

**UNIVERSITY OF MICHIGAN HOSPITALS AND HEALTH CENTERS**  
**DEPARTMENT OF PHARMACY SERVICES POLICIES AND PROCEDURES**

**REPORTING OF ADVERSE DRUG REACTIONS**

**I. POLICY STATEMENT**

It shall be the policy of the University of Michigan Health System to identify all known adverse drug reactions (ADRs) as discovered by voluntary reporting, medication incident reports, and analysis of event (E) codes. Further, it shall be our policy to actively participate in reporting adverse drug reactions to the Food and Drug Administration for the purpose of assisting in post-market assessment of medications. Adverse drug reaction reports will be evaluated to determine whether there are medication use process changes that can be implemented to minimize the potential for adverse reactions in patients.

**II. POLICY PURPOSE**

The purpose of this policy is to provide guidelines that define adverse drug effects, identify procedures for reporting ADRs to the Food and Drug Administration, offer guidance for internal reporting to the MedSafe Committee and Corporate Quality Improvement, and describe a process of evaluation to determine whether medication use process changes can be implemented to minimize the potential for adverse reactions in patients.

**III. DEFINITIONS**

A. Adverse Drug Reaction (ADR): Any response to a drug that is noxious and unintended and that occurs in man at doses for prophylaxis, diagnosis, or therapy, including:

1. New, rare, or previously poorly documented reactions
2. ADRs associated with newly marketed medications
3. Serious, life-threatening, or fatal reactions
  - a. According to the Food and Drug Administration, a serious adverse event is one in which the patient outcome is death, life-threatening), disability, hospitalization (initial or prolonged), a congenital anomaly, or necessitates medical or surgical intervention to prevent permanent impairment or damage.
4. Unusual increases in numbers or severity of reactions
5. Allergic reactions and idiosyncratic reactions are also considered ADRs, if they are deemed to be serious, life threatening, or fatal, as described above.

For the purposes of this policy, the definition of ADR shall not include:

1. Adverse effects of the drug which are expected, well-known reactions which do not result in changing the care of the patient. These adverse effects are those effects occurring predictably and effects whose intensity and occurrence are related to the size of the dose.
2. Drug withdrawal, drug-abuse syndromes, accidental poisoning, and drug-overdose complications also should not be defined as ADRs (e.g., drowsiness from diphenhydramine).
3. Reactions which are extensions of the pharmacologic effect for which the drug is given (e.g., bone marrow suppression with antineoplastic agents).
4. Disturbances totally dependent on the pathological state (e.g., diarrhea from cancer and not from a laxative).

B. ADRS associated with the following medications or devices shall not be reported on MedWatch Forms and shall be reported through separate established reporting mechanisms:

1. Medical device problems shall be reported to the Medical Center Risk Management per UMHHC policy 05-02-006.
2. Vaccine ADRs shall be reported through the Vaccine Adverse Event Report System (VAERS) on a VAERS form. Criteria have been established for reportable ADRS related to vaccines.
3. Investigational drugs ADRs shall be reported by the primary investigator through criteria established in the study protocol. The Investigational Drug Service shall be notified of all ADRS associated with investigational drugs.
4. Veterinary drug ADRs shall be reported on a veterinary adverse drug reaction form (form 1932a).

