**GENERAL STATEMENT of PURPOSE**

This policy and procedure is designed to improve the safety and quality of healthcare provided throughout Northwell Health by establishing a timely, standardized, and confidential framework for recognition and analysis of serious adverse sentinel events. This policy and procedure describes potential adverse (sentinel) event categories and processes for internal and external reporting, analysis and follow-up.

Northwell Health facilities will comply with all governmental and accrediting agency requirements concerning the reporting of unexpected adverse events as dictated by agency regulations or standards.

**POLICY**

Serious adverse events, one patient safety event category, will be identified and evaluated in accordance with procedures for immediate response to medical/healthcare events that may impact adversely on patient outcomes or in specific instances applied to staff, licensed independent practitioners, visitors and/or vendors on site. In order to do so, a detailed root cause analysis is required for unexpected occurrences, which lead to death, severe temporary harm, permanent harm/impairment of bodily function or identify significant undesirable patterns, trends, or variations in its performance related to the safety or quality of care. The analysis must be interdisciplinary in nature and use performance improvement methodologies.

These analyses created for and used by Quality Management are an integral part of the facility’s Quality Assurance program. Such reports are privileged and confidential, and protected from disclosure under N.Y.S. Education Law § 6527 and N.Y. S. Public Health Law § 2805-m as well as under the Federal Nursing Home Reform Act, 42 U.S.C. § 1396(r)(b)(1)(B)(ii). Northwell Health will maintain compliance with mandatory Department of Health (DOH) reporting through the New York Patient Occurrence Reporting and Tracking System (NYPORTS) and The Joint Commission’s (TJC) Sentinel Event Policy requirements that recommend voluntary self-reporting of sentinel events.

**POLICY/GUIDELINE TITLE:** Serious Adverse (Sentinel) Event Policy

**ADMINISTRATIVE POLICY AND PROCEDURE MANUAL**

**POLICY #:** ADM I 30.1  
**System #:** 100.65  
**System Approval Date:** 6/7/17  
**Site Implementation Date:** 7/21/17  
**Prepared by:** Institute for Clinical Excellence & Quality  
**CATEGORY:** Administrative  
**Effective Date:** 11/2004  
**Last Reviewed/Approved:** 3/19/2015  
**Superseded Policy(s)/#/Notations:** N/A
Northwell Health will review and report into NYPORTS, based on criteria, the following applicable serious adverse events requiring root cause analysis:

1. Death or serious injury associated with a medication error;
2. Surgery or other invasive procedure performed on the wrong site, wrong patient, or wrong procedure;
3. Unintended retention of a foreign object in a patient after surgery or other invasive procedure;
4. Patient death and/or serious injury associated with a fall while being cared for in a healthcare setting;
5. Maternal death or serious injury associated with labor or delivery while being cared for in a healthcare setting;
6. Death or serious injury of a neonate associated with labor and delivery;
7. 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 is intended;
8. Death or serious injury of a patient or staff member resulting from physical assault (i.e. battery) that occurs within or on the grounds of a healthcare setting;
9. Death or serious injury resulting from the irretrievable loss of an irreplaceable biologic specimen;
10. Death or serious injury associated from failure to follow up or communicate lab, pathology, or radiology test results;
11. Death or serious injury of patient or staff associated with introduction of a metallic object into the MRI area;
12. Death or serious injury associated with the use of physical restraints or bedrails while being cared for in healthcare setting;
13. Patient death or serious injury in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards;
14. Patient suicide, attempted suicide or self-harm while being cared for in a healthcare setting;
15. Patient death or serious injury associated with patient elopement;
16. Abduction of a patient of any age;
17. Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person;
18. Sexual abuse/sexual assault on a patient or staff member within or on the grounds of a healthcare facility;
19. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in the healthcare setting.

Northwell Health will review and report into NYPORTS, based on criteria, the following applicable serious adverse events which may not require a root cause analysis:

1. Misadministration of radiation or radioactive material including the misadministration of contrast media;
2. Strike by hospital staff;
3. External disaster outside the control of the hospital which affects facility operation;
4. Termination of any services vital to the continued safe operation of the hospital or to the health and safety of its patients and personnel;
5. Poisoning occurring within the hospital;
6. Hospital fire or other internal disaster disrupting patient care or causing harm to patients or staff.

