LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES
HARBOR-UCLA MEDICAL CENTER

SUBJECT: CRITICAL CLINICAL EVENTS, INCLUDING SENTINEL AND ADVERSE EVENTS, REPORTING AND FOLLOW UP

POLICY NO. 612B

CATEGORY: Safety	**EFFECTIVE DATE:** 3/99
POLICY CONTACT: Lan Soeur, RN	**UPDATE/REVISION DATE:** 10/21
REVIEWED BY COMMITTEE(S): Medicolegal Committee	

PURPOSE:
To ensure that all workforce members report and follow up on all potential or known critical clinical events, including sentinel events and adverse events.

POLICY:
Workforce members shall report all potential or known critical clinical events to the Risk Management department **within 4 hours after discovery of the event.**

All critical clinical events are reviewed by Risk Management to determine if they meet the reviewable sentinel event criteria of the Joint Commission or the adverse event reporting requirements of the California Department of Public Health (CDPH).

DEFINITIONS:

I. **Critical Clinical Event**
An unexpected adverse occurrence (or the risk thereof) that, in the judgment of Risk Management or the Chief Executive Officer, requires immediate investigation. Included in these events are sentinel events and adverse events.

II. **Sentinel Event**
An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Such events are called "sentinel" because they signal the need for immediate investigation and response.

A sentinel event defined by the Joint Commission is 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 death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm), or is one of the events on the Joint Commission's list of specific sentinel events. Events that meet the Joint Commission's definition of sentinel event are subject to review by the Joint Commission.

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APPROVED BY:

Anish Mahajan, MD
Chief Executive Officer

Anish Mahajan, MD
Chief Medical Officer

Joy LaGrone, RN, MSN
Interim Chief Nursing Officer

Note: *severe harm* is defined as 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 or a surgery, invasive procedure, or treatment to resolve the condition.
Note: *permanent harm* is defined as any level of harm that permanently alters and/or affects an individual's baseline.

III. Adverse Event
A patient safety event that resulted in harm to a patient.

Reportable adverse events to CDPH are defined within California Health and Safety Code 1279.1 and are outlined in 7 categories (surgical; product or device; patient protection; care management; environmental; criminal; and an adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor). These events are commonly called "never events" because they are considered serious and preventable errors that should never happen.

IV. Serious Disability
A physical or mental impairment that substantially limits one or more of the major life activities of an individual, or the loss of bodily function, if the impairment or loss lasts more than 7 days or is still present at the time of discharge from the health care facility, or the loss of a body part.
Note: A distinction is made between an adverse outcome that is related to the natural course of the patient's illness or underlying condition (not reportable) and a death or loss of bodily function that is associated with the treatment, or lack of treatment, of the underlying condition (reportable).

Examples of critical clinical events, including those that might meet the criteria of Joint Commission reviewable sentinel events or CDPH reportable adverse events, are listed in Appendix 1.

PROCEDURE:

I. <u>Initial Reporting</u>

A. Timeline to Report
Critical clinical events must be reported to Risk Management **within 4 hours after the discovery of the event**.

Events shall be reported within this time frame even if the information gathering is incomplete.

B. How to Report
Reporting of critical clinical events is accomplished by calling Risk Management and submitting an event report via the Safety Intelligence (SI) system.

Critical events shall also be reported up the chain of command.

1. Call Risk Management at extension 66330 or pager (310) 501-1277 (after-hours).
2. Enter the event into the SI System.
3. Report to immediate supervisor.
4. House Supervisor report to appropriate administrative staff.

II. Initial Investigation

a. Risk Management, or designee, shall immediately begin an investigation and initiate any mitigation actions that may be indicated.
b. Risk Management will determine whether further investigation or follow up is required.

III. Root Cause Analysis (RCA)

a. If Risk Management determines that an event meets the criteria for a sentinel event review (Joint Commission or SB 1301), a root cause analysis and corrective action plan shall be completed within 45 days from the date of the event.
b. Risk Management will determine whether a non-sentinel or non-reportable event requires RCA.
c. The RCA process shall focus on systems and processes to identify the causal and contributory factors.
d. Corrective actions shall be defined and accompanied by planned implementation dates.

IV. External Reporting

All critical clinical events are reviewed by Risk Management to determine if they meet the Joint Commission's reviewable sentinel event criteria or the reporting requirements to CDPH. A summary of the critical clinical event and investigation shall be reported by Risk Management to the Chief Executive Officer, who shall determine whether reporting to any outside departments and/or regulatory agencies is required.