#### **IV. POLICY STANDARDS**

- A. Adverse drug reactions meeting at least one of the criteria stated in definition III A shall be reported.
- B. The individual who suspects or identified the adverse drug reaction shall report the incident by calling the pharmacy or the Drug Information Service (936-8200).
- C. The Drug Information Service and all pharmacies shall have the Food and Drug Administration (FDA) Voluntary MEDWATCH Form (FDA Form 3500, Exhibit A) available for use at all times, and shall immediately record the required information on the form and contact the patient's primary physician when an ADR has been identified.
- D. Pharmacy staff members who detect a potential adverse drug reaction are responsible for investigating the suspected ADR. If the suspected ADR fits the ADR definition given above (section III A), the pharmacist shall obtain and complete the FDA Voluntary MEDWATCH Form and contact the patient's primary physician.
- E. The patient's primary physician shall note the potential ADR in the patient's medical record.
- F. The pharmacist shall forward the completed MEDWATCH Form to the Drug Information Service. G. The Drug Information Service shall record and file all ADRs.
- H. Medical Information Service shall provide the pharmacy with weekly reports of Event ("E") codes for ADRs that contain the patient name, registration number, and admission dates.
- I. A pharmacist shall check the files to see if a MEDWATCH Form has been previously filed for the patients identified using the "E" codes. If no report has been filed, the reviewing pharmacist shall review the patient's computerized medical information and determine if the "E" code may be considered an ADR necessary to report to the FDA. If the pharmacist considers the ADR necessary to report to the FDA, the patient's chart will be reviewed and a MEDWATCH form will be completed. All "E" codes will be reviewed by the pharmacist. A record will be kept of ADRs identified from "E" codes in order to provide a comprehensive ADR-monitoring and reporting program for the health-system.
- J. For those suspected adverse drug reactions that indeed are associated with the administration of the suspected agent and fit the definition of an ADR as provided in section III A, the Drug Information Service shall file copies of the Voluntary MEDWATCH Forms. The pharmacist who reviews ADRs shall forward a copy of the original form to the FDA.
- K. A copy of a form that is sent to the FDA shall also be sent to the manufacturer of the drug, if deemed necessary.
- L. The MedSafe Committee shall review all reported ADRs each month and make recommendations for to the Pharmacy and Therapeutics Committee monthly, and the Continuous Quality Improvement Program office on a quarterly basis.

#### **V. PROCEDURE ACTIONS**

- A. UMHS Staff (nurse, physician, physician assistant, or pharmacist) shall identify any suspected adverse drug reaction.
- B. Non-pharmacists shall report the suspected adverse drug reaction by calling the pharmacy or the Drug Information Service (936-8200).
- C. Upon detecting a potential ADR or receiving a report of an ADR form from another health care professional, UMHS staff shall completely investigate the potential ADR. If the suspected ADR is determined to fit the definition of an ADR (Section III A.), the pharmacist shall complete a copy of the FDA Voluntary MEDWATCH Form.

D. UMHS staff shall forward completed FDA MEDWATCH Forms to the Drug Information Service. E. UMHS staff shall contact the patient's primary physician regarding the ADR.

F. The patient's primary physician shall make a notification of the suspected ADR in the patient's medical record.

G. The Drug Information Service shall keep copies of FDA MEDWATCH Forms for all valid and clinically significant ADRs (defined in Section IIiA).

H. A pharmacist shall review all MEDWATCH Forms and shall forward copies of all MEDWATCH Forms for valid and clinically significant ADRs by fax or mail to the FDA.

I. A reviewing pharmacist shall forward a copy of the original report sent to the FDA to the manufacturer of the drug, if deemed appropriate.

J. The patient's primary physician shall be responsible for confirming or ruling out any suspected adverse reaction reported to them or identified by them. The patient's primary physician shall document the reaction in the patient's medical record when an adverse drug reaction has been confirmed.

K. Medical Information Service shall provide the pharmacy with weekly reports of the "E" codes for ADRs to improve detection of serious ADRs that are not captured through voluntary reporting.

L. The reviewing pharmacist shall formally review or investigate patients identified with ADRs through the "E" code process. A health record analyst will screen all "E" codes by reviewing the patient's computerized medical information. A pharmacist shall determine if further investigation of the ADR "E"-code is needed by reviewing the patient's medical record based on the health record analyst's preliminary review. A MEDWATCH Form shall be completed, if necessary.

M. The Drug Information Service shall maintain a record of identified ADRs from "E" codes in order to provide a comprehensive ADR-monitoring and reporting program for UMHS.

N. The Medication Safety Coordinator shall notify the reviewing pharmacist of any medication incident reports they have received that involve a potential adverse drug reaction. Medication incidents or errors that have been reported on MEDWATCH forms shall be forwarded to Risk Management for evaluation.

O. All reported ADRs shall be reviewed monthly by the MedSafe Committee and, if needed, recommendations for action will be made to the Pharmacy & Therapeutics Committee for endorsement.

P. A summary of reported ADRs will be forwarded to the Continuous Quality Improvement Program on a quarterly basis.

## **VI. EXHIBITS**

A. FDA MEDWATCH Form...FDA form 3500.

## **VII. REFERENCES**

A. FDA Medical Products Reporting Program

## **VIII. AUTHORS**

A. Department of Pharmacy Services

## **IX. APPROVED**

A. Pharmacy Managers, 9/2001, 11/2002

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