Northwell Health will review and consider for reporting to TJC the following events defined by TJC as “reviewable;” based on the following criteria:

1. The event has resulted in an unanticipated death, severe temporary harm or permanent harm/loss of function, not related to the natural course of a patient’s illness or underlying condition or;
2. The event falls into one of the following categories, even if the outcome was not death or permanent loss of function unrelated to the natural course of the patient’s illness or underlying condition:
   a) Suicide of any individual 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);
   b) Unanticipated death of a full term infant;
   c) Abduction of any individual receiving care, treatment or services;
   d) Discharge of an infant to the wrong family;
   e) Rape, assault (leading to death, permanent harm or severe temporary harm), or homicide of any patient receiving care, treatment and services on site at the hospital;
   f) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups);
   g) Invasive and surgical procedure on the wrong patient, wrong site or wrong procedure;
   h) Unintended retention of a foreign object in an individual after surgery or other invasive procedures;
   i) Severe neonatal hyperbilirubinemia (bilirubin greater than 30 milligrams/deciliter);
   j) Prolonged fluoroscopy with cumulative dose greater than 15GY (1500 rads) to a single field, or any delivery of radiotherapy to the wrong body region, or greater than 25% above the planned radiotherapy dose;
   k) 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 healthcare organization;
   l) Any intrapartum (related to the birth process) maternal death, or severe maternal morbidity;
   m) 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;
   n) Fire, flame or unanticipated smoke, heat or flashes occurring during an episode of patient care.

Northwell Health investigators will review and report Serious Adverse Events (SAE) in research to the IRB of record.

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ADM 7A - Serious Adverse (Sentinel) Event Policy
Any serious adverse events which occur in a clinical research protocol must be submitted to and reviewed by the Institutional Review Board (IRB) of record for that protocol, in accordance with the IRB’s policies, in addition to Quality Management’s review. The IRB of record should be contacted for guidance on submission. The requirement for external notification is time dependent and as a result it is extremely important to contact the IRB as soon as a SAE is noted.

**SCOPE**

This policy applies to all Northwell Health employees, as well as medical staff, volunteers, students, trainees, physician office staff, contractors, trustees and other persons performing work for or at Northwell Health; faculty and students of the Hofstra Northwell School of Medicine conducting research on behalf of the School of Medicine on or at any Northwell Health facility; and the faculty and students of the Hofstra Northwell School of Graduate Nursing and Physician Assistant Studies.

**DEFINITIONS**

1. **Serious Adverse or sentinel event**: an unexpected occurrence involving death, severe temporary harm, permanent harm/impairment of bodily function. Severe temporary harm is critical, potentially life threatening harm lasting for a limited time with no permanent residual, which may require transfer to a higher level of care, monitoring for a prolonged period of time, or treatment to resolve the condition. The event is called “sentinel” because it sends a signal or sounds a warning that requires immediate investigation and response.

2. **Patient safety event**: 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 call, and hazardous conditions.

3. **NYPORTS—New York Patient Occurrence Reporting and Tracking System**: The New York Patient Occurrence Reporting and Tracking System (NYPORTS) is an adverse event reporting system implemented pursuant to New York State Public Health Law Section 2805-1, Incident Reporting. For the purpose of NYPORTS reporting, an occurrence is an unintended, adverse, and undesirable development and/ or outcome in an individual patient’s condition occurring in a hospital. More serious occurrences defined as patient deaths or impairment of bodily functions in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards are investigated individually and may require the hospital to conduct a root cause analysis.

4. **Debriefing**: a stepwise tool designed to rigorously analyze a critical event to examine what occurred and to facilitate an improved outcome next time.

5. **Root Cause Analysis (RCA)**: a process for identifying the basic or causal factors that underline variation in performance, including the occurrence or possible occurrence of a sentinel event. A RCA 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 or determine, after analysis that no such improvement opportunities exist.

