TITLE: Reporting of Unusual Occurrences Involving Patients

Policy Number: ADM 3.08 Operations **Dept: Administration**

PURPOSE:

To establish a system for identifying, reporting, and investigating unusual occurrences that involve patients, thus enhancing patient safety through quality improvement efforts. In addition, this system meets the reporting requirements related to equipment failure (Safe Medical Devices Act, FDA), sentinel events (The Joint Commission), serious reportable events (National Quality Forum) and disclosure (Responding Justly to Adverse Outcomes).

RATIONALE:

Mercy Medical Center encourages the reporting of all types of errors, injuries, near misses, sentinel events and serious reportable events. Any occurrence that is not consistent with the routine operations of the hospital or the routine care of a particular patient is reported and documented in accordance with this policy.

Mercy Medical Center acknowledges that medical errors and adverse outcomes occur and are not intentional. The reporting process is a way to monitor current systems/processes and make changes where necessary. The focus/goal of the occurrence reporting process is to improve patient safety through quality improvement efforts without fear of repercussion/disciplinary action to those involved in occurrences or filling out reports.

DEFINITIONS:

Adverse Outcome: A negative outcome stemming from the provision of or omission of medical care, treatment, diagnostic test, surgical intervention or procedure and differs significantly from what is anticipated.

Attending Physician: Physician on record, who may or may not be involved in the patient's treatment when an adverse outcome occurs.

Decision-making capacity: A patient is presumed to have decision-making capacity. A patient does not lack decision-making capacity with regard to medical treatment decisions because he/she is confused about other aspects of life such as the date, events of the day, the identity of people or because he/she makes a medical treatment choice that others do not agree with. A patient has decisional capacity if he/she can understand:

1. The nature of his/her medical condition
2. The medical treatment options the physician has offered him/her, and
3. The general implication of his/her choice among these medical options.

Disclosure: Communication of information regarding an Adverse Outcome to the patient and designated family member/surrogate decision-makers stemming from the provision of or omission of medical care, treatment, diagnostic test, surgical intervention or procedure. Such communication is not considered an admission of liability.

Equipment Failure: Equipment, supplies, or devices that are involved in a serious patient incident resulting in harm to a patient.

Harm: Temporary or permanent impairment of the physical, emotional or psychological function or structure of the body and/or pain requiring medical intervention. (Permanent harm is a serious reportable event resulting in harm with no expected change in clinical condition; includes events resulting in permanent loss of organ, limb, physiologic or neurologic function or disfigurement.)

Severity of the Event

Level 1:	An event occurred, but the patient was not harmed.
Level 2*	An event occurred that resulted in the need for increased patient assessments but no change in vital signs and no patient harm.
Level 3*:	An event occurred that resulted in the need for treatment and/or intervention and caused temporary patient harm.
Level 4*:	An event occurred that resulted in initial or prolonged hospitalization and caused temporary patient harm.
Level 5*:	An event occurred that resulted in permanent patient harm or near death event, such as anaphylaxis.
Level 6*:	An event occurred that resulted in patient death.

*Levels 2 through 6 shall be discussed with patient, family and/or surrogate decision-maker.

Medication Error: Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

Sentinel Event: A sentinel event is a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in any of the following: death, permanent harm, or severe temporary harm (*severe temporary harm is critical, potentially life-threatening harm lasting for a limited time with no permanent residual, but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition).* Such events are called "sentinel" because they signal the need for immediate investigation and response. The terms "sentinel events" and "medical error" are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events. **Sentinel events include, but are not limited to, the following (even if the outcome was not death or major permanent loss of function):**

1. Suicide of any patient receiving care, treatment or services in a staffed around-the clock care setting or within 72 hours of discharge, including from the hospital's emergency department (ED)
2. Unanticipated death of a full-term infant
3. Abduction of any patient receiving care, treatment or services
4. Discharge of an infant to the wrong family
5. Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on site at the hospital.

