

**YOUR MEDICAL CENTER
POLICY AND PROCEDURE**

**SUBJECT: PERFORMANCE IMPROVEMENT/QUALITY ASSESSMENT PLAN
SENTINEL EVENTS POLICY**

SUPERSEDES: NONE

NUMBER: 119.08

RECOMMENDATION:

PAGE: 1 of 9

APPROVAL: _____ **EFFECTIVE DATE:** _____

I. POLICY:

- A. YOUR Medical Center is committed to providing quality care to the patients in its community. This commitment is reflected in the Hospital's Performance Improvement/Quality Assessment Plan. It is also evidenced by the Hospital's ongoing and continuous quality improvement efforts and its willingness to devote substantial resources to these efforts.
- B. As part of the Hospital's commitment to quality care, it will take appropriate steps to prevent the occurrence of sentinel events within its facility. The Hospital will also seek to identify all sentinel events that have occurred and conduct a thorough review and root-cause analysis of any such events. Upon the discovery of a sentinel event, the Hospital will conduct a thorough review and analysis of the event and will undertake the necessary steps to eliminate or substantially reduce the likelihood that a similar event will occur in the future.
- C. The Hospital is confident that its existing performance improvement/quality assessment program appropriately outlines a process to identify and remedy sentinel events that might occur. Therefore, all sentinel events shall be reviewed and analyzed as an integral part of the Hospital's Performance Improvement/Quality Assessment Plan.
- D. Although this policy deals exclusively with sentinel events, it is recognized that other serious incidents may occur in the Hospital which may warrant significant review, action, and/or change in the Hospital's protocols and processes. In these situations, the Hospital's performance improvement/quality assessment review process will also be followed.

YOUR MEDICAL CENTER

POLICY AND PROCEDURE

SUBJECT: PERFORMANCE IMPROVEMENT/QUALITY ASSESSMENT PLAN SENTINEL EVENTS POLICY

SUPERSEDES: NONE

NUMBER: 119.08

PAGE: 2 of 9

II. DEFINITIONS

- A. A “sentinel event” is 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 following are also considered sentinel events:
- (1) suicide: patient suicide in a setting where the patient receives around-the-clock care (e.g., hospital, residential treatment center, crisis stabilization center);
 - (2) infant abduction or infant discharge to the wrong family;
 - (3) rape (by another patient or staff);
 - (4) hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; and
 - (5) surgery on the wrong patient or the wrong body part.¹
- B. The phrase “*or the risk thereof*” includes any deviation in the process which carries a significant chance of a serious adverse outcome. (A “near miss” of a sentinel event is also considered to be a sentinel event.)
- C. A “*root-cause analysis*” is a written review and analysis performed to determine the underlying errors, deficiencies and problems in process and procedure that allowed or caused the sentinel event to occur. A root-cause analysis will include a plan for improvement and a mechanism for monitoring the plan for improvement. The JCAHO has requested that root-cause analysis reports be separated into two distinct documents – the review and analysis as one, the plan for improvement as the other. In this Policy, except where described differently, these two documents are together referred to as the

YOUR MEDICAL CENTER POLICY AND PROCEDURE

¹ For other examples of sentinel events, see the attached listing of Examples of Sentinel Events.

**SUBJECT: PERFORMANCE IMPROVEMENT/QUALITY ASSESSMENT PLAN
SENTINEL EVENTS POLICY**

NUMBER: 119.08

SUPERSEDES: NONE

PAGE: 3 of 9

“root-cause analysis” or the “root-cause analysis report.”

- D. “Accreditation Watch” is a term used by the Joint Commission on Accreditation of Healthcare Organizations (“JCAHO”) to indicate that it has placed an accredited health care organization on a monitored status while the organization completes, or permits the JCAHO to review, its root-cause analysis and/or other specified documents concerning the sentinel event.

