

TITLE: ADVERSE MEDICATION EVENTS & POTENTIAL ADVERSE MEDICATION EVENTS - REPORTING AND MONITORING

**ISSUING SOURCE: PATIENT CARE SERVICES
PHARMACY**

APPROVED BY

PAGE 1 OF 3

**REVIEWED BY:
DATE:**

**REVIEWED BY:
DATE:**

PURPOSE: To provide a standardized mechanism for identifying, reporting, and monitoring medication errors and adverse medication events (AME's) and to provide a consistent mechanism for improving the medication use process.

POLICY: encourages reporting of errors, adverse medication events (AME's), and potential adverse medication events (PAME's) as a means to assess and improve the medication use process and provide a safe environment for patient care. The purpose of the reporting errors is to learn about the cause of the error and enhance the medication system to make it difficult for practitioners to commit errors. Practitioners involved in medication use are required to participate in the detection and reporting of errors, the identification of the system-based causes of errors, and the facilitation of system enhancements to reduce the likelihood of errors. Thus, the focus of the program is quality improvement, not punishment. The institution verifies the competence of each practitioner employed and assumes that practitioners are doing their very best and that errors and AME's are not the result of incompetence or misconduct. Therefore, employees are not subject to disciplinary action when making or promptly reporting errors. In the event it becomes clear that staff competency is the root cause for a pattern of errors, management will make every reasonable effort to ensure staff can reliably deliver safe care. If it becomes clear that a staff member cannot practice in reliably safe manner, even with extra education and counseling, this situation will be treated as a staff competency issue through normal disciplinary procedures.

The Pharmacy, Therapeutics, and Nutrition Committee reviews quarterly AME/PAME reports and recommendations by the Pharmacy and/or Nursing CQI teams.

Pharmacy will report Adverse Medication Reactions (AMR's) to the Food & Drug Administration (FDA) if they are serious, associated with a new medication, or not listed in the medications's labeling

AME's/PAME's are reported by physicians, nurses, pharmacists, patients, medical records/OA personnel or any member of hospital staff.

To report an error, refer to the procedure portion of this policy.

An AME that results in permanent patient harm, near death event (such as anaphylaxis), or death will be classified as a sentinel event. The

Administrator on call will be contacted and the policy for Sentinel events will be followed. (See Policy #1000 A-46).

DEFINITIONS:

Adverse Medication Event (AME) - A deviation in the medication use process (prescribing, dispensing, administering, monitoring) OR undesirable clinical manifestation that is unintended, undesirable, and unexpected that is consequent to and caused by the administration a medication that requires discontinuing a medication or modifying the dose, requires initial or prolonged hospitalization, results in disability, requires treatment with another medication, results in cognitive deterioration or impairment, are life-threatening, results in death, or results, in congenital anomalies.

Potential Adverse Medication Event (PAME) - A hazardous situation that could lead to an error.

Adverse Medications Reaction (AMR) - A subset of AME's that includes any clinical manifestation that is unintended, undesirable, and unexpected that is consequent to and caused by the administration of a medication that requires discontinuing a medication or modifying the dose, requires initial or prolonged hospitalisation, results in disability, requires treatment with another medication, results on cognitive deterioration or impairment, are life-threatening, results in death, or results in congenital anomalies.

Preventable AMR - An ADR that resulted from a deviation in the medication use process that could be reasonably anticipated based upon existing policies and procedures, patient data, medical literature or accepted medical practice.

AME/PAME Report Form - Form completed by any member of MRMC staff to document a possible AME.

PROCEDURES:

I. Identifying an AME

- A. Staff who suspect an AME notify prescriber immediately if the event is significant or may alter the patient's plan of care.
- B. Staff assess the patient.
- C. Staff collaborate with clinical and supervisory resource personnel if unsure how to proceed.
- D. Staff implement adjustments in patient's treatment as ordered.
- E. Staff documents the factual description of the AME, notification of physician and subsequent monitoring in the progress record.

II. Reporting an AME

- A. The Supervisor/Teamleader or Director/Division Manager is notified immediately and an AME/PADE Report Form is completed within 24 hours of discovery.
- B. The form will be reviewed for completeness by the Director/Division Manager, signed and forwarded to the Director of Pharmacy.
- C. The Director of Pharmacy will review the form sign, and forward to the VP of Patient Care Services.
- D. The VP will review, sign and forward to the Risk Manager.
- E. Security of Information
 1. No copies are made of the AME forms.
 2. Forms are secured in the Pharmacy or Risk Management.
 3. Data is kept on a secure data base.

- III. Reviewing AME's
 - A. Supervisor/manager completes timely evaluation of the circumstances surrounding the event.
 - B. Director of Pharmacy assesses all reports, to verify and collect additional data, and assign severity level.

- IV. Trending/Reporting/Improving the Medication Use Process
 - A. The Director of Pharmacy will monitor for trends, report any trends notified to the Pharmacy, Therapeutics and Nutrition Committee as well as any appropriate Supervisors/Directors/Division Managers.
 - B. When trends are identified appropriate CQI steps will be applied to prevent further errors.

Not all situations can be covered in a policy and procedure. If any situations occur that are not covered in this policy, all steps will be taken to provide appropriate patient care while complying with State and Federal laws. The occurrence of such a situation should be reported to the appropriate person(s) or supervisor(s).

Any questions should be directed to the Director of Pharmacy or the Vice President of Patient Care Services.

Adverse Medication Event Reporting Form

CONFIDENTIAL

DO NOT COPY

Route to
Pharmacy Immediately

The purpose of this form is to reduce morbidity and mortality. This information is to be reported to a hospital committee and is for that use only. Communicate only the facts of the incident. Do not state opinions, assumptions or conclusions. Do not place this form in the patient's chart or send to medical records. This report is privileged and confidential and is NOT to be reproduced.

Time Occurred	Date Occurred	Date Reported	<input type="checkbox"/> Medication Error	<input type="checkbox"/> Potential Medication Error
□□ : □□	□□□□□□	□□□□□□	<input type="checkbox"/> Adverse Event	<input type="checkbox"/> Potential Adverse Event

Type of Error

<input type="checkbox"/> Omission	<input type="checkbox"/> Delayed Dose	<input type="checkbox"/> Wrong Time	<input type="checkbox"/> Other Error (briefly explain) _____
<input type="checkbox"/> Transcription	<input type="checkbox"/> Wrong Medication	<input type="checkbox"/> Wrong Rate	_____
<input type="checkbox"/> Extra Dose	<input type="checkbox"/> Wrong Patient	<input type="checkbox"/> Known Allergy	_____
<input type="checkbox"/> Wrong Dose	<input type="checkbox"/> Order Entry	<input type="checkbox"/> Charting Error	_____

Specific Information:

Medication(s) involved : _____

What medication should have been given (Medication, Strength, Route, Time) N/A

What medication was given (Medication, Strength, Route, Time) N/A

Other necessary information: _____

Cause of Error or Potential Error

Identify the primary cause: _____

Were there any other contributing factors? _____

Medication Process System Problems

What part of the system failed: _____

Continue on the back side

(Patient Name or Addressograph)

Briefly describe the reaction/event: _____

System Correction

What steps can be taken to prevent similar errors in the future: _____

Person(s) Involved in Event: _____

Person Completing Report: _____

Immediate Supervisor: _____

Department Director (s): _____

Vice President: _____

Pharmacy / Pharmacy & Therapeutics Findings & System Corrections: _____

