LOS ANGELES GENER MEDICAL CENTER POLICY

Subject:	Original Issue Date:	Policy #
EVENT NOTIFICATION GUIDELINES	4/2/85	**300**
	Supersedes: 2/27/23	Effective Date: 4/8/24

Policy Owner(s): Office of Risk Management
Executive Sponsor(s): Chief Medical Director

Departments Consulted:	Reviewed & approved by:	Approved by:
Office of Regulatory Affairs Quality Improvement Patient Safety Nursing Services	Attending Staff Association Executive Committee Senior Executive Officer	(Signature on File) Chief Medical Officer (Signature on File) Chief Executive Officer

PURPOSE

To establish uniform guidelines to promptly identify, evaluate, investigate, and report incidents, events, or injuries that may result in harm or future claims or litigation against Los Angeles County or its workforce members, and to comply with County, State, and Federal laws & regulations for external reporting to the California Department of Public Health (CDPH) Licensing and Certification Program; The Joint Commission; and the Los Angeles County Department of Mental Health Patient Rights' Office as designated LPS facility.

The event notification includes Unsafe Conditions, Near Misses, No-Harm Events, Therapeutic Misadventures, Errors, Adverse Events, Sentinel Events, Critical Clinical Events, Reportable Unusual Occurrences, and patient/family dissatisfaction about the treatment or results of treatment provided.

Event Notification Reports are privileged, confidential communication between the Department, County Counsel, and Third-Party Administrators. At no time should event reports be referenced in the patient's medical record, printed, or copied.

POLICY

In support of its commitment to continuously improve safety and quality of care, the Los Angeles General Medical Center requires that any workforce member who becomes aware of an incident, event, or injury ("event") involving a patient, visitor, or workforce member notifies their direct supervisor and reports the event in the Safety Intelligence (SI) System.

Workforce members cannot be disciplined or retaliated against for reporting an event in good faith.

All events shall be reported even if only partial statements of fact are available at the time of the report. The event must be reported by the end of the shift of occurrence of the event or by the end of the shift when becoming aware of the event.

At no time should the entry of an event be delayed more than 24 hours after the occurrence or awareness of an event.

Events resulting in severe injury or death shall be reported to the Medical Center Office of Risk Management at (323) 409-6657 or (323) 409-4906 (Weekend, holiday, and after-hours operator).

DEFINITIONS

Safety Intelligence (SI) System: Electronic event reporting database maintained by Vizient®, in conjunction with the Los Angeles County Department of Health Services (DHS) for reporting, tracking, and trending patient safety events. The SI System is accessible via the Los Angeles General Medical Center Intranet to all workforce members.

An unsafe condition: A situation or circumstance that has a potential for harm**.**

A near miss (or "close call""): A patient safety event that did not reach the patient**.**

A no-harm event: A patient safety event that reaches the patient but does not cause harm.

Therapeutic Misadventure: An injury or an adverse event caused by medical management rather than by an underlying disease.

Error: Inadvertently doing other than what should have been done: slip, lapse, or mistake, or missed.

Adverse Event: An adverse event is a patient safety event that resulted in harm to a patient. It does not mean that there was an error. These events are commonly called the "Never 28" and are found in Attachment A.

Sentinel Event: 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).
The Joint Commission considers the list of events found in Attachment B, although not comprehensive, to be sentinel events if they occur under any Joint Commission–accredited health care organization.

Critical Clinical Event: An unexpected occurrence that in the judgment of the Chief Executive Officer or designee, Chief Medical Officer, Chief Nursing Officer, Chief Quality Officer, Patient Safety Officer, or Director of Risk Management requires immediate investigation. A list of events, although not comprehensive, is found in Attachment C

Reportable Unusual Occurrence: Title 22 requires general acute care hospitals, acute psychiatric hospitals, and primary care clinics to report any occurrence such as an epidemic outbreak, poisoning, fire, major accident, disaster, other catastrophe, or unusual occurrence which threatens the welfare, safety, or health of patients, personnel, or visitors, as soon as reasonably practicable to CDPH.

Comprehensive Analysis: Comprehensive clinical and administrative review of the factors contributing to the event. It includes development of a corrective action plan that identifies the

issues, actions to be taken to resolve the issues, assigned specific responsibilities, and implementation dates.

