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Owner	Joseph Higgins: Risk Manager
Area	Risk Management
Applicability	Emerus Corporate Shared Content

Safety Event Reporting and Management

Referece #: 7098

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1. SCOPE

1.1 This policy applies to all health care professionals and staff members of Emerus Management Company ("Company") or for any of its affiliated Joint Venture Facilities or subsidiaries, operated by the Company. Health care professionals include physicians, allied health professionals and other licensed health care professionals. Staff members include all employees, agency personnel, contractors, consultants, students, and volunteers. This Policy provides standard Company guidelines which are superseded by State law to the extent such law is more prescriptive.

Note: Employee work-related injury and **patient grievance** do not fall under this policy. If an employee is involved in a work-related injury, the employee must notify his or her supervisor immediately and the employee must complete an Employee Injury Report in the Patient Safety Reporting System. Anyone receiving a patient complaint or grievance must make a report using the Complaints and Grievances Policy. (Complaints and Grievances Policy 7012).

2. PURPOSE

2.1. To provide a systematic multidisciplinary approach for reporting, investigating and conducting a systematic multidisciplinary Root Cause Analysis for patient safety events and other safety risks in order to achieve and maintain a safe environment for patients, medical staff, visitors, volunteers, and employees. This system-wide program allows Emerus the opportunity to improve patient safety and reduce Adverse Events by utilizing real-time escalation, standard definitions, track and trend events and near-misses, benchmark events across the Company, develop process improvements, and promote best practice.

2.2. Emerus takes the position that Adverse Events are not typically the result of individual misconduct,

but rather system or process failures influenced by the system.

3. DEFINITIONS

3.1. Patient Safety Reporting System, ("PSRS"): An internal electronic safety reporting tool utilized system-wide at all Emerus sites that is used for the purposes of identifying, documenting, and reporting safety events, near-misses, Hazardous Conditions, and Adverse Events while promoting a Just Culture. If the Patient Safety Reporting System is down, then a paper format of event report will be utilized and uploaded in PSRS as soon as practicable.

3.2. Just Culture: A phrase that refers to a way of safety thinking that promotes a questioning attitude, is resistant to complacency, is committed to excellence, and fosters both personal and corporate accountability in safety matters. Key elements of a Just Culture are as follows:

- Promotes a learning environment rather than an environment of blame;
- Establishes individual accountability;
- Does not hold individuals responsible for system failures;
- Promotes a non-punitive (blame-free) culture;
- Supports and encourages a culture of reporting and learning from safety events;
- Ensures open discussion of Adverse Events;
- Commits to improving and implementing change based on pattern and trends;
- Safety Event investigations are fair and free from bias over the outcome of the event or from hindsight bias.

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3.3. Reportable Event: means an event that is not consistent with the routine operation of the Hospital or the routine care of a patient or patients. The potential for accident, injury, illness or property damage commonly referred to as a "Near Miss" is sufficient for an event to be considered a Reportable Event. Reportable Events may or may not result in negative consequences to the patient. Reportable Events may include a system error, or an individual error of judgment of action or inaction. Reportable Events include Hazardous Conditions, Near Miss events, and Adverse Events, which are defined as follows:

3.3.1. Hazardous Condition: Any set of circumstances (exclusive of the disease or condition in which that patient is being treated) that significantly increases the likelihood of a serious adverse outcome. i.e. Environmental hazards, inadequate equipment, lack of resources, etc.

3.3.2. Near Miss Event: Any process variation, occurrence, or set of circumstances that transpired and had the potential to cause harm but did not reach the patient. i.e. Incorrect medication dosage was prepared, but the error was caught prior to administration of medication to the patient.

3.3.3. Adverse Event: Any event that is not consistent with routine patient care or the routine operation of the facility and may adversely affect or threaten to affect the health, life, comfort, or property of a patient, visitor, employee, or independent contractor. Each event is categorized in the PSRS based on the level of impact or severity.

