence of a serious event.

Date of Event Occurrence: _____

Date Patient/Family Informed: _____

Time Informed: _____

Staff who provided notification: _____
(Print Name)

(Print Name)

Should you have further questions please contact _____
(Patient Safety Officer)

at _____
(insert phone number)

I hereby attest that disclosure of this event was provided to the patient/family.

(Signature of staff who provided notification)

Date

(Signature of staff who provided notification)

Date

4. Sample Patient Safety Improvement and Management Program Plan

This sample plan has been developed to assist hospitals in complying with Pennsylvania's Act 13 of 2002, as well as the Joint Commission on Accreditation of Healthcare Organizational Standards.

Overview and Purpose

Attention to maintaining and improving patient safety and well being is inherent in (*Hospital's*) commitment to the relief of suffering and improvement in the quality of life to those in the community it serves. In committing ourselves to safeguarding individuals, (*Hospital*) must fully understand the processes and systems that are utilized by the organization to deliver patient care. From this deeper understanding, (*Hospital*) will be able to analyze, evaluate, develop, and implement changes that will continuously improve the way we deliver care to patients.

The results of these efforts will:

- Demonstrate (*Hospital*) commitment to the community it serves.
- Hardwire (*Hospital*) and individuals who work and practice at (*Hospital*) to respond appropriately to adverse events, proactively identify risk-reduction strategies, and participate in process and system redesigns to reduce risk of patient harm.
- Allow (*Hospital*) to implement processes, technology, or systems that will reduce the risk of errors reaching patients and causing harm.
- Promote greater medical staff and employee involvement in improving clinical care, which will result in improved employee and medical staff satisfaction.
- Translate into a more efficient and cost-effective model of care at (*Hospital*).
- Begin the healing process for those individuals suffering from serious events.

(*Hospital*) leadership, medical staff, managers, and employees must actively embrace and support the patient safety improvement and management program in order to achieve the results outlined above. The purpose of the patient safety plan is to provide a framework for the implementation of various components of the patient safety program at (*Hospital*).

Principles

(*Hospital's*) patient safety plan is based on the following principles.

- Improvement in patient safety will not occur unless there is a commitment by (*Hospital's*) governing body and senior management and an overt, clearly defined, and ongoing effort on the part of hospital leaders, physicians, managers, and employees to sustain the organization's interest and focus on patient safety. The leadership of (*Hospital*) will keep the hospital board of directors apprised of any adverse outcomes, safety problems, and efforts directed at improving patient safety.
- Communication about the importance of patient safety must be well conceived, repeated, and consistent across the entire organization. In its communication with physicians, managers, employees, and patients, (*Hospital*) will stress that safety problems are quality problems and that all

persons must be involved in the patient safety reporting system, identifying deficiencies in current care processes, and in designing and executing solutions needed to create safer systems. All individual concerns and ideas about how to improve patient safety will be valued and respected.

- Responsibility and accountability for patient safety must be clearly articulated to physicians, managers, and employees. (*Hospital*) will incorporate patient safety accountability into position descriptions, orientation, and ongoing education and training.
- Feedback about how the sharing of information and reporting of various types of events was acted upon and used to make improvements in the care delivery system is important. (*Hospital*) will provide feedback to those employees and health care providers who have reported or disclosed errors. This feedback may range from acknowledgment that the report has been received to results of detailed root cause analyses.
- Punitive approaches toward individuals involved in various events pushes reporting and disclosure underground, thereby preventing an opportunity for the organization to appropriately intervene to correct the underlying problems. (*Hospital*) is committed to developing ways to reward rather than discourage reporting of errors or patient safety concerns and will celebrate successes at improving the reporting of patient safety concerns and errors and how such information has been used to make improvements in hospital processes, systems, and care delivery.
- Abundant evidence in human factors and cognitive psychology literature recognizes that most human errors are symptoms of underlying system failures, not personal failures. When human failures do occur, they are most often consequences of inevitable, “built-in” limitations of human cognition or endurance. Individuals involved in incidents and serious events will not be blamed for the occurrence or subjected to retribution. Rather, (*Hospital*) will offer support and counseling to individuals involved in an event with an unanticipated outcome and involve these individuals in assisting the organization to learn from the event and develop strategies to avoid the possibility of having such an event occur again. At (*Hospital*), employee accountability may include any or all of the following: acknowledging the risks involved with complex health care delivery; acknowledging that an error occurred with possible resultant injury; providing remedial or restorative care; assisting in possible root cause analysis of the processes involved; and cooperating in fixing the problem(s) in the processes.
- (*Hospital*) will ensure that processes, functions, and services are designed with a focus on patient safety. This will be accomplished by using available information from within and external to the organization to design or redesign processes to minimize risk to patients. To the extent possible, (*Hospital*) will analyze or pilot test the new design or redesign to ensure that no new risks have been embedded into the new or redesigned process prior to its implementation.
- (*Hospital*) will seek to reduce variation in how patients are cared for in the organization and will devise strategies to avoid reliance on memory through the use of standardized protocols, checklists, work processes, and use of technology/automation.

