Beaumont
HEALTH

Title	Location	Functional Area
Serious Safety Events	**ALL Beaumont Health**	**Administration, Clinical, General**
Policy Owner	Document Type	Effective Date
Pt Safety Officer VP Sys Qual & Pt Safe,Sr Vice President & Chief Quality Officer	**Policy**	**02/23/2016**

I. CORPORATE AUTHORITY

Beaumont Health ("BH") as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., ("Subsidiary Hospitals") establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals' workforces are collectively designated as BH workforce throughout BH policies.

II. PURPOSE AND OBJECTIVE

: This policy establishes standardized guidelines for investigating and responding to serious safety events in an effort to improve the safety of patients, visitors and employees.

III. POLICY STATEMENT

: Beaumont Health (BH) establishes this Serious Safety Event Policy and Procedure to assure serious safety events are promptly identified, investigated, and managed.

IV. DEFINITIONS:

A. **Serious Safety Event (SSE)**, is an unexpected occurrence involving unanticipated death, serious physical or psychological injury, or the risk thereof, not related to the natural course of the patient's illness or underlying condition. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of serious adverse outcome. Serious injury specifically includes loss of limb or major permanent loss of function. Event Taxonomy:
   1. **Sentinel Event (SE):** any case listed in Appendix A. Warrants a Root Cause Analysis (RCA) and system correction
   2. **High Priority Review (HPR):** Other serious events with/without harm but significant risk of harm and/or in judgment of the Serious Safety Event Review Team (SERT) group warrants a Root Cause Analysis (RCA) and system correction.

B. **Other Event:** Cases that meet neither Sentinel Event nor High Priority review status, but are considered high risk. Follow up may include department review, 'go and see's' peer review or others as defined by the SERT.

C. **BH case assignment identification:** SE and HPR cases will be identified in a serial annual taxonomy including site initials, event type, year (last 2 digits) and case number (starts annually with 01). Examples: RO SE 15-01 would be a Royal Oak Sentinel Event, 2015, first case. D HPR 15-02 would indicate Dearborn High Priority Review, 2015, second case. Year will be based on date of event awareness (which may differ from calendar year of event).

D. **Root Cause Analysis (RCA)** is the process for identifying the basic or causal factor(s) that underlie variations in performance including the occurrence or possible occurrence of a SSE.

Beaumont HEALTH

Title	Location	Functional Area
Serious Safety Events	**ALL Beaumont Health**	**Administration, Clinical, General**
Policy Owner	Document Type	Effective Date
Pt Safety Officer VP Sys Qual & Pt Safe,Sr Vice President & Chief Quality Officer	**Policy**	**02/23/2016**

The goal of this process is to evaluate and improve patient care and to reduce morbidity and mortality.

E. **Action Plan** is the product of the RCA, which identifies the risk reduction strategies that the organization intends to implement to reduce the risk of similar events occurring in the future.

F. **Serious Safety Event Review Team (SERT)** is a Beaumont Health clinical team comprising 2 representatives from each hospital. One will be the Physician Patient Safety Officer and the other may be the site CMO, site elected medical staff representative or site Quality and Safety Director. The second representative will be appointed by consensus of hospital and medical staff leaders at the site. The Corporate Patient Safety Officers and a representative from Legal/Risk Management will also serve on the SERT.

V. **PROCEDURE**: The order of procedures listed below is a suggested general guideline recognizing that individual circumstances will factor into the exact order of events.

A. **Stabilize the Patient.** Attend to the immediate needs of the patient.

B. **Immediate Notifications.**
1. Physician
2. Site Chain of Command/Department Supervisor and/or Manager and/or Director
3. The site Quality Director/Patient Safety Director – SSE are investigated principally by Quality/ Patient Safety staff. Investigation will be conducted under the auspices of Quality/Peer Review.
4. The unit manager or impacted department administrator will ensure support is offered to the employees involved in the event (Employee Assistance Program, etc.)
5. The site Quality Director/Patient Safety Director will notify the legal department and administration of the event.
6. The event site will review and consider need for immediate containment notification.

