PURPOSE:

To provide a clear organizational response for adverse events determined to be one of the following:

- Sentinel Events, as defined by The Joint Commission (TJC) (See Attachment A).
- Serious Reportable/Never Events, as defined by the National Quality Forum (NQF) (See Attachment B).
- Texas Department of State Health Services (TDSHS) events as defined by the TDSHS Patient Safety Program (See Attachment C).

Additionally, the purposes are to:

- To have a positive impact in improving patient care, treatment and services in preventing unintended harm;
- To focus the attention of a hospital that has experienced a sentinel event on understanding the factors that contributed to the event (such as underlying causes, latent conditions, and active failures in defense systems, or Hospital culture), and on changing the hospitals' culture, systems and processes to reduce the probability of such an event in the future;
- To increase the general knowledge about the patient safety events, their contributing factors, and strategies for prevention;
- To maintain the confidence in the public, clinicians, and hospitals that patient safety is a priority in accredited hospitals.

This procedure outlines the administrative components of a comprehensive institutional process, and supports an organizational culture that values transparency, patient safety, ongoing learning, and information dissemination. In addition, specific expectations for the management of these events through the Root Cause Analysis (RCA) or Apparent Cause Analysis (ACA) processes are addressed.

The major components are:

- A formalized team response that stabilizes the patient, discloses the event to the patient and family and provides support for the family as well as the staff involved in the event,
- Notification to hospital leadership,
- Immediate investigation,
- Completion of a comprehensive systemic analysis for identifying the causal and contributory factors,
- Strong corrective actions derived from the causal and contributing factors that eliminate or control system hazards or vulnerabilities and result in sustainable improvements over time,
- A timeline for the corrective actions,
- Systemic improvements,
- Sharing of lessons learned across the health system.

SCOPE:

All Parkland Health & Hospital System (“Parkland”) facilities, including but not limited to hospitals, ambulatory surgery centers, clinics, correctional health and all corporate departments/divisions.

PROCEDURE:

1. Actions to be immediately initiated when an event is identified:

   A. A formalized clinical team response is mobilized to stabilize the patient which will be led by Patient Safety.

B. Notifications to minimally include the attending physician, immediate hospital and nursing or operational leadership, Administrator on call, Patient Safety & Clinical Risk Management on call.

C. Ensure that the patient/family is provided with all necessary care and services to ensure the best possible outcomes.

D. Identify personnel to maintain communications with the patient/family as needed. This may include disclosure of the event once facts of the case are available (see section on disclosure).

E. Obtain, sequester or preserve any appropriate evidence, including but not limited to medication containers (used and unused) or medical equipment, until approved for release through the appropriate channels.

F. Determine whether the adverse event puts other patients at immediate risk and address accordingly.

G. Supervisor/manager will ensure a Safety Post is entered through the Safety Center.

H. Leadership will determine which individuals or group can best support and assist staff/providers post event.

2. Preserve Evidence:

A. Criminal Events - staff should secure the area where the incident occurred. The Dallas County Hospital District Police Department (DCHDPD) will be contacted and will conduct a crime scene search and evidence recovery for possible prosecution as the situation dictates. Evidence should not be tampered, compromised or altered in any way.

B. Non-Criminal Event - staff should secure physical evidence involved in the adverse event, including but not limited to:

1) Medical devices and equipment including original packaging with lot and model numbers, if available,

2) Retained foreign objects which later shall be sent to Pathology for processing,

3) Medications, containers, package labels or inserts IV bags and tubing, syringes and pumps,

4) Supply containers and packaging,

5) Lab and pathology specimens,

6) Any other applicable physical evidence that might be of use in an Investigation.

C. Take pictures where appropriate.

D. Do not tamper with, clean or otherwise modify any physical evidence.

E. Report the event to the Food & Drug Administration via the Medwatch/Medsun site/form within ten working days or as soon as possible for a patient death or serious injury related to a piece of equipment.