- Patients are encouraged to actively participate in care decisions. Those who are informed of their treatment plan and properly educated and coached to question something that doesn't seem right can often prevent an error from occurring. (*Hospital*) will include patients as active participants in their care and promote patient and family questioning of the organization's routine, procedures, and processes whenever something does not "look" or "feel" right. (*Hospital*) will disclose information about errors that cause harm to that patient and/or patient's family in fulfilling its ethical responsibility and as a means of demonstrating the organization's commitment to patient safety and the community that it serves. In the event of a serious event, the disclosure will be made in writing to the patient or patient's family within seven days of the occurrence or discovery of the serious event.
- As the field of patient safety evolves, the effectiveness of various approaches to improving patient safety will be studied and evaluated. (*Hospital*) will consult the literature, examine the experiences of others who have responded to similar issues, and consider recommendations made by various authoritative groups in developing alternatives to reduce the possibility of error or having the error reach the patient.

Key Definitions

- **Error** – The failure of a planned action to be completed as intended (i.e., error of execution) or the use of an incorrect plan to achieve an aim (i.e., error of planning). [Institute of Medicine Report, *To Err is Human: Building a Safer Health Care System*] or an unintended act, either of omission or commission, or an act that does not achieve its intended outcome. [Joint Commission on Accreditation of Healthcare Organizations]
- **Adverse Event** – An injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a "preventable adverse event." [Institute of Medicine Report, *To Err is Human: Building a Safer Health Care System*]
- **Sentinel Event** – An unexpected occurrence involving death or serious physical or psychological injury. Serious injury specifically includes loss of limb or function. Sentinel events that are subject to review by the Joint Commission on Accreditation of Healthcare Organizations include: suicide of a patient in a setting where the patient receives round-the-clock care; infant abduction or discharge to the wrong family; rape; hemolytic transfusion reaction involving the administration of blood or blood products having major blood group incompatibilities; and surgery on the wrong patient or wrong body part. [Joint Commission on Accreditation of Healthcare Organizations]
- **Near Miss** – Any process variation which did not affect the outcome, but for which a recurrence carries a significant chance of a serious adverse outcome. [Joint Commission on Accreditation of Healthcare Organizations]
- **Root Cause Analysis** – A process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not individual performance. It progresses from special causes in clinical processes to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future. [Joint Commission on Accreditation of Healthcare Organizations]

- **Failure Mode Effects and Criticality Analysis** – A proactive approach to assessing the intended and actual implementation of a process to identify steps in the process where there is, or may be, undesirable variation or failure modes; the possible effect on patients for each identified failure mode; and how serious or critical the possible effect could be on the patient. For the most critical effects, a root cause analysis is conducted to determine why the variation leading to that effect may occur in order to better design the process or system to minimize the risk of that failure mode or protect patients from the effects of that failure mode. [Joint Commission on Accreditation of Healthcare Organizations]
- **Action Plan** – The product of root cause analysis that identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the future. The plan addresses responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions. [Joint Commission on Accreditation of Healthcare Organizations]
- **Serious Event** – An event, occurrence, or situation involving the clinical care of a patient in a medical facility (hospital, ambulatory surgery facility, or birthing center) that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health services to the patient. [Pennsylvania Act 13 of 2002, Medical Care Availability and Reduction of Error Act] Serious events are reportable to the Patient Safety Authority and Department of Health under Act 13.
- **Incident** – An event, occurrence, or situation involving the clinical care of a patient in a medical facility (hospital, ambulatory surgery facility, or birthing center) which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. [Pennsylvania Act 13 of 2002, Medical Care Availability and Reduction of Error Act] Incidents are reportable to the Patient Safety Authority under Act 13.
- **Infrastructure Failure** – An undesirable or unintended event, occurrence, or situation involving the infrastructure of a medical facility (hospital, ambulatory surgery facility, or birthing center) or the discontinuation or significant disruption of a service, which could seriously compromise patient safety. [Pennsylvania Act 13 of 2002, Medical Care Availability and Reduction of Error Act] Infrastructure failures are reportable to the Pennsylvania Department of Health under Act 13.
- **Patient Safety** – Freedom from accidental injury while receiving health care services.

