**PLAZA COLLEGE**

**HT108 Health Care Data, Indexes and Registries 3 Credits (2 Didactic, 1 Lab)**

**Case Study: Sentinel Event Policy and Procedure Analysis (NEW)**

**Student Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_**

**Domain III:** Informatics, Analytics and Data Use

**SubdomainIII.H*.*1:** Information Integrity and Data Quality

**Competency:** Apply policies and procedures to ensure the accuracy and integrity of health data both internal and external to the health system (BL3)

**Curricular Consideration:**  Disease management process; Quality assessment & improvement (process, collection tools, data analysis, and reporting techniques).

**Domain V:** Compliance

**SubdomainV.A.1:** Regulatory

**Competency:** Analyze policies and procedures to ensure organizational compliance with regulations and standards (BL4)

**Curricular Consideration:** Internal and external standards, regulations, and initiatives; Health Insurance Portability and Accountability Act (HIPAA), The Joint Commission, Quality Integrity Organizations (QUIs), Meaningful Use (MU), risk management, & patient safety.

**Domain VI:** Leadership

**Subdomain VI.C.2:** Work Design and Process Improvement

**Competency:** Identify cost-saving and efficient means of achieving work processes and goals (BL3)

**Curricular Consideration:** Incident response, medical reconciliation, and sentinel events.

**Subdomain VI.C.3:** Work Design and Process Improvement

**Competency:** Utilize data for facility – wide outcomes reporting for quality management and performance improvement (BL3)

**Curricular Consideration:**  Data for outcomes reporting; Continuous Quality Improvement (CQI).

**Objectives:**

1. Identify policies and procedures that ensure compliance with data quality and integrity in the process of quality assessment and improvement (III.H.1- BL3)
2. Examine organizational compliance with regulatory standards as it relates to the Joint Commission and patient safety standards (V.A.1- BL4)
3. Analyze different methods of compliance with Quality Improvement Organizations (V.A.1- P)
4. Identify performance improvement tools used in healthcare to monitor patient performance (VI.C.1- BL3)
5. Utilize data for decision making in the process of performance improvement (VI.C.3- BL3)

**TASKS:**

You are the Quality Assurance/Quality Improvement Director for Plaza Medical Center. As a member of the QA/QI Committee, you have been asked to analyze and recommend improvements to the Sentinel Event Policy, review the Root Cause Analyses and Actions (RCA2) process for its effectiveness, discuss use of the Cause and Effect Diagram (AKA Fishbone diagram) tool which provides leadership a way to explore all the potential factors that may be causing or contributing to a particular problem (effect). In addition, analyze sentinel event data provided by the Joint Commission to identify trend and problem areas to develop strategies or initiatives to address these areas (e.g., education campaign, policy and procedure changes).

* Analyze Sentinel Event policy provided and recommend improvements to Policy
	+ Research at least two other sentinel event policies for comparison.
	+ Discuss importance of timely response to a sentinel event.
	+ Review the Root Cause Analyses and Actions (RCA2) process.
	+ Discuss use of Cause and Effect Diagram (AKA Fishbone diagram) tool.
	+ Locate and analyze sentinel event data published by Joint Commission and recommend quality improvement activities.
		- Hint: https://www.jointcommission.org/sentinel\_event.aspx
* Using Microsoft Word, compose a detailed two page essay double spaced using Times New Roman, size 12 font.
	+ Provide a works cited page with at least five sources.

**Standards:** Students must achieve a minimum of 70%.

**TASKS:**

Analysis of Sentinel Event policy \_\_\_\_\_\_\_/20

Analysis of sentinel event data \_\_\_\_\_\_\_/15

Recommend ways to improve the existing policy \_\_\_\_\_\_\_/15

Discuss the Root Cause Analyses and Actions (RCA2) process \_\_\_\_\_\_\_/15

Discuss use of Cause and Effect Diagram tool \_\_\_\_\_\_\_/15

Recognize the goal and focus of health care institutions policy \_\_\_\_\_\_\_/10

