**Adverse Drug Event Reporting**

**Section:** Pharmacy Operations

**Compliance:** URAC Specialty Pharmacy 2.1

**URAC Standards:** PHARM Core 4, 17, PHARM-OP 14, SDrM 2, 5

**Policy ID:** 7.1

**Approved by:**

**POLICY**

All adverse drug events will be documented, investigated, and resolved in a consistent and timely manner in order to ensure quality patient care. **[PHARM Core 4 (c)] [SDrM 2 (c)][SDrM 5 (a, c, d)]**

**PROCEDURE**

1. An adverse drug event (ADE) shall be defined as any medication error, potential adverse drug event, or an adverse drug reaction (ADR)
2. Medication error is any preventable event that may cause or lead to inappropriate medication use or form while the medication is in control of the healthcare professional or patient. This may include prescribing errors, dispensing errors or medication administration errors. **[PHARM-OP 14 (a-i, ii)]**
3. Potential adverse drug event (PADE) is a mistake in prescribing, dispensing, or planned medication administration that is detected and corrected through intervention, by healthcare worker or patient, before actual medication administration **[PHARM-OP 14 (a-i, ii)]**
4. Adverse drug reaction (ADR) is an unintended physical reaction to a drug when it is used in the approved manner. An allergic reaction and an idiosyncratic reaction are also considered ADR’s. Side effects are not included in this definition
5. A standardized reporting mechanism will be employed: **[PHARM-OP 14 (b-i, ii, iii)][SDrM 5 (a, c, d)]**
   1. All ADEs will be referred to a pharmacist for appropriate follow-up;
   2. Forms will be thoroughly and accurately completed with factual, specific, and objective information so that the circumstances can be critically evaluated;
   3. All clinically significant ADEs will be communicated to the prescribing physician immediately;
   4. If the ADE is an ADR, new information (i.e., allergy) must be immediately documented in the patient’s medical record
6. Completed forms will be routed according to policy and procedure:
   1. The Pharmacy Manager will be notified within 24 hours of the event;
   2. The Pharmacy Director will be notified within 48 hours
7. The Pharmacy Manager and the Pharmacist shall meet quarterly to discuss any ADEs during the quarter. A detailed analysis shall be compiled which includes a possible plan of correction and a process for quality improvement or the discussion will take place during QMC meetings. **[SDrM 5 (e)]**
8. Summary analysis will be submitted to Quarterly Quality Management Committee for review and any required follow-up **[PHARM Core 17] [PHARM-OP 14 (c)] [SDrM 5 (e)]**
9. All follow-up activities and reports shall be monitored by the Pharmacy Manager and the Pharmacist(s) for a period of one year following initiation of the plan of correction

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