C. **Ongoing Discovery.** The Clinical Manager/Supervisor of the area with support of the Quality and Safety department, will collaborate in the event investigation including, but not limited to, the following:
1. Preservation of evidence, supplies, packaging, equipment, medical record.
2. Direct communication with patient/family in collaboration with physician(s).
3. Interviews with staff, physicians, and other witnesses.
4. Ensure completion of an incident report.

D. **Event Determination.** The site Physician Patient Safety Officer will present cases to the SERT at its weekly meeting including; a brief overview of the case with a synopsis of pertinent elements, status of disclosure, immediate containment actions already in place, and recommended categorization of the case (Sentinel Event, High Priority Review, other). The classification of an event (taxonomy) will be recommended by the site using the system taxonomy model. The SERT will discuss and form consensus on the event categorization,

Beaumont HEALTH

Title	Location	Functional Area
Serious Safety Events	**ALL Beaumont Health**	**Administration, Clinical, General**
Policy Owner	Document Type	Effective Date
Pt Safety Officer VP Sys Qual & Pt Safe,Sr Vice President & Chief Quality Officer	**Policy**	**02/23/2016**

recommend whether disclosure should occur (if not already done) and evaluate risk for the same/similar event at each local site to decide if immediate system countermeasures are needed. Cases for consideration will be brought within a week of event awareness to the SERT for review. In the event of disagreement between the event site and SERT determination, the BH Chief Quality and Safety Officer will have the ultimate decision making authority.

E. **Event Communication.** Following each system SERT session, the site Quality and Patient Safety Director will create a SSE communication to be issued for all serious safety events to defined leadership across Beaumont Health. The communication will be completed by the site responsible party and distributed by the system Quality office within 48 hours of the SERT. This communication will alert the organization to the event, the event taxonomy and any immediate containment actions or education to prevent further harm while the event undergoes root cause analysis. All events will also be shared at the system Quality Leadership Team meeting.

F. **Root Cause Analysis (RCA).** A Root Cause Analysis (RCAs) ordinarily shall be completed within 45 days of event discovery and submitted to the system Quality Office.
   1. The Root Cause Analysis will be led by a clinical member of the site and members will include; impacted clinical area staff (at the site and across system), quality leadership from across the BH sites, staff involved in the event, legal and others as determined by the Clinical and Senior administrative RCA leader.
   2. RCA team members will be identified by the site RCA leader, site P-PSO and site leadership.
   3. A written Action Plan will be developed based on the event analysis and approved by the appropriate department leaders.
   4. Site Quality and Patient Safety staff will record the RCA minutes and maintain the action plan.
   5. The Action Plan developed through the RCA shall be implemented and monitored by the Accountable Party/accountable administrator.
   6. Documentation of the event RCA and action plan will be completed in a defined system wide application. This application will serve as the tool for communication, monitoring and reporting of event actions and performance outcomes.
   7. Cases deemed Sentinel Events will be reported to the Board Quality and Safety Committee. Sentinel Events reported to the board quality committee will meet all CMS and Joint Commission requirements.
   8. The error-reduction strategies created by the root cause analysis team will focus on ensuring the highest level of protection from reoccurrence. (Figure 1)

Beaumont HEALTH

Title	Location	Functional Area
Serious Safety Events	**ALL Beaumont Health**	**Administration, Clinical, General**
Policy Owner	Document Type	Effective Date
Pt Safety Officer VP Sys Qual & Pt Safe,Sr Vice President & Chief Quality Officer	**Policy**	**02/23/2016**

Figure 1.

Rank Order of Error-Reduction Strategies

Score	Error-Reduction Strategy	Power (leverage)
9	Fail-safes and constraints	High
8	Forcing functions	
7	Automation and computerization	
6	Standardization	
5	Redundancies	
4	Reminders and checklists	
3	Rules and policies	
2	Education and information	
1	Suggestions to be more careful or vigilant	Low

Source: ISMP https://www.ismp.org/newsletters/ambulatory/archives/200602_4.asp

G. **Reporting and Tracking.** The site Accountable/responsible party will monitor the effectiveness of each action item as outlined in the action plan. Further action plan monitoring will be determined by the sites based on process improvement performance and outcomes.

