RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

# ADMINISTRATIVE POLICY AND PROCEDURE



**Subject:** EVENT REPORTING **Policy No.:** B704

| | | | |
|---|---|---|---|
| Supersedes: | November 1, 2021 | Review Date: | June 30, 2023 |
| Origin Date: | August 1, 1991 | Revision Date: | June 30, 2023 |

**PURPOSE:**
To establish a process of reporting unsafe conditions or events which have or could result in an injury to patient, staff, or visitor.

**POLICY:**
Rancho Los Amigos National Rehabilitation Center (Rancho) encourages and expects workforce members who become aware of an unsafe or potentially unsafe condition involving a person or their environment to ensure safety of person first, notify immediate supervisor, and enter an online event report before the shift ends. This process ensures timely identification and investigation events, and to comply with regulatory or accreditation reporting mandates.

The Risk Manager, or designee, is responsible for reviewing and screening the events reported into the online event notification system to determine if further investigation or follow up is required. The Regulatory/Accreditation Director or designee is responsible for complying with reporting of events to outside agencies. Safety Officer is responsible for reviewing and reporting of Workplace Violence events to outside agency. The location manager is expected to enter a review of the events in their designated areas as soon as possible and without exceeding 45 days.

Participation of all workforce members in reporting events is necessary to enhance a culture of safety. Workforce members may choose to report events anonymously. The goal is to improve patient safety and promote system improvement by identification, evaluation, and correction of events reflecting current and potential issues.

**DEFINITIONS:**
**Error:** The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim with actual or potential negative consequences for the patient.

**Event:** An untoward incident involving a patient, staff, visitor, or an unsafe condition within the jurisdiction of Rancho or the County of Los Angeles, Department of Health Services.

**Near Miss:** An event that did not reach the patient due to the fail safe designed into the process and /or a safeguard worked effectively, or the spontaneous action by the patient, staff, or visitor prevented the event from reaching the patient.

**Permanent Harm**: An event or condition that reaches the individual, resulting in any level of harm that permanently alters and/or affects an individual's baseline health.

**Severe Harm:** An event or condition that reaches the individual, resulting in life-threatening bodily injury (including pain or disfigurement) that interferes with or results in loss of functional ability or quality of life that requires continuous physiological monitoring and/or surgery, invasive procedure, or treatment to resolve the condition.

## I. EVENT TYPES:

**A. Adverse Event:** Any event in which a person receiving care is harmed which is not caused by the patient's underlying disease, not consistent with routine patient care or routine operation of the facility, and which adversely affects or has the potential to affect the health, life, or comfort of the patient.

**REPORTABLE ADVERSE EVENTS also known as "Never 28"**

Health and Safety Code, Section 1279.1

Surgical events, including the following:

1. Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.
2. Surgery performed on the wrong patient.
3. The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery, or a situation that is so urgent as to preclude the obtaining of informed consent.
4. Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.
5. Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

Product or device events, including the following:

6. Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.
7. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.
8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

Patient protection events, including the following:

9. An infant discharged to the wrong person.
10. Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decision making capacity.

11. A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, AFL 07-10 Page 4 July 27, 2007 excluding deaths resulting from self-inflicted injuries that were the reason for admission to the health facility.

Care management events including the following:

12. A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.
13. A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
14. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days post-delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.
15. Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a health facility.
16. Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. For purposes of this subparagraph, "hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.
17. A Stage 3 or 4 ulcer, acquired after admission to a health facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
    *Note:* This includes unstageable ulcer acquired after admission to the facility.
18. A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

Environmental events, including the following:

19. A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric counter shock.
20. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.
21. A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.
22. A patient death associated with a fall while being cared for in a health facility.
23. A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

Criminal events, including the following:

24. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
25. The abduction of a patient of any age.
26. The sexual assault on a patient within or on the grounds of a health facility.
27. The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

28. An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.

B. **Events involving Abuse, Neglect, and Mistreatment:** All workforce members are mandated reporters of suspected child abuse/neglect or elderly/dependent abuse/neglect to outside agencies including law enforcement agency, Child Protective Services, Adult Protect Services, and Ombudsman's Office. Please refer to Policy B708 "Reporting of Known or Suspected Patient Abuse."

Allegation of abuse, neglect, or mistreatment of a patient by Rancho workforce member requires telephone or email notification of Regulatory/Accreditation Director or Risk Manager or designee within 24-hours.

**Abuse** is the *willful* infliction of injury, unreasonable confinement, intimidation or punishment. Refer to Policy B708 "Reporting of Known or Suspected Patient Abuse."

