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

SUBJECT: GUIDELINES FOR HANDLING ADVERSE DRUG EVENTS (MEDICATION ERRORS & ADVERSE DRUG REACTIONS) **POLICY NO.** 330

CATEGORY: Provision of Care	**EFFECTIVE DATE:** 3/85
POLICY CONTACT: Jennie Ung, PharmD	**UPDATE/REVISION DATE:**
REVIEWED BY COMMITTEE(S): Medication Safety	

PURPOSE:
To provide guidelines for reporting adverse drug events and define actions to be taken to prevent future events.

POLICY:
Harbor-UCLA Medical Center has a proactive, coordinated adverse drug event reporting system designed to enable data to be collected, shared, compared, analyzed and evaluated. The reports of adverse drug events are reviewed; safety hazards are identified and improvements are developed, and evaluated for their effectiveness.

DEFINITIONS:
Adverse Drug Event (ADE): An adverse drug event is an injury resulting from a deviation in the medication use process (prescribing, dispensing, administering, monitoring) or undesirable clinical manifestation that is consequent to and caused by the administration of medication.

Adverse Drug Reaction (ADR): An adverse drug reaction is a subset of ADEs that includes any clinical manifestation that is undesired, unintended, or unexpected that is consequent to, and caused by, the administration of medications that is recognized in accepted medical practice.

Medication Error: A medication error is a subset of ADEs that includes any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional or the patient. Such events may be related to professional practice, health care products, procedures and systems, including prescribing; order communication; product labeling; packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring and use.

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APPROVED BY:

Anish Mahajan Digitally signed by Anish Mahajan Date: 2023.02.10 18:00:21 -08'00'
Anish Mahajan, MD
Chief Executive Officer
Chief Medical Officer

Griselda Gutierrez, MD Digitally signed by Griselda Gutierrez, MD Date: 2023.01.09 10:50:04 -08'00'
Griselda Gutierrez, MD
Associate Chief Medical Officer

Jason Black Digitally signed by Jason Black Date: 2023.01.06 17:06:57 -08'00'
Jason Black, MBA, DNP, RN
Chief Nursing Officer

PROCEDURE:

A. Reporting:

1. Any staff who witnesses any suspected ADE must notify the patient's Registered Nurse (RN) or provider on duty.
2. The RN shall report the ADE specified in *Table A* to the Attending physician immediately. When the Attending physician is unavailable, the covering physician must be notified. Once the covering physician has been informed, the patient's Attending physician must be notified by the covering physician as soon as s/he is available. (CMS Condition of Participation 482.25(b) (6)).
3. The RN shall report ADE specified in *Table A* to her/his immediate supervisor, House Supervisor (if after hours), and pharmacist.
4. In addition, all ADE should be reported by anyone aware of the event via Safety Intelligence (SI) using the procedure described in Hospital Policy #612A.
5. All potential and known critical events resulting in severe injury, death or unexpected outcome to patient or non-patient require Risk Management notification within four (4) hours after the discovery of the event.
   (See Hospital Policy #612B).

Table A. The categories of ADE that require an immediate reporting to an Attending physician (or covering physician):

Adverse Drug Events (ADE)	
Adverse Drug Reactions (ADR)	Medication Errors
a. Probable drug reactions that have not previously been reported in the literature (any reaction that is observed after administration of a drug thought to be drug-related). b. Serious or unusual reactions to medication, particularly if active intervention is needed to correct the event. c. All admissions to the hospital related to serious ADR, or drug reactions necessitating prolongation of hospitalization (excluding patient-induced poisoning or drug-overdose). d. Serious ADR related to iatrogenic causes. e. Examples of reactions to report or not report: <u>Report:</u> Anaphylactic reactions, angioedema, bronchospasm, hypotension, exfoliative dermatitis or severe hives. <u>Do Not Report:</u> A mild rash/pruritus responding to drug discontinuation and/or diphenhydramine.	a. Medication administration errors: • Medication administration errors that require intervention of drug therapy and/or additional monitoring. • Medication administration errors that may potentially result in harm score of 3 or higher. b. Incompatibilities (which occurs when drugs interfere with one another chemically or physiologically)

B. Documentation:

1. The RN will document all ADE in the patient's medical record, all the events associated with reporting the suspected ADE to include, but not limited to the following:
   a. Signs and symptoms that prompted ADE reporting procedure;

   b. Date and time the Attending/covering physician was notified of the suspected ADE.
2. The physician will document in the patient's medical record the ADE along with the interventions, if any were necessary.

C. Disclosure:

1. For any questions regarding disclosing the ADE to the patient and/or patient's responsible party, Risk Management should be consulted as soon as possible.
2. A licensed physician from the primary team will notify the patient and/or patient's family/caregiver that an ADE has occurred for all events.

D. Follow-up and Assessment:

1. An investigation of each reported medication error shall commence as soon as is reasonably possible, but no later than two (2) business days from the date the medication error is discovered.
2. Risk Management will review all ADEs reported via SI (See Policy #612A).
3. Clinical Quality and Safety Department will review ADR resulting in patient harm with harm score 6 to 9 (See Appendix A) for appropriate action as deemed necessary.
4. The Medication Safety Office will review all ADE reports in SI and do the following:
   a. Analyze and trend the data;
   b. Provide a Quarterly Adverse Drug Reaction Summary Report and Medication Error Summary Report to the Medication Safety Committee (MSC).
5. The MSC will do the following:
   a. Review ADR and Medication Error Summary Reports to identify the contributing factors;
   b. Send medication errors data to the Clinical Data Monitoring Panel for review;
   c. Report significant ADR to the Food and Drug Administration.

Reviewed and approved by
Medical Executive Committee – 11/2022

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

Appendix A

Harm Scoring System Used by Safety Intelligence (SI):

	Harm Score	Descriptions
Near Miss (No Physical Harm)	1	Unsafe condition
	2	Near miss (requires selection of one of the following): • Fail-safe designed into the process and/or a safeguard worked effectively; • Practitioner or staff who made the error noticed and recovered from the error; • Spontaneous action by a practitioner or staff member prevented the event from reaching the patient; • Action by the patient or patient's family member prevented the event from reaching the patient • Other • Unknown
Reached the Individual	3	No harm evident, physical or otherwise: • Event reached patient, but no harm evident.
	4	Emotional distress or inconvenience: • Event reached patient; mild and transient anxiety or pain or physical discomfort, but without the need for additional treatment other than monitoring. • Distress/inconvenience since discovery and/or expected in future as a direct result of event.
	5	Additional treatment: • Injury limited to additional intervention during admission or encounter; • Increased length of stay, but no other injury; • Additional treatment required since discovery and/or expected in future as a direct result of event.
Harm	6	Temporary harm: • Bodily or psychological injury, but likely not permanent.
	7	Permanent harm: • Lifelong bodily or psychological injury or increased susceptibility to disease.
	8	Severe permanent harm: • Severe lifelong bodily or psychological injury or disfigurement that interferes significantly with functional ability or quality of life.
	9	Death – Dead at time of assessment.