F. The Medwatch/Medsun report shall be completed by a member of the Patient Safety Risk Management Team.

G. The Patient Safety & Risk Manager (PSR) will also update the Safety Post with the required documentation in the Quality Safety Process Improvement (QSPI) section of the Safety Post

H. Preservation of electronic data.

1) Consult with Information Technology regarding preservation of the integrity of electronic data.

2) Back up or otherwise preserve electronic data.

3) Obtain printout of electronically stored data if the information may be overwritten.

3. Relief and Support of Caregivers

A. Clinical supervisors should immediately evaluate the impact of the adverse event on involved staff and provide support accordingly.

B. Physician leaders should immediately evaluate the impact of involved physicians and provide support accordingly.

C. Supervisors should immediately address patient ratios and redistribute patient loads, if necessary, to allow involved caregivers time to cope with the situation.

D. Supervisors should address individual accountability by consistent and transparent application of “Just Culture” principles.

4. Documentation Guidelines

   A. Appropriate documentation should be entered in the medical record regarding the event with guidance from the PSR and a legal representative, as needed.

5. The PSR will swiftly launch the following activities:

   A. Ensure all appropriate leadership is notified which may include but is not limited to Executive Leadership, Administrator on Call (AOC), Legal Affairs/Institutional Risk Management, Regulatory & Accreditation, and Corporate Communications. One of the Executive Chiefs shall ensure notification of the Chair of the Board of Managers and the Chair of the Board of Managers Quality Committee and a member of the Quality Review Organization (QRO), as appropriate.

   B. Initiate a confidential case investigation which shall include interviews of involved personnel as soon as practicable.

   C. Submit a formal bill hold request to “Risk Team Bill Hold‟ email account within twenty four hours (24 hours) of the event. The PSR shall note the bill hold in the Safety Post

   D. Collaborate with the service line Vice President, Director or designee to determine if/when a RCA or ACA is required and the required attendees.

   E. Additional Reporting:

1) All suspected transfusion reactions are to be reported to Transfusion Services (see Transfusion/Blood Bank Department intranet pages).

2) All serious and unexpected adverse events involving patients on research protocols should be reported to the Office of Research Administration.

6. Assessment and Support of Involved Physicians and Staff

   A. Clinical supervisors and administrative leadership should immediately evaluate the impact of the adverse event on involved staff and witnesses and provide support accordingly.

   B. Physician leaders should immediately evaluate the impact of involved physicians and provide support accordingly.

   C. Supervisors should immediately address patient ratios and redistribute patient loads, if necessary, to allow involved caregivers time to cope with the situation.

   D. Consideration should be given to any immediate support or mental health needs of care providers involved in adverse events such as:

      1) Referral to Employee Assistance Program (EAP) or internal mental health support services, as optional or mandatory, if required within department procedures

      2) Referral for mental health services through the individual's health insurance coverage.

      3) Referral to the Parkland Victim Intervention Program (VIP).

7. The PSR will:

   A. Facilitate a Root Cause Analysis meeting with the involved persons within 45 business days of the event date or becoming aware of the event. Expediting the formal review may be necessary for specific cases.

   B. The RCA is a systematic analysis that must be thorough and credible. In order for the RCA to be thorough, it must include the following:

1) An analysis which repeatedly asks a series of "Why" questions until it identifies the systemic causal factors associated with each step in the sequence that led to the outcome;

2) The analysis focuses on systems and processes; not solely on performance;

3) A determination of the human and other factors most directly associated with the sentinel event and the process(es) and systems related to its occurrence;

4) An inquiry into all areas appropriate to the specific type of event;

5) An identification of risk points and their potential contributions to the type of event;

6) A determination of 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;

7) Identifies corrective actions to be taken to reduce the risk or recurrence.

C. In order for the RCA to be credible, it must include the following:

1) Include participation by a process owner who is not a member of the response team; typically this is a senior leader of the hospital or a designee;

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 bibliography of any relevant literature.

D. Confirm that the Root Cause Analysis Framework Meets TJC Standards:

1) Shall be prepared using the Joint Commission Framework for Root Cause Analysis.

