Incident (Patient Safety Event) Reporting/Sentinel Event Management

1. **Purpose**

Incident and sentinel event reporting is an important part of error prevention. Aurora Health Care learns from patient safety events to promote system education, initiate process improvement and prevent and mitigate healthcare error.

The purpose of this policy is to outline the requirements of the Aurora Health Care incident (patient safety event) reporting and sentinel event management policy that will result in the best patient outcomes, utilizing the Aurora Health Care values that every patient deserves the best care, in responsibly managing resources, and in accountability, teamwork and respect.

2. **Scope**

This policy applies to Aurora Health Care, Inc. and any entity or facility owned or controlled by Aurora Health Care. External occurrences and disasters shall be handled as provided in the Hospital Safety Policies.

3. **Definitions**

3.1 **Centers for Medicare and Medicaid Services (CMS) Hospital Acquired Conditions:**

   a) Foreign object left in a patient after surgery;
   b) Air embolism;
   c) Blood incompatibility;
   d) Catheter-associated urinary tract infections;
   e) Stage III and IV Pressure ulcers;
   f) Vascular catheter associated infections
   g) Surgical site infection, specifically mediastinitis after coronary artery bypass graft, bariatric surgery, cardiac implantable electronic device or certain orthopedic procedures;
   h) Hospital acquired injury due to external causes such as falls (injuries can include fracture, dislocation, intracranial injury, crushing injury, burn, and other unspecified effects).
   i) Deep vein thrombosis or pulmonary embolism following certain orthopedic procedures
   j) Iatrogenic pneumothorax with venous catheterization

3.2 **Patient Safety Event:** An event, incident, or condition that could have resulted or did result in harm to a patient. Patient Safety Events are not determined based upon perceived
negligence or wrongdoing on the part of a staff member or department. Not all patient safety events are preventable. Event analysis is warranted in order to identify weaknesses and whether remedial action is indicated.

3.3 Adverse Event: A patient safety event that resulted in harm to a patient.

3.4 Fair and Just Principles of Aurora Health: Incident reporting is a part of the Just and Fair Principles of Aurora Health Care, which:
   a) Create a learning culture;
   b) Create an open and fair culture;
   c) Design safe systems; and
   d) Manage behavioral choices.

3.4 Incident Reporting: The web-based or paper form used to report facts surrounding a patient safety event. The incident report is a part of the Aurora Health Care health services evaluation process (Wisconsin Statute secs.146.37 and 146.38), and is not a part of the medical record or the employee personnel file. Incident reports are used to identify trends relating to patient care. Certain facilities have incident reporting hotlines that may be used for incident reporting.

3.6 Sentinel Event: A subcategory of Adverse Events, 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:
   a) Death
   b) Permanent harm
   c) Severe temporary harm

The subset of Sentinel Events that is subject to review by the Joint Commission includes any occurrence that meets any of the following criteria:

   a) Suicide of any patient receiving care, treatment and services in a staffed around the clock care setting or within 72 hours after discharge, including from the hospital’s emergency department (ED)
   b) Unanticipated death of a full term infant;
   c) Discharge of an infant to the wrong family;
   d) Abduction of any individual receiving care, treatment or services;
   e) 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;
   f) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups);
   g) 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;
   h) Rape, assault (leading to death or permanent loss of function) or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the health care organization;
   i) Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure;
   j) Unintended retention of a foreign object in a patient after an invasive procedure, including surgery;
   k) Severe neonatal hyperbilirubinemia (bilirubin>30 milligrams per deciliter);
l) Prolonged fluoroscopy with cumulative doses > 1500 rads to a single field, or any delivery of radiotherapy to the wrong body region or >20% above the planned radiotherapy dose;

m) Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care; and

n) Any intrapartum (related to the birth process) maternal death or sever maternal morbidity.

3.7 **Severe Temporary Harm:** 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.

3.7 **No-harm Event:** A Patient Safety Event that reaches the patient but does not cause harm.

3.8 **Near Miss (Close Call or Good Catch):** A patient safety event that did not reach the patient.

3.9 **Medication Event:** Any Patient Safety Event in which use of a medication resulted in or could have resulted in an adverse outcome in a patient; includes drug administration errors, drug incompatibility and adverse drug reactions

3.9.1 **Drug Administration Error:** Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the 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.

