SUBJECT: SENTINEL EVENTS

POLICY:
The Sentinel Event Policy defines patient safety events that need immediate investigation and response. The patient safety event will be reported to the New York State Department of Health if it meets the criteria for an office based surgery event. It will also be considered to report the event to The Joint Commission under their voluntary reporting standard.

PHILOSOPHY:
The organization’s philosophy is one of taking a proactive approach to preventing errors. As such, all employees are encouraged to report situations where a risk for a patient safety event is present and/or where events have occurred. Every employee has the responsibility to:

- Take immediate action to safeguard the patient from harm, including notification to the physician.
- Report any error or unsafe condition immediately to their supervisor.
- Participate in a root cause analysis of an error or “near miss” to discuss the patient safety event and develop solutions so that these do not occur in the future.

Patient safety events that do occur should be reported immediately to the supervisor and on an adverse event report as specified in policy. These patient safety events will then be evaluated to determine whether they are a sentinel event or a near miss.

Goals of the Sentinel Event Policy:
The policy has the following four goals:

1. To have a positive impact in improving patient care, treatment, or services and in preventing unintended harm.
2. To focus the attention of the organization, if a sentinel event occurs, on understanding the factors that contributed to the event (such as underlying causes, latent conditions and active failures in defense systems, or organization culture), and on changing the organization’s culture, systems, and processes to reduce the probability of such an event in the future.
3. To increase the general knowledge about patient safety events, their contributing factors, and strategies for prevention.
4. To maintain the confidence of the public, clinicians, and organizations that patient safety is a priority for the organization.
Definition of Sentinel Event:

Sentinel events are one category of patient safety events. A patient safety event is an event, incident, or condition that could have resulted or did result in harm to a patient. A patient safety event can be, but is not necessarily, the result of a defective system or process design, a system breakdown, equipment failure, or human error. Patient safety events also include adverse events, no-harm events, close calls, and hazardous conditions, which are defined as follows:

- An **adverse event** is a patient safety event that resulted in harm to a patient.
- A **no-harm event** is a patient safety event that reaches the patient but does not cause harm.
- A **close call** (or “near miss” or “good catch”) is a patient safety event that did not reach the patient.
- A **hazardous** (or “unsafe”) **condition(s)** is a circumstance (other than a patient’s own disease, process, or condition) that increases the probability of an adverse 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
- Severe temporary harm

An event is also considered sentinel if it is one of the following:

- 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 organization’s emergency department (ED)
- Unanticipated death of a full-term infant
- Discharge of an infant to the wrong family
- Abduction of any patient receiving care, treatment, or services
- Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting (including the ED) leading to the death, permanent harm, or severe temporary harm of the patient
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, or services while on site at the organization†
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization
- Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure‡
- Unintended retention of a foreign object in a patient after an invasive procedure, including surgery§
- Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
- Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose
- Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care
- Any intrapartum (related to the birth process) maternal death or severe maternal morbidity
PROCEDURE:

Immediate response to a sentinel event:

1. The Clinical Director will be notified of the sentinel event. The Clinical Director/designee will evaluate the event, and meet with the respective disciplines involved to determine whether in fact, this qualifies as a "Sentinel Event". A determination will be made as to whether any other immediate actions need to be taken such as:
   - Stabilization of the patient
   - Disclosure of the event to the patient or surrogate decision maker
   - Provision of support for the family
   - Provision of support for the staff involved in the event
   - Notification of organization leadership

   The following are considered with respect to meeting the Sentinel Event Reporting criteria:
   - A distinction is made between an adverse outcome that is related to the natural course of the patient's illness or underlying condition (not reportable) and a death or major permanent loss of function that is associated with the treatment, or lack of treatment, of that condition (voluntarily reportable).
   - "Major permanent loss of function" means sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or life-style change.
   - When "major permanent loss of function" cannot be immediately determined, reporting is not expected until either the patient is discharged with continued major loss of function, or two weeks have elapsed with persistent major loss of function, whichever occurs first.

2. If a patient safety event is believed to meet the Sentinel Event reporting criteria, the respective disciplines will discuss the issue with the Clinical Director. A decision will be made as to whether the Sentinel Event will be reported to Joint Commission (JC). (Note: Reporting the event to the New York State Department of Health is not voluntary and will be determined based upon the office based surgery adverse event reporting criteria).

