HACKETTSTOWN REGIONAL MEDICAL CENTER
ADMINISTRATIVE POLICY MANUAL

EVENT REPORTING & MANAGEMENT – EXTERNAL AGENCIES

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SCOPE

All departments and services of Hackettstown Regional Medical Center [HRMC]

PURPOSE

To outline the reporting process and types of events that are either reportable to the New Jersey Department of Health and Senior Services or are considered reviewable by The Joint Commission.

POLICY

It is the policy of Hackettstown Regional Medical Center to report events to the New Jersey Department of Health and Senior Services in accordance with *[Hospital Licensing Standards, N.J.A.C. 8:43G:5.6]*, and to comply with the "Patient Safety Act", P.L. 2004,C.9 that establishes a statistically mandated reporting system for certain adverse events that occur in licensed health care facilities.

The Joint Commission will be voluntarily notified of any reviewable sentinel event in order to participate in healthcare quality and patient safety practice improvement.

The Infection Prevention and Control Practitioner will report infectious and communicable diseases in accordance with the requirements of N.J.A.C. 8:57-1 et seq.

PROCEDURE

I. Operational Events (reportable, but NOT subject to the NJ Patient Safety Act):

A. The Administrative Supervisor will review the circumstances of the event with the Administrator-on-Call to determine if a report is indicated.

The Administrative Supervisor, or designee will:

- Notify the Department of Health and Senior Services [NJDHSS] ***immediately*** **(defined as "no later than 3 hours after discovery of the event")** by telephone at **1-800-792-9770**, followed by any documentation requested by NJDHSS during the telephone report.
- Notify the Administrative Director, Quality & Patient Safety, by e-mail, of any reports made and provide a copy of any documentation exchanged.

B. Events reportable to NJDHSS include, but are not limited to:

Physical Plant and Operational Interruptions – Examples:

- Loss of heat or air conditioning
- Loss or significant reduction of water, electrical power, or any other essential utilities necessary to operation of the facility
- Fires, disasters, or accidents that result in serious injury or death of patients or employees, or in evacuation of patients from all or part of the facility
- A labor stoppage or staffing shortage sufficient to require the temporary closure of a unit or service

Criminal Acts –Actual and Suspected**:**

- All criminal acts or suspected criminal acts that occur within the facility, and pose a danger to the life or safety of patients, staff or members of the public present in the facility, are to be immediately reported to the appropriate police authorities.
- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- Abduction of a patient of any age
- Sexual assault on a patient, staff member, or visitor within or on the grounds of the facility

- Death or significant injury of a patient, staff member, or visitor resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the facility

II. <u>Events Subject to the NJ Patient Safety Act or Joint Commission Review:</u>

A. The Patient Safety Officer and Administrative Director of Quality & Patient Safety must be notified within 5 (five) business days of discovery of any of the events listed in IIB & IIC.

B. Events reportable to NJ Patient Safety Authority include, but are not limited to:

1. Patient death, loss of body part, disability or loss of bodily function lasting more than seven days or still present at discharge, associated with:

- a medication error (such as errors involving the wrong drug, wrong dose, wrong patient or resident, wrong time, wrong rate, wrong preparation, or wrong route of administration);
- a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products;
- labor or delivery in a low-risk pregnancy while in a health care facility (relative to mother);
- hypoglycemia, the onset of which occurs while the patient is being cared for in the health care facility;
- spinal manipulative therapy provided in a health care facility;
- electric shock while being cared for in a health care facility (events involving planned treatments, such as electric countershock (heart stimulation) or elective cardioversion, are excluded);
- incidents 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
- a burn incurred from any source while in a health care facility;
- a fall while in a health care facility;
- the use of restraints or bedrails while in a health care facility;
- use of generally detectable contaminated drugs, medical devices, or biologics provided by the health care facility, regardless of the source of contamination or product ("generally detectable" means capable of being observed with the naked eye or with the use of detection devices in general use);
- the use or function of a medical device in patient or resident care in which the device is used or functions other than as intended, including, but not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators;
- the use of a new or reprocessed single-use device in patient or resident care in which the device is used or functions other than as intended;
- patient elopement

2. Surgery-related events, including, but not limited to:

- surgery initiated (whether or not completed) on a patient that is not consistent with the patient's documented informed consent, including, but not limited to, a surgical procedure intended for a patient "A" that is initiated on the wrong body part of patient "A," and a surgical procedure intended for another patient of the facility, but initiated on patient "A". (excludes emergent situations that occur in the course of surgery and as to which exigency precludes obtaining informed consent;