3.9.2 **Drug Incompatibility:** Occurs when drugs interfere with one another chemically or physiologically. A drug incompatibility error occurs when two drugs known to be incompatible with one another are mixed, administered together, or administered in a timeframe known to interfere with one another

3.9.3 **Adverse Drug Reaction (ADR):** A non-preventable event that includes Any unexpected, unintended, undesired, or excessive response to a drug that:
- Requires discontinuing drug (therapeutic or diagnostic)
- Requires changing therapy
- Requires modifying the dose (except for minor dosage adjustments)
- Necessitates admission to the hospital
- Prolongs stay in a health care facility
- Necessitates supportive treatment
- Significantly complicates diagnosis
- Negatively affects prognosis
- Results in temporary or permanent harm, disability, or death consistent with the definition, an allergic reaction (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug) and an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs.

3.10 **Event Review Committee (ERC):** A committee that reviews sentinel and significant events for site specific and system improvement opportunities. The ERC meets regularly, and, is a part of the Aurora Health Care health services evaluation process (Wisconsin Statute 146.37 and 146.38)
3.11 Executive event review committee (EERC): A committee to review sentinel events and significant events, along with trended data and other information such as Hospital Acquired Conditions in regard to patient care error, for site specific and system improvement opportunities. The Executive Event Review Committee is chaired by the Chief Medical Officer (co-chair), the Chief Clinical Officer (co-chair). The Risk Management Committee meets regularly, and is a part of the Aurora Health Care health services evaluation process. (Wisconsin Statute Secs 146.37 and 146.38).

3.12 Root cause analysis (RCA): A type of comprehensive systematic analysis used to identify basic or causal factors underlying variation in performance, including the occurrence or possible occurrence of a Sentinel Event. Prepared under the direction of the quality and/or risk management team on behalf of each site, the EERC has overview of the program and review. The Root Cause Analysis is a part of the Aurora Health Care health services evaluation process. (Wisconsin Statute 146.37 and 146.38)

4. Policy

4.1 Aurora Health Care fosters fair and just principles and evidence based practice to maintain an environment in which patients, their families, staff and health care practitioners can identify, manage and learn from actual and potential risks to patient safety, with the goal of preventing patient safety events.

4.2 Incident Reporting, using the Fair and Just Principles of Aurora Health Care, is strongly encouraged. Reporting is necessary from a systems perspective to reduce Patient Safety Events and improve outcomes.

4.3 All components of the incident reporting/sentinel event process, including, but not limited to, Incident reports, Near Misses, Sentinel and Patient Safety Events, Root Cause Analysis, and the Event Review and Executive Event Review Committees, the review process, discussion, and documentation thereof, are conducted by Aurora Health Care as part of its health care services review process. (Wisconsin Statute Secs. 146.37 and 146.38).

5. Procedures

5.1 Reporting

a) Caregivers are expected to report Patient Safety Events in the web-based incident reporting system. If caregivers are uncomfortable reporting an incident, they may utilize other available resources such as the site patient safety hotline, the appropriate chain of command, or the facility and system Patient Safety Officers.

b) Drug Administration Errors that have harmed or have potential to harm the patient must be reported immediately to the attending physician. If the outcome of a Drug Administration Error is unknown, the event must be reported immediately to the attending physician. Drug Administration Errors that result in no or insignificant harm to the patient must also be documented in the medical record but do not require immediate reporting to the attending physician.

c) Refer to Addendum 1 for a patient safety event reporting guide that outlines types of errors that should be reported.
5.2 Immediate Response to Events

a) In the event of a Patient Safety event, caregivers should take immediate action to ensure the safety of the patient, staff, and visitors.

b) Patient Safety Events should be reported as follows:

i. All potential Sentinel Events (CMS Hospital Acquired Conditions may be Sentinel Events) shall be phoned to the responsible manager or director and the facility Risk Management Department immediately. Site leadership will notify the Vice President of Clinical Risk Management. After hours or on weekends, the facility leadership on call and the Vice President of Clinical Risk Management shall be notified. See Sentinel/Significant Event/Root Cause Analysis Framework below for further information.

ii. Any caregiver who discovers witnesses or is involved in a Patient Safety Event shall complete a web-based incident report as soon as possible. The incident report shall include all pertinent facts specific to the event. The cause of the event should be noted whenever possible. The incident report shall not be placed in the patient’s medical record or the personnel file of any caregiver.

iii. If web-based incident reports are unavailable or if there is an information system downtime, a paper incident report shall be completed. Incident reporting hotlines are available in some areas and may be used to report events.

iv. If the event will involve police or security investigation, the site of the patient safety event should be sequestered and not be disturbed once patient care has been rendered.