6. Rape, assault (leading to death, permanent harm, or sever temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the hospital.
7. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
8. Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure
9. Unintended retention of a foreign object in a patient after an invasive procedure, including surgery
10. Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
11. Prolonged fluoroscopy with cumulative dose > 1,500 rads to a single field of any delivery of radiotherapy to the wrong body region or > 25% above the planned radiotherapy dose.
12. Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting (including the ED), leading to death, permanent harm, or severe temporary harm to the patient
13. Fire, flame or unanticipated smoke, heat, or flashes occurring during an episode of patient care
14. Any intrapartum (related to the birth process) maternal death
15. Severe maternal morbidity when it (not primarily related to the natural course of the patient's illness of underlying condition) reaches a patient and results in any of the following: permanent harm or severe temporary harm

Patient Safety Events: An event, incident, or condition that could have resulted or did result in harm to a patient. These may include the following:

- Adverse event: A patient safety event that resulted in harm to a patient
- No harm event: A patient safety event that reaches the patient but does not cause harm

- Close call (near miss or good catch): A patient safety event that did not reach the patient
- Hazardous or "unsafe" condition: A circumstance (other than a patient's own disease process or condition) that increases the probability of an adverse event

Examples of Sentinel Events that **Are Reviewable** Under The Joint Commission's Sentinel Event Policy are:

- Any patient death, paralysis, coma, or other major permanent loss of function associated with a medication error
- A patient commits suicide within 72 hours of being discharged from a hospital setting that provides staffed around-the-clock care
- Any elopement, that is unauthorized departure, of a patient from an around-the-clock care setting resulting in a temporally related death (suicide, accidental death, or homicide) or major permanent loss of function
- A hospital operates on the wrong side of the patient's body
- Any intrapartum (related to the birth process) maternal death
- Any perinatal death unrelated to a congenital condition in an infant having a birth weight greater than 2,500 grams
- A patient is abducted from the hospital where he or she receives care, treatment, or services
- Assault, homicide, or other crime resulting in patient death or major permanent loss of function
- A patient fall that results in death or major permanent loss of function as a direct result of the injuries sustained in the fall
- Hemolytic transfusion reaction involving major blood group incompatibilities
- A foreign body, such as a sponge or forceps, that was left in a patient after surgery

Note: An Adverse Outcome that is directly related to the natural course of the patient's illness or underlying condition; for example, terminal illness present at the time of presentation, is not reportable except for suicide in, or following elopement from, a 24 hour care setting (see above).

Examples of Events that **Are Not Reviewable** Under The Joint Commission's Sentinel Event Policy are:

- Any "near miss"
- Full or expected return of limb or bodily function to the same level as prior to the adverse event by discharge or within two weeks of the initial loss of said function
- Any sentinel event that has not affected a recipient of care (patient, client, resident)
- Medication errors that do not result in death or major permanent loss of function
- Suicide other than in an around-the-clock care setting or following elopement from such a setting

- A death or loss of function following a discharge "against medical advice (AMA)"
- Unsuccessful suicide attempts unless resulting in major permanent loss of function
- Minor degrees of hemolysis not caused by a major blood group incompatibility and with no clinical sequelae

Note: In the context of its performance improvement activities, an organization may choose to conduct intensive assessment, for example, Root Cause Analysis, for some not reviewable events.

Sentinel Event Team: A team of persons assigned to review unexpected occurrences against the definition of Sentinel Event and reporting requirements. The President, Vice-President of Patient Care Services, Director of Performance Improvement, and the Risk Manager will perform this review as appropriate and may obtain legal guidance in determining whether the event will be reported to The Joint Commission. When a Sentinel Event involves a Medical Staff member, the Chairperson of the Medical Staff Executive Committee and Chairperson of the Medical Staff Clinical Department of the involved physician will be asked to participate in the review.

Serious Reportable Events: The NQF–Endorsed list of Serious Reportable Events are included below:

1. **Surgical or Invasive Procedure Events**
   - Surgery or other invasive procedure performed on the wrong site
   - Surgery or other invasive procedure performed on the wrong patient
   - Wrong surgical or other invasive procedure performed on a patient
   - Unintended retention of a foreign object in a patient after surgery or other invasive procedure
   - Intraoperative or immediately postoperative/post procedure death in an ASA Class 1 patient
2. **Product or Device Events**
   - Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting
   - Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
   - Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting.
3. **Patient Protection Events**
   - Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
   - Patient death or a serious injury associated with patient elopement (disappearance)

- Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting

4. **Care Management Events**
   - Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
   - Patient death or serious injury associated with unsafe administration of blood products
   - Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting
   - Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
   - Patient death or serious injury associated with a fall while being cared for in a healthcare setting
   - Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting
   - Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
   - Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results
5. **Environmental Events**
   - Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting
   - Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances
   - Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting
   - Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting
6. **Radiologic Events**
   - Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area
7. **Potential Criminal Events**
   - Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
   - Abduction of a patient/resident of any age

- Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting
- Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting

Surrogate decision-maker: A person designated to make decisions on behalf of a person who is incapable of making decisions. A surrogate decision-maker may be selected in advance of a person becoming incapable of making decisions or may be selected after a patient has become incapable of making decisions.

