



MONTANA STATE HOSPITAL POLICY AND PROCEDURE

ADVERSE DRUG REACTION REPORTING

Effective Date: November 8, 2017

Policy: PH-10

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- I. PURPOSE:** To establish a mechanism to ensure that adverse drug reactions are systematically reported and reviewed.
- II. POLICY:** Montana State Hospital (MSH) direct care staff, in cooperation with the pharmacy, has the responsibility of reporting, documenting, and monitoring adverse drug reactions that occur within the facility's population.
- III. DEFINITIONS:**
 - A. Adverse drug reaction (ADR) is any noxious, unintended, undesirable, or unexpected response to a drug that occurs at doses used in humans for prophylaxis, diagnosis, therapy of disease, or for modification of psychological function. This definition is understood to exclude predictable, dose-related side effects due to drugs which result in little or no change in patient management, and in particular mild extrapyramidal side effects due to neuroleptic drug therapy.
 - B. Indications of an ADR: include anaphylaxis, arrhythmia, convulsions, hallucinations, shortness of breath, rashes, itching, hypotension, dystonia, leukopenia, urinary retention, symptoms associated with neuroleptic malignant syndrome, initial report of tardive dyskinesia, EPS related to non-antipsychotic drugs and also includes true allergic (hypersensitivity) reactions and idiosyncratic reactions.

A significant adverse drug reaction is one that:

 - requires discontinuing the drug
 - requires large, (greater than 50%) dosage decrease
 - necessitates admission to an acute care hospital
 - delays anticipated discharge/placement from MSH
 - necessitates supportive treatment
 - significantly complicates diagnosis
 - negatively affects prognosis
 - results in temporary or permanent harm, disability, or death.
 - C. Licensed Independent Practitioner (LIP): an active, provisional or part-time physician or APRN and/or CNS who attends to the care of the patients at MSH.
- IV. RESPONSIBILITIES:**
 - A. Direct Care Staff: Observe and report suspected adverse drug reactions.

- B. Licensed Nurses: Observe, report to LIP, and document suspected adverse drug reactions
- C. Licensed Independent Practitioner (LIP): Observe, assess, prescribe, document and complete ADR report.
- D. Pharmacist: Evaluate report, present ADR report to Pharmacy and Therapeutics Committee.
- E. Pharmacy and Therapeutics Committee: Evaluate ADR report, make recommendations, and submit to the Quality Improvement Committee.
- F. Medical Director: Evaluate and submit significant ADR reports to FDA and manufacturer.

V. PROCEDURE:

A. Reporting:

- 1. Any staff who witnesses a suspected adverse drug reaction will notify the RN/LPN on duty.
- 2. The RN/LPN will immediately contact the attending LIP and nursing supervisor to report the possibility of an adverse drug reaction.
- 3. The LIP will examine the individual, order necessary intervention, if needed, and discontinue or decrease the suspected medication. The LIP will indicate potential adverse drug reaction on the order form.
- 4. This indication will alert the pharmacy of ADR and prompt the Pharmacy to send the ADR report to the LIP where they will complete the medical section of the ADR report if have not already done so.
- 5. The LIP will forward the report to the pharmacy for evaluation by a registered pharmacist and the Pharmacy and Therapeutics Committee.
- 6. The pharmacist will present the adverse drug reaction to the Pharmacy and Therapeutics Committee for review at the next scheduled meeting.
- 7. The Pharmacy and Therapeutics Committee will evaluate each report and, when appropriate, will make recommendations for further evaluation by the medical director, to submit significant ADR reports to the FDA, and the manufacturer.

B. Documentation:

- 1. The RN/LPN will document in the patient's medical record, all the events associated with reporting the suspected ADR to include, but not limited to:
 - a. signs and symptoms which prompted the ADR reporting procedure;
and

b. date and time the LIP and nurse supervisor were notified of the suspected ADR.

2. The LIP will document in the patient's medical record, the adverse drug reaction along with the interventions, if any were necessary.
3. The pharmacy will maintain all ADR reports and communicate pertinent data related to these reports to the Quality Improvement Committee no less than yearly.

VI. REFERENCES: None

VII. COLLABORATED WITH: Pharmacy Director, Director of Nursing, Quality Improvement Director, Pharmacy and Therapeutics Committee Chair.

VIII. RESCISSIONS: PH-10, Adverse Drug Reaction Reporting dated August 1, 2012; PH-10, *Adverse Drug Reaction Reporting* dated July 1, 2009; PH-10, *Adverse Drug Reaction Reporting* dated August 22, 2006; PH-10, *Adverse Drug Reaction Reporting* dated March 31, 2003; Policy NS-01, *Adverse Drug Reaction Reporting* dated February 14, 2000; H.O.P.P NS-02-96-N, *Adverse Drug Reaction Reporting* dated May 31, 1996.

IX. DISTRIBUTION: All hospital policy manuals.

X. ANNUAL REVIEW AND AUTHORIZATION: This policy is subject to annual review and authorization for use by either the Administrator or the Medical Director with written documentation of the review per ARM § 37-106-330.

XI. FOLLOW-UP RESPONSIBILITY: Medical Director

XII. ATTACHMENTS: For internal use only.

A. Adverse Drug Reaction Report Form

Signatures:

Jay Pottenger
Hospital Administrator

Thomas Gray, MD
Medical Director