Risk Management will notify the Accreditation and Licensing Officer of any event that requires reporting to CDPH. The Accreditation and Licensing Officer will submit the initial report to CDPH no later than 5 days after the adverse event has been detected; or, if the event is determined to represent an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, the report will be submitted no later than 24 hours after the adverse event has been detected. The report shall be sent concurrently to CDPH, Risk Management, and the DHS Director of Quality Improvement and Patient Safety.

The Accreditation and Licensing Officer will serve as liaison with CDPH during the subsequent investigation process. Disclosure of individually identifiable patient information shall be consistent with applicable law. The facility Accreditation and Licensing Officer will provide Risk Management with copies of all documents submitted to CDPH.

If the facility is uncertain whether an event should be reported to CDPH, the DHS Chief Medical Officer or the DHS Director shall be contacted and a decision to report or not to report to CDPH will be made jointly between the facility and Health Services Administration. If after discussion with Health Services Administration there is still uncertainty about reporting, the facility's General Counsel may be consulted.

V. Disclosure

The patient, or the party responsible for the patient, shall be notified of the nature of the adverse event by the time the report to CDPH is made. Such disclosure shall be reflected in the patient's medical record. The patient or the party responsible for the patient shall **not** be provided with a copy of the SI/CDPH report. These reports should **not** be placed in the patient's medical record.

VI. Reference

Hospital and Medical Administration Policy No. 612A "Event Notification Reports"

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Reviewed and Approved by:
Medical Executive Committee on 10/2021

Beverley A. Petrie

Beverley A. Petrie, M.D.
Professional Staff Association, President

APPENDIX 1

Critical Clinical Events (may be Joint Commission reviewable sentinel events and CDPH reportable adverse events) *:

1. Death, permanent harm, severe temporary harm, or serious disability associated with
   - an adverse medication reaction or medication error
   - a fall while being cared for in the facility
   - the use of restraints or bedrails
   - the use of a contaminated drug, device, or biologic provided by the facility
   - the use or function of a device in which the device is used or functions other than as intended
   - any elopement of a patient
   - an electric shock, excluding events involving planned treatments, such as electric countershock
   - a burn incurred from any source while cared for in the facility
   - intravascular air embolism, excluding deaths associated with neurosurgical procedures
2. Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient
3. Severe maternal morbidity
4. Intrapartum (related to the birth process) maternal death
5. Unanticipated death of a full-term infant
6. Permanent birth/brain injury unrelated to a congenital condition
7. Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
8. Discharge of an infant to the wrong person
9. Development of a neurologic deficit not present on admission, including coma, paralysis, nerve damage, blindness, related or unrelated to a medical or surgical procedure
10. Major permanent loss of function or death directly associated with a Harbor-UCLA health care acquired infection
11. 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
12. Unplanned removal of an organ during surgery
13. Pathology/Tissue mismatch resulting in undiagnosed cancer or delay in diagnosis of cancer
14. Unintended retention of a foreign object in a patient after an invasive procedure, including surgery
15. Procedures performed by unlicensed staff
16. 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 severe temporary harm, permanent harm, or death
17. 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
18. Admission as a result of an adverse occurrence in the outpatient setting
19. Significant equipment-related injury
20. Abduction of any patient receiving care, treatment or services
21. A patient suicide or attempted suicide resulting in serious disability after admission, excluding deaths resulting from self-inflicted injuries that were the reason for admission, or within 72 hours of discharge
22. Sexual abuse/assault, physical assault, or homicide of a patient while receiving care, treatment, and services while on site at the organization/facility or while under the supervision/care of the organization

23. Sexual abuse/assault, physical assault, or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization/facility or while providing care/supervision to patients/clients
24. Intrafacility transfers resulting in disability or death
25. Interfacility transfers resulting in disability or death
26. Major disease outbreaks
27. Fluoroscopy resulting in permanent tissue injury when clinical and technical optimization were not implemented and/or recognized practice parameters were not followed
28. Any delivery of radiotherapy to the wrong patient, body region, unintended procedure or > 25% above the planned radiotherapy dose
29. Stage 3 or 4 ulcer acquired after admission, excluding progression from stage 2 to stage 3 if stage 2 was recognized upon admission
30. Death or serious disability due to spinal manipulative therapy performed at the facility
31. 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
32. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
33. Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the hospital
34. Fall in a staffed-around-the-clock 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; or death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall)

***This list is not meant to be all-inclusive.**