III. INITIAL REPORTING

- A. All events that are or may be sentinel events must be reported immediately to the Risk Manager. The initial report may be made in person or by telephone. If the Risk Manager determines that the event constitutes a sentinel event, a sentinel event form, including all preliminary findings, will be prepared.
- B. The sentinel event report will be forwarded to the Chief Executive Officer (“CEO”), who shall convene a meeting of the Sentinel Event Task Force, which shall consist of the CEO or a designee, the Chief of Staff, the President of the Medical Staff, and the Director of Quality Services.
- C. The Sentinel Event Task Force shall review all findings and confirm whether a sentinel event has occurred. If a determination is made that a sentinel event has occurred, the CEO shall inform the Chairperson of the Hospital’s Board of Directors.
- D. The Sentinel Event Task Force shall also make a recommendation whether the event should be reported to the JCAHO. The CEO will make the final decision regarding reporting. Any determination to report a sentinel event shall be made in consultation with the Hospital’s legal counsel. No report should be made to the JCAHO unless the sentinel event affects a patient and has involved a death or serious physical or psychological injury not related to the natural course of the patient’s illness or underlying condition and/or is a patient event listed in paragraphs (1) through (5) of Section II A of this policy.

**YOUR MEDICAL CENTER
POLICY AND PROCEDURE**

**SUBJECT: PERFORMANCE IMPROVEMENT/QUALITY ASSESSMENT PLAN
SENTINEL EVENTS POLICY**

NUMBER: 119.08

SUPERSEDES: NONE

PAGE: 4 of 9

- E. Any decision to report a sentinel event shall be made in a timely manner so that the Hospital can report such an event, as required to the JCAHO, within five (5) business days from the date on which the Director of Quality Services first learned of its occurrence. (As used in this Policy, this date is referred to as the date of the known sentinel event.)
- F. The Sentinel Event Task Force may determine at any time in the process that the conduct of a member of the Medical Staff or a hospital employee warrants professional review pursuant to the Hospital's credentialing policy or the applicable human resources policies. If such a review is warranted, it shall also be undertaken consistent with the applicable policies.
- G. It is intended that this policy will complement the credentialing policy and applicable human resources policies. It is further intended that all information gathered through the root-cause analysis will be shared with the appropriate medical staff committee and/or human resources personnel, unless the Sentinel Event Task Force determines that the sharing of information would be inconsistent with this policy or would jeopardize the protections that might otherwise be available for such information.
- H. The CEO shall meet with the Hospital's Director of Marketing/Public Relations regarding all sentinel events. The designation of the Hospital's office spokesperson shall be made at that time to address any public or media questions regarding the event.
- I. The Director of Quality Services/Risk Management shall be responsible for contacting the Hospital's insurance carrier at the appropriate time.
- J. If it is determined that a sentinel event must be reported to any entity including any governmental agency, the Sentinel Event Task Force shall make sure that all such reports are made.

**YOUR MEDICAL CENTER
POLICY AND PROCEDURE**

**SUBJECT: PERFORMANCE IMPROVEMENT/QUALITY ASSESSMENT PLAN
SENTINEL EVENTS POLICY**

NUMBER: 119.08

SUPERSEDES:

PAGE: 5 of 9

IV. PROCEDURE FOR ROOT-CAUSE ANALYSIS

- A. A root-cause analysis shall be performed for all sentinel events regardless of whether a report is filed with the JCAHO.
- B. The Director of Quality Services, in consultation with the other members of the Sentinel Event Task Force, shall assemble a Performance Improvement Team ("PI Team") to perform the root-cause analysis. When the underlying issue is of a clinical nature, at least one of the members of the PI Team shall be a physician. The CEO may request legal counsel to assist the PI Team.
- C. The PI Team will expeditiously undertake a review and analysis of the sentinel event. The review and analysis process may include, but need not be limited to, the following:
 - 1. interviewing all Hospital personnel, including but not limited to medical staff members and Hospital employees, who witnessed or have any knowledge/information regarding the sentinel event;
 - 2. interviewing the physicians involved;
 - 3. inspecting and/or reviewing all relevant material, equipment and devices and securing the same;
 - 4. meeting with and interviewing the patient and/or the family of the affected patient, as appropriate; and
 - 5. reviewing the medical record, the original of which shall be secured.
- D. All root-cause analyses will consider human error, process deficiencies, systems issues, environmental factors, external factors, and leadership issues. As part of the root-cause

**YOUR MEDICAL CENTER
POLICY AND PROCEDURE**

**SUBJECT: PERFORMANCE IMPROVEMENT/QUALITY ASSESSMENT PLAN
SENTINEL EVENTS POLICY**

NUMBER: 119.08

SUPERSEDES: NONE

PAGE: 6 of 9

analysis, the PI Team will conduct a relevant review of the literature. A detailed outline of the issues to be addressed in a root-cause analysis report is attached as Appendix A.