**Neglect** is the failure to provide good and services necessary to avoid physical harm, mental anguish or mental illness.

**Mistreatment** is an action that causes harm or the potential to cause harm whether or not harm to the patient was intended.

C. **Unusual Occurrences:** Title 22, California Code of Regulations, Section 70746 requires hospitals to report to California Department of Public Health (CDPH) "unusual occurrences" that threaten the welfare, safety or health or patients, staff or visitors. Hospital Administrators or designee are responsible for reporting to CDPH. Workforce members shall follow hospital policies and procedures for handling unusual occurrences and shall enter the events on to online event reporting system. Below are examples of reportable "unusual occurrences:"

- Epidemic Outbreaks
- Poisoning
- Fire and Earthquake
- Major accident
- Death from unnatural cause(s) or unusual incident
- Any discontinuance or disruption or services
- Threat of a walkout of a substantial number of employees
- Incident which threaten the welfare, safety or health of patients, staff or visitors

D. **Privacy Breach** is the acquisition, access, use or disclosure of protected health information (PHI) in a manner not permitted under law and regulations, which compromises the security or privacy of protected health information. This includes inappropriate access, review, or viewing of patient medical information without a direct need for medical diagnosis, treatment, or other lawful use. Inadvertent misdirection within the same facility or health care system within the course of coordinating care or delivering services is not reportable to California Department of Health Services. (CDPH).

E. **Provider Preventable Conditions (PPCs)**--The Federal Affordable Care Act (ACA) requires that providers report all PPCs that are associated with claims for Medicaid (Medi-Cal in California) payment or with courses of treatment furnished to a Medicaid patient for which Medicaid payment would otherwise be available. Workforce members are expected to enter an online event report upon confirmation of any of the following:

- Air embolism

- Blood incompatibility
- Falls and trauma that result in fractures, dislocations, intracranial injuries, crushing injuries, burns and electric shock
- Foreign object retained after surgery
- Iatrogenic pneumothorax with venous catheterization
- Manifestations of poor glycemic control
    - Diabetic ketoacidosis
    - Nonketotic hyperosmolar coma
    - Hypoglycemic coma
    - Secondary diabetes with ketoacidosis
    - Secondary diabetes with hyperosmolarity
- Stage III and IV pressure ulcers
- For non-pediatric/obstetric population, deep vein thrombosis (DVT)/ pulmonary embolism (PE) resulting from:
    - Total knee replacement
    - Hip replacement
- Wrong surgical or other invasive procedure performed on a patient
    - Surgical or other invasive procedure performed on the wrong body part
- Surgical or other invasive procedure performed on the wrong patient

Upon confirmation of events meeting the criteria for PPC reporting, the Infection Control Director or Risk Manager or designee shall notify hospital administrators and shall report the event to the Department of Health Services, Audits and Investigation Division, Occurrence of Provider Preventable Conditions within 5 days. The Risk Manager shall review the online event notification reports for any qualifying PPC event and shall notify appropriate personnel for confirmation. The Infection Control Director shall review hospital acquired infection reports and shall report any cases meeting PPC reporting requirements.

F. **Sentinel Event:** Sentinel events are a subcategory of adverse events. A sentinel event is a patient safety event (not primarily related to the natural course of a patient's illness or underlying condition) that reaches a patient and results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm). Sentinel events also include events that occur during the care and treatment of individuals. Sentinel events require investigation, analysis, and corrective action plan within 45 days. The corrective actions includes measurable outcomes.
Sentinel events include but is not limited to the following list of events:

- 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 health care organization's emergency department (ED)
- Unanticipated death of a full-term infant
- Homicide of any patient receiving care, treatment, and services while on site at the organization or while under the care or supervision of the organization
- Homicide of a staff member, visitor, or vendor while on site at the organization or while providing care or supervision to patients
- Any intrapartum maternal death
- Severe maternal morbidity (leading to permanent harm or severe harm)
- 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

- Sexual abuse/assault of a staff member, visitor, or vendor while on site at the organization or while providing care or supervision to patients
- Physical assault (leading to death, permanent harm, or severe harm) of any patient receiving care, treatment, and services while on site at the organization or while under the care or supervision of the organization
- Physical assault (leading to death, permanent harm, or severe harm) of a staff member, visitor, or vendor while on site at the organization or while providing care or supervision to patients
- 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
- Discharge of an infant to the wrong family
- Abduction of any patient receiving care, treatment, and services
- Any elopement (that is, unauthorized departure) of a patient from a staffed around the-clock care setting (including the ED), leading to death, permanent harm, or severe harm to the patient
- 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§
- Unintended retention of a foreign object in a patient after an invasive procedure, including surgery
- Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
- Fluoroscopy resulting in permanent tissue injury when clinical and technical optimization were not implemented and/or recognized practice parameters were not followed
- Any delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or >25% above the planned radiotherapy dose
- Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the organization. To be considered a sentinel event, equipment must be in use at the time of the event; staff do not need to be present.
- **Fall** in a staffed-around-the-clock care setting or fall in a care setting not staffed around the clock during a time **when staff are present resulting** in any of the following:
    - Any fracture
    - Surgery, casting, or traction
    - 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
    - A patient with coagulopathy who receives blood products as a result of the fall
    - Death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall)