Scope and Components of the Program

Leadership and Continuous Improvement – The leadership of (*Hospital*) supports a systematic, coordinated, and continuous approach to the improvement and management of patient safety. This will be achieved through the establishment of policies, procedures, and protocols to support effective responses to actual adverse events; ongoing proactive risk reduction activities to minimize the occurrence of errors or the probability that those errors will reach the patient; involvement of the medical staff, employees, and patients/families; and designing or redesigning processes and systems on the basis of what has been learned internally and externally through patient safety initiatives.

Internal Reporting – In order to have an effective patient safety improvement and management program, there must be an emphasis on reporting all types of events that may harm or have harmed patients. *(Hospital)* has adopted a non-punitive approach in its management of adverse events and reporting. All members of the medical staff and employees are required to report suspected and/or identified medical errors and should do so without the fear of reprisal in relationship to their employment. *(Hospital)* focuses first and foremost on system/process improvements and will not blame the individual(s) involved in the event or seek retribution against the individual for reporting the event.

However, in the event that a member of the medical staff or employee participates in willful or malicious misconduct, sabotage, substance abuse, criminal activity, fails to report the event truthfully or in a timely fashion, or makes an egregious error demonstrating a lack of fundamental knowledge necessary to carry out his/her job responsibilities, *(Hospital)* may institute disciplinary or corrective action. Failure to report may also cause *(Hospital)* to report a licensed health care professional to his/her respective state professional licensure board in accordance with Pennsylvania's Medical Care Availability and Reduction of Error Act (Act 13). *(Refer to (Hospital's) Policy on Corrective Action. A comparable medical staff policy should be modified to comply with these provisions in Act 13.)*

Retrospective Analysis – The following types of events may be addressed by the patient safety program.

- **Near-Miss and Actual Medication Errors** (wrong dose, wrong route, missed dose, wrong drug, wrong patient, wrong administration time)
- **Adverse Drug Events** (defined as patient harm related to medication use)
- **No Harm, Near Miss Events or Incidents**
- **Adverse Clinical Events** (missed diagnosis, body fluid exposure, wrong surgery site, infection, transfusion reactions, communication error)
- **Sentinel Events**
- **Patient Falls** (those resulting in patient injury)
- **Patient Restraint and Seclusion Events** (those resulting in patient injury)
- **Selected Administrative Incidents** (patient identification, discharge problems, documentation, informed consent issues, advance directives)
- **Other Situations or Incidents** (other situations which may involve infrastructure/environmental issues, work design, patient care products or equipment)

Prospective Analysis – Annually, at least one high-risk process will be selected for risk assessment and hazard analysis. Selection will in part be based on information published by JCAHO that identifies the most frequently occurring types of sentinel events.

Medical Staff and Employee Education –

Each hospital should outline what its programs are with respect to medical staff and employee education related to patient safety. In particular, to demonstrate compliance with Act 13, hospitals should consider having medical staff and employees sign a document that outlines what their responsibilities are relative to patient safety. For new physicians, this may need to be part of the initial credentialing and privi-

leging process, and for new employees, it should be incorporated into the orientation process. On an ongoing basis, reinforcement of these responsibilities needs to occur as part of the recredentialing and performance evaluation for medical staff and employees. The organization should also consider addressing any programs/initiatives aimed at team training around patient safety in this section to demonstrate that they are meeting the intent of human resource standards in the JCAHO hospital accreditation manual.

It is recommended that each hospital work with their medical staff as it relates to patient safety education.

Patient and Family Education –

Each hospital should address what they are actually doing to foster patient and family education in regard to patient safety and what materials they might be using to assist in those education efforts. Organizations may want to include how they collect information from patients and families about how they can improve patient safety to demonstrate that they are meeting the intent of improving organizational performance standards in the JCAHO hospital accreditation manual. Additionally, organizations can document here that they are including consumer representatives on the patient safety committee which is required as part of Act 13.

Disclosure –

Patients, and when appropriate, their families are informed by the attending physician or his/her designee involved in the care of that patient about the outcomes of care, including unanticipated outcomes. At least one hospital representative will be present at the time of the disclosure. The physician or his/her designee will clearly explain the unanticipated outcome to the patient and/or family members as soon after the event or incident as is possible and appropriate. The hospital and medical staff have developed an algorithm to assist in determining which events or incidents must be discussed with the patient and/or family members. Additionally, serious events as determined by use of an approved algorithm must be disclosed to the patient and/or family in writing within seven days of the occurrence of the event or the discovery of the event. (Refer to (Hospital) Disclosure Policy – see example of disclosure policy and written disclosure notification form)

The patient safety plan should clearly specify who will be designated to perform the disclosure and how evidence that the disclosure occurred will be documented. As a starting point, hospitals should review current policies to comply with the Joint Commission notification requirements and modify the process accordingly. Training on how to communicate with patients should be given to anyone designated to perform the disclosure. Planning for each disclosure encounter is essential.