3. If a decision is made to report Sentinel Event to JC, reporting of the Sentinel Event will be made to the Joint Commission Sentinel Event Unit at (630) 792-3700 by the Clinical Director, or another individual as designated by the Clinical Director. Reporting can be done via the JC Website (www.jointcommission.org). Reporting of Sentinel Events to the JC should be done within 5 business days of the occurrence or knowledge of the event. In order to maintain confidentiality, the report to JC should not include any patient or practitioner identifier.

4. A comprehensive systematic analysis for identifying the causal and contributory factors will be completed.
   A thorough and credible Root Cause Analysis, which focuses on systems and processes, will be used to identify the factors that underlie the sentinel event must be completed within 45 days (using the Joint Commission’s Sentinel Event Standards/Guidelines). Emphasis will be placed on the following:
   - The management of the patient before and after the identification of the event / infection.
   - What should we have done to prevent this from having occurred?
   - What can we do to prevent this in the future?

Key aspects involved in this analysis will include:
   a. Determining whether the occurrence is a "Special Cause" in clinical processes or "Common Cause" in organizational processes.
   b. Determining the immediate/proximate cause(s) of the Sentinel Event.
   c. Evaluating beyond the immediate cause to:
      - Focus primarily on systems and processes, not on individual performance.
Identify risk points and their potential contributions to this type of error.

For any event in one of the categories currently identified in the TJC RCA matrix, inquiry into each identified area for that category of event sufficient in depth to determine that there is, or is not, an opportunity within the associated systems processes or functions to redesign or otherwise take action to reduce risk.

When appropriate, use PI tools, such as a fishbone cause/effect diagram and flowcharting, brainstorming, "5 whys".

Provide a rationale for any conclusion that a relevant process, system or function is not applicable to the event or offers no opportunity for risk reduction.

Consider any relevant literature.

d. When corrective actions are planned, identify:
   - What action will be taken?
   - Who is responsible for implementation?
   - When the actions will be implemented (timelines)?
   - How the effectiveness of the actions will be evaluated?
   - Strategies for sustaining the change.

The focus of a Root Cause Analysis is to evaluate systems and processes, as well as the behavioral choices of our employees within those systems. Individuals most closely involved in the processes or systems under review should therefore be involved in the evaluation. Events will be evaluated to determine if the contributing factors were due to systems, at risk behavior or reckless disregard for procedures. Individuals who intentionally engage in reckless behavior involving a conscious disregard of a substantial and unjustifiable risk of causing harm will be subject to disciplinary action.

1. The analysis and corrective action plan recommendations, developed by the RCA Team, will be submitted to leadership for review/acceptance and the action plan initiated.

2. The Clinical Director will report the Sentinel Event, the root cause analysis and the planned corrective actions to the Co-CEOs. The Clinical Director will keep the aforementioned informed of the status and implementation of the Corrective Action Plan, and any interactions with the JC, including any impact on JC Accreditation Status.

3. If a decision is made to report a Sentinel Event to the JC or if the JC becomes aware of a Sentinel Event within the organization, discussions will be held regarding the best method of providing evidence to the JC that a thorough and credible root cause analysis was conducted and corrective actions were taken. A determination will be made as to how to fulfill this requirement and maintain confidentiality protections under NY State Statute (e.g., on site review, interviews, submission of written documentation, etc.). The Joint Commission (The Sentinel Event Unit of the Office Quality and Patient Safety) must receive this evidence within 30 days of notification to the JC. (If the JC was not notified, this documentation must be retained as evidence of evaluation and provided, if requested, to the JC upon survey).

4. All documentation related to Sentinel Events including root cause analysis, actions plans, performance improvement and any required follow-up reports will be maintained in a confidential manner by the organization.

5. Performance improvement (PI) measures will be implemented, where appropriate in order to determine whether corrective actions were effective. PI data will be collected, analyzed and reported by the department(s) involved in implementing the actions to the Clinical Director and the Co-CEOs, until satisfactorily completed.
Notification of Patient/Family of Medical Errors/Sentinel Events:

It is the practice of the medical staff to inform the patient about unanticipated outcomes of the care, treatment, or services that relate to sentinel events as defined by Joint Commission. This discussion is documented in the medical record.

Sentinel Event Alerts:

Sentinel Event Alerts are published by the JC periodically to notify organizations of sentinel events being reported by other healthcare organizations, identify trends in failed processes, and actions which can be taken in order to prevent future occurrences. When these are received, the organization will communicate these alerts to the appropriate individuals within our organization and request that these individuals evaluate our processes and determine whether actions are required to reduce risk of medical error.

Date Policy to be reviewed: 02/17