2) Contain an action plan with measurable action items.

   a) Identifies changes that can be implemented to reduce risk or formulates a rationale for not undertaking such changes;

   b) Identifies, in situations where improvement actions are planned, who is responsible for implementation, when the action will be implemented, how the effectiveness of the actions will be evaluated, and how the actions will be sustained;

   c) Communicates systemic shares for global learning.

3) The Action Plan will be reviewed with the key stakeholders in attendance and shall be sent to those in attendance at the RCA/ACA along with the framework within fifteen (15) business days after the final RCA/ACA meeting has been conducted.

8. The Apparent Cause Analysis (ACA) Process:

   A. The ACA is reserved for cases whereby the event did or did not reach the patient and did not cause significant harm. This process allows for formal review and the implementation of proactive risk reduction strategies to assist in harm prevention.

   B. Similar to the RCA, the ACA will have a formal framework and action plan completed.

9. Measure the Effectiveness of the Action Plan

   A. Action plans will be monitored at three (3) and six (6) month intervals or more as the case warrants to determine if effectiveness of corrective action is maintained and reported to the appropriate Hospital Department committees (Adverse Event and Performance Improvement Committees).

   B. Open action items shall be monitored for closure by the lead PSR.

C. Open action items shall be reported through the Quality of Care and Patient Safety Committee (QCPSC) and Quality Committee of the Board of Managers (QBoM) at routine intervals.

10. External Reporting

A. Federal, State and Local reporting requirements must be considered.

B. The Chief Quality & Safety Officer and the Director of Regulatory and Accreditation Affairs are responsible for ensuring that timely compliance with all reporting requirements occurs to the appropriate agency.

11. Oversight and Responsibility

A. The oversight of this policy is through the Patient Safety & Risk Management Department which shall review and revise the policy.

B. The Parkland Hospital Leadership and the Board of Managers shall be responsible for maintaining compliance with the regulatory standards.

C. The Sentinel Event information shall be routinely reported to the Quality of Care Patient Safety Committee and the Quality Committee of the Board of Managers on a routine basis where events and open action plan items will be reviewed and trended.

DEFINITIONS:

Action Plan: The product of the comprehensive systemic analysis (RCA or ACA) which identify the strategies to be implemented in order to reduce the risk or future similar occurrences. Elements of the action plan include but are not limited

- Actions to be taken
- Responsible person for implementation
- Time lines for completion

- Strategies for evaluating effectiveness
- Strategies for sustaining change

Adverse Event: an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.

Apparent Cause Analysis (ACA): process for determining the most probable cause based on readily available information during a limited investigation of an event.

Hazardous or unsafe condition: a circumstance (other than a patient's own disease process or condition) that increases the probability of an adverse event.

Medical Error: the failure of a planned action to be completed as intended, the use of a wrong plan to achieve an aim, or the failure of an unplanned action that should have been completed, which results in an adverse event.

Near Misses/Close Call: a patient safety event that did not reach the patient.

No Harm Event: a patient safety event that reaches the patient but does NOT cause harm.

Patient Safety Event: an event, incident or condition that could have resulted in harm to a patient.

Root Cause Analysis (RCA): An interdisciplinary process used for identifying the causal and contributing factors that underlie variation in performance associated with Serious Harm Events, Sentinel Events or Near Misses. A RCA focuses primarily on systems and processes, not on individual performance used for identifying the factors that led to the outcome.

Sentinel Event: is one category of patient safety events. These are defined by The Joint Commission (TJC) is a patient safety event (not primarily related to the natural course of the patient's illness or underling condition) that reaches a patient and results in any of the following. Such events are called sentinel as they signal the need for immediate

investigation and response. The outcomes to a patient, employee vendor or visitor include:

- Death
- Permanent Harm
- Severe Temporary Harm and intervention required to sustain life.