**PROCEDURE/GUIDELINES**

1. When a serious adverse event has occurred at a facility, Senior Administrative/Clinical Leadership and Quality Management (QM) at the facility are immediately notified and an investigation initiated. At a minimum, all potential TJC sentinel events and reportable events to the New York State Department of Health under the NYPORTS incident reporting program must be reviewed to determine if a possible sentinel event has taken place.

2. Organizational Senior Leadership will notify Northwell Health Leadership. Consultation with Risk Management, the Legal Department and other resources such as Corporate Compliance will transpire as needed.

3. An occurrence report is generated. If the event involves malfunctioning equipment, the equipment is sequestered to assist with the investigative process.

4. A debriefing should be conducted, generally within 48 hours, with key individuals involved in the event and clinical leadership. The debriefing process includes: discussion of the events; determining chronology of the event; review of an updated assessment of the status of any patient(s) involved in the incident; determination of any continued patient safety risk and any necessary immediate actions; determination of need for staff emotional support/follow-up/referrals; discussion of communication to Executive Leadership, Clinical Leadership and the Northwell Health Institute for Clinical Excellence and Quality; discussion of communication/disclosure with the patient/family; delineation of responsibilities for follow-up.

5. Based on occurrence, interviews should be completed in a timely manner, preferably within 72 hours.

6. Events that meet the criteria for NYPORTS will be reported within 24 hours of organizational awareness that reporting criteria was met, by the Director/designee of Quality. Events that meet TJC sentinel event reporting criteria will be communicated to the Northwell Health VP for the Institute for Clinical Excellence and Quality/designee. The decision of whether to voluntarily report the event to TJC will be made and appropriate process followed (Refer to Appendix A).

7. RCA meeting(s) will be conducted. The RCA discussion points include: establishing consensus on the problem or event; identifying and establishing consensus on the immediate cause of the problem; review of staffing; identifying root causes; initiating immediate corrective actions; and establishing recommendations and process improvements. Some non-reportable adverse events may necessitate an RCA, as determined by the site. The NYPORTS required RCA’s should be completed within 30 days of the date of the awareness and submitted to NYPORTS. A 30 day extension may be requested if needed to insure thorough review.
8. The Director/designee for Quality will be responsible to ensure that preliminary RCA findings, conclusions and improvement plans are disseminated for review and comment to the RCA team members. The improvement plan must include risk reduction strategies and process improvement that will reduce risk of recurrence, identification of accountability for implementation with timeframes, and evaluation of the effectiveness of the plan through measurement or monitoring.

9. A final written summary and analysis will be presented to appropriate Hospital Committees such as Performance Improvement Coordinating Group (PICG). All RCAs will be presented to the Hospital Medical Board for amendment and endorsement.

10. In the spirit of process improvement and with Northwell Health commitment to patient safety, valuable information and lessons learned from these events will be shared within Northwell Health Institute for Clinical Excellence and Quality structure. This is accomplished through periodic case presentations at the Health System’s Performance Improvement Coordinating Groups and the Committee on Quality.

11. The Director/designee of Quality will annually aggregate, analyze and trend all the root causes and report these results to the Hospital-wide PICG/Medical Board. These findings will be used to develop organization wide risk reduction strategies and process improvement priorities. The Director/designee of Quality will aggregate and track all the root causes, and corrective actions to ensure implementation of recommended performance improvement processes and adherence with ongoing monitoring activities. All action items will be forwarded to the appropriate Committee/Departments/PICG for follow-up.

12. Routine reporting of adverse (sentinel) events through the Northwell Health Committee on Quality occurs on a regular basis. On a yearly basis, aggregated data reflecting number and type of sentinel events, whether the patient/families were informed of the event, identified causes, and actions taken to improve safety are reported.