3.3.4 Adverse Event Requiring RCA: a patient safety event (**not primarily related to the natural course of the patient's illness or underlying condition**) that reaches a patient and results in any of the following:

3.3.4.1. Death

3.3.4.2. Severe Harm (regardless of duration of harm)

3.3.4.3. Permanent Harm (regardless of severity of harm)

3.3.4.4. Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the healthcare organization's emergency department

3.3.4.5. Unanticipated death of a full-term infant

3.3.4.6. Homicide of any patient while receiving care, treatment, and services while on site at the organization or while under the care or supervision of the organization

3.3.4.7. Homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization or while providing care of supervision to patients

3.3.4.8. Any intrapartum maternal death

3.3.4.9. Severe maternal morbidity (leading to permanent harm or severe harm)

3.3.4.10. Sexual abuse/assault of any patient receiving care, treatment, and services while on site at the organization or while under the care or supervision of the organization

3.3.4.11. Sexual abuse/assault of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization or while providing care or supervision to patients

3.3.4.12. Physical assault (leading to death, permanent harm, severe harm, or as otherwise determined necessary) of any patient receiving care, treatment, and services while on site at the organization or while under the care or supervision of the organization.

3.3.4.13. Physical assault (leading to death, permanent harm, severe harm or as otherwise determined necessary) of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization or while providing care or supervision to patients

3.3.4.14. Surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong (unintended) procedure for a patient regardless of the type of procedure or the magnitude of the outcome

3.3.4.15. Discharge of an infant to the wrong family

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3.3.4.16. Abduction of any patient receiving care, treatment, and services

3.3.4.17. Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock setting (including the ED), leading to death, permanent harm, or severe harm to the patient or as otherwise determined necessary

3.3.4.18. Administration of blood or blood products having unintended ABO and non-ABO (Rh, Duffy, Kell, Lewis, and other clinically important blood groups) incompatibilities, hemolytic transfusion reactions, or transfusions resulting in death, permanent harm, or severe harm

3.3.4.19. Unintended retention of a foreign object in a patient after an invasive procedure, including surgery

3.3.4.23. Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the organization. To be a Adverse Event, equipment must be in use at the time of the event; staff do not need to be present

3.3.4.24. Fall in a care setting resulting in any of the following:

3.3.4.24.1. Any fracture

3.3.4.24.2. Surgery, casting, or traction

3.3.4.24.3. Required consult/management or comfort care for a neurological (for example, skull fracture, subdural or intracranial hemorrhage) or internal (for example, rib fracture, small liver laceration) injury

3.3.4.24.4. A patient with a coagulopathy who receives blood products as a result of the fall

3.3.4.24.5. Death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall)

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3.4. Level of Impact/ Severity: Each event is classified in the PSRS based on the level of impact or severity.

(Items A - I in the PSRS):

3.4.1. Category 'A' - Unsafe Condition (Non-Event);

3.4.2. Category 'B1' – Near Miss, No Harm, Did Not Reach Patient, Caught by Chance;

3.4.3. Category 'B2' – Near Miss, No Harm, Did Not Reach Patient because of Active Recovery by Caregivers;

3.4.4. Category 'C' – No Harm, Reached Patient, No Monitoring Required;

3.4.5. Category 'D' – No Harm, Reached Patient, Monitoring Required;

3.4.6. Category 'E' – Harm, Temporary, Intervention Needed;

3.4.7. Category 'F' – Harm, Temporary, Hospitalization Needed;

3.4.8. Category 'G' – Harm, Permanent;

3.4.9. Category 'H' – Harm, Permanent, Intervention Required to Sustain Life;

3.4.10. Category 'I' – Death.

3.5. Comprehensive Systematic Analysis : Root Cause Analysis (RCA), which focuses on systems and processes, is the most common form of Comprehensive Systematic Analysis used for identifying the factors that underlie an Adverse Event.

3.6. Action Plan: The product of a Comprehensive Systematic Analysis, which identifies strategies the organization intends to implement in order to reduce the risk of similar events occurring in the future. The Action Plan includes:

3.6.1. Identification of corrective actions to eliminate or control system hazards or vulnerabilities directly related to causal and contributory factors

3.6.2. Responsible owners for implementation

3.6.3. Timelines for completion

3.6.4. Strategies for evaluating the effectiveness of the actions

3.6.5. Strategies for sustaining change

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4. POLICY

4.1. Emerus employees are required to report any, and all, safety events including but not limited to, Adverse Events, Near Miss Events, human errors, existence of Hazardous Conditions and any other related areas for improvement. It is the responsibility of all employees to report such events in the PSRS. Emerus employees ordinarily shall report the event into the PSRS before end of shift and no later than 24 hours following the occurrence of the event.