- E. All documents generated as a result of the sentinel event, including but not limited to the initial report and findings and the root-cause analysis report, shall be maintained in a strictly confidential manner.
- F. A root-cause analysis report shall be prepared by the PI Team and forwarded to the CEO. The CEO shall review and discuss the report with the Sentinel Event Task Force, which may be aided in its review by legal counsel.
- G. Root-cause analysis reports shall be managed as follows:
 - 1. If the Hospital has reported the sentinel event to the JCAHO, the root-cause analysis report and action plan must be forwarded by the CEO (or a designee) to the JCAHO within forty-five (45) days from the date of the known sentinel event, or the JCAHO must perform an on-site review of materials in the same time period. The CEO will determine, with the assistance of legal counsel, which of the following alternatives to choose:
 - (i) the root-cause analysis report and action plan are to be sent to the JCAHO, or
 - (ii) the Hospital Representative will hand deliver the Root Cause Analysis and Action Plan Documents to the JCAHO for review and bring these documents back to the hospital the same day.
 - (iii) the Hospital will request the JCAHO to do an on-site review of the root-cause analysis report and the action plan, and other specific materials requested by the JCAHO.
 - (iv) the Hospital will request the JCAHO to do an on site review of the action plan and other specific materials requested by the JCAHO, or

**YOUR MEDICAL CENTER
POLICY AND PROCEDURE**

**SUBJECT: PERFORMANCE IMPROVEMENT/QUALITY ASSESSMENT PLAN
SENTINEL EVENTS POLICY**

- (v) upon execution of appendix D by the CEO, the Hospital will request the JCAHO to do an on-site review without a review of either the root cause analysis or the action plan.
2. If the Hospital has been placed on Accreditation Watch, the root-cause analysis report must be forwarded to the JCAHO or an on-site review by the JCAHO be performed, within fifteen (15) days from the date when Accreditation Watch commenced. The CEO will determine, with the assistance of legal counsel, whether (i) the root-cause analysis report and action plan and are to be sent to the JCAHO; or (ii) a Hospital representative will hand-deliver the action plan documents to the JCAHO for review and bring these documents back to the Hospital the same day; or (iii) the Hospital will request the JCAHO to do an on-site review of either the root-cause analysis and the action plan, or the action plan any other specific materials requested by the JCAHO but not including the root cause analysis; or (iv) upon execution of Appendix D by the CEO, the Hospital will request the JCAHO to do an on-site review without a review of either the root-cause analysis or the action plan.
 3. If the Hospital decides to request that the JCAHO do an on-site review, the request must be received by the JCAHO within thirty (30) days from the date of the known sentinel event.
 4. Documentation supporting the root-cause analysis report must include a description of the process that was followed by the PI Team and the Sentinel Event Task Force and must identify the individuals on both the PI Team and the Sentinel Event Task Force by their position in the Hospital.

V. MONITORING AND COMPLIANCE

Consistent with the Hospital's Performance Improvement/Quality Assessment Plan, the root-cause analysis report shall include recommendations for ongoing monitoring and compliance, including specific time frames for such. The Sentinel Event Task Force shall establish the monitoring and compliance schedule, the protocol, and the procedure for implementation. All monitoring and compliance efforts will be conducted within the larger framework and

YOUR MEDICAL CENTER POLICY AND PROCEDURE

**SUBJECT: PERFORMANCE IMPROVEMENT/QUALITY ASSESSMENT PLAN
SENTINEL EVENTS POLICY**

procedures of the Hospital's performance improvement/quality assessment program.