Treating Physician: The physician primarily responsible for treating the patient when an adverse outcome occurs.

POLICY:

1) Any occurrence that either did or could directly result in an injury to a patient shall be submitted through the organization patient incident reporting system. The patient incident report will not be referenced in the patient's medical record, or included in the medical record. These reports are confidential. They should be protected as any other peer review documents.
2) A factual statement of the occurrence shall be documented in the patient's medical record.
3) When a Sentinel Event or Serious Reportable Event occurs, a Root Cause Analysis is performed, action plans implemented, and performance improvement monitored, as appropriate. The Root Cause Analysis will not be referenced in the patient's medical record or included in the medical record. The Root Cause Analysis should be protected as any other peer review documents.
4) Equipment, supplies, and devices are immediately removed from service when they are involved with a serious patient incident. An investigation and analysis is conducted. Equipment, supplies, and device failures are reported to the FDA in accordance with the Safe Medical Devices Act.
5) The rights of patients are supported through the following statements:
   a) Patients or their surrogates are the ultimate decision-makers about their healthcare
   b) Patients will be provided with sufficient information necessary to make an informed decision about treatment
   c) A patient is presumed to have decision-making capacity
   d) Patients and designated family members/surrogate decision makers will be informed promptly about Adverse Outcomes
   e) Having a legal guardian does not exempt a health care professional from communicating with a conscious patient after an Adverse Outcome

f) It is the responsibility of all employees and physicians to report any Adverse Outcome immediately to their immediate supervisor and the Risk Manager, and
g) Information received and any subsequent evaluation of the facts will be conducted in a non-punitive manner while appropriate action is taken to ensure compliance with facility policies and procedures.

IMPLEMENTATION:

1) The patient incident reports are to be initiated by the employee involved in or responding to the unusual occurrence. The documentation should be an objective account of the occurrence stating only the facts. The report will contain the writer's analysis of what could have prevented the event. The report should not contain attribution of fault. Patient incidents include but are not limited to:

a) Incidents involving inconsistencies with written hospital policies and procedures
b) Sudden unexpected adverse results to professional care and treatment
c) Incidents which necessitate additional hospitalization or dramatic change in patient treatment regimen, and
d) Patients leaving the hospital against medical advice.

2) The Risk Manager will review all patient incident reports. The Risk Manager and/or automated incident reporting notification system will forward the report to the appropriate department director for review and the director will follow-up with the employee involved/ submitting the report, as appropriate. Any reports or other documents arising out of this review and follow up process are confidential and should be protected as any other peer review documents.

3) **Equipment Failures:**

Equipment, supplies, or devices that are involved in a serious patient incident will be immediately removed from service and impounded. No control settings will be changed. No cleaning or processing of equipment or supplies will be done. Labeling and packaging will be kept intact. Equipment information will be documented on the appropriate Bio-Med sticker, with a patient incident report completed describing the incident. The Director of the involved department or House Supervisor shall immediately notify the Bio-Med Department or on-call Bio-Med staff, to coordinate the steps of a safety analysis, and to impound the equipment or supplies involved in unusual occurrences. In addition, the Risk Manager will be notified immediately of occurrences, which involve serious or potentially serious injury/liability factors.

When investigation and analysis by the Risk Manager indicates there is a probability that a device or product has caused or contributed to a serious event of a patient, the Risk Manager shall file a report of the information to the FDA using the approved form. The report will be sent

to the FDA within ten working days with a copy to the manufacturer.