Give examples of Sentinel events identified by the TJC \_\_\_\_\_\_\_\_/5

Correct spelling, punctuation, grammar and formatting \_\_\_\_\_\_\_\_/5

Total Points: \_\_\_\_\_\_\_/100

**Instructor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| --- | --- | --- |
| **[Hospital Logo]** | [Insert Manual Name]  | No. CO-2.010 |
| Title: Sentinel Event Response and Reporting  | Page: 1 of 9 |
| Origination Date: 02-08-16; 06-19-14; 09-21-12; 06-01-08; 07-22-05; 08-15-02; 08-28-00; 10-01-96 |
| Effective Date: xx-xx-xx |
| Retires Policy Dated: xx-xx-xx |
| Previous Policy Dated: xx-xx-xx |
| Medical Staff Approval Date: xx-xx-xx |
| Hospital Governing Board Approval Date: xx-xx-xx |

1. SCOPE:

**This policy applies to [insert Hospital name] (“Hospital”), its staff, Medical Staff, patients and visitors regardless of service location or category of patient. This policy shall not be used in isolation but as a supplement to the Hospital’s overall Clinical Risk Management/Patient Safety Plan.**

1. PURPOSE:

The purposes of this policy are to:

A. Seek to improve patient care by reviewing and responding to Sentinel Events as set forth by The Joint Commission (TJC) Sentinel Event policy and procedures[[1]](#footnote-1) (see [CO-2.010.01](https://portal.etenet.com/Lists/Policies/CO-2.010.01_TJC-NQF_Reporting_Requirements.docx));

B. Support the improvement of patient safety and quality improvement initiatives by complying with the state-mandated reporting requirements; Hospital will work with Regional Counsel to update policy against state reporting requirements annually (see [CO-2.010.02](https://portal.etenet.com/Lists/Policies/CO-2.010.02_Summary_of_State_Reporting_Requirements.docx));

C. Support patient safety improvement by reviewing any event which meets the description of any one of the National Quality Forum (NQF) Safe Practices[[2]](#footnote-2) (see [CO-2.010.01](https://portal.etenet.com/Lists/Policies/CO-2.010.01_TJC-NQF_Reporting_Requirements.docx)); and

D. Evaluate all TJC reviewable Sentinel Events with Home Office Senior Director of Quality Management and Corporate Regulatory Counsel to determine if a voluntary report shall be made to TJC.

**III. DEFINITIONS:**

* 1. “**Adverse Event**” means an untoward incident, therapeutic misadventure, iatrogenic injury or other unexpected event with the potential for harm that may meet the definition of a Sentinel Event and is directly associated with the care or services provided within the Hospital.
	2. “**Anticipated Outcome**”means the outcome expected from a diagnostic or therapeutic intervention or lack of intervention. This includes the known risks of a treatment or procedure. Anticipated outcomes, including potential adverse anticipated outcomes, such as known risks, shall be disclosed as part of informed consent and ongoing communication by the provider performing the procedure.
	3. “**Care Associated with a Preventable Event**”refers to the care directly related to provider error or process failure which resulted in a Preventable Event with Permanent, Severe Temporary, or Temporary Harm.
	4. “**Disclosure**”means the communication of information regarding the outcome of diagnostic tests, medical treatment, or surgical intervention to a patient and, when appropriate, their families about outcomes of care, including preventable events resulting in harm/errors.
	5. “**Error**,” as defined byThe Institute of Medicine in 2001, means a failure of a planned action to be completed as intended. Errors are unintended, undesirable, and result from a defect or failure of a diagnostic, therapeutic, or supportive process, at any point in the continuum of care. Errors may be either human or technological. An error may or may not have a negative outcome. Errors may be acts of commission or omission. Many errors are seen as “system” failures, even when it may appear that a single person or device is at fault. Errors shall be reported by using the Patient Safety Reporting System (PSRS) if they :

Require a significant change in further diagnosis or treatment;

Lead to initial or prolonged hospitalization;

Are life threatening;

Result in disability, death, significant cognitive impairment, or congenital abnormality.