Root Cause Analysis and Actions (RCA2). Root cause analysis and actions is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. It includes the following characteristics:

- The analysis focuses primarily on systems and process, not individual performance.
- The analysis progresses from special causes in clinical processes to common causes in organizational processes.
- The analysis exhausts all possibilities until no additional logical answer can be identified.
- The analysis identifies potential improvements in systems and processes (through either redesign or development of new systems or processes) that would tend to decrease the likelihood of such events occurring in the future; or determines that no such improvement opportunities exist.
- The product of the analysis is an action plan that identifies strategies to reduce the risk of similar events occurring in the future and addresses responsibility for implementation, oversight, pilot testing as appropriate, timelines, and methodologies for measuring the effectiveness of the actions.

PROCEDURE

An Event Notification Report shall be submitted for any unforeseen result, whether the treatment has been proper or improper, as defined above.

Managing the Event

- Address the immediate needs of the patient/family.
- Provide support to workforce members involved (refer to the H3 Program).
- Document the event in the patient's medical record identifying the facts as they are known. Do not include interpretations of the event. **Do not reference the completion of a report (SI). Do not reference any discussion with the Office of Risk Management.**
- Continue to communicate with patient/family.

Reporting & Investigation (Section I – Internal Reporting)

All events shall be reported even if only partial statements of fact are available at the time the report is entered.

Disclosure:

The patient or the party responsible for the patient, will be notified of the event. Such disclosure shall be reflected in the patient's record. (DHS Policy No. 311.201; Medical Center ASA 102).

Frontline Reporter (Medical Center Workforce Members)

- The workforce member shall report the event to their immediate supervisor or department head/designee.
- The workforce member shall report the event in the Safety Intelligence (SI) System. For specific directions on how to complete a SI report, please see the Risk Management Website located on the Los Angeles General Medical Center Intranet.
- If access to the SI system is not available, reports are to be manually generated, but must be subsequently entered into the SI system by the reporter or manager. Forward all manual reports to Risk Management within 3 business days.
- The workforce members will participate in the event investigation and may be contacted if additional information and/or follow-up are required.

Manager (Area Manager/Director, Administrator or Designee)

- Reports shall be reviewed by the appropriate Manager for completeness and the need to initiate the external reporting process (Section II). **If the incident resulted in severe injury or death, the Manager shall immediately report the event to the Office of Risk Management at (323) 409-6657 or (323) 409-4906 (after hours pager operator).**
- The Manager Review will take place within 14 days after the event is entered into the SI system.
- The Investigation of the event includes interviews with workforce members and patient/family, Actions/Consultations to other disciplines and ancillary departments, referrals to committees for review, etc.
- The Event Review will be completed within 30 days of the entry of the event and includes follow up and/or corrective actions.
- Follow-up and corrective action documentation on the individual incidents that cannot be entered into the SI system shall be forwarded to The Medical Center Office of Risk Management, as appropriate.
- The manager is responsible for providing feedback to the reporter. In special circumstances, the manager may request the feedback to be given by an alternate administrator or the Office of Risk Management.

Medical Center Office of Risk Management

- Responsible for maintaining the data in the SI system and for the coordination of reports generated from the SI system.
- Reviews all events with harm score greater than 6 within 3 business days.
- Forwards events, as appropriate, to the Quality, Risk, Safety Committee (QRS) and other committees based on the need for more extensive follow up, and to the Office of Regulatory Affairs for external reporting (Section II).
- Alerts Inter care as soon as feasible of those events requiring additional investigation as to possible litigation.

Reporting & Investigation (Section II – External Reporting)

Reporting & Investigation Requirements

Adverse Event: Requires immediate investigation. Based on event, intensive Assessment or RCA[2].

Title 22 requires general acute care hospitals, acute psychiatric hospital, or special hospital to report to the California Department of Public Health (CDPH), any adverse event, as defined, **within 5 days of the event or learning of the event.**

Adverse events that are ongoing urgent or emergent, threatening the welfare, health, or safety of patients, personnel, or visitors, shall be reported to the California Department of Public Health (CDPH) **within 24 hours after the adverse event is detected.**

Sexual assault of a patient, including allegations of sexual assault of a patient, shall be reported to the California Department of Public Health (CDPH) **within 24 hours after detection.**

Adverse Events involving a psychiatric patient require notification to the Los Angeles County Department of Mental Health via the Patients' Rights Office **within 24 hours of occurrence or by the next business day if event occurs on a weekend or holiday**. Events include deaths and critical incidents (suicides, homicides, and physical/emotional abuse, taser use, or serious injury) for patients on LPS Holds.

