COUNTY OF LOS ANGELES **DEPARTMENT OF HEALTH SERVICES**

HARBOR-UCLA MEDICAL CENTER

SUBJECT: CRITICAL CLINICAL AND NEVER EVENTS (INCLUDING SENTINEL EVENT) REPORTING AND FOLLOW-UP **POLICY NO. 612B**

PURPOSE:
To ensure that all workforce members report and follow-up on all potential critical clinical events.

POLICY:
Workforce members shall report all potential critical clinical events to the Office of Risk Management via the Safety Intelligence (SI) system **within 4 hours after discovery of the event**.

All events are reviewed by Risk Management to determine if they meet the reviewable sentinel event criteria of the Joint Commission or the reporting requirements of California Health and Safety Code 1279.1. Risk Management will coordinate an investigation of the source of critical clinical events and initiate any mitigation actions that may be indicated. Critical events that are reviewable by Joint Commission require a root-cause analysis.

DEFINITIONS:

I. Critical Clinical Event
A critical clinical event is an unexpected adverse occurrence (or the risk thereof) that, in the judgment of the Chief Medical Officer or Hospital Risk Manager, requires immediate investigation.

II. Joint Commission Reviewable Sentinel Events
Joint Commission-reviewable sentinel events are:

Critical clinical events that result in unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition.
Note: Major permanent loss of function means a sensory, motor, physiologic, or intellectual impairment that is not present on admission and that requires continued treatment or life-style change.

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 considered Joint Commission reviewable sentinel event**) and a death or major permanent loss of function that is associated with the treatment, or lack of treatment, of the underlying condition (Joint Commission **reviewable sentinel event**). Examples of potential critical clinical

EFFECTIVE DATE: 3/1/99 **SUPERSEDES:**
REVISED: 2/04, 3/06, 7/07, 8/11, 5/14, 2/15, 12/17
REVIEWED: 2/02, 2/04, 7/11, 5/14, 2/15, 12/17
REVIEWED COMMITTEE: Medical Executive Committee

APPROVED BY:

Kim McKenzie, RN, MSN, CPHQ
Chief Executive Officer

Anish Mahajan, MD
Chief Medical Officer

Patricia Soltero Sanchez, RN, BSN, MAOM
Chief Nursing Officer

Signature(s) on File.

events including those that might meet the criteria as a Joint Commission reviewable sentinel event are included in Appendix 1.

III. Never Events are specific to the California Health and Safety Code 1279.1 and are outlined in 7 categories (surgical; product or device; patient protection; care management; environmental; criminal; and other events that cause the death or serious disability of a patient, personnel, or visitor). These events include the entire Joint Commission reviewable sentinel events in addition to the other events listed in Appendix 1.

PROCEDURE:

I. Initial Reporting

A. Timelines

1. Potential or known critical clinical events must be reported **within 4 hours after the discovery of the event**.

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

B. How to Report

Reporting of all events, including critical events, is accomplished by entering the event into the SI online reporting system or by calling the Hospital Risk Manager (ext. 2168).

Critical events resulting in severe injury, death or unexpected outcome to the patient or non-patient shall be reported up the chain of command when the emergency situation is over, if applicable, or within 4 hours as follows:

1. Enter into the SI system
2. **Report** to Risk Management Department at extension 2168
3. Report to immediate supervisor
4. Supervisor to report to appropriate administrative staff.

C. Notification of Facility Accreditation and Licensing Officer

For California Health and Safety Code 1279.1 reportable adverse events, the facility Accreditation and Licensing Officer will be notified of the event by the Hospital Risk Manager.

II. Investigation

A. Initial Investigation

1. The Hospital Risk Manager, Chief Medical Officer or their designee shall immediately begin an initial investigation including a risk management analysis.
2. Upon completion of the preliminary analysis, the facility shall determine whether the event requires an intensive assessment with or without a root-cause analysis investigation.

B. Intensive Assessment

1. The intensive assessment shall reveal that a comprehensive clinical and administrative review of the event has occurred.
2. A root-cause analysis is required on those events defined by the Joint Commission as reviewable sentinel events, and shall be completed within 45 days from the date of first notification of the event.
3. Analysis shall include any contributory factors.
4. Corrective actions shall be defined and accompanied by planned implementation dates.