External Reporting – Depending on the severity of the event or incident, the appropriate authorities, including the Patient Safety Authority and/or the Department of Health will be notified utilizing the required reporting format. (Refer to (Hospital) Sentinel Event and Other Event Reporting Policy(ies))

Because of the confidentiality provisions of Act 13, information that falls strictly in the purview of the patient safety committee should not be voluntarily shared with other groups external to the organization, including JCAHO and other patient safety organizations, particularly those documents produced within the committee prepared or created as part of the review, investigation, or evaluation of the event, such as root cause analyses.

Organizations will need to consider which option under the JCAHO sentinel event policy they might wish to exercise, if confronted with having to provide information on the event to JCAHO in order to demonstrate their compliance with JCAHO standards related to reviewable sentinel events. Organizations should consider exercising sentinel event option 3 where a health care organization can request an on-site discussion of the root cause analysis for the sentinel event in question with a JCAHO surveyor. Under this option, the root cause analysis is not shared with the surveyor, but the actual action plan may be shared. Alternatively, organizations may choose to exercise sentinel event option 4. Under this option, the JCAHO surveyor again comes to the organization and conducts interviews and reviews relevant documentation to obtain information about the process and findings of the root cause analysis and resulting action plan, without actually reviewing the root cause analysis or action plan. However, under option 4, the organization is subject to a standards review and potential recommendations from JCAHO resulting from such review. Should an organization decide to share the root cause analysis with JCAHO, it could potentially lose its protection from discovery under Act 13. Organizations will need to determine whether they want this additional protection. The root cause analysis could potentially be protected under the peer review protection act; however, its protection is considerably strengthened under the provisions afforded under Act 13.

Authority and Responsibility

Board of Directors – The overall authority for direction of the patient safety improvement and management program rests with (*Hospital*) board of directors. The board of directors delegates its authority to implement and maintain the various components of the patient safety improvement and management program to the president and chief executive officer of (*Hospital*).

President and Chief Executive Officer – The president and chief executive officer in collaboration with administrative, managerial, and clinical staff ensures that the patient safety improvement and management program is implemented throughout the organization and integrated appropriately with other activities within the organization which contribute to the maintenance and improvement of patient safety, such as performance improvement, environmental safety, and risk management. The president and chief executive officer will designate a qualified individual in the organization to manage the organization-wide patient safety improvement and management program at (*Hospital*).

Patient Safety Officer – An individual designated by the president and chief executive officer who is responsible for the organization-wide patient safety improvement and management program and is accountable directly to (*Hospital*) board of directors and president/chief executive officer. The patient safety officer will:

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- Oversee the creation, review, and refinements to the patient safety improvement and management program.
- Coordinate and prioritize the activities of the patient safety committee.
- Develop and implement adequate information and management systems to support the activities of the patient safety improvement and management program.
- Identify and secure the necessary resources to fully implement the patient safety improvement and management program.
- Ensure compliance with sentinel event, serious event, incident, and infrastructure failure reporting requirements as mandated by law/regulations or to meet accreditation standards.
- Oversee the investigation of serious events and as appropriate identified incidents.
- Ensure that disclosure of serious events to patients and/or families is carried out in accordance with organizational policy and law/regulations.
- Devise strategies to enlist medical staff, employee, and patient family input into the organization's patient safety improvement and management plan.
- Serve as the direct link to the board of directors and chief executive officers on all matters related to patient safety.
- Ensure that the organization conducts proactive hazard analyses.

Organizations may determine whom they want to designate as patient safety officer. If your hospital has already identified a central point of control for existing Department of Health serious event reporting you may want to consider designating that individual the patient safety officer. You also may want to consider a physician, the quality assurance director, the risk manager, the corporate compliance officer, or other qualified clinical personnel as the patient safety officer.

Management Staff – (*Hospital*) managers will ensure that the patient safety improvement and management program will be given high priority and will support the program. Managers will:

- Assure allocation of adequate resources for organizational and departmental patient safety initiatives.
- Assign staff to participate in risk reduction activities.
- Ensure that sufficient time is available for staff participation in patient safety activities at both the department and organizational level.
- Reinforce reporting expectations and management of an adverse event resulting from an error that has reached the patient resulting in harm.
- Establish a non-punitive culture that encourages reporting.
- Make sure that staff attend all required patient safety education programs.
- Supplement mandatory education programs with other patient safety education and training that relates directly to the jobs performed by employees in that area of the organization.