Reportable Unusual Occurrence: Requires immediate investigation.

Title 22 requires general acute care hospitals, acute psychiatric hospitals, and primary care clinics to report any occurrence such as an epidemic outbreak, poisoning, fire, major accident, disaster, other catastrophe, or unusual occurrence which threatens the welfare, safety, or health of patients, personnel, or visitors, **as soon as reasonably practicable** to CDPH.

Sentinel Event: Requires immediate investigation. The Joint Commission requires an RCA2.

Critical Clinical Event: Requires immediate investigation and**. comprehensive analysis.**

Disclosure: The patient, or the party responsible for the patient, will be notified of the event by the time the report to CDPH/DHS is made. Such disclosure shall be reflected in the patient's record. (DHS Policy No. 311.201; Medical Center ASA 102).
The patient or the party responsible for the patient **shall not be provided** with a copy of the SI/CDPH/DHS reports. **These reports will not be placed in the medical record**.

Reporting

Adverse Events, Reportable Unusual Occurrences, Sentinel Events, and Critical Clinical events should be reported immediately upon discovery of the event, even if the information gathering is incomplete.

Frontline Reporter (Medical Center Workforce Members)

- In addition to following Section I, the workforce member completes the appropriate Reportable Unusual Occurrence Form and submits it to their direct supervisor or designee within 24 hours of occurrence or becoming aware of the incident. The forms include:

    a. MC300 Attachment D - Reportable Unusual Occurrence form
    b. MC300 Attachment E - Los Angeles County Department of Mental Health Report of Adverse Event/Unusual Occurrence (for Psychiatric Patients with LPS holds)

Area Manager/Director, Administrator or Designee

- Shall contact the Office of Risk Management within 24 hours of occurrence or becoming aware of the Adverse Event, Reportable Unusual Occurrence, Sentinel Event, and Critical Clinical Event.

- In addition to following Section I, the Manager reviews the Reportable Unusual Occurrence Form submitted by the workforce member for completeness and initiates the additional reporting processes including, but not limited to, following the appropriate steps as delineated in the applicable Medical Center policies:

    a. MC304 – Medical Device Report
    b. MC305 – Patient Death While Patient is Restrained or in Seclusion Report.
    c. MC312 – Medi-Cal Provider-Preventable Conditions Reporting
    d. DHS Policy 321.000 –Patient Safety: Sexual Abuse and/or Inappropriate Behavior toward a Patient.

- Sign the completed Reportable Unusual Occurrence Forms and submit them to the Office of Regulatory Affairs for processing.

Medical Center Office of Risk Management

- Refer all the Adverse Events, Reportable Unusual Occurrences, Sentinel Events, and Critical Clinical Events reported via SI to the Office of Regulatory Affairs (ORA) in a timely manner for evaluation of reporting criteria. The Office of Risk Management provides the available supporting documentation to ORA.

- Refer reported events to the Quality, Risk, and Safety (QRS) Executive Committee for initial evaluation.

- Shall ensure that the third-party claims administrator is notified in accordance with DHS Policy No. 311.2 and Medical Center policies.

Medical Center Office of Regulatory Affairs

The Office of Regulatory Affairs (ORA) is responsible for receiving and reporting all Adverse Events, Reportable Unusual Occurrences, Sentinel Events, and Critical Clinical Events meeting criteria for Reportable Events initiated by Medical Center work force members. The ORA will:

- Notify the Chief Executive Officer or designee of all reportable events and request approval to report to CDPH, Joint Commission, and Department of Mental Health.

- Request any additional support documentation (i.e., further investigation, root cause analysis and actions, corrective actions taken, etc.) from involved area/management or the Office of Risk Management as may be needed for report purposes.

- Notify the Chief Executive Officer of the occurrence/event in a written summary.