- retention of a foreign object in a patient after surgery, excluding objects intentionally implanted as part of a planned intervention, objects present prior to surgery that were intentionally retained, and retained broken microneedles;
- intraoperative or post-operative (that is, within 24 hours) coma, death, or other serious preventable adverse event in any patient of an ambulatory surgery facility, in any hospital same-day surgery patient, or in any American Society of Anesthesiologists (ASA) Class I hospital inpatient (includes all patient deaths, coma or other serious preventable adverse events in situations where anesthesia was administered, regardless of whether the planned surgical procedure was carried out)

3. Other:

- death or kernicterus associated with failure to identify and treat hyperbilirubinemia in a neonate while the neonate is a patient in a health care facility;
- stage III or IV pressure ulcers acquired after admission of the patient or resident to a health care facility (progression from stage II to stage III is excluded, provided that stage II was recognized and documented upon admission);
- intravascular air embolism that occurs while the patient or resident is in the facility (does not include deaths or disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism);
- discharge of an infant to the wrong person;
- patient suicide or attempted suicide while in a health care facility

C. Events reviewable by the Joint Commission include, but are not limited to:

- Unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition
- Death or serious illness/injury related to a hospital-acquired infection
- Suicide of any individual receiving care, treatment or services
- Unanticipated death of a full-term infant
- Perinatal death unrelated to a congenital condition in an infant greater than 2,500 grams
- Intrapartum maternal death
- Abduction of any individual receiving care, treatment or services
- Discharge of an infant to the wrong family
- Rape
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities
- Surgical and nonsurgical invasive procedure on the wrong patient, wrong site, or wrong procedure
- Unintended retention of a foreign object in an individual after surgery or other procedure
- Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
- Prolonged fluoroscopy with cumulative dose > 1500 rads to a single field, radiotherapy to the wrong body region, or > 25 percent above the planned radiotherapy dose

IV. Event Responsibilities:

A. Hospital Staff :

a. Notify Security (if appropriate). Security will notify police as needed.
b. Notify the Department Manager or the Administrative Supervisor immediately.
c. Complete an incident report (see incident reporting policy).
d. Report near misses (occurrences that did not, but could have resulted in any of the above noted outcomes) to the Department Manager or Administrative Supervisor

B.) Department Manager/Administrative Supervisor:

a. Immediately notify the Administrator-On-Call and the Patient Safety Officer (Risk Manager)
b. Take any necessary actions to prevent immediate recurrence.
c. Obtain a list of witnesses. (employees, visitors, family members, etc.)
d. Perform brief initial investigation.
e. Immediately secure a copy of the medical record and any equipment involved in the Risk Manager's office.
f. Provide Patient Safety Officer (Risk Manager) with any requested documentation of follow-up by mutually agreed upon date/time. [Example: Incident Investigation for Managers form]

C.) Administrator-On-Call:

a. Notify the President and the Patient Safety Officer (Risk Manager)
b. Include briefing in AOC report to President's Council

D.) Patient Safety Officer (Risk Manager):

a. Secure the medical record.
b. Facilitate a detailed investigation of the occurrence.
c. Notify the insurance carrier and General Counsel.
d. Enter report, and follow-up RCA if required, in NJ Patient Safety Authority database.
d. Coordinate a root cause analysis (RCA) by the Patient Safety Committee within 45 days of knowledge of the incident.
e. Communicate the RCA outcomes and action plan to the appropriate Administrative Directors, hospital staff, and medical staff.

E.) Administrative Director, Quality & Patient Safety:

a. Notify The Joint Commission of a sentinel event in consultation with the President
b. Present findings and action plan from the RCA to the President's Council, Quality & Patient Safety Council, Professional Practice Committee and Governing Board.
c. Complete responsibilities of Patient Safety Officer in his/her absence

DEFINITIONS *(Source "Patient Safety Act", P.L. 2004,C.9, unless otherwise noted)*

Adverse Event: An event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.

Allergic Reaction: An abnormal immune response to a substance or allergen that does not normally cause a reaction and that results in a broad range of inflammatory responses.

1. Allergies are caused by inherited sensitivity or sensitivity acquired over time to a foreign substance.
2. Immediate reactions may be local, such as urticaria, angioedema, or systemic, such as severe bronchial obstruction, vasodilation, pulmonary edema, and shock.