APPENDIX 4...

- Ensure safe practice by all staff through observation and use of other appropriate evaluative processes.

Medical Staff – Members of (*Hospital*) medical staff are responsible for actively participating in (*Hospital*) patient safety improvement and management program. An active participant will:

- Assume responsibility for identifying processes or systems that could potentially lead to errors and adverse events.
- Know and follow organizational and departmental policies and procedures applicable to assigned duties.
- Avoid taking shortcuts or encouraging others in the organization to shortcut established policies and procedures as a means of facilitating patient care.
- Inform patients and families about care, medications, treatments, and procedures; encourage them to ask questions and participate with caregivers in the development of their treatment plan.
- Use sound judgment and awareness of potential hazards before taking action.
- Participate in required organizational and departmental patient safety education programs and other activities designed to improve departmental and organizational patient safety.
- Promptly report serious events and incidents in accordance with established hospital policy and procedure.
- Assume responsibility for one's own professional development and education to improve individual performance and promote patient safety.

Hospital Employees and Volunteers – (*Hospital*) employees and its volunteers are responsible for actively participating in (*Hospital*) patient safety improvement and management program. An active participant will:

- Assume responsibility for identifying processes or systems that could potentially lead to errors and adverse events.
- Know and follow organizational and departmental policies and procedures applicable to assigned duties.
- Avoid taking shortcuts or encouraging others in the organization to shortcut established policies and procedures as a means of facilitating patient care.
- Inform patients and families about care, medications, treatments, and procedures; encourage them to ask questions, and participate with caregivers in the development of their treatment plan.
- Use sound judgment and awareness of potential hazards before taking action.
- Participate in required organizational and departmental patient safety education programs and other activities designed to improve departmental and organizational patient safety.
- Promptly report serious events and incidents in accordance with established hospital policy and procedure.
- Assume responsibility for one's own professional development and education to improve individual performance and promote patient safety.

Patients and Families – (*Hospital*) recognizes that patients and their families play a critical role in ensuring patient safety. In particular, the patient and family can often serve as the final checkpoint to avoid an error and adverse outcome. As such, (*Hospital*) will provide appropriate education to patients and families to make sure patients and families:

- Disclose relevant medical and health information to caregivers to facilitate appropriate care delivery.
- Report unexpected changes in a patient’s condition or perceived risks to the patient’s health and well being to responsible caregivers.
- Question any variation in medications, treatment, or plan of care from what the patient or family was informed to expect.
- Encourage completion of any specific questionnaires related to satisfaction, quality, or patient safety.

Patient Safety Improvement and Management Committee

Composition - The Patient Safety Improvement and Management Committee is an interdisciplinary committee comprised of individuals with organizational responsibility for quality, safety, and risk management, representatives from various clinical departments, and representatives from other hospital and medical staff committees wherein patient safety is of vital importance, (i.e. the pharmacy and therapeutics committee, infection control committee, corporate safety committee, performance improvement committee, transfusion committee, and others). Additionally, (*Hospital*) Patient Safety Improvement and Management Committee will include the patient safety officer, hospital in-house legal counsel, an identified member from the hospital’s board of directors, and two residents of the community served by (*Hospital*). All members of (*Hospital*) will be required to sign a confidentiality attestation, which outlines their responsibilities relative to the sharing or discussion of information dealt with in the committee.

The patient safety committee must be comprised of at least three health care workers (including at least one nurse and one physician), the patient safety officer, and two community residents who are not employed by the medical facility. Organizations are only permitted to have one board member on the committee; otherwise there are no limits on the size of the committee. The committee must meet monthly.

There is no requirement in Act 13 that the patient safety officer needs to chair this committee. Organizations may determine that the patient safety officer serves as staff or chair to the committee. If the patient safety officer serves as staff, the organization may elect to appoint another person as chair to the committee.

Organizations may choose to appoint community residents who are familiar with the organization, such as former board members, volunteers, auxiliaries, or the spouse of an employee/medical staff member. Act 13 is not clear on whether a current board member may serve as a community representative. An organization may also choose to appoint a patient or family member of a patient who sustained an injury as a result of a serious event on this committee.

Functions – The Patient Safety Improvement and Management Committee:

- Provides the oversight and management of the patient safety program. This includes making recommendations to organization leaders and the board of directors about the adequacy of resources

allocated to support patient safety activities.