v. Any event involving the murder, suicide, assault, rape or abduction of a patient, caregiver or visitor, should immediately be phoned to Loss Prevention and the facility Risk Management Department. The facility leadership on call and the system Vice President of Clinical Risk Management shall be notified after hours or on weekends.

vi. Equipment involved in a Patient Safety Event shall be removed from use, tagged and sequestered on the unit. Tubing or disposable products such as IV tubing and bags shall be kept with the equipment. Clinical Engineering shall be notified and shall check and/or service the equipment as soon as possible. Until released by Clinical Engineering, in certain circumstances with consent of Risk Management Department, equipment involved in a patient event shall not be used, cleaned or disturbed. Specific serial numbers of the equipment should be noted on the occurrence report. Products involved in a patient event shall be removed from patient use, sequestered and saved. The serial or lot number should be noted on the occurrence report. Purchasing shall be notified as soon as possible.

c) If a foreign object is left in the patient because of a clinical determination that the relative risk to the patient of searching for and removing the object exceeds the benefit of removal, this would not be considered a Sentinel Event to be reviewed. In such cases:
i. The unintended retention shall be disclosed to the patient; and

ii. A record will be kept of the retentions to identify trends and patterns that may identify opportunities for improvement.

d) Certain Patient Safety Events may not be easily categorized as to whether a Sentinel Event, patient confidentiality issue, employee event, or some combination thereof. In such cases, site and system risk management, compliance, loss prevention, media relations and any other clinical or departmental area involved in the event shall work collaboratively to determine the appropriate response and plan of coordination.

e) Confidentiality and Communication of Patient Incident Report and Related Materials

i. The Aurora Health Care incident report and Root Cause Analysis process, meetings of the ERC and EERC; any related meetings, documentation and/or discussion related to the incident report and root cause analysis processes, or any patient care error reporting or process which relates to a patient care error, are each a part of the Aurora Health Care health services evaluation process (Wisconsin Statute secs.146.37 and 146.38). This incident reporting/sentinel event process is designed to review and improve patient care at Aurora.

ii. Care should be taken to maintain confidentiality of incident report and Sentinel Event data.

a. Information shall not be left on computer screens in web based applications.

b. Care should be taken to print a minimum of information needed.

c. Printed incident report data should be placed in a secure location and not in the patient chart or out in open spaces.

d. De-identified data, after risk management or department/unit approval, may be shared for patient safety and performance improvement activities.

iii. All written documents prepared by the facility or site of the Patient Safety Event, the Event Review Committee and the Executive Event Review Committee and individual team/committee members working on behalf of these committees should be labeled “Privileged and Confidential Health Care Services Review Record.” Documents prepared by other individuals for use by a Site Team and/or the Event Review Committee should be labeled “Privileged and Confidential Health Care Services Review Record, prepared as part of Aurora’s quality improvement processes at the request of Aurora’s health care services review organizations.”

5.3 Sentinel Event/Significant Event/Root Cause Analysis Framework

Sentinel Events require review as follows:

a) The facility Risk Manager will, upon learning of a potential sentinel event, immediately notify the site-specific leadership, the system Vice President of Clinical Risk Management, and regional leadership as requested by site leadership. The system Vice President of Clinical Risk Management will notify the system Chief Operating Officer,
Chief Medical Officer, and the Chief Clinical Officer. Additional persons may be notified based upon the nature of the event.

i. Notification occurs when a facility learns of a potential sentinel event, and not after the facility determination of a sentinel event.

ii. After hours, the facility leadership on call, as well as the system Vice President of Clinical Risk Management shall be notified.

b) Site leadership, quality, and other caregivers, in conjunction with the site risk manager, will determine a team to conduct a root cause analysis in relation to the potential Sentinel Event.

i. A root cause analysis will be performed on all potential Sentinel Events.

ii. Patient Safety Events not deemed as sentinel by site and system leadership may require a root cause analysis. Either the facility or the system leadership team may direct a Root Cause Analysis in these cases.

iii. A Root Cause Analysis may be done for any event for analysis and improvement purposes.

c) The RCA team shall initially review the Sentinel Event within three working days of notification of the sentinel event. A thorough and credible root cause analysis and action plan should be completed within 45 calendar days of the sentinel event or of becoming aware of the event.


i. Review and understand the causes that underlie the event. The root cause analysis must be thorough:
   1. Ask a series of “Why” questions, until it identifies the systemic causal factors associated with each step in the sequence that led to the sentinel event.
   2. Focus of systems and processes, not solely on individual performance.
   3. Determine human and other factors most directly associated with the sentinel event and the process(es) related to its occurrence.
   4. Analyze underlying systems and processes through the series of “Why” questions to determine where redesign might reduce risk.
   5. Identify risk points and their potential contribution to this type of event.
   6. Determine potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis that no such improvement opportunities exist.