Anonymous: Information is presented in a form and manner that prevents the identification of the person filing the report.

Biologics: Therapeutics and products, including blood and vaccines, derived from living sources (such as humans, animals, and microorganisms).

Disability: A physical or mental impairment that substantially limits one or more major life activities of an individual.

1. A physical impairment is any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary, hemic, lymphatic, skin, and endocrine.
2. A mental impairment is any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities.

Event: A discrete, auditable, and clearly defined occurrence.

Health Care Professional: An individual who, acting within the scope of her or his licensure or certification, provides health care services, and includes, but is not limited to, a physician, dentist, nurse, pharmacist or other health care professional whose professional practice is regulated pursuant to Title 45 of the Revised Statutes.

Health Care System: A licensed health care provider or entity that either owns and operates more than one licensed facility within the State or can document operational control over more than one licensed facility within the State, but is not a management company.

Hyperbilirubinemia: Bilirubin levels greater than 30 milligrams per deciliter

Hypoglycemia: A physiologic state in which the blood sugar falls below 60 milligrams per deciliter and physiological or neurological dysfunction begins.

Informed Consent: A process of communication between a patient and physician that results in the patient's written authorization or agreement to undergo a specific medical intervention.

Kernicterus: The medical condition in which elevated levels of bilirubin cause brain damage.

Low-Risk Pregnancy: A pregnancy in a woman aged 18 through 39, with no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome.

Medical Device: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar article that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease.

Near-Miss:
An occurrence that could have resulted in an adverse event, but the adverse event was prevented.

Neonate: An infant in its first 28 days of life.

Patient Elopement: A situation in which a registered or admitted patient, excluding competent adults, leaves a health care facility without staff being aware that the patient has done so.

Pressure Ulcer: A skin ulcer that develops as a result of pressure on the skin. ("Pressure Ulcer" does not include a skin ulcer that develops as a result of an underlying vascular etiology, including arterial insufficiency, venous insufficiency, and/ or venous hypertension; or that develops as a result of an underlying neuropathy, such as a diabetic neuropathy.)

> Stage II pressure ulcer" means a pressure ulcer resulting in partial-thickness skin loss involving the epidermis or dermis.
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> "Stage III pressure ulcer" means a pressure ulcer resulting in full-thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia.
>
> "Stage IV pressure ulcer" means a pressure ulcer resulting in full-thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structure such as tendon or joint capsules.

Preventable Event: An event that could have been anticipated and prepared against, but occurs because of an error or other system failure.

Root Cause Analysis (RCA): An in-depth analysis of a preventable adverse event that is designed to identify both direct and underlying causes of the event, in order to develop corrective actions that could reduce the potential for similar preventable adverse events in the future.

Sentinel Event: An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response. The terms "sentinel event" and "medical error" are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events. *(Source: jointcommission.org)*

Serious Preventable Adverse Event:
An adverse event that is a preventable event and results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility.

Spinal Manipulative Therapy: All types of manual techniques, including spinal mobilization (movement of a joint within its physiologic range of motion) and manipulation (movement beyond its physiologic range of motion), regardless of their precise anatomic and physiologic focus or their discipline of origin.

Surgery: An invasive operative procedure in which skin or mucous membranes and connective tissue is resected, including minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. Includes a range of dermatological procedures including biopsy, excision and deep cryotherapy for malignant lesions to extensive multi-organ transplant. Surgery begins at point of surgical incision, tissue puncture, or insertion of an instrument into tissues, cavities or organs.Surgery ends after the surgical incision has been closed and operative devices, such as probes, have been removed and counts have concluded, regardless of setting (recovery room or surgical suite.)

Toxic Substance:
A chemical that is present in sufficient concentration to pose a hazard to human health.

REFERENCES:

Patient Safety Plan – AD86
Safe Medical Device Reporting – AD96A
Safe Medical Device Tracking Program – AD96B
Incident Reporting – AD64
Disclosure – AD41
Joint Commission Sentinel Event Policy www.jointcommission.org (accessed 11/2012)

www.lexisnexis.com/hottopics/njcode (accessed 11/2012)
Title 8. Health
Chapter 43E. General licensure procedures and standards applicable to all licensed facilities
Subchapter 10. Patient or resident safety requirements and reportable events
N.J.A.C. 8:43E-10.6 (2012)