**Adverse Events**

**Section:** Quality Management

**Compliance:** URAC Specialty Pharmacy 2.1

**URAC Standards:** PHARM Core 4, 21, 35, PHARM-OP 14, SDrM 2, 5

**ACHC Standards:** DRX6-3F

**Policy ID:** 8.2

**Approved by:**

**POLICY**

An adverse event is an unexpected occurrence involving death or serious physical or psychological injury of a patient/consumer, or the risk of such of occurrence. Serious injury specifically includes loss of limb or function. Adverse events signal the need for immediate investigation and response. **[PHARM Core 4 (c)] [PHARM Core 35 (a, d, e)] [PHARM-OP 14 (a-i)] [SDrM 5 (a)]**

**PROCEDURE**

1. The goals of this policy are: **[PHARM Core 35 (a, d, e)] [SDrM 2 (c)]**
   1. to have a positive impact in improving patient care;
   2. to focus attention on understanding the causes that underlie the event;
   3. to reduce the probability of a reoccurrence of the event in the future;
   4. to increase the general awareness and enhance strategies for prevention
2. When adverse events occur in a health care organization, it is necessary that appropriate individuals within the organization be aware of the event; investigate and understand the causes that underlie the event; and make changes in the organization's systems and processes to reduce the probability of such an event in the future. The leaders are responsible for establishing processes for the identification, reporting, analysis, and prevention of adverse events and for ensuring the consistent and ongoing implementation of a root cause analysis. **[PHARM Core 4 (c)] [PHARM Core 21 (a, f, g, h)] [PHARM-OP 14 (b-i, ii, iii)] [SDrM 5 (a, b, c, d, e)]**
3. Adverse Events that are subject to review by advisory boards and accrediting bodies include:
   1. an occurrence or event which results in an unanticipated death; or
   2. an event in which major permanent loss of function (not related to the natural course of the patient's illness or condition) occurs **[PHARM Core 4 (c)]**
4. When such an event occurs, <insert practice name> is expected to prepare a thorough and credible root cause analysis and action plan within <X calendar days> of the event or of becoming aware of the event. The organization may submit the written analysis and plan to its accrediting body at its discretion and as advised by their legal counsel. **[PHARM Core 4 (c)]**
5. If applicable, <insert practice name> will conduct a root cause analysis which includes the following elements: **[PHARM Core 21 (a, f) [PHARM-OP 14 (b-i, ii, iii)] [SDrM 5 (d)]**
   1. focuses primarily on systems and processes, not on individual performance;
   2. progresses from special causes in clinical processes to common causes in organization processes;
   3. repeatedly delves deeper by asking "why?" and then "why" again;
   4. identifies changes which could be made in systems and processes that would reduce the risk of such events occurring in the future;
   5. is thorough and credible
6. <insert practice name>, as it provides patient/consumer care in the delivery of medical equipment and rehabilitation technological services, utilizes the FDA Med-Watch criteria in establishing its definition and reporting requirement of adverse events. **[PHARM-OP 14 (a-i, ii)]**
7. The following are reportable adverse events: **[PHARM Core 4 (c)] [SDrM 5 (d)]**
   1. **Death** -when a medication causes death or contributed to the death of a patient;
   2. **Life-threatening** - when a medication may have resulted in the death of a patient if use of the medication had continued;
   3. **Hospitalization** - when the medication caused or contributed to the hospitalization of a patient;
   4. **Disability** -when a medication may have caused or contributed to a permanent injury or impairment of the patient;
   5. **Intervention** - if medical or surgical intervention was necessary to preclude permanent damage due to the use of the medication.
8. The Pharmacy Manager will be notified when a reportable adverse event occurs, and appropriate action will be taken. All adverse events will be reported to the Quality Management Committee for review and analysis. **[PHARM Core 21 (a, f, h)] PHARM-OP 14 (c)] SDrM 5 (e)]**

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