An event can be considered sentinel even if the outcome was not death, permanent harm or severe temporary harm, and intervention was required to sustain life. (These will be reviewed on a case by case basis to determine the need for a RCA after a thorough review has been completed by the local leadership as some cases will warrant transfer to a higher level of care due to a change in the underlying condition or an extension of the patient's disease process.

Severe Temporary Harm: is critical and can be 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 and, or additional major surgery, procedure or treatment to resolve the condition.

REFERENCES:

The Joint Commission, Comprehensive Manual for Participation, Standard EC.02.01.01 (2017)

The Joint Commission, Comprehensive Manual for Participation, Standard LD.04.04.05 (2017)

The Joint Commission, Sentinel Event Policy (2017)

Condition of Participation: Quality Assessment and Performance Improvement Program, 42 C.F.R. §482.21 (2017)

Attachment A - The Joint Commission (TJC) Sentinel Events

Sentinel Event is one category of patient safety events. These are defined by The Joint Commission (TJC) and is a patient safety event (not primarily related to the natural course of the patient's illness or underling condition) that reaches a patient and results in any of the following. Such events are called sentinel as they signal the need for immediate investigation and response. The outcomes to a patient, employee vendor or visitor include:

- Death
- Permanent Harm
- Severe Temporary Harm (is critical and can be 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 and, or additional major surgery, procedure or treatment to resolve the condition).

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

- Suicide of any patient receiving care, treatment and services in staffed around the clock care setting within 72 hours of discharge, including the hospital's emergency department.
- Unanticipated death of a full-term infant.
- Discharge of an infant to the wrong family.
- Abduction of any patient receiving care, treatment and services.
- Any elopement (that is unauthorized departure) of a patient from a staffed around the clock care setting (including the emergency department) leading to death, permanent harm or severe temporary harm to 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 a staff member, licensed independent practitioner, visitor, or vendor while on site at the hospital.
- 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 the 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.
- Severe maternal morbidity (not related to the natural course of the patient's illness or underlying condition) when it reaches a patient and results in permanent harm or severe temporary harm.

Attachment B - National Quality Forum (NQF) Serious Reportable Events (previously known as 'Never Events')

Defined by the NQF as events that, based on evidence, are almost always preventable and should never occur. These include:

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 post-operative/post-procedure death in an ASA Class 1 patient.

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.

PATIENT PROTECTION EVENTS

- Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person.
- Patient death or 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.

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.
- Artificial insemination with the wrong donor sperm or wrong egg.
- 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.

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.

RADIOLOGIC EVENTS

- Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area.

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.

Attachment C - Texas Department of State Health Services (TDSHS) Patient Safety Program Events

- A medication error resulting in a patient's unanticipated death or major permanent loss of bodily function in circumstances unrelated to the natural course of the illness or underlying condition of the patient.
- A perinatal death unrelated to a congenital condition in an infant with a birth weight greater than 2,500 grams.
- The suicide of a patient in a setting in which the patient received care 24 hours a day.
- The abduction of a newborn infant patient from the hospital or the discharge of a newborn infant patient from the hospital into the custody of an individual in circumstances in which the hospital knew, or in the exercise of ordinary care should have known, that the individual did not have legal custody of the infant.
- The sexual assault of a patient during treatment or while the patient was on the premises of the hospital or facility.
- A hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products with major blood group incompatibilities.
- A surgical procedure on the wrong patient or on the wrong body part of a patient.
- A foreign object accidentally left in a patient during a procedure.
- A patient death or serious disability associated with the use or function of a device designed for patient care that is used or functions other than as intended.

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 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.

Adverse Drug Reaction:

- Defined by The American Society of Health-System Pharmacists (ASHP) as any unexpected, unintended, undesired, or excessive response to a drug that:
- Requires discontinuing the drug (therapeutic or diagnostic), or
- Requires changing the drug therapy, or
- Requires modifying the dose (except for minor dosage adjustments), or
- Necessitates admission to a hospital, or
- Prolongs stay in a health care facility, or
- Necessitates supportive treatment significantly complicates diagnosis, or
- Negatively affects prognosis, or
- Results in temporary or permanent harm, disability, or death.