HIGH DESERT HEALTH SYSTEM

High Desert Health System POLICY AND PROCEDURE

POLICY NUMBER: 643
VERSION: 1

SUBJECT: SUSPECTED ADVERSE DRUG REACTION, REPORTING OF

STATEMENT:

Suspected adverse drug reactions shall be reported to the physician and Pharmacy Department according to the guidelines of this policy/procedure.

WHO MAY PERFORM:

Suspected adverse drug reaction reporting may be done by any health care professional licensed or certified to administer and/or dispense medications.

DEFINITION:

An adverse drug reaction (ADR) is defined as any untoward reaction from a medication that results in one or more of the following:

a. A dosage change
b. Discontinuation of the medication
c. Changing to a different medication
d. Treatment of symptoms which may include additional clinic visits, hospitalization, or change in level of care.

Suspected adverse drug reactions are categorized as mild, moderate, or severe. The severity rating can include one or more criteria in any category.

MILD: Intervention was required, including the discontinuation of the drug, but no increase in hospital stay was required.

MODERATE: Caused hospitalization or prolonged hospital stay by at least one day.

SEVERE: Reaction is life threatening, permanently disabling, requires admission to a critical care unit, requires hospitalization longer than 15 days, or contributes to the death of the patient.

I. Reporting Suspected Adverse Drug Reactions

1. Identify signs and symptoms of suspected ADR. The attached list of criteria and symptoms is intended as a guide only. Signs and symptoms of a suspected ADR are not restricted to this list.

2. Physician will be notified immediately upon identification of a suspected ADR by the health care professional licensed or certified to administer and/or dispense medications.

3. After notifying the physician suspected ADRs shall be reported by one of the following methods:

   A. Call ADR hotline extension 8565 to report the following information:
      i. Patient Name
      ii. PF number
      iii. Unit/area and date
      iv. Brief description of the reaction

-OR-

   B. Complete the ADR Surveillance Form according to the following:
      i. Stamp the form with the patients identification card
      ii. Record the patient's unit/area and the date
      iii. Check the type of ADR reaction, and write in the adverse effect (s) and the name of the suspected drug.
      iv. Forward the form to the Pharmacy Department by the end of the shift.

II. Role of the Pharmacy Department

1. Pharmacy will evaluate the reported suspected ADR and assign a probability consisting of one of the following:

   A. DEFINITE
      - Follows a reasonable temporal sequence after a medication is given or from the time the medication concentration has been established in body fluids or tissues
      - Follows a well-known response pattern to the suspected medication
      - Lessens or disappears on stopping the medication
      - Reappears if the medication is restarted (rechallenged)

   B. PROBABLE
      - Follows a reasonable temporal sequence after a medication is administered
      - Follows a known response pattern to the suspected medication
      - Lessens or disappears on stopping the medication
      - Could be explained by the patient's underlying clinical state

C. POSSIBLE
- Follows a reasonable temporal sequence after a medical is given
- Possibly follows a known pattern to the suspected medication
- Could be explained by the patient's underlying clinical state or other Factors or modes of therapy administered to the patient.

D. DOUBTFUL
- Does not follow a reasonable temporal sequence after a medication is given
- Can likely be explained by the patient's underlying state or other factors or modes therapy administered to the patient

2. Adverse drug reaction shall be reported immediately to the physician who ordered the medication. An Adverse Drug Reaction Report will be completed by the pharmacist investigating the issue, and forwarded to the Director of Pharmacy Services for review.

3. The completed ADR Report shall be reviewed by the Medical Safety Committee and referral to the Pharmacy and Therapeutics Committee for further action.

4. Any significant drug reaction shall be reported to the Food and Drug Administration (FDA) on a Drug Experience Report.

REFERENCES

JCAHO CAMH TX.3

Approved By: Beryl Brooks (ADMR,COMP AMB HEALTH CARE CENTER), Ruth Oren (CHIEF PHYSICIAN I ANESTHESIOLOGY), Susan Knapp (CHIEF NURSING OFFICER I)	
Date: 06/10/2014	Original Date: 07/01/2003
Reviewed: 06/10/2014	Next Review Date: 06/10/2015
Supersedes:	