Source: Comprehensive Accreditation Manual for Hospitals "Sentinel Event Policy" Update Effective July 1, 2023

**G. MEDICAL DEVICE OR EQUIPMENT:** The Safe Medical Devices Act Of 1990 requires hospitals to report to MedWatch, incidents involving medical devices that have or may have caused or contributed to the serious injury or death of the patient. Refer to Policy B600 "Medical Device Reporting Process." The facility may also voluntarily report medical device quality issues or concerns to MedWatch. Workforce members are expected to sequester the device or equipment, report the incident to their immediate supervisor, and enter an online event report. The Risk Manager or designee is responsible for notifying hospital

administrators and reporting to MedWatch within 10 days. Bio-Medical Department is responsible for notifying the manufacturer. Device related issues may include:

- Quality, performance, or safety concerns including questionable stability of the medical device
- Defective components
- Poor packaging or labeling
- Therapeutic failures
- Suspected contamination
- Suspected counterfeit product

H. **Workplace Violence:** Title 8, California Code of Regulations, Section 3342 requires hospitals to report and log incidents of "workplace violence" to Cal OSHA. "Workplace violence" is defined as "any act of violence or threat of violence that occurs at the work site" that threatens the welfare, safety or health of employees of a General Acute Care Hospital.

Workforce members are expected to notify their immediate supervisor of any event of "workplace violence." An employee that experienced or witnessed "workplace violence" shall enter the event onto the Safety Intelligence system as soon as possible but no later than the end of their shift. The event should be entered as a "Staff" and designated as "Assault" for event type. The event report should include as much detail as possible.

The Safety Officer or designee is responsible for reviewing "workplace violence" events and reporting to CAL OSHA. Safety Officer shall maintain the "workplace violence log."

**PROCEDURE:**

A. Upon detection of an unsafe or potentially unsafe condition involving a person or environment workforce members shall ensure safety of person first, notify immediate supervisor, and then enter an online event report as soon as possible or before reporting off duty. When there is a doubt if an incident should be reported or not, the expectation is to go ahead and report.

B. Enter an event by logging on to the Rancho intranet site and clicking on the "Event Reporting" icon. Events may be entered anonymously. Information entered shall include but not limited to the following:

1. Name of patient, visitor, or staff affected. If the event pertains to unsafe condition, identify the type of condition.
2. Date and time of the event occurrence and the discovery of the event.
3. Location of the event and/or clinical service.
4. Event type from "drop down arrow" in the system.
5. Harm Score
6. Narrative or summary of the incident. Include event details leading to and after the event.
7. Name of persons knowledgeable about the incident.

C. The primary care physician is responsible for communicating unanticipated outcome of any treatment, procedure, or diagnostic test to the patient or legally authorized representative. Refer to Administrative Policy B518 "Disclosure of Unanticipated Outcomes."

D. The clinician, staff, or designee shall document patient related events or incidents and discussions with the patient into the patient's medical record. The documentation shall include a factually based description of the event. **Entry of events via online event notification system**

**and/ or consultation with Risk Management, Quality Consultants, or Hospital Administration shall NOT be documented in the patient's medical record and shall NOT be included in the discussion with patients.**

E. Notify Risk Management, or Regulatory/Accreditation Director, or Hospital Administrator, or designee via telephone or via email within 24-hours of adverse events, sentinel events, PHI breach, or unusual occurrences including but not limited to allegation of abuse involving workforce member.

F. If the online event notification system is not available, contact Risk Management by phone or via email. The reporter or person knowledgeable about the incident as soon the online event reporting system is available shall enter the event.

G. Online event reporting entries and attachments are privileged and strictly confidential under state law, including Evidence Code Section 1157 relating to medical professional peer review and quality improvement documents and Government Code section 6254 [c] relating to personnel. The following precautions shall be taken to maintain the confidentiality of event entries:

- Do not copy or print online event entry.
- Do not discuss online event entry with patient/family/visitor/or patient's legally authorized representative.
- Do not discuss events or incidents with other workforce members who are not participating in the care of the patient.
- Do not write Event Notification Report completed or reference event report in the medical record.
- Do not write Risk Manager notified/contacted/or consulted in the patient's medical record.