13. Other agencies which require mandatory reporting of events will be provided information based on the following:
   a) Blood Bank Reporting: Blood Bank and Transfusion Services will report and investigate transfusion-related incidents to the Wadsworth Center, New York State Department of Health in accordance with Section 5B-2.3 (f) and 58-2.16 (a) of Title 10 (NYCRR).
   b) Reporting to the Justice Center for the protection of people with special needs and to the Office of Mental Health (OMH): all licensed mental health programs are responsible for reporting allegations of abuse and neglect and significant incidents. Refer to Behavioral Health policies and procedures for reporting guidelines.
   c) Safe Medical Devices Act: all incidents involving medical devices are reported to the appropriate governmental agency.
   d) Radiation Safety: the Radiation Safety Officer will report and investigate all radiation related incidents and exposures to the following: The New York City facilities are licensed under Article 175 by the Bureau of Radiological Health, New York City Department of Health; Nassau and Suffolk facilities are licensed under Chapter 1 – Part 16 of the New York State Sanitary Code on Ionizing Radiation. The licensing agency is the Bureau of Environmental Radiation
Protection, New York State Department of Health.
e) Office of Health Systems Management (OHSNM): all suspected cases of alleged abuse, neglect or mistreatment of residents will be reported to the Patient Care Investigator’s Office and the OHSNM Hotline.

14. For detailed guidance and reporting requirements for serious adverse events which occur in clinical research protocols, the Office of the IRB shall be contacted at 516-562-3101.

REFERENCES TO REGULATIONS AND/OR OTHER RELATED POLICIES

- The Joint Commission, Sentinel Event Policy/Procedure – 2017 Hospital Accreditation Standards
- NYSDOH: NYPORTS 2013 Reportable Codes Requiring a Root Cause Analysis (Level I); 2013 NYPORTS Reportable Codes Not Requiring a Root Cause Analysis (Level II) Section 405 of the New York State Health Code
- Adverse Event Reporting Program: MedWatch – Administrative Policy #100.36
- Occurrence Reporting #100.04
- Bill Waiver/Claims Management Related to Serious Reportable Events #100.71

CLINICAL REFERENCES
N/A

ATTACHMENTS
N/A

FORMS
N/A

| APPROVAL: |
|-----------------|-----------------|
| System Administrative P&P Committee | 4/27/17 |
| System PICG/Clinical Operations Committee | 6/07/17 (evote) |
| SIUH MEC | 2/7/11;5/7/11;11/4/13;4/6/15;7/10/17 |

Standardized Versioning History:
* = Policy Committee Approval; ** = PICG/Clinical Operations Committee Approval
12/14/10 * 1/27/11 **
1/10/12 * 3/22/12 **
2/26/15* 3/19/15**
Appendix A

TJC Sentinel Event Procedure

A. Each facility will have in place a process for notification of hospital leadership and disclosure of a sentinel or adverse event to the involved patient, and family members when appropriate.

B. Events that meet TJC sentinel event reporting criteria will be communicated to the Northwell Health VP, Institute for Clinical Excellence and Quality/designee. The decision of whether to voluntarily report the event to TJC will be made and appropriate process followed.

C. The facility will submit electronically a Joint Commission Sentinel Event Self-Report form.

D. The Northwell Health Institute for Clinical Excellence and Quality will be available to the hospitals, clinics and practices as a resource throughout the comprehensive systematic analysis/RCA process, and act as a liaison between TJC and the hospital or other Health System facility/entity during TJC review process of the RCA report as needed. The hospital will forward the completed RCA and corrective action plan to the Vice President, Institute for Clinical Excellence and Quality/designee for review.

E. A thorough and credible root cause analysis and action plan must be submitted to TJC within 45 calendar days from the date of occurrence or of becoming aware of the event. If the determination that an event is reviewable under the Sentinel Event Policy occurs more than 45 calendar days following the known occurrence of the event, the organization will be allowed 15 calendar days for its response.

F. TJC will notify the hospital when they have a request for revisions to the RCA and/or action plan. If these were received within the stipulated time frame, TJC will provide consultative support and allow an additional 15 days for submission of an acceptable RCA and action plan.

G. TJC will notify the hospital directly when they have accepted the RCA report and corrective action plan as being thorough and credible. The hospital will be given a date when the Sentinel Event Measure of Success (SE MOS) is due, which is four months after the RCA and action plan are determined acceptable.

H. The VP, Institute for Clinical Excellence and Quality/designee will review the SE MOS report completed by the hospital and the organization will submit the report to TJC within the designated timeframe.

I. TJC will notify the hospital when the four-month SE MOS report has been accepted, officially closing the matter. The hospital in turn, will notify the Institute for Clinical Excellence and Quality of the date that TJC has accepted the report.