



El Paso - Ambulatory Clinic Policy and Procedure

Title: ADVERSE DRUG EVENT REPORTING	Policy Number: EP 4.6
Regulation Joint Commission LD.04.04.05 Reference:	Effective Date: 08/2022

Policy Statement:

It is the policy of Texas Tech Physicians of El (TTP-EP) to report and record significant adverse drug reactions and medications errors.

Scope and Distribution:

This policy applies to all TTP-EP ambulatory clinics. This policy applies to drugs administered at and prescribed from the 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. **Medication error Defined:** An error made during the prescription or administration of a medication regardless the effect on a patient.
3. **Staff process:**
 - a. During in-clinic drug administration, provide emergency treatment as needed and notify prescribing or covering provider immediately.
 - b. During ambulatory use: notify nurse and/or provider for evaluation.
 - c. Document in the medical record description, notifications and actions taken.
4. **Documentation:** Providers must document in the medical record:
 - a. Pertinent signs and symptoms
 - b. Actions taken or recommendations made to the patient
 - c. The adverse drug reaction in the allergies or problems section/s as applicable.
5. **Internal Reporting:** The following must be reported internally via the Occurrence reporting system as described in EP 8.4 by staff or providers:
 - a. Serious (requiring specific additional visits or referrals) or fatal reactions
 - b. Events developed during in-clinic drug administration
 - c. Any medication error
6. **External Reporting:** For specific drugs, providers may be required to report adverse events to the manufacturer or the FDA. The FDA 3500 reporting form may be found at <http://www.fda.gov/medwatch/>. For questions about these requests, providers may contact the Office of Compliance.

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Signatory approval on file by: Juan Figueroa, M.D. Director of Clinical Operations Clinic Medical Directors Committee, Chair Texas Tech Physicians of El Paso 	