4) **Medication Error:**

The following Medication Error Index is used for categorizing medication errors as follows:

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TYPE OF ERROR	RESULT
No Error Category A	Category (A)- Circumstances or events that have the capacity to cause error.
Error, No Harm Category B	Category (B)- An error occurred but the medication did not reach the patient (An "error of omission" does not reach the patient)
Category C	Category (C)- An error occurred that reached the patient but did not cause patient harm
Category D	Category (D)- An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm

Error, Harm Category E	Category (E)- An error occurred that may have contributed to, or resulted in, temporary harm to the patient
Category F	Category (F)- An error occurred that may have contributed to, or resulted in temporary harm to the patient and required initial or prolonged hospitalization
Category G	Category (G)- An error occurred that may have contributed to or resulted in permanent harm
Category H	Category (H)- An error occurred that required intervention necessary to sustain life
Error, Death Category I	Category (I)- An error occurred that may have contributed to or resulted in the patient's death
DEFINITIONS: **HARM:** temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body, and/or pain resulting there from 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.)	

5) If an employee is injured, please refer to Mercy Medical Center-Dubuque's Personnel Policy Handbook, Section V.3.

6) **Sentinel Event/Root Cause Analysis:**

For those incidents that meet The Joint Commission's definition of "Sentinel Event," and after review by the "Sentinel Event Team," the Risk Manager will convene an appropriately selected multidisciplinary group to complete a thorough and credible root cause analysis and action plan. When the event involves a Medical Staff member, the Chairperson of the Medical Staff Clinical Department of the involved physician and the involved physician will be asked to participate in the quality improvement meetings.

When investigation and analysis indicates a Sentinel Event has occurred, the Risk Manager with direction from the Sentinel Event Team, may voluntarily file a report to The Joint Commission using the approved form. The report will be sent to The Joint Commission within 5

calendar days and followed up with a thorough Root Cause Analysis and Action Plan report within 45 days of the event, or of becoming aware of the event, using The Joint Commission

approved formats. To the extent permitted by law, the report will be considered privileged and confidential. The filing of a report will not be referenced in the patient's medical record.

A thorough Root Cause Analysis (RCA) and Action Plan will be conducted on Sentinel Events. The RCA document must contain the following characteristics:

1) An analysis focusing primarily on systems and processes.
2) An analysis that progresses from special causes in clinical processes to common causes in organizational processes.
3) The analysis digs deeper by asking "Why?" until no additional logical answer can be identified.
4) The analysis identifies change that could be made in systems and processes to improve level of performance, and diminish likelihood of future sentinel events.
5) The analysis is thorough and credible.
6) The action plan identifies the strategies the organization intends to implement to reduce the risk of similar events occurring in the future.
7) The action plan will address responsibility for implementation, oversight, pilot testing as appropriate, timelines, and strategies for measuring the effectiveness of the actions taken.

7) **Serious Reportable Event (SRE)/Root Cause Analysis:**

1. All serious reportable events (SRE's) should be reported as soon as possible after discovery to the Risk Manager and hospital leadership. The Risk Manager will place the event in the STARS system within five (5) business days of discovery. If the event resulted in death or permanent harm it will be reported in STARS immediately but no later than one (1) business day after the discovery of the event.
2. Should an event results in death or permanent harm the President or his/her designee will call the Trinity Health Executive Vice President and Chief Clinical Officer or the Senior Vice President Clinical Quality and Patient Safety no later than one (1) business day after discovery of the event. The President/designee will be expected to discuss the facts of the event, investigation conducted to date, status of the RCA, risk manager involvement, status of disclosure to patient and/or family, staff support provided, and any needs the hospital may have related to the event.
3. A completed Root Cause Analysis (RCA) should be reported to the Home Office within three (3) weeks of discovery. RCA for events that result in death or permanent harm should commence immediately but in no circumstances longer than 3 business days after discovery.
4. The Risk Manager will prepare a status report of the RCA Action Plan that will be shared with the Home Office within six (6) months of discovery and placed in the STARS system.

5. A Serious Reportable Events Council within Trinity Health will meet monthly to discuss serious patient safety events and patterns among our Ministry Organizations.

8) **Discovery/Reporting**

1. Take all necessary action to mitigate the extent of the harm to the patient that may be caused by the Adverse Outcome.
2. Immediately notify the patient's treating Physician, the Department Director, the Risk Manager, and other personnel as appropriate.
3. Complete a patient incident report.
4. Upon request, participate in an investigation to identify the cause of the outcome and determine actions that may prevent future like occurrences, as appropriate.