- Guides the development and revision of organization-wide and departmental-specific patient safety policies and procedures to ensure compliance with law, regulation, and accreditation standards and to foster a non-punitive environment for error reporting.
- Establishes and maintains systems for the reporting, tracking, and trending of incidents and other risk management investigations/activities.
- Establishes appropriate mechanisms for the review and analysis of incidents, near misses, serious events, sentinel events, and infrastructure failures, including the appointment of teams to conduct root cause analysis.
- Reviews summaries of all serious and sentinel event root cause analyses to determine whether the review has been thorough and credible in ascertaining the causal factors for the event.
- Recommends corrective action resulting from review and analysis related to any type of event to appropriate hospital and medical staff committees.
- Integrates information gleaned from patient complaints, concerns, and other opinion/feedback as well as employee and medical staff feedback that is directly related to patient safety, either an event that has already occurred or as part of the proactive hazard analyses.
- Identifies opportunities for sharing appropriate information within the organization to demonstrate the impact of the patient safety program to medical staff, employees, and board of directors.
- Reviews and acts on recommendations issued by the Joint Commission on Accreditation for Healthcare Organizations, the National Quality Forum, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Patient Safety Authority, the Pennsylvania Department of Health, the Institute for Safe Medication Practices, the Occupational Safety and Health Administration, the Agency for Healthcare Research and Quality, and other groups as appropriate.
- Researches and implements best practice ideas gained from networking and literature reviews.
- Recommends patient safety education and training opportunities for medical staff and employees based on information developed in the committee and may include case studies, communication skill development, and team training.
- Coordinates all patient safety activities across the organization.
- Develops an annual evaluation process with medical staff and employees to assess progress in developing a culture of safety in the organization.
- Submits periodic and annual reports on the activities and results of the patients safety program to the board of directors.

Structure and Reporting Relationships –

Since the confidentiality provisions of Act 13 are limited solely to the functions of this act, organizations need to consider seriously whether the patient safety committee should conduct other quality of care or peer review activities. Organizations may establish the patient safety committee separately as a hospital committee or as a subcommittee of the hospital's quality improvement committee or council. Organiza-

tions must be cautious to not include other business unrelated to patient safety in this committee, since it could risk jeopardizing any confidentiality and discoverability protections afforded under this act by including such business.

In any event, the details of any specific incident or event should not be shared with other hospital or medical staff committees. Rather, the recommended actions can and should be shared with these other committees as a result of the lessons learned through the investigation of an event. Additionally, the organization may create comparable case studies based on the actual events reviewed by the patient safety committee to share as a learning experience with others in the organization and to reinforce the recommended actions.

Each licensed hospital, ambulatory surgery facility, and birth center must have a designated safety officer, safety committee, and safety plan. If there are multiple licensed facilities that make up the health care system, each organization may have a separate plan, officer, and committee to be compliant with the provisions of Act 13. Or, there may be separate designated officers that report through the same patient safety committee utilizing the same plan. In this case, both hospitals would have a patient safety committee and plan that happens to be the same. If a health system determines that it will utilize the same officer, plan, and committee for each of its licensed organizations, it must be able to demonstrate that patient safety issues are adequately addressed in each organization through that structure.

Management of Events and Reporting

Immediate Management of Event

Upon identification of an error, incident, or event, the patient care provider should:

- Take appropriate steps to care for the patient and minimize negative outcomes.
- Contact the patient's attending physician and other physicians as appropriate to report the error, incident, or event and implement any additional therapy or treatment as ordered by the physician.
- As appropriate, implement steps to contain the risk to others as in possibly a drug or medical device recall.
- Preserve any information or evidence that may be helpful in analyzing the error, incident, or event. This includes physical evidence such as preservation of IV tubing, fluid bags, equipment such as pumps, the unit of blood, or medication labels.
- Report the error, incident, or event immediately to the staff member(s) immediate manager(s).
- Complete the required incident report forms according to (*Hospital*) policy and procedure.
- Obtain appropriate support for staff members involved in the error, incident, or event as needed.

Internal Reporting

Each organization needs to briefly describe its internal error, incident, or event reporting system. In some hospitals, this reporting has been automated. In others, an incident form and other forms that score the severity of the error, incident, or event may be used. There must be a process in place where selected individuals in the organization—likely a named list of individuals from the Patient Safety Improvement and Management Committee—will need to review the information.

External Reporting

A serious event report or incident as defined in Act 13 must be submitted to the Patient Safety Authority and/or the Department of Health no later than 24-hours after the occurrence or discovery of the serious event or incident. Organizations must address how reporting will occur during the week and on weekends. Organizations may also need to make adjustments to this plan depending upon what decisions are made concerning the format and manner in which the authority and the Department of Health want reports submitted.