4.1.1. Emerus employee who witnesses, discovers, or has direct involvement in and/or knowledge of a Reportable Event must complete an Event Report in the PSRS. More than one individual may complete an Event Report concerning the same issue. Hospital medical professionals may complete an Event Report or request that another Hospital employee with direct knowledge of the event complete the form.

4.2. Safety Event Reports are confidential reports utilized for peer/professional review and should never be a part of or be referenced in the patient's medical record.

4.3. Emerus promotes a Just Culture environment that encourages and supports all employees to report safety events, including self-reporting, without concern of repercussion and/or punitive action. No Hospital Staff Member may intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any employee or other individual for reporting, in good faith. In addition, reports may be submitted anonymously to help encourage reporting.

4.4. Exceptions to Just Culture will occur if an individual knowingly or willingly conceals a safety event or hinders a safety investigation, or causes an Adverse Event or commits an unsafe act that results from:

4.4.1. An illegal act;

4.4.2. A breach of confidentiality;

4.4.3. A purposeful or reckless unsafe act;

4.4.4. An act committed under the influence of alcohol, or other substances or involves drug diversion;

4.4.5. A persistent issue not resolved through performance improvement.

Note: If the Event is thought to be the result of a criminal act, a purposefully unsafe act, related to substance abuse by provider or staff, or involves suspected abuse of any kind, immediately notify the appropriate local and corporate leaders and the Legal Department, regardless of whether the patient has been harmed.

4.5. The Hospital Quality Leader will initiate an immediate investigation and management of the event.

4.6. The Hospital Administrator and Quality Leader will review each event submitted on a routine basis.

4.7. The Hospital Administrator and Quality Leader considers containment actions in collaboration with department and Senior leaders if determined that immediate actions may prevent recurrence.

4.8. The Hospital Administrator and Quality Leader works with accountable leaders to monitor follow-up and ordinarily shall answer these questions for safety events at all severity levels:

4.8.1. What happened?

4.8.2. Why did it happen?

4.8.3. Were there any deviations from policy, guideline, or process?

4.8.4. What changes were made, or actions taken to prevent recurrence?

4.8.5. Was there follow-up with frontline staff?

4.9. The Hospital Administrator and Quality Leader determine if the safety event meets Adverse Event Requiring RCA criteria and initiates notification to appropriate local and corporate leaders, ordinarily within 24 hours. (Attachment: Event Management Algorithm)

4.10. The Quality Leader ensures **all Adverse Events Requiring RCA** complete a thorough Comprehensive Systematic Analysis (for identifying causal and contributory factors) and Action Plan which may take as much as **45 days** depending upon the complexity of the event (date of event) or becoming aware of the event (date of discovery/reported date)

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4.11. DO NOT disclose the Event Report or your hospital's Event investigation to third parties, including but not limited to state or federal investigators, unless you have received prior approval from the Legal Department.

4.12. The *Emerus RCA Workbook* should be used to outline 'what should have happened' compared to 'what actually happened'.

4.13. The Company may voluntarily report the event to DNV, in consultation with the Chief Legal Officer.

4.14. Cooperating in Investigations by State or Federal Authorities While federal and state laws may require investigations into Adverse Events, such laws also often protect quality improvement committee investigations from disclosure in judicial and administrative proceedings. If you are in a state where federal or state surveyors routinely ask for your investigation, show surveyors this policy and be prepared to explain the steps you took to investigate and respond to an event. You may need to prepare an independent report for the government investigator; if so, please call the legal department for advice on protecting the confidentiality of the information and complying with your state's reporting requirements. You may show surveyors aggregate performance improvement data containing no patient specific information (such as statistical data) and a blank copy of the tool or device you use to collect the data (such as this policy and its forms)