The patient's treating Physician, the Department Director, and the Risk Manager will take the following steps upon notification an Adverse Outcome has occurred:

1. Identify appropriate individuals to investigate the cause of the outcome and determine actions that may prevent future like occurrences, as appropriate.
2. Identify an individual who will coordinate the disclosure process.
3. Offer a referral to spiritual care and Employee Assistance Program to involved employees, if appropriate.
4. Notify senior management.

9) **Disclosure of Adverse Outcomes to Patient and Designated Family Member/ Surrogate Decision-Makers**

Mercy Medical Center is committed to providing quality medical care to its patients and the communities it serves. Despite constant and committed efforts to provide and improve patient care, medical errors do occur. Mercy Medical Center is committed to respecting the right of patients, their families, and/or surrogate decision-maker to be informed about such events.

Once it has been determined that an Adverse Outcome has occurred, disclosure is necessary. The treating Physician, Department Director and the Risk Manager will identify the most appropriate time and manner for disclosure. The treating physician, and/or attending physician, and appropriate hospital representatives should participate in the disclosure process.

The treating physician has the responsibility for disclosure of all physician related adverse outcomes. In those cases where the adverse outcome is associated with non-physician staff, the responsibility usually rests with the attending physician and the staff with the most thorough knowledge of the outcome. If the attending physician is unwilling or unable to disclose the

adverse outcome associated with non-physician staff, the Risk Manager works with Administration to identify appropriate personnel to participate in the disclosure process. Depending upon the severity of the adverse event, senior management is informed.

If there is disagreement or uncertainty on either the method of disclosure or need for disclosure, the issue will be immediately referred to the ethics consult team for recommendation. The hospital administration will be advised of the ethics consult team's recommendations. The hospital administration and an ethics consult team representative will jointly develop a decision about disclosure. The Risk Manager is available to assist in achieving consensus in the decision-making process.

Disclosure should be conducted in accordance with the following guidelines:

1. The treating physician and others shall meet with the patient and designated family member/surrogate decision-maker as appropriate, as soon as possible given the patient's clinical condition. The disclosure should take place within 24 hours of identifying the adverse outcome, as appropriate.
2. Present the nature, severity, and cause (if known) of the adverse outcome in a straightforward and non-judgmental manner.
3. Disclose whether and what type of medical attention is required. When appropriate, offer a second opinion and transfer of care to another practitioner.
4. Offer a referral to spiritual care, if appropriate.
5. Identify a contact person for the patient and family to ensure prompt follow-up and communication on all unanswered questions.
6. Offer an apology to the patient and designated family members/surrogate decision-makers. An apology or expression of sorrow is not an admission of guilt.
7. Avoid attributive blame, as events are rarely attributable to a single action or individual.
8. Avoid speculation. Focus on what is known at the time of discussion, and answer all questions to the best of one's ability at the time but advise that additional information may change the conclusion.
9. View disclosure as an ongoing process.

10) **Documentation**

Disclosure of Adverse Outcomes should be documented in the medical record by the individual(s) who provided the disclosure and shall include the following elements:

1. A full description of the facts of the outcome without conjecture/opinion as to the cause or attribution of fault.

2. The substance of the disclosure discussions with the patient and designated family members'/surrogate decision-makers, as appropriate, about the outcome, including dates, times, and the names and relationships of those present.
3. The patient's and designated family member's/surrogate decision-makers' decision to decline disclosure.
4. The identity of the contact person for the patient and family who will ensure prompt follow-up and communication on all unanswered questions.
5. The identity of any interpreter whose services may have been used.
6. The reason for any decision to withhold some or all of the information about the outcome.
7. Any follow-up discussions with the patient and designated family members/surrogate decision-makers.
8. Offers, referrals or requests for spiritual care.

The disclosure process is not an acceptance of liability and does not involve attribution of fault or other actions that may be inappropriate given the status of the investigation.

11) **Debriefing**

To promote safety and minimize risk of an event from reoccurring, debriefing and case review after near-miss/adverse events may be conducted as a quality improvement activity and without waiving the privileges associated with the peer review process.

REFERENCES

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