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Objective:

I. To identify those unexpected occurrences that result in, or present the risk of loss of life or bodily harm, disruption of clinical operations, or threaten the reputation or assets of Tuality Health Alliance (THA) members, physicians, and staff.

II. To encourage and support providers' efforts to develop risk reduction strategies and action plans which include measurement of the effectiveness of processes and system improvements to reduce risk.

III. Attention to and review of such will result in detection, correction, and prevention of errors and adverse variation in system performance. The overall objective of this policy is full discovery and disclosure, free from fear and blame, in order to serve the health and well being of THA members, physicians and staff.

Definition:

An adverse event is any unexpected occurrence involving death or serious physical or psychological injury, or risk thereof. Serious injury specifically includes the loss of limb or function. The phrase "or risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. (Joint Commission January, 2011) These events signal the need for immediate investigation and response.

Policy:

I. THA Medical Management staff will conduct reviews of all identified occurrences of potential adverse events listed below.

II. Clinical information will be reviewed by the Medical Management Manager or designee, and/or Medical Director. All findings will be shared with the THA Quality Management Committee (QMC) and the health care organization where the potential adverse event occurred.

III. Recommendations for root cause analysis and/or corrective action plans will be provided as appropriate.

IV. Once clinical records are received, the adverse event investigation will be completed within a three month period.

V. All individuals engaged in THA's adverse event investigation and review process will agree to maintain the confidentiality of the information with which they review. Staff signs confidentiality statements at the beginning of employment and

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annually. QMC committee members also sign confidentiality statements initially and on an annual basis thereafter.

VI. At a minimum and upon becoming aware; adverse events will be assigned to the appropriate severity levels:
- A. Level One
- B. Level Two
- C. Level Three
- D. Level Four

VII. Level One Adverse Event

A. Level One classification is assigned when it meets the following criteria:
1. Death of a member with a non-terminal diagnosis
2. Unanticipated death of a full term infant
3. Infant abduction
4. Infant discharge to the wrong family
5. Rape of a patient in a 24-hour inpatient setting
6. Hemolytic transfusion reaction involving blood or blood products having major incompatibilities
7. Surgery on the wrong patient
8. Surgery on the wrong body part
9. Suicide of a THA patient while in a 24- hour inpatient setting

B. The following actions will be taken upon identification that a Level 1 Adverse Event has occurred:
1. Medical Management staff will notify the Medical Management Manager and the Medical Director within 24 hours.
2. Within 48 hours, the Medical Management Manager or designee will obtain the name, age and gender of the affected patient, medical record number, the date the event occurred, the facts that led to the identification and classification of the event, the presumptive cause of the event and a summary of actions taken since the event discovery.
3. The Medical Management Manager and or Medical Director will notify the THA COO within 72 hours of identification of the incident.

C. Analysis
1. A thorough analysis to establish the root cause of the event including the identification of the systems or processes that contributed to the event shall be concluded within 45 days of the event date discovery.

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2. A Level 1 event may require a root cause analysis as defined by the Joint Commission (JC). THA will participate in the root cause analysis completed by a contracted facility through their existing quality systems.
3. An immediate corrective action may be necessary to abate any obvious or suspected threat to patient safety or well being.

D. Action Planning and Final Reporting
1. The complete report, signed by the appropriate manager will be presented to the QMC Committee for review, approval and implementation.
2. The Medical Management Manager or designee will provide and send a quarterly summary of the event, findings and actions taken indicating that a thorough and credible review process occurred to the THA Board of Directors via the QMC.
3. State or federal regulatory reporting requirements may apply.
4. Action plans will include measurement of the effectiveness of the process and systems improvements identified to reduce future risk.

VIII. Level Two Adverse Event
A. A Level Two event requires a quality review/investigation and action plan to be completed within 120 calendar days of the event or of the date of the event was discovered when the occurrence meets one or more of the following criteria:
1. The event is associated with a significant adverse deviation from the usual process (es) for providing health care services or managing healthcare operations.
2. Outbreak of an infectious disease of nosocomial origin or a food borne illness within a hospital setting
3. The event or related circumstances evokes actual or threatened adverse media involvement, involvement by the member, family, or representative of the family or media contact to the organization.
4. Internal or external disaster that adversely affects THA operations or requires the activation of the local emergency preparedness and disaster plan.
5. Significant adverse interaction with regulatory or accrediting bodies resulting in significant sanctions (JC validation survey by CMS; an EMTALA investigation, JC unannounced survey for cause).

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C. Notification
The following actions will be taken upon recognition that a Level 2 Adverse Event has occurred:
1. THA staff will notify the Medical Management Manager, the Medical Director or the THA Plan Director.
2. Notification will include the names of all affected patients, facts that led to the identification and classification of the event, and a summary of actions taken since event discovery.

D. Final reporting
1. The completed analysis, summary and action plan shall include a description of the issue, and conclusions and actions taken.
2. The complete report shall be presented to the QMC for approval and implementation. The Medical Management Manager or designee will send a quarterly summary of the event, findings and actions taken to the THA Board.
3. State or federal regulatory reporting requirements may apply.

IX. Level Three Adverse Event
A. Assessment
Criteria for classification of a Level 3 Adverse Event include trends identified through existing reporting, potential quality or safety issues, and/or any other potential issues that were avoided.
1. Readmission within 30 days with the same diagnosis
2. Unplanned return to surgery
3. Severe medication reaction requiring additional treatment

B. Notification and Analysis
1. Identify notification, analysis and prevention strategies through local management structures.
2. Upon analysis, a cluster of Level 3 Adverse Events (cluster is defined as three or more events occurring closely together, usually within a quarter) may result in the change of the Adverse Event to a category 2, depending on the severity and trending nature identified.

C. Action Planning and Final Reporting
1. If strategies require a systems approach and/or additional resources, the QMC will prioritize improvement opportunities.
2. Level 3 Adverse Events do not need to be reported to the QMC unless a cluster of Level 3 Events are deemed to constitute a Level 2 Adverse Event as described above.

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X. Analysis and Action Improvement

A. Performance improvement methods and tools will be utilized to identify root causes or variation or deviation in system performance. The process of analysis will focus primarily on system improvement opportunities and education rather than individual performance.

B. A systems analysis should be performed even when individual performance issues have been identified.

C. Systems and processes to prevent, detect, and correct errors or deviations are priorities that will be implemented.

XI. Confidentiality

Root cause analyses and other analyses conducted under this policy are confidential and privileged quality/peer review documents and must be handled as such under applicable state law. Due to this, such analyses will not be provided to any external agency, unless otherwise required by law.

XII. Level Four

No Adverse Event; care appropriate.

References: 42CFR 438.240(e)(2).
OAR 410-141-0200;
NCQA 2013 HP Standard CR 9 Ongoing Monitoring

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