UAB MEDICINE **Interdisciplinary Policy**

Title: *Suspected Adverse Drug Reaction Reporting*			
Author: *Tomie Ann Boackle* 2021 Tomie Ann Boackle, Pharm.D. Date Pharmacy Department	Author: NA Date	Distribution: See Scope	
Endorsed: *Craig J. Hoesley* 04/07/21 Craig Hoesley, MD Date Chairman Pharmacy & Therapeutics Committee	Endorsed: *Richard S. Rosenthal* 04/12/21 Richard S. Rosenthal, MD Date Associate CMO, Ambulatory Services Medication Services Committee	Pages 1 of 5 Written 04/01/93 Reviewed 04/07/21 Revised 04/07/21 Issued 04/23/21	
Approved: *Mark Todd* 04/12/21 Mark Todd, Pharm. D Date Assist Vice President	Approved: *Medical Executive Committee* 04/20/21 Medical Executive Committee Date	Discontinued:	

PURPOSE: To establish guidelines to:

A. Establish a uniform mechanism for the reporting of Suspected Adverse Drug Reactions (SADRs) to the primary caregiver and to other necessary persons or groups which influence the provision of care.
B. Provide a formal system for the review and evaluation of significant adverse drug reactions.

SCOPE: This policy applies to all areas of UAB Medicine Clinical Facilities as defined by the Medical Bylaws.

ASSOCIATED INFORMATION:

A. **Definitions:**
   1. ***Adverse Drug Reaction (ADR)*** in the UAB Hospital is defined as an unexpected toxicity, unrelated to the drug's pharmacological effects which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function. Adverse Drug Reactions (ADRs) may be subdivided on the basis of severity as follows:
      a. **Minor** – Reaction may require increased monitoring, but does not require alteration of therapy, pharmacologic treatment, hospitalization, or increased length of stay in hospitalized patients.
      b. **Moderate** – In addition to increased monitoring, reaction requires alteration of current therapy, specific pharