PURPOSE:

To define the mechanisms for identification, notification, analysis, evaluation and response to adverse patient events, thereby positively impacting the ongoing improvement of patient care and services.

This policy will provide guidelines for identifying, investigating and addressing unanticipated adverse patient events by way of:

- Assigning responsibility of the management of Level I and Sentinel Events.
- Providing guidance and direction for such investigations.
- Specifying a time frame and action plan for managing Level I and Sentinel Events.

1.0 DEFINITIONS

1.1 Unanticipated Adverse Patient Event: A negative or bad result not related to the natural course of a patient’s illness or underlying medical condition stemming from a diagnostic test, medical treatment or surgical intervention which may or may not result from an error by the healthcare worker.

1.2 Sentinel Event: An unexpected occurrence involving death or serious physical or psychological injury or risk thereof. Serious injury specifically includes loss of limb or permanent loss of use of limb or other function not related to the natural course of the patient’s illness or underlying condition or risk thereof. Also included as a sentinel event are certain harm events. The term “sentinel event” is not synonymous with “medical error”; not all sentinel events occur because of an error and not all errors result in sentinel events. Examples of sentinel events include but are not limited to:

1.2.1 Suicide of a patient in a setting where the patient receives around the clock care or within 72 hours of discharge.

1.2.2 Abduction of a patient receiving care, treatment and services.

1.2.3 Discharge of an infant to the wrong family.

1.2.4 Unanticipated death of a full term infant.

1.2.5 Rape.

1.2.6 Hemolytic blood transfusion reaction involving administration of blood products having major blood group incompatibilities.

1.2.7 Surgery on the wrong patient or wrong body part, or wrong procedure.

1.2.8 Unintended retention of a foreign object in a patient after surgery or procedure.

1.2.9 Severe neonatal hyperbilirubinemia (bilirubin>30 miligrams/ deciliter).
1.2.10  Prolonged fluoroscopy with a cumulative dose > 1500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose.

1.2.11  Rape, assault (leading to death or permanent loss of function), or homicide of a staff member, licensed independent practitioner, visitor or vendor while on site at the health care organization.

1.3  “The risk thereof”: Any process variance for which a recurrence would carry significant chance of serious adverse outcome.

1.4  Level I Adverse Event: An unexpected occurrence related to a patient’s medical treatment and not related to the natural course of the patient’s illness or underlying disease condition that results in death or serious disability. Serious disability is defined as a physical or mental impairment that substantially limits one or more of the major life activities of an individual lasting more than seven days or still present at the time of discharge. This is an event reportable to the Maryland Department of Health and Mental Hygiene (DHMH) Office of Health Care Quality that requires an RCA and/or peer review.

1.5  Level II Adverse Event: An unexpected occurrence related to a patient’s medical treatment and not related to the natural course of the patient’s illness or underlying disease condition that requires a medical intervention to prevent death or serious disability. This is an event that requires an RCA.

2.0  PROCEDURE

2.1  Any and all persons working for or on behalf of Shore Health System will immediately report any such unanticipated adverse patient event by completing an online incident report. Events resulting in a serious adverse outcome to the patient or that may meet the criteria for a Level 1 event or one of the examples of a possible sentinel event should be reported to the Risk Manager and the Administrator on Call by way of the Chain of Command.

2.2  Incident reports are confidential. They should not be copied or circulated without permission from Risk Management. These reports are made pursuant to the evaluations and improvement of quality health care functions set forth in Section 1-401 of the Health Occupations Article of the Annotated Code of Maryland and are intended as a record of a medical review committee as defined in that statute.

2.3  The incident report is not part of the medical record. Documentation about an occurrence and medical intervention should be written in the medical record. However, no statements about completion of an incident report or notification of Risk Management should be mentioned in the medical record.

2.4  The Risk Manager will initiate an investigation of serious adverse events and notify senior leadership of findings as appropriate.
2.4.1 An Adverse Event Administrative “Committee” will be convened by the Chief Medical Officer within 72 hours of receiving the Risk Manager’s report of the event, to determine if the event, based on the Maryland Patient Safety Regulations and the Joint Commission Standards, constituted a Sentinel Event or Level I or II Event.

2.4.2 Core membership of this Adverse Event Administrative Committee (UAEAC) may include:

- Chief Medical Officer
- Chief Nursing Officer
- Patient Safety Officer
- Risk Manager
- Director of Performance Measurement and Improvement

2.5 If the Committee determines that there has been a Sentinel Event, Level One, or Level Two event, the following actions should occur:

2.5.1 As soon as possible after the event, involved persons will ensure that everything possible is being done to provide follow-up care/services to the patient to ensure best possible outcomes for involved patients/staff and/or property.

2.5.2 Obvious system failures will be corrected to mitigate the possibility of reoccurrence.

2.5.3 If Level One, the Office of Health Care Quality will be notified by the Patient Safety Officer, within 5 days of notification of the event by the Risk Manager.