VI. CONFIDENTIALITY OF FILES RELATING TO THE SENTINEL EVENT

- A. All files and written materials generated as a result of a sentinel event shall be maintained in a confidential manner by the Director of Quality Services, and shall be classified and marked as "Confidential, Peer Review Documents, Protected and Maintained under the Peer Review Statute of Your State." Certain of these documents may also, if applicable, be marked as "Confidential, Attorney Work Product" or "Confidential, Attorney-Client Communication," as directed by the Hospital's legal counsel.

- B. If the Hospital has determined that it must report the sentinel event to the JCAHO, precautions shall be taken to protect the confidentiality of the root-cause analysis report. These precautions shall include, but are not limited to, entering into a confidentiality agreement with the JCAHO and sending the root-cause analysis report to the JCAHO with a detailed cover letter outlining the protections to which they are entitled. A draft confidentiality agreement and cover letter are attached as Appendix B and Appendix C, respectively.

VII. EDUCATION

The Hospital recognizes that the best way to prevent the occurrence of sentinel events is to continuously educate and encourage participation of Hospital employees, medical staff members, administrative staff and the governing Board in the Performance Improvement/Quality Assessment Plan. Educational programs consistent with the existing Performance Improvement/Quality Assessment Plan will be held as appropriate to address performance improvement generally and sentinel events specifically.

**YOUR MEDICAL CENTER
POLICY AND PROCEDURE**

**SUBJECT: PERFORMANCE IMPROVEMENT/QUALITY ASSESSMENT PLAN
SENTINEL EVENTS POLICY**

VIII. AMENDMENTS

This policy may be amended by the Board of Directors on its own motion to reflect changes in applicable law or regulations and to cure ambiguities, formal defects or omissions.

GUIDE TO ROOT-CAUSE ANALYSIS

I. WHAT ARE THE DETAILS OF THE EVENT?

II. WHAT AREA/SERVICE WAS IMPACTED?

III. WHAT ARE THE CAUSES?

A. Human Error

1. What was the error?
2. What human factors contributed to the outcome?

B. Process Deficiency

1. What are the steps in the process?
2. What steps were involved in the event?
3. Was a step missed?
4. Was there a weak step?
5. What can be done to prevent failure at this step?

C. Underlying Systems and Processes

1. Human Resource Issues:
 - a. Is staffing adequate? How does it compare with ideal levels?
 - b. Does planning include contingencies that would deal with reduced staffing levels?
 - c. Are staff properly qualified and currently competent for their responsibilities?
 - d. Is staff performance in the operant process(es) addressed?

- e. Can orientation and in-service training be improved?
- 2. Information Management Issues:
 - a. Is all necessary information available when needed? Accurate? Complete? Unambiguous?
 - b. Is communication among participants adequate?

D. Environmental Factors

- 1. Environmental Management Issues:
 - a. Was the physical environment appropriate for the processes being carried out?
 - b. Are systems in place to identify all possible environmental risks?
 - c. Are emergency and failure-mode responses adequately planned and tested?
- 2. Mechanical Malfunction:
 - a. What malfunctioned?
 - b. What was or could have been done to prevent malfunction?
- 3. Uncontrollable External Factors:
 - a. What are the uncontrollable factors?
 - b. Are they truly beyond the organization's control?
 - c. What steps can be taken to protect against these factors?

E. Role of Leadership

- 1. System wide Culture:
 - a. Is the culture conducive to risk identification and reduction?
 - b. What can be done to improve culture to lead to greater identification and reduction of risk?

2. Encouragement of Communication:

- a. Are there barriers to communication of potential risk factors?
- b. What are the barriers?
- c. How can the barriers be eliminated or reduced?

3. Clear Communication of Priorities:

Is the prevention of adverse outcomes adequately communicated as a high priority?

IV. WHAT ARE THE RISK REDUCTION STRATEGIES?

V. WHAT MEASURES WILL BE TAKEN TO MONITOR COMPLIANCE WITH RISK-REDUCTION STRATEGIES?

- A. Identify person(s) responsible for monitoring compliance.
- B. Include specific time frames for monitoring.