* 1. “**Event Report**”means an event report that is completed to document an adverse event or near miss event in the PSRS.
	2. “**Hospital staff**” means the Hospital’s employees, agency staff, contractors and volunteers.
	3. “**Intense** A**nalysis**” means the review process by which all Adverse Events undergo. When events do not meet Sentinel Event criteria for Root Cause Analysis, Intense Analyses can be completed on those events using the Intense Analysis formats available (see Conducting a Root Cause Analysis (RCA) procedure [CO-2.010.03](https://portal.etenet.com/Lists/Policies/CO-2.010.03_Conducting_Root_Cause_Analysis.docx)). Intense assessments shall be conducted in accordance with state peer review, quality assurance, performance improvement or other state statute.
	4. “**Near Miss**” means any event with process variation if reoccurrences would carry a significant chance of a serious adverse outcome.
	5. “**Outcome of Care**”means the result of the performance (or non-performance) of a diagnostic or therapeutic process. Outcomes may be preventable or unpreventable.
	6. “**Preventable Event**” means an outcome that differs significantly from the anticipated result of a treatment or procedure. A Preventable Event resulting in harm associated with the performance of a treatment or procedure may be negative or positive. Negative Preventable Events resulting in harm are usually considered adverse events. They are usually with an error (American Society for Healthcare Risk Management), and they are not necessarily the result of negligence. A Preventable Event resulting in harm may or may not be considered a reviewable Sentinel Event. Known risks without errors that are common to a procedure do not constitute a Preventable Event resulting in harm or error. Most Preventable Events resulting in harm shall be discussed with the patient; however, those that do not harm the patient and that do not impact current or future patient health care decisions do not need to be disclosed but may be disclosed at the discretion of the responsible health care professional. Preventable Events resulting in harm may involve Hospital staff or physician error in delivery of care and result in patient temporary or significant harm.
	7. “**Root Cause Analysis**” means a process for identifying the base or contributing causal factors that underlie variations in performance associated with Adverse Events, Sentinel Events or Near Misses (see [CO-2.010.03](https://portal.etenet.com/Lists/Policies/CO-2.010.03_Conducting_Root_Cause_Analysis.docx)).
	8. “**Sentinel Event**” is a patient safety event not primarily related to the natural course of the patient’s illness or condition that reaches a patient and results in death, permanent harm, or severe temporary harm. (See also [CO-2.010.01](https://portal.etenet.com/Lists/Policies/CO-2.010.01_TJC-NQF_Reporting_Requirements.docx).) The PSRS is the mechanism for hospital staff member to complete an event report for patient safety events or near misses (See [CO.2008 Event Reporting](https://portal.etenet.com/Lists/Policies/CO-2.008_Event_Reporting.docx)).
	9. “**Permanent Harm**” means death or permanent disability that does not allow a patient to return to his/her level of activity that existed prior to the event.
	10. “**Severe Temporary Harm**” is critical, potentially 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, or additional major surgery, procedure, or treatment to resolve the condition.
	11. “**Temporary Harm**” involves limited injury or additional medical treatment needed in response to a preventable event. Patient returns to normal function after a period of time.
	12. “**Unanticipated Outcome**” means an outcome that is not anticipated in the normal course of the patient’s care.
	13. “**Unpreventable Event**” means an outcome that is within the known risks of the procedure and no error is involved in care delivery. Unpreventable events resulting in harm may result in patient temporary or significant harm.
1. POLICY:
2. The Risk Manager shall utilize the patient safety reporting system (PSRS) to identify, address, document and report to their appropriate Supervisor and, Senior Director of Patient Safety/Clinical Risk Management of all potential Sentinel Events. In response to each Sentinel Event, the Hospital shall:
3. timely report the event via the PSRS to the Senior Director of Patient Safety/Clinical Risk Management (see also [CO-2.008 Event Reporting](https://portal.etenet.com/Lists/Policies/CO-2.008_Event_Reporting.docx));
4. conduct a timely, thorough and credible root cause analysis via Root Cause Meetings within 14 days of the event being identified where attendees are multidisciplinary groups (including Medical Staff) based on the event;
5. develop an action plan with measurable intermediate and high strength human factor action items designed to implement improvements to reduce risk;
6. implement those improvements; and
7. monitor the effectiveness of those improvements.

B. Determination of Reporting of Sentinel Events to TJC

The Hospital shall perform a Root Cause Analysis for Sentinel Events and shall evaluate reporting Sentinel Events to TJC after consultation with Home Office Senior Director of Quality Management and Regulatory Counsel.