H. **External Reporting.** All Sentinel Events will be reported to the Michigan Hospital Association Patient Safety Organization (pending membership)

Appendix A.

Event Type	The Joint Commission defined Sentinel Events	National Quality Forum Serious Reportable Events
The event has resulted in an unanticipated death, major permanent loss of function, or severe temporary harm not related to the natural course of the patient's illness or underlying condition	√	

Beaumont HEALTH

Title	Location	Functional Area
Serious Safety Events	**ALL Beaumont Health**	**Administration, Clinical, General**
Policy Owner	Document Type	Effective Date
Pt Safety Officer VP Sys Qual & Pt Safe,Sr Vice President & Chief Quality Officer	**Policy**	**02/23/2016**

Event Type	**The Joint Commission defined Sentinel Events**	**National Quality Forum Serious Reportable Events**
Suicide (or attempted suicide) of any patient receiving care, treatment and services in a staffed around the-clock care setting or within 72 hours of discharge	√	√
Unanticipated death of a full-term infant	√	
Abduction of any patient receiving care, treatment, and services	√	√
Discharge of an infant to the wrong family (person)	√	√
Rape (Sexual assault on a patient within or on the grounds of a healthcare facility)	√	√
Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)	√	√
Surgical and nonsurgical invasive procedure on the wrong patient, wrong site, or wrong procedure	√	√
Unintended retention of a foreign object in a patient after surgery or other procedure	√	√
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	√	
Any patient death, paralysis, coma, other major permanent loss of function, or severe temporary harm associated with a medication error	√	√
A patient fall that results in death, major permanent loss of function, or severe temporary harm as a direct result of the injuries sustained in the fall	√	√
Assault, homicide, or other crime resulting in patient death, major	√	

Beaumont HEALTH

Title	Location	Functional Area
Serious Safety Events	**ALL Beaumont Health**	**Administration, Clinical, General**
Policy Owner	Document Type	Effective Date
Pt Safety Officer VP Sys Qual & Pt Safe,Sr Vice President & Chief Quality Officer	**Policy**	**02/23/2016**

Event Type	**The Joint Commission defined Sentinel Events**	**National Quality Forum Serious Reportable Events**
permanent loss of function, or severe temporary harm		
Any intrapartum (related to the birth process) maternal death OR Severe maternal morbidity, defined as a patient safety event that occurs intrapartum through the immediate postpartum period (24 hours) that requires the transfusion of four or more units of blood products (fresh frozen plasma, packed red blood cells, whole blood, platelets) and/or admission to the intensive care unit	√	√
Any elopement, that is, unauthorized departure, of a patient from an around-the clock care setting resulting in a temporally related death (suicide, accidental death, or homicide), major permanent loss of function, or severe temporary harm	√	√
Intraoperative or immediately postoperative death in a ASA Class I patient		√
Patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by the healthcare facility		√
Patient death or serious disability 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 disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility		√
Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility		√
Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility *		√

Beaumont HEALTH

Title	Location	Functional Area
Serious Safety Events	**ALL Beaumont Health**	**Administration, Clinical, General**
Policy Owner	Document Type	Effective Date
Pt Safety Officer VP Sys Qual & Pt Safe,Sr Vice President & Chief Quality Officer	**Policy**	**02/23/2016**

Event Type	**The Joint Commission defined Sentinel Events**	**National Quality Forum Serious Reportable Events**
Patient death or serious disability due to spinal manipulative therapy		√
Artificial insemination with the wrong donor sperm or wrong egg		√
Patient death or serious disability associated with an electric shock while being cared for in a healthcare 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 healthcare facility		√
death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility		√
Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider		√
Death or significant 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 facility		√

*Considered a SSE when there is no evidence of an existing pressure ulcer on admission. Annually, each facility will assess the events for trends and opportunities.

Committee Approvals:

QLT (date: 7/5/2015)

Board Quality Committee (date: 7/2015)