YOUR MEDICAL CENTER

CONFIDENTIALITY AGREEMENT

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has adopted a Sentinel Event Policy, a stated purpose of which is to encourage all accredited organizations to voluntarily report sentinel events that occur in their facilities. A critical part of the JCAHO's Sentinel Event Policy is the performance of a root-cause analysis.

A "root-cause analysis" is a written review and analysis performed to determine the underlying errors, deficiencies and problems in process and procedure that allowed or caused the sentinel event to occur, and also includes a plan for improvement and a mechanism for monitoring the plan for improvement. The JCAHO has requested that root cause analysis reports to be reviewed by the JCAHO be separated into two distinct documents - the review and analysis as one, the plan for improvement as the other. In this Agreement, except where described differently, these two documents are together referred to as the "root-cause analysis" or the "root-cause analysis report".

The JCAHO recognizes that the root-cause analysis and other documents generated as a result of a hospital's review of a sentinel event are integral parts of the performance improvement/quality assessment process and the performance of peer review. As such, the root-cause analysis and other documents generated as a result of the sentinel event are highly confidential. The JCAHO further recognizes the importance of maintaining such documents in a confidential manner

Therefore, the JCAHO agrees to the following:

1. to preserve the confidentiality of the root-cause analysis report and any other information relating to the sentinel event, to the extent allowed by law;
2. to notify YOUR Medical Center prior to the disclosure of the root-cause analysis report and any other information relating to the sentinel event, whether pursuant to a subpoena or otherwise, and to cooperate with any efforts of YOUR Medical Center to contest that disclosure; and
3. to return the root-cause analysis report to YOUR Medical Center as soon as the necessary information has been abstracted from it and the JCAHO has completed its review of the same.

Signature and Title

Date

CONFIDENTIAL

**PEER REVIEW PRIVILEGE
ATTORNEY WORK PRODUCT**

**VIA CERTIFIED MAIL-
RETURN RECEIPT REQUESTED**

DATE

Joint Commission on Accreditation
of Healthcare Organizations
One Renaissance Boulevard
Oakbrook Terrace, IL 60181

Dear _____:

Enclosed please find a Root-Cause Analysis Report prepared by YOUR Medical Center pursuant to the Joint Commission's Sentinel Event Policy. The Report identifies relevant findings, risk-reduction strategies and measurement strategies pertaining to a sentinel event that occurred at the Hospital. It was prepared under the direct supervision of the Sentinel Event Task Force, which includes the Chief of Staff, the President of the Medical Staff, the Director of Quality Services/Risk Management and on which I serve as Chairperson.

The Report is a written review and analysis performed to determine the underlying errors, deficiencies and problems in process and procedure that allowed or caused the sentinel event to occur, and also includes a plan for improvement and a mechanism for monitoring the plan for improvement. We understand that the JCAHO has requested that root-cause analysis reports be separated into two distinct documents – the review and analysis as one and the plan for improvement as the other. In this letter, except where described differently, these two documents are together referred to as the Report.

The report was prepared as part of the Hospital's performance improvement/quality assessment program and its peer review processes. Consistent with its privileged nature, the Hospital has maintained the Report, at all times, in a strictly confidential manner. By providing the JCAHO with a copy of the Report, the Hospital does not intend to compromise the Report's confidentiality or waive any privilege to which the Report is entitled.

C-1

APPENDIX C

PI / WP / 11-98 / MI

The Hospital is forwarding the Report to the JCAHO in reliance on representations that the Report will be kept confidential and that copies of the Report will not be provided to any third party. Along these lines, it is the Hospital's understanding that, in the event the JCAHO receives a subpoena for the Report, it will oppose the subpoena and will notify the Hospital immediately so the Hospital can take appropriate legal action.

It is also the Hospital's understanding that the JCAHO will abstract certain information from the Report for inclusion in its sentinel event database, but that this information will not identify the Hospital. Upon completion of its review, the JCAHO will either return the Report to the Hospital or destroy it. The Hospital is confident that these practices will protect the integrity of the Report as a confidential document and is providing the Report to the JCAHO in reliance on such.

Please feel free to call me if you have any questions or need clarification of any part of the Report. We await your progress report on the enclosed Root-Cause Analysis Report.