1. PROCEDURE:

A. Hospital Implementation

The Hospital’s Risk Manager[[3]](#footnote-3)3, Event Manager, or other appropriate person with responsibility for these functions (the “Risk Manager”) shall ensure that the following steps are followed to comply with this policy. Some steps may occur concurrently.

* 1. Complete an Event Report
		1. All Hospital staff are required to report events which reach the level of a Sentinel Event pursuant to the Hospital’s Event Reporting policy (see [CO-2.008 Event Reporting](https://portal.etenet.com/Lists/Policies/CO-2.008_Event_Reporting.docx)).
		2. The Risk Manager shall review all event reports to determine whether they meet the definition of a Sentinel Event.
		3. The Risk Manager shall identify all potential Sentinel Events in the PSRS by completing a Serious Reportable Event cue which shall notify Senior Director of Patient Safety/Clinical Risk Management.
		4. For all potential Sentinel Events and Near Misses, the Risk Manager shall ensure that the PSRS contains a description of the event as well as the date of event and medical record number(s).
		5. For research subjects involved in a serious adverse event (SAE) the Risk Manager is to be notified along with the principle investigator and Home Office Director of Clinical Research. Refer to policy [CO-2.030 Serious Adverse Events Involving Research Patients](https://portal.etenet.com/Lists/Policies/CO-2.030_Serious_Adverse_Events_Involving_Research_Study_Patients.docx).
	2. Report to the Appropriate Person

1. The Risk Manager shall report all potential Sentinel Events to Hospital Administration and the Compliance Officer. The report shall include the following information:

a. Patient name and event date;

b. Description of the event;

c. Current status of the patient and discharge date;

d. If the patient expired, whether the death was related to the natural course of the patient’s underlying condition;

e. If the patient expired, whether the case shall be referred to the medical examiner;

f. Whether notification of the event has been made to the patient and/or family; and

g. Whether the Risk Manager believes that any state or Federal reporting obligations are triggered (*i.e.,* reporting to DHS; reporting restraint deaths to the Centers for Medicare and Medicaid Services (CMS); reporting pursuant to the Safe Medical Devices Act, etc.).

2. The Risk Manager shall also notify:

a. Director of Revenue Analysis (DRA) or designee, to place the bill on hold while the potential Sentinel Event is being investigated as described below;

b. The Litigation Manager or defense counsel as appropriate; and

c. The Hospital’s Regulatory and Regional Counsel as appropriate.

1. Regional Clinical Operations Leadership as appropriate.

D. Complete the Root Cause Analysis and Action Plan

Within fourteen (14) calendar days of the date of event, the Risk Manager shall complete the RCA and human factors based action plan.

* 1. Billing Procedures for Reviewable Sentinel Events

The Risk Manager shall follow the procedures outlined in Bill Hold Process for Possible Preventable Events resulting in harm [CO-2.010.04](https://portal.etenet.com/Lists/Policies/CO-2.010.04_Bill_Hold_Process_for_Possible_Preventable_Events.docx) to update accounts placed on bill hold as required by the notification process (see Subsection V.C.2.c.).

* 1. **Disclose to the Patient/Family**

Patients and, when appropriate, their families, shall be promptly informed about the outcomes of care, including preventable events resulting in harm. All Preventable Events resulting in harm shall be disclosed to the patient. In most cases, the disclosure shall be made in the ordinary course of treatment. The disclosure shall be made as described in Disclosure of Outcomes procedure [CO-2.010.05](https://portal.etenet.com/Lists/Policies/CO-2.010.05_Disclosure_of_Outcomes_to_Patients.docx) if an occurrence that meets Sentinel Event definition and involves error. Near miss events are not included in this disclosure process plan.

* 1. Immediately Review Restraint Deaths

If the potential Sentinel Event involves death in or resulting from restraints (see Clinical Operations policy [CO-4.004 Restraint and Seclusion](https://portal.etenet.com/Lists/Policies/CO-4.004_Restraint_and_Seclusion.docx) to determine reportability based on type of restraint used),

the Hospital’s Risk Manager shall immediately consult with Home Office Senior Director of Quality or Regional Quality Management to determine whether the restraint death requires a report to CMS in accordance with [42 C.F.R. 482.13](http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42:5.0.1.1.1;cc=ecfr#42:5.0.1.1.1.2.4.3).

