DEPARTMENT: Risk Management **POLICY:** RM-630

SUBJECT: Sentinel Event

PURPOSE: To establish a sentinel event policy as an integral part of performance improvement and risk management programs at FMDH. It is designed to ensure risk prevention activities are taken in conjunction with peer review and performance improvement activities by the facility in response to a significant or sentinel event.

RESPONSIBILITY: Risk Manager and Organization Wide

DEFINITIONS:

1. A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or major permanent loss of function, 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 change or a serious adverse outcome.

2. Major permanent loss of function not related to the natural course of the patient's illness or underlying condition. Examples of events classified as adverse sentinel events include but are not limited to the following:
    a. Significant medication events and adverse reactions
    b. Confirmed transfusion reaction
    c. Surgery on the wrong patient or body part
    d. Infant abduction or discharge to wrong family
    e. Rape
    f. Death of patient who is restrained or in seclusion

3. Major permanent loss of function is defined as an unanticipated sensory, motor, physiological, or intellectual impairment not present on admission requiring continued treatment or life-style change lasting longer than two weeks.

4. Near Miss is an unplanned event that did not result in injury, illness, or damage - but had the potential to do so. Only a fortunate break in the chain of events prevented an injury, fatality or damage. Although human error is commonly an initiating event, a faulty process or system invariably permits or compounds the harm, and is the focus of improvement. Other familiar terms for these events is a "close call", or in the case of moving objects, "near collision."

5. Root cause analysis (RCA) is the asking "Why," and digging deeper in an event until no additional logical reasons can be identified. It must be "thorough" and "credible." A root cause analysis may be also performed for significant events that affect patient care and/or safety even though they do not meet the definition of a sentinel event.
    a. Thorough: To be thorough, the analysis needs to identify the probable cause, common causes(s), systems, and processes that were involved in the event and potential improvements that can be made to avoid recurrences.
    b. Credible: To be credible the analysis requires consistency with participation of leaders within the organization as well as those closest to the process under review. It focuses primarily on systems and processes, not individual performance.

6. Confidentiality-All proceedings, minutes, records or reports compiled or accumulated to review and evaluate the quality of medical or hospital care, including the identification, investigation, or analysis of a significant or sentinel event, is peer review/performance improvement information. Therefore, all proceedings, minutes, records and reports are to be treated as highly confidential and privileged information.

POLICY: When a sentinel event, or sentinel near miss occurs, staff will notify the Risk Manager, and/or CEO, as soon as possible of the event. All sentinel events or near misses are to be reported using the facility wide Risk Master Incident Report System. If the incident involves a piece of medical equipment, follow the procedures outlined in EOC-550 Safe Medical Device Act (SMDA) policy (located on the HOME Drive). All documentation is to remain confidential (see definition). A Root Cause Analysis (RCA) will be conducted to completely understand the cause behind the event and identify necessary actions to eliminate or mitigate the possibility of a recurrence. Changes in the organization's systems and processes shall be made if warranted on the basis of the RCA findings and if reasonably possible, to reduce the probability of such an event occurring again.

All patient, staff, and medical staff identifiers will be removed from the Root Cause Analysis and action plan as to preserve and protect information from discovery in possible future litigation and unauthorized disclosure under state and federal law.

All requests to copy, review, or remove sentinel event-related materials by independent third-parties, including licensing, accrediting and other governmental agencies, shall be pre-approved for release by the CEO.

Center for Medicare Services will be notified per their hotline (406-444-4193), after being pre-approved for release by the CEO, regarding any patient deaths that occur while a patient is restrained or in seclusion or where it is reasonable to assume that a patient's death is the result of restraint or seclusion.

PROCEDURE: All facility and medical staff members have the responsibility to identify and report any event or concern that may involve an actual or potential risk to patient safety. Significantly severe occurrences require immediate verbal notification to the Risk Manager, CEO or COO with a written incident report to follow.

1. Identification: When an event is reported, the Risk Manager, in consultation with others, shall determine whether it is a sentinel event as defined in this policy.

2. Notification: The Risk Manager shall immediately notify the Chief Executive Officer (CEO) and the Montana Health Network corporate risk manager of the occurrence of a sentinel event. The CEO shall determine when and how to communicate with the Medical Staff and the Board of Trustees.

3. Intervention: Immediate interventions shall be made to assure the safety of any patients or staff involved.

4. Communication: Disclosure to the relevant parties, such as the patient and/or their family, following the occurrence will be carried out by the most appropriate staff member, based on the situation, and as soon as possible.

5. Support: Emotional support and problem-solving help will be provided to staff involved with a significant or sentinel event, as needed. The MHN Corporate Risk Manager may be summoned to be a part of this support.

6. Coordination: The hospital Risk Manager shall coordinate a RCA by assembling a team to assess the event consisting of individuals closest to the issue and those with decision making authority. The team shall meet and identify changes, either through redesign or development of new systems or processes that would reduce the risk of this type of event from occurring again.

7. Timeline for analysis: The initial fact finding and determination of a sentinel event will be initiated within the first 48 hours of notification. This causal analysis will be completed as soon as possible to obtain an accurate account of events and to preserve any relevant physical evidence. The root cause analysis team shall attempt completion within 30 days.

8. Reporting: The Root Cause Analysis (RCA) team shall report the findings and their recommendations for corrective actions and risk reduction strategies to the Quality Assurance Committee (QAC), a subcommittee of the Medical Staff for review and discussion.

9. The RCA Team may need to be established on an ad hoc basis. The team should include staff at all levels closest to the issue(s) involved, those with decision-making authority, and individuals critical to the implementation of potential recommended changes.

10. Follow up and monitoring: The RCA Team will oversee the implementation of any corrective action plan developed. It will determine the appropriate reporting intervals for monitoring the actions and outcomes, with no less than at six and 12 months. At 12 months, the RCA Team/QAC will determine if the action plan can be deemed closed. It must be satisfied that there has been no reoccurrence and that the identified improvements have been adequately addressed.

11. All sentinel events that are caused by a medical device shall also be reported to the Food and Drug Administration per the facility wide Safe Medical Device Act Policy EOC-550. Sentinel events are reported annually to the Board of Trustees on the Environment of Care Committee Annual Evaluation Report.

REVIEW PROCESS:

The review process is scheduled every two years or as necessary. Review will be initiated by the Risk Manager, and will include the Medical Staff/QAC, CEO and Board of Trustees. Document originated 06/27/2007.