- Report all reportable events via e-mail or verbally to the CDPH, Licensing and Certification Program, Joint Commission, or Department of Mental Health after approval by the Chief Executive Officer, or designee.

- Prepare a final report to CDPH, Joint Commission, and/or Department of Mental Health for the Chief Executive Officer's signature.

- Maintain all Adverse Events, Reportable Unusual Occurrences, Sentinel Events, and Critical Clinical Events meeting criteria for Reportable Events and any support documentation associated with the respective reports for the required retention period.

Investigation

The Office of Risk Management in collaboration with the QRS Committee shall begin an initial investigation, including a risk management analysis.

Upon completion of the preliminary analysis by the QRS Committee,

- If the event is determined to be a Critical Clinical Event, the Executive QRS Committee shall determine if a comprehensive analysis is required.

- If the event is determined to be a Sentinel Event, the Executive QRS Committee shall determine whether the event requires a root cause analysis and action (RCA2)

Comprehensive Analysis
The QRS Committee and others as appropriate, shall conduct. a comprehensive analysis. The comprehensive analysis shall demonstrate that a comprehensive clinical and administrative review of the event has occurred. Corrective actions shall be defined and accompanied by planned implementation dates.

Root Cause Analysis and Actions (RCA2)

The QRS Executive Committee shall appoint team members to conduct an **RCA2** .The team is empowered to do the analysis and make recommendations for change. The team shall ensure that the QRS Executive Committee is informed of the **RCA2** progress. The **RCA2** plan shall be completed within 45 calendar days of the event or becoming aware of the event.

RESPONSIBILITY

All workforce members
Facility/Area Administrators
Nursing Directors
Department Managers, Administrative and/or Clinical
Office of Regulatory Affairs
Office of Risk Management
Quality Management Department
Chief Executive Officer or designee
Chief Medical Officer
Chief Quality Officer
Patient Safety Officer

REFERENCES

California Health and Safety Code Section 1279.1 (Reportable Adverse Events(b)
Title 22, California Code of Regulations, Section 70737 (general acute care hospital)
Title 22, California Code of Regulations, Section 70972 (adverse event reporting requirements)
Title 22, California Code of Regulations, Section 71535 (acute psychiatric hospital)
Title 22, California Code of Regulations, Section 75053 (primary care clinics)
Evidence Code, Sections 1157 and 1157.7 (medical professional peer review confidentiality)
Government Code, Section 62.54[c] (personnel records confidentiality)
Joint Commission Sentinel Event Policy & Procedures
Senate Bill 1301 – “Never 28”
Los Angeles County Department of Mental Health LPS Designation Guidelines and Process for Facilities Within Los Angeles County, Seventh Edition (Revised February 2016).
DHS Policy #311.2, Critical Clinical Event (Including Sentinel Event) Reporting and Follow-Up

DHS Policy #311.201 Communications of Unanticipated Outcomes
DHS Policy #311.202 Adverse Event Reporting to the State Department of Public Health
DHS Policy #321.000 Patient Safety: Sexual Abuse and/or Inappropriate Behavior toward a Patient
DHS Policy #932 Role of Employee – Security and Reporting of Hazards/Incidents
DHS Policy #934 Reporting Incidents
Medical Center Attending Staff Policy and Procedure ASA102 Disclosure of Outcomes: Anticipated and Unanticipated.
Medical Center Policy #300 Event Notification Report
Medical Center Policy #304 Medical Device Report
Medical Center Policy #305 Patient Death While Patient is Restrained or in Seclusion Report
Medical Center Policy #312 Medi-Cal Provider-Preventable Conditions Reporting

ATTACHMENTS

Attachment A - Reportable Unusual Occurrences, Never 28 List.
Attachment B - The Joint Commission Sentinel Event List.
Attachment C – Critical Clinical Events List
Attachment D - Reportable Unusual Occurrence Form.
Attachment E - Los Angeles County Department of Mental Health Report of Adverse

Event/Unusual Occurrence for Psychiatric Patients in LPS designated facility

REVISION DATES

February 15, 1994; November 13, 1998; April 15, 1999; March 12, 2002; March 10, 2005; January 9, 2007, October 15, 2008, April 12, 2016; April 26, 2019; February 27, 2023; April 8, 2024