2.5.4 Appropriate members of Administration (including the Chief Executive Officer) and, when applicable, Public/ Media Relations will be informed in order to provide consistent information to appropriate outside parties.

2.5.5 Any regulatory reporting requirements will be followed.

2.5.6 All appropriate information will be documented in the medical record, an online incident report (administrative policy Incident Reporting) will be completed, and other policies will be complied with as required.

2.5.7 Consultations with MMCIP Office of Risk Management, Ethics Committee and other resources will be initiated as needed.

2.5.8 Appropriate evidence will be secured (e.g., video or photographs of location, etc.) or sequestered and preserved (e.g., equipment that may have malfunctioned, physical evidence).

2.5.9 Detailed information will be gathered about the event, including interviews of staff involved in the event, witnesses to the event and experts in the area of focus if necessary.
2.5.10 The confidentiality of circumstances surrounding the incident and the patient will be protected.

2.5.11 Members of the Root Cause Analysis (RCA) team will be identified and a team meeting will be initiated if indicated.

2.5.12 In cases where peer review rather than an RCA is the appropriate action, the event will be referred to the Medical Staff Office.

3.0 ROOT CAUSE ANALYSIS

3.1 The Root Cause Analysis Team will conduct an intensive root cause analysis of the Sentinel Event in compliance with the most recent guidelines from the Joint Commission or of a Level 1 event in compliance with DHMH requirements.

3.2 The root cause analysis and action plan:

3.2.1 Focuses primarily on systems and processes, not individual performance.

3.2.2 Addresses at least the minimum scope of root cause analysis and progresses from common cause to special cause in clinical and operational processes.

3.2.3 Progresses from special causes in clinical processes to common causes in organization processes.

3.2.4 Repeatedly digs deeper by asking "Why"; then when answered, "Why" again, and so on.

3.2.5 Identifies changes which could be made in systems and processes, either through redesign or development of new systems or processes, that would reduce the risk of such events occurring in the future.

3.2.6 Is thorough and credible.

3.2.6.1 To be thorough, the root cause analysis must include:

3.2.6.1.1 A determination of the human and other factors most directly associated with the sentinel event, and the processes and systems related to its occurrence.

3.2.6.1.2 Analysis of the underlying systems and processes through a series of "Why" questions to determine where redesign might reduce risk.

3.2.6.1.3 Identification of risk points and their potential contributions to this type of event.
3.2.6.1.4 A determination of potential improvements in processes or systems that would tend to decrease the likelihood of such events recurring in the future, or a determination, after analysis, that no such improvement opportunities exist.

3.2.6.2 To be **credible**, the root cause analysis must:

3.2.6.2.1 Include participation by the leadership of the organization and by the individuals most closely involved in the processes and systems under review.

3.2.6.2.2 Be internally consistent, that is, not contradict itself or leave obvious questions unanswered.

3.2.6.2.3 Provide an explanation for findings considered as “non-applicable” or “non-contributory” elements.

3.2.6.2.4 Include consideration of any relevant literature.

3.2.7 An action plan will be considered **acceptable** if:

3.2.7.1 It identifies changes that can be implemented to reduce risk or formulates a rationale for not undertaking such changes.

3.2.7.2 Where improvement actions are planned, it identifies who is responsible for implementation, when the action will be implemented, including any pilot testing, and how the effectiveness of the actions will be evaluated.

3.3 Upon determination of the root cause(s) of the event, the RCA team will present its findings to the Patient Safety Committee, Performance Management Committee and Shore Health System Board Patient Safety and Quality Committee.

3.4 RCA team will establish a plan to address identified opportunities for improvement or formulation of a rationale for not undertaking such changes. The plan to address identified opportunities will include time frame, person responsible and criteria to evaluate effectiveness of the actions.

3.5 The Patient Safety Officer will ensure that the RCA is completed within 45 days of notification of the event.

3.6 The Patient Safety Officer will ensure that the completed RCA and action plan is submitted to the Office of Health Care Quality within 60 days of notification of the event.
4.0 RESPONSIBILITIES

4.1 All Shore Health System employees are responsible for incident reporting, elevating potentially serious events via the chain of command and to Risk Management.

4.2 The Risk Manager is responsible for the conduct of the investigation.

4.3 The Patient Safety Officer or the Director of Performance Measurement and Improvement are responsible for chairing the RCA team.

4.4 Required notification of the DHMH Office of Health Care Quality for any Level I event, as described in the Maryland Patient Safety Regulations, is the responsibility of the Patient Safety Officer.

4.5 The Patient Safety Officer or the Director of Performance Measurement and Improvement are responsible for ensuring that the RCA action plan is completed within the assigned time frames by the assigned individuals. A RCA database will be used to track completion of the proposed action items.

Gerard M. Walsh, Chief Operating Officer

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