Sincerely,

Chief Executive Officer

Enclosure

cc: Chairperson, Board of Directors
Legal Counsel

EXAMPLES OF SENTINEL EVENTS

I. Examples of Sentinel Events That Are Voluntarily Reportable Under the Joint Commission's Sentinel Event Policy

- A. Any patient death, paralysis, coma or other major permanent loss of function associated with a medication error.
- B. Any suicide of a patient in a setting where the patient is housed around-the-clock, including suicides following elopement from such a setting.
- C. Any elopement, i.e., unauthorized departure, of a patient from an around-the-clock care setting resulting in a temporally related death (suicide or homicide) or major permanent loss of function.
- D. Any procedure on the wrong patient, wrong side of the body or wrong organ.
- E. Any intrapartum (related to the birth process) maternal death.
- F. Any perinatal death unrelated to a congenital condition in an infant having a birth weight greater than 2,500 grams.
- G. Assault, homicide or other crime resulting in patient death or major permanent loss of function.
- H. A patient fall that results in death or major permanent loss of function as a direct result of the injuries sustained in the fall.
- I. Hemolytic transfusion reaction involving major blood group incompatibilities.

NOTE: An adverse outcome that is directly related to the natural course of the patient's illness or underlying condition, e.g., terminal illness present at the time of presentation, is not reportable except for suicide in, or following elopement from a 24-hour care setting (see preceding list).

II. Examples of Events That Are not Reportable to the Joint Commission

- A. Any “near miss”
- B. Full return of limb or bodily function to the same level as prior to the adverse event by discharge or within two weeks of the initial loss of said function.
- C. Any sentinel event that has not affected a recipient of care (patient, client, resident).
- D. Medication errors that do not result in death or major permanent loss of function.
- E. Suicide other than in an around-the-clock care setting or following elopement from such a setting.
- F. A death or loss of function following a discharge “against medical advice (AMA)”
- G. Unsuccessful suicide attempts.
- H. Unintentionally retained foreign body without major permanent loss of function.

AFFIRMATION

RESPECTING THE SELECTION OF ALTERNATIVE 4, PROVIDING SENTINEL EVENT-RELATED INFORMATION TO THE JOINT COMMISSION

On behalf of YOUR Medical Center, I hereby affirm that the following specific legal considerations pertaining to the relevant statutes, existing privileges, and case law have been reviewed as the basis for determining the most appropriate alternative available to YOUR Medical Center for sharing sentinel event-related information with the Joint Commission. Specifically, the organization has:

- Identified and reviewed peer review and/or relevant statutes;
- Examined whether its peer review or similar committee, which has prepared or will prepare the root-cause analysis and Improvement Plan in response to a sentinel event as defined by the Joint Commission (collectively "sentinel event response information"), is protected under its state's peer review and/or related state statutes;
- Examined whether sentinel event response information is protected from disclosure under its state's peer review and/or related state statutes as proceedings and/or records of a peer review or similar committee;
- Examined whether sentinel event response information is protected from disclosure under its state's peer review and/or related state statutes as proceedings and/or records of the Joint Commission;
- Examined whether its state's peer review and/or related state statutes permit disclosure of sentinel event response information to the Joint Commission without waiving the protections afforded to peer review materials;

- Examined whether case law in the state addresses any of the specific issues described above;

- Examined whether any risk of waiving legal protections for sentinel event response information can be eliminated or substantially reduced by appointing or designating the Joint Commission (by contract or other means) as a member of, consultant to, or participant in the activities of its peer review or similar committee;

- Examined whether sentinel event response information is protected from disclosure under any common law privilege or principle in its state such as (i) the peer review privilege; (ii) the self-critical analysis privilege; (iii) the work product doctrine; or (iv) the Attorney-Client privilege.

I further affirm that on behalf of YOUR Medical Center, I have considered the Sentinel Event Policy and Alternative 1, Alternative 2, and Alternative 3 (as referenced in the transmittal letter) for providing root-cause analysis and other sentinel event-related information to the Joint Commission and have concluded that use of any of these other alternatives may increase the risk of waiving existing confidentiality protections for this information.

CEO

Date