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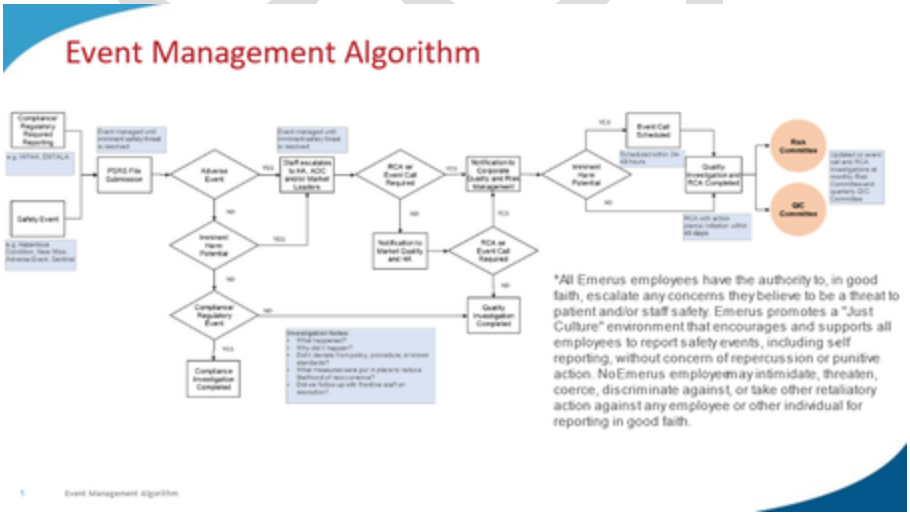
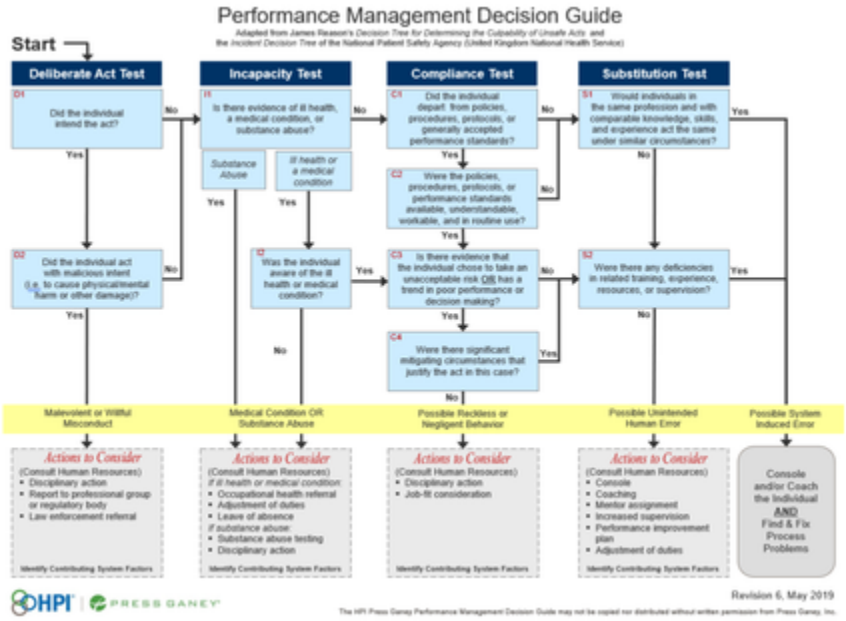
5. ATTACHMENTS

Event Management Algorithm

Performance Management Decision Guide





Attachments

[Event Management Algorithm]

[Performance Management Decision Guide]

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Approval Signatures

Step Description	Approver	Date
	David Mitchell: VP, Nursing and Chief Nursing Officer	12/2023
	Jennifer Atkins: Quality Director	12/2023
	Joseph Higgins: Risk Manager	12/2023

Applicability

AHN Neighborhood Hospital, Ascension Wisconsin Hospital, Baptist Neighborhood Hospital, Baylor Scott & White Emergency Hospital, Dignity Health St. Rose Dominican, Emerus Corporate, Integris Community Hospital, The Hospitals of Providence