Program Review

In addition to periodic reports to (*Hospital*) Board of Directors about the organization's patient safety program and specific events, the patient safety officer will present an annual report to the Board of Directors about the occurrence of sentinel events, serious events, and incidents; medical staff, employee, and patient family education and involvement; proactive hazard analysis; actions taken to improve patient safety; and other key information related to patient safety. Together with the committee, the patient safety officer will review and update the organization's patient safety plan on a yearly basis.

5. Sample Patient Safety Officer Position Description

Introduction – The designation of the patient safety officer is an important step towards improving patient safety and patient outcomes within health care organizations. The Institute of Medicine report strongly suggested that each organization consider appointing a patient safety officer to signal the importance of patient safety in the organization to ensure that patient safety related issues received the highest attention and priority in the organization.

The Joint Commission for the Accreditation of Health Care Organizations (JCAHO) has also included similar language in the patient safety standards that were integrated into the hospital accreditation manual in 2001. JCAHO leadership standard LD.5. requires that “the leaders ensure implementation of an integrated patient safety program throughout the organization,” as demonstrated by the “designation of one or more qualified individuals or interdisciplinary group to manage the organization-wide patient safety program.”

The individual chosen to serve as the patient safety officer will play an important leadership role in the organization. This designation does not require that an additional position be created in the organization, although some organizations have chosen to do so. Organizations may choose to designate an individual in an already existing role to serve as the patient safety officer through modification of his/her present responsibilities and position description. Organizations have met this standard by identifying a key individual for this role, typically a risk manager, director of quality improvement, vice presidents for patient care services, or other clinical leaders, such as a chief nursing officer, director of nursing, chief medical officer, medical director, or chief of the medical staff. If the designated patient safety officer is not a physician, the organization should also consider identifying a patient safety “physician champion” to work directly with the patient safety officer to ensure that the medical staff are apprised of and involved in the organization’s patient safety initiatives.

It is important that the individual selected as the patient safety officer display strong interpersonal, organizational, and analytical skills as well as the ability to motivate and sustain interest in improving patient safety. The designated patient safety officer must also possess superior management skills to facilitate the acquisition of the appropriate resources to implement the program, ensure that the various components of the program are effectively executed, and serve as a change agent in the organization.

It is not contemplated by Act 13 that a single patient safety officer can always be available 24/7. Therefore, facilities must also identify how they will ensure compliance with Act 13 reporting requirements in the absence of the patient safety officer.

Following is a template that your organization may choose to use in developing a position description for a patient safety officer.

Position Summary –The designated patient safety officer will have primary oversight of the organization-wide patient safety improvement and management program. This leadership role will direct others within the organization in system and process improvements that will support the reduction of medical errors and other factors that contribute to unintended adverse patient outcomes. The patient safety officer provides leadership for safety assessments and investigations; coordinates the activities of the patient safety committee; identifies and secures the resources necessary to fully implement the patient safety program; educates others in the organization on the system-based causes for medical error; consults with management, employees, and the medical staff on issues related to patient safety; ensures the implementation of strategies to enhance patient safety; and ensures that information about patient safety is shared throughout the organization, including the organization’s senior leadership and board of directors.

Essential Functions: The patient safety officer will:

