El Paso - Ambulatory Clinic Policy and Procedure

Title: ADVERSE DRUG EVENT REPORTING
Policy Number: EP 4.6

Regulation Reference: Joint Commission LD.04.04.05
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.