III. External Reporting

The facility Accreditation and Licensing Officer will submit the initial report to the California Department of Public Health (CDPH) no later than 5 days after the event is discovered. 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 event is discovered. The Accreditation and Licensing Officer will serve as liaison with CDPH during the subsequent investigation process. Disclosure of individually identifiable patient information is permitted and shall be consistent with applicable law.

Critical events and a summary of the intensive assessment shall be reported by Risk Management to the Chief Executive Officer and the Chief Medical Officer, who shall determine whether reporting to any outside departments and/or regulatory agencies is required.

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.

IV. Disclosure of Adverse Event to Patient or Patient's Representative

The patient, or the party responsible for the patient, will 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 report. The report to CDPH should **not** be placed in the patient's medical record but should be retained by the Accreditation and Licensing Officer.

V. Reference

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

APPENDIX 1

Examples of Critical Events (May be Joint Commission reviewable sentinel events and California Health and Safety Code 1279.1 reportable adverse events)

1. An unanticipated death not related to the natural course of the patient's illness or underlying condition*
   Includes, but is not limited to:
   - Any patient death associated with an adverse medication reaction or medication error, fall, or procedure*
   - Intrapartum maternal death related to the birth process*
   - Unanticipated death of a full-term infant*
   - Patient death directly associated with a Harbor-UCLA health care acquired infection*
2. A major permanent loss of function not related to the natural course of the patient's illness or underlying condition*
   Includes, but is not limited to:
   - Development of a neurologic deficit not present on admission, including coma, paralysis, nerve damage, blindness, related or unrelated to a medical or surgical procedure*
   - Adverse medication reaction resulting in permanent disability*
   - Permanent birth/brain injury unrelated to a congenital condition*
   - Major permanent loss of function directly associated with a Harbor-UCLA health care acquired infection*
3. Medical/surgical intervention on the wrong patient, wrong body side or wrong organ*
4. Unplanned removal of an organ during surgery
5. Pathology/Tissue mismatch resulting in undiagnosed cancer or delay in diagnosis of cancer
6. Unplanned foreign bodies left in patients*
7. Procedures performed by unlicensed staff
8. Hemolytic transfusion reactions involving major blood group incompatibility*
9. Accidental burns
10. Admission as a result of an adverse occurrence in the outpatient setting
11. Significant equipment-related injury
12. Abduction of any individual receiving care, treatment or services*****
13. A patient suicide in a setting in which the patient is housed around the clock or within 72 hours of discharge*
14. Discharge of an infant to the wrong person*
15. A patient elopement from an around-the-clock setting, resulting in a temporally related death (suicide or homicide) or major permanent loss of function*
16. Rape by another patient or staff*

17. Staff sexual misconduct with a patient
18. Intra-facility transfers resulting in disability or death
19. Inter-facility transfers resulting in disability or death
20. Major disease outbreaks
21. Unintended retention of a foreign object in an individual after surgery or other procedure*
22. Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)*
23. Prolonged fluoroscopy with cumulative dose >1500 rads to a single field*
24. Any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose*
25. Death or serious disability associated with use of a contaminated drug, device, or biologic provided by the health facility
26. Death or serious disability associated with the use or function of a device in which the device is used or functions other than as intended
27. Death or serious disability associated with intravascular air embolism excluding deaths associated with neurosurgical procedures
28. Death or serious disability associated with patient disappearance for more than 4 hours excluding events involving adults with competency or decision-making capacity
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
31. Death or serious disability associated with an electric shock excluding events involving planned treatments, such as electric countershock
32. 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
33. Death or serious disability associated with a burn incurred from any source while cared for in a health facility
34. Death or serious disability associated with the use of restraints or bedrails
35. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider

*Joint Commission reviewable sentinel event

Reviewed and Approved on behalf of Medical Executive Committee without substantive changes on 12/8/2017:

_____

Brant Putnam, M.D.
Professional Staff Association, President

Signature(s) on File.