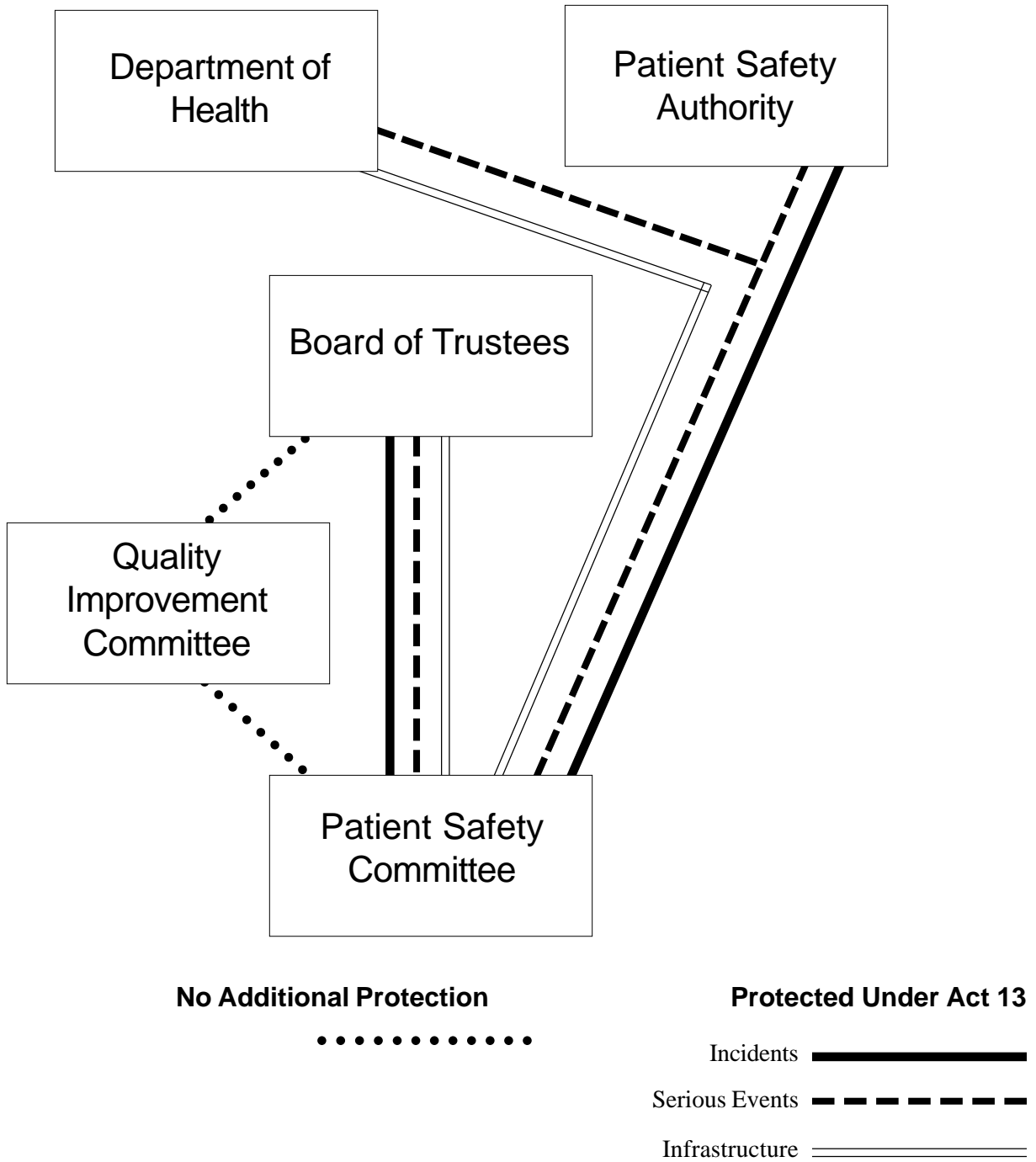
1. Oversee the creation, review, and refinement to the patient safety improvement and management program.
2. Identify and secure the necessary resources to fully implement the patient safety improvement and management program.
3. Coordinate and prioritize the activities of the patient safety improvement and management committee.
4. Coordinate the development and implementation of policies and procedures that support the activities of the patient safety program.
5. Develop and implement adequate internal information and management systems and utilize information from external sources to support the activities of the patient safety improvement and management program.
6. Oversee and coordinate the investigation of serious events and as appropriate, identify incidents.
7. Ensure compliance with sentinel event, serious event, incident, and infrastructure failure reporting requirements as mandated by the law/regulations or to meet accreditation standards.
8. Ensure the disclosure of serious events to patients and/or families is carried out in accordance with organizational policy and law/regulations.
9. Devise strategies to enlist medical staff, employee, and patient family input into the organization’s patient safety improvement and management program.
10. Support and encourage error reporting throughout the organization through a non-punitive error reporting approach.
11. Recommend and facilitate change within the organization to improve patient safety based on identified risks and proactive risk assessment.
12. Assist in the identification and development of organizational and unit-based educational programs to promote an understanding of the organization’s patient safety improvement and management program and each individual’s responsibility and accountability in the success of the program.
13. Develop and implement mechanisms for internal communication of patient safety related information.

14. Serve as the direct link to the board of directors and chief executive officer on all matters related to patient safety. Provide periodic reports on specific events, actions taken, proactive risk assessment, and barriers to implementation of various initiatives to improve patient safety in the organization.
15. Serve as a resource for clinical departments on issues of patient safety.

Qualifications:

1. Advanced degree in public health, epidemiology, or other health care related field desired. An individual with a bachelor's degree and the appropriate prerequisite knowledge, experience, and skills will also be considered.
2. Experience with the organization's identified quality improvement program.
3. Knowledge of risk management principles and issues relating to patient safety.
4. Superior organizational, interpersonal, and analytical skills.
5. Strong leadership qualities (task completion, motivation).
6. Effective change agent.

6. Event Reporting and Peer Review Protection Under Act 13



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