And credible:
   1. Include participation by a process owner who is not a member of the response team.
2. Include individuals most closely involved in the processes and systems under review.
3. Be internally consistent.
4. Provide an explanation for all findings of "not applicable" or "no problem"
5. Include a biography of relevant literature.

ii. Determine a risk reduction strategy and action plan that includes the measurement of the effectiveness of process and system improvements to reduce risk or formulates a rationale for not undertaking such challenges. Such action plan will include responsibility and a time frame for the identified actions.

iii. Any new or modified processes identified as actions by the team shall:
   a. Be consistent with Aurora Health Care’s mission, vision, values, goals and objectives and plans;
   b. Meet the needs of the individual’s served, staff, and others;
   c. Be evidence-based;
   d. Be consistent with sound business practices;
   e. Incorporate available information from other organizations: and
   f. Incorporate the results of performance improvement activities.

iv. De-identified paper or electronic root cause analyses shall be shared with the Vice President of Clinical Risk Management.
   a. Key team caregivers will report the sentinel event and findings of the team to the Event Review Committee (ERC).
   b. The Event Review Committee will review and approve the completed root cause analysis. RCA team members and the System Director of Risk Management shall coordinate scheduling the review at an ERC meeting. The ERC, in concert with the RCA team, will determine whether an event is sentinel, significant, or any other classification.
   c. Progress regarding the root cause analysis will be reported to the above referenced committee until such time that the actions have been completed as per the plan. Measurements of process and system improvements will be reported to the above bodies at regular intervals until such time as the Event Review Committee determines the process has been stabilized. The Event Review Committee may determine that the processes be measured at periodic intervals to confirm effectiveness of the actions.
   d. The Executive Event Review Committee will review all sentinel and significant event reviews, along with trended information and action plans. Final accountability for the process improvement lies with the Quality Management Committee to the Aurora Board of Directors, and each the Aurora North and South Board of Directors.
   e. Risk identification and system improvements as a result of the sentinel event shall be shared through Aurora system and facility committees to ensure organizational understanding and learning.
   f. Minutes of the proceedings of each of the teams and committees
involved in the root cause analysis will be recorded and maintained as peer review documents.

5.4 Timeline for Event Analysis

The initial review of a potential Sentinel Event must be initiated within the first three working days of notification of the event. A thorough and credible root cause analysis and action plan should be completed within 45 calendar days of the event or of becoming aware of the event. The summary report to the Event Review Committee should be completed no later than 45 days. Root Cause Analyses that are not potential Sentinel Events may be prioritized based on the risk and patient safety factors.

5.5 Patient Disclosure of Sentinel Events

When an error or incident results in an unanticipated patient outcome, the patient and/or the patient’s family should be informed as soon as reasonably possible. The unanticipated patient outcome should be discussed with the family by the attending physician or his or her designee. Prior to discussing the unanticipated outcome with the patient and/or patient’s family, site administration, the attending physician or designee should, unless time constraints or circumstances dictate otherwise, consult with Risk Management, hospital administration, or legal counsel. Refer to the “Patient Disclosure” Policy for specific information.

5.6 Staff and Patient Support

When any patient event occurs, assistance from chaplains, administration, patient representatives and Risk Management staff may be utilized to support the patient, family, and caregivers. Caregivers should be referred to the Critical Incident Response Team Program and/or the Employee Assistance Program in the case of a sentinel or any event in which the staff member could benefit from supportive dialogue.

5.7 Reporting of Sentinel Events and Unusual Occurrences

a) An annual report on the occurrence of medical/health care events and actions taken to improve patient safety, both in response to actual occurrences, and proactively, will be presented to the Aurora Quality Committee to the Board. Regular reports will be provided to appropriate unit, facility, and system committees.

b) The facility, in conjunction with the Event Review Committee, will determine when a report shall be generated to the Joint Commission or other authorities.

5.8 Continued Monitoring of Events, Near Misses or Proactive Assessments

The site risk manager, in conjunction with the system Director of Risk Management and the Patient Safety Officer, will work with appropriate departments, units, services, and/or physicians to establish mechanisms to continuously monitor the effectiveness of actions in relation to events, near misses, or proactive risk assessment; based, in part, on information published periodically by the Joint Commission that identifies the most frequently occurring types of sentinel events and patient safety risk factors.

