

El Paso - Ambulatory Clinic Policy and Procedure

Title: ADVERSE DRUG EVENT REPORTING	Policy Number: EP 4.6
Regulation Joint Commission Reference:	Effective Date: 03/2014

Policy Statement:

It is the policy of Texas Tech University Health Sciences Center at El Paso (TTUHSC at El Paso) to report and record significant adverse drug reactions.

Scope and Distribution:

This policy applies to all TTUHSC at El Paso ambulatory clinics. This policy applies to drugs administered at and prescribed from TTUHSC at El Paso ambulatory clinics.

Procedure:

1. Adverse Drug Event Defined. An adverse drug event is defined as an action of unexpected nature or severity that is not of therapeutic, diagnostic or prophylactic benefit to the patient.
2. Report significant *adverse drug events* with emphasis on:
 - a. serious or fatal reactions
 - b. uncommon or unusual reactions
 - c. drug interactions
 - d. reactions to newly marketed drugs
3. Process:
 - a. At the time a significant drug reaction is known or suspected, the nurse or physician discovering the reactions should initiate 8.02.A, Occurrence Report Form, recording what is known and forwarding it to the appropriate department
 - b. Nursing/CMA responsibilities are as follows:
 - 1) monitor patient
 - 2) notify the physician
 - c. **KEY POINT: BEGIN EMERGENCY TREATMENT AS NEEDED**
4. Documentation:
 - a. Record in Progress Notes:
 - 1) specific signs and symptoms
 - 2) time physician notified
 - 3) any specific measures taken
 - b. Record adverse drug reaction the Electronic Medical Record (EMR) when confirmed. This should be recorded on the section designed for allergies.

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- c. The reaction should be evaluated by the physician noting:
 - 1) onset of suspected reaction
 - 2) severity of suspected reaction
 - 3) duration of suspected reaction
 - 4) cause of suspected reaction
 - 5) *any untoward effect on patient outcomes*
- d. The Occurrence Report is to be completed by clinic staff within 24 hours of the adverse drug event.
- e. The form is routed to the designated individual listed on [8.02.A, Occurrence Report Form](#), for review and trending.
- f. Severe drug reactions should be reported to the manufacturer and the FDA by the physician. The FDA 3500 reporting form may be found at <http://www.fda.gov/medwatch/>.

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