**REPORTING TO OUTSIDE AGENCIES:**

**A. Adverse Events, PHI Breach, Unusual Occurrences and Sentinel Events:**

1. Risk Manager or designee shall notify Regulatory/Accreditation Director and Hospital Administrators upon discovery of a potentially reportable event to outside agency.
2. Location Manager or Area Supervisor or Physician shall initiate the investigation of the suspected event.
3. For events relating to Protected Health Information (PHI) Breach, the HIPAA Coordinator or designee shall coordinate the completion of the investigation.
4. Risk Manager or Regulatory/Accreditation Director, or designee shall provide a summary of the event to the Chief Executive Officer, Chief Medical Officer, Chief Nursing Officer, and Chief Operations Officer for a decision if the event is reportable to CDPH. If there is a disagreement, the Chief Executive Officer shall have the final decision.
5. Regulatory/Accreditation Director or designee shall be responsible for meeting the mandated deadline of reporting to outside agencies. Adverse events are reportable within 5 days of detection and PHI breach is within 15 days. Certain unusual occurrences are reportable within 24 hours. The Joint Commission (TJC) does not require hospitals to report sentinel events to TJC, however the event may be reportable to CDPH.
6. Regulatory/Accreditation Director or Risk Manager, or designee shall send a copy of the report to DHS-QIPS.
7. The Risk Manager or designee is responsible for completing the Corrective Action Plan (CAP) of adverse events reported to CDPH except for hospital acquired pressure injuries.

The completed CAP shall be sent to DHS-QIPS within the 45 days of receiving a Notice to Complete the CAP from DHS-QIPS.

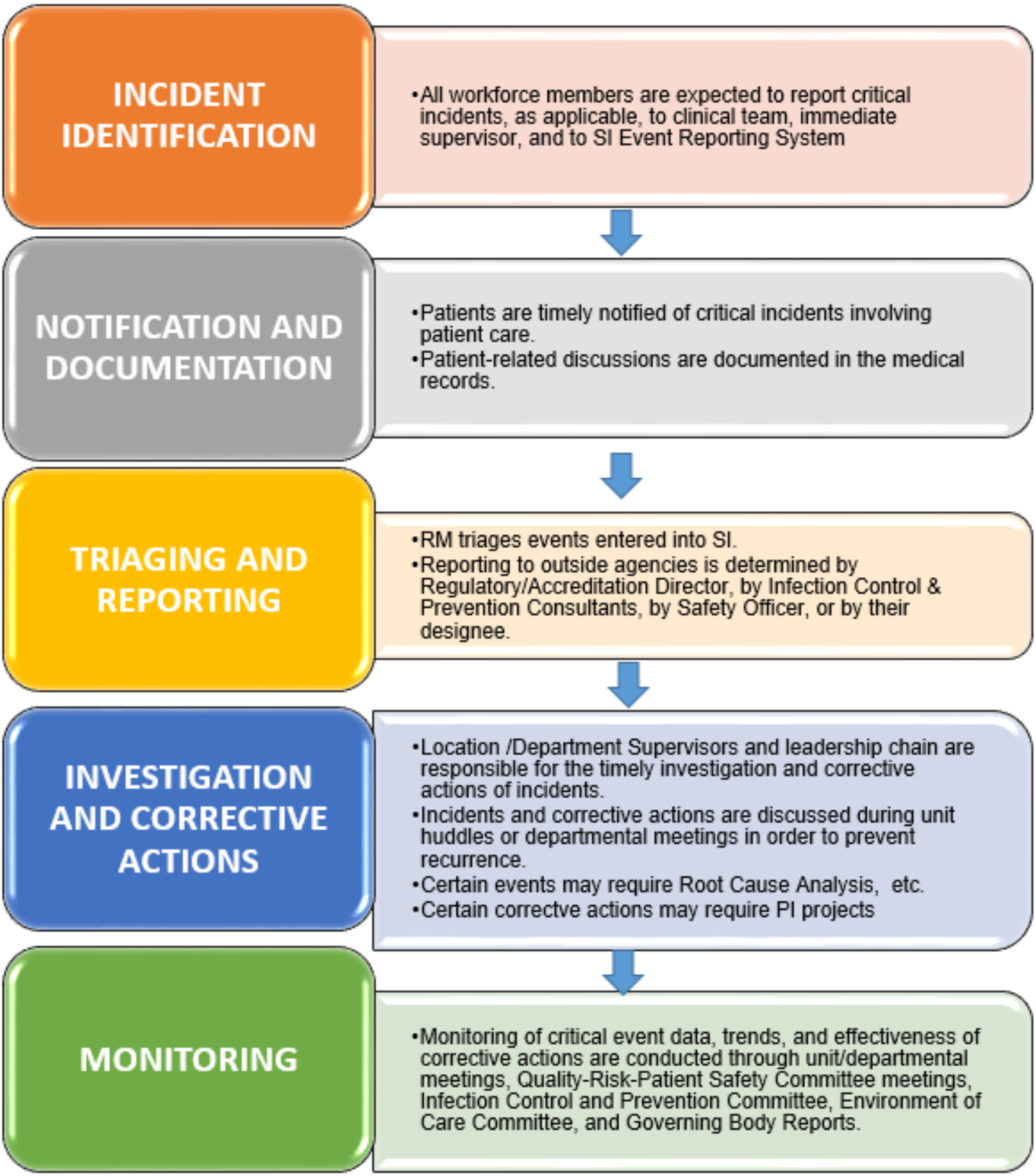
8. The Chief Nursing Officer or designee is responsible for completing the CAP for Hospital Acquired Pressure Injuries (HAPI).
9. Regulatory/Accreditation Director or designee is responsible for record keeping of event documents reported to CDPH and shall coordinate response to CDPH surveyor queries or citations.