5.9 External Occurrences and Disasters

External occurrences and disasters shall be handled as provided in the Hospital Safety
Policies.

Cross References: Patient Disclosure Policy, Patient Rights and Responsibilities, Patient Complaint and Grievance Policy, Abuse Policy

Owner: Vice President of Clinical Risk Management


Hospital Acquired Conditions, CMS.gov, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html, accessed 3/22/15

Review Dates: Every two years
POLICY ADDENDUM #1
PATIENT SAFETY EVENT REPORTING

Caregivers are encouraged to report patient safety events, including near misses. Studies show that patient safety events are underreported, particularly errors that may seem like complications of the patient’s condition. Following is a list of patient safety events that should always be reported, along with complications that in some cases could indicate an error. It should be noted that all known patient safety events should be reported, not just those that result in severe injury or death.

Patient Safety Events Related to Medications:

Must report:
- Medication events, especially those that result in patient death or serious disability (eg, events involving the omission of a drug, the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)

Report if complication unanticipated and medication event is suspected. Note: If a reaction occurs at a dose normally used, report as an ADVERSE DRUG EVENT.
- Acute renal insufficiency/or renal failure
- Allergic reaction or side effect related to skin
- Allergic reaction to blood or related product
- Cardiac complications
- Delirium or change in mental status
- Dysrhythmia
- Excessive bleeding
- Gastrointestinal complication
- Hypoglycemic event
- Hypotension
- Medical emergency/code
- Respiratory complication
- Severe allergic reaction
- Severe headache or dizziness
- Severe hypotension
- Thrush and other opportunistic infection

Events Related to Patient Care Events:

Must report:
- Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
- Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy
• Patient death or serious disability associated with hypoglycemia
• Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
• Missing, mislabeled, lost and or irreplaceable specimens.
• Stage 3 or 4 pressure ulcers acquired after admission to a health care facility
• Patient death or serious disability due to spinal manipulative therapy
• Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility
• Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used for functions other than as intended
• Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility

Report if complication unanticipated
• Aspiration
• DVT, pulmonary embolism
• Exacerbation of pre-existing medical condition
• Failure to treat constipation or obstipation
• Intravenous infiltrate with symptoms
• Intravenous volume overload
• Patient fall with injury
• Skin tear, laceration or other breakdown
• Stage 1, 2 or unstaged pressure ulcer
• Tachycardia or dysrhythmia

Patient Safety Events Related to Surgery or other Procedures
Must Report
• Surgery performed on wrong body part
• Surgery performed on wrong patient
• Wrong surgical procedure performed on a patient
• Iatrogenic pneumothorax during central line placement
• Unintended retention of a foreign object in a patient after surgery or other procedure
• Intraoperative or immediately post-operative death in an American Sociiety of Anesthesiologist Class 1 patient

Report if complication unanticipated
• Acute coronary syndrome
• Blood clot or other occlusion
• Cardiac complication
• Excessive bleeding
• Iatrogenic pneumothorax
• Post-operative ileus
• Post-operative or post-procedural hypotension
• Post-operative or post-procedural hypotension
• Postoperative urinary retention
• Prolonged nausea and vomiting  
• Respiratory complication  
• Severe hypotension  
• Surgical tear or laceration  
• Urinary catheter–associated trauma  
• Urinary retention  

**Patient Safety Events Related to Infection**  
**Must report**  
• Healthcare–acquired infection resulting in death or serious harm  
• Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility  
• Improper processing of equipment (scopes, etc.)  

**Report if healthcare-acquired:**  
• Bacterial infection  
• Bloodstream infection  
• Respiratory infection  
• Surgical or procedural site infection  
• Urinary tract infection  
• Vascular catheter infection  

**Patient Safety Events Related to Patient Protection, Environmental and Criminal Events**  
**Must report**  
• Infant discharged to the wrong person  
• Patient death or serious disability associated with patient elopement (disappearance)  
• Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a health care facility  
• Patient death or serious disability associated with an electric shock or electrical cardioversion while being cared for in a health care facility  
• Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances  
• Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility  
• Any patient fall, including death or serious disability, while being cared for in a health care facility  
• Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility  
• Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider  
• Abduction of a patient of any age  
• Sexual assault on a patient within or on the grounds of the health care facility
• Death or significant injury of a patient or staff member resulting from a physical assault (ie, battery) that occurs within or on the grounds of the health care facility
• Prolonged fluoroscopy with cumulative doses > 1500 rads to a single field, or any delivery of radiotherapy to the wrong body region or >20% above the planned radiotherapy dose.