H. Review Potential Sentinel Events with Regulatory Counsel to Determine State Reporting Obligations

The Risk Manager shall immediately consult with Regulatory Counsel when the Risk Manager believes that state law requires a report of a Sentinel Event.

* 1. Refer the Event to the Appropriate Medical Staff/Nursing Committee

If the Event Report requires physician or nursing review, the Risk Manager shall forward the event information to the appropriate medical staff/nursing review committee for follow-up.

* 1. Responsible Person

The Risk Manager is responsible for ensuring that all individuals adhere to the requirements of this policy, that these procedures are implemented and followed at the Hospital and that instances of non-compliance with this policy are reported to the **[insert title of senior individual with leadership/operational oversight for the area]**.

* 1. Auditing and Monitoring

Audit Services will audit compliance with this policy.

* 1. Enforcement

All employees whose responsibilities are affected by this policy are expected to be familiar with the basic procedures and responsibilities created by this policy. Failure to comply with this policy will be subject to appropriate performance management pursuant to all applicable policies and procedures, including the Medical Staff Bylaws, Rules and Regulations.

1. REFERENCES:

- [The Joint Commission](http://www.jointcommission.org/) (SE Chapter), 2015

- [National Quality Forum Serious Reportable Events, 2012](http://www.qualityforum.org/)

- [Regulatory Compliance policy COMP-RCC 4.21 Internal Reporting of Potential Compliance Issues](https://portal.etenet.com/Lists/Policies/COMP-RCC_4.21_Internal_Reporting_of_Potential_Compliance_Issues.pdf)

- [Payments and Adjustments section, Conifer Standard Tables and Request Forms SharePoint site](https://sharepoint.etenet.com/sites/ConiferIT/ConiferStandardTables/default.aspx)

- [Medicare Conditions of Participation, Patient Rights 42 C.F.R. 482.13](http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42:5.0.1.1.1;cc=ecfr#42:5.0.1.1.1.2.4.3)

- [Centers for Medicare and Medicaid Services website](http://www.cms.gov/)

**-** [Standards of Conduct](https://sharepoint.etenet.com/sites/Compliance/ComplianceCentralForms/Shared%20Documents/Standards%20of%20Conduct/SOC-FINAL-110515.pdf)

- [Quality, Compliance and Ethics Program Charter](https://sharepoint.etenet.com/sites/Compliance/ComplianceCentralForms/Read/Tenet_Quality_Compliance_Ethics_Program_Charter.pdf)

- [CO-2.010.01 The Joint Commission/National Quality Forum Reporting Requirements](https://portal.etenet.com/Lists/Policies/CO-2.010.01_TJC-NQF_Reporting_Requirements.docx)

- [CO-2.010.02 Summary of State Reporting Requirements](https://portal.etenet.com/Lists/Policies/CO-2.010.02_Summary_of_State_Reporting_Requirements.docx)

- [CO-2.010.03 Conducting a Root Cause Analysis (RCA)](https://portal.etenet.com/Lists/Policies/CO-2.010.03_Conducting_Root_Cause_Analysis.docx)

- [CO-2.010.04 Bill Hold Process for Possible Preventable Events Resulting in Harm](https://portal.etenet.com/Lists/Policies/CO-2.010.04_Bill_Hold_Process_for_Possible_Preventable_Events.docx)

- [CO-2.010.05 Disclosure of Outcomes to Patients](https://portal.etenet.com/Lists/Policies/CO-2.010.05_Disclosure_of_Outcomes_to_Patients.docx)

1. TJC Sentinel Event Policies and Procedures are set forth in the Comprehensive Accreditation Manual for Hospitals, Sentinel Events Chapter. [↑](#footnote-ref-1)
2. National Quality Forum Safe Practices are available through the NQF website <http://www.qualityforum.org/> and are summarized on [CO-2.010.01](https://portal.etenet.com/Lists/Policies/CO-2.010.01_TJC-NQF_Reporting_Requirements.docx). [↑](#footnote-ref-2)
3. 3The Hospital’s Patient Safety Officer/Director of Continuous Quality Improvement may also perform the duties of the Risk Manager described in this policy. [↑](#footnote-ref-3)