**REFERENCES:**
DHS Policy No 311 “Incidents Involving Potential Claims Against the County”
DHS Policy No.311.202 “Adverse Event and Reporting”
Administrative Policy B518 “Disclosure of Unanticipated Outcomes.”
Title 22, California Code of Regulations, Section 70746

**ATTACHMENTS:**
Critical Incidents Algorithm and Crosswalk of Policies and Procedures for Critical Incidents

# CRITICAL INCIDENTS ALGORITHM

**CRITICAL INCIDENTS-- are events that involve harm or injury to patients, staff, or visitors.**



# CROSSWALK OF POLICIES AND PROCEDURES FOR CRITICAL INCIDENTS

| CRITICAL INCIDENTS | POLICY AND PROCEDURES | REPORTING |
|---|---|---|
| Medication error | Admin. B704 "Event Reporting" | • Enter an SI Event Report |
| Incidents involving injury, Aggression or Violence, | Admin. A 258.1 "Workplace Violence Prevention Plan" Workplace Violence Algorithm | • Enter an SI Event Report<br>• Safety Officer to determine if reportable to Cal OSHA |
| Suicide/Suicide attempt, | Admin. B806 "Suicide Risk Assessment and Prevention Plan" | • Enter an SI Event Report<br>• Regulatory/Accreditation Director to determine if reportable to CDPH |
| Sentinel Events | Admin. B704 "Event Reporting" | • Enter an SI Event Report<br>• Regulatory/Accreditation Director to determine if reportable to CDPH |
| Seclusion, Restraint | Admin. B814.2 "Reporting of a Hospital Death Associated with Use of Restraints" | • Enter an SI Event Report<br>• Regulatory/Accreditation Director to determine if reportable to CDPH |
| Communicable Disease, Infection Control | IC 500 "Bioterrorism and Infections Disease Disaster Readiness Infection Control Plan IC 700 "Airborne Transmissible Disease Control Plan" | • Enter an SI Event Report<br>• Infection Control and Prevention staff to determine if reportable to outside agencies |
| Use of unauthorized possession of weapons | Admin. B711 "Code Silver Person With a Weapon Response Plan" | • Enter an SI Event Report<br>• Safety Officer to determine if reportable to Cal OSHA |
| Wandering, Elopement | Admin. B707 "Patient Elopement" | • Enter an SI Event Report<br>• Regulatory/Accreditation Director to determine if reportable to CDPH |
| Vehicular Accidents | Admin. A325 "County Vehicles" | • Enter an SI Event Report<br>• Notify Transportation Department/Facilities Management |
| Biohazard Accidents | Admin. A405 "Hazardous Materials/ Waste Management Program" | • Enter an SI Event Report<br>• Notify Facilities Management |
| Unauthorized possession of legal or illegal substance, Overdose | Admin. B807 "Management of Patient Substance Abuse" | • Enter an SI Event Report |
| Abuse, Neglect, Assault | Admin. B708 "Reporting Known or Alleged Patient Abuse" | • Enter an SI Event Report<br>• Regulatory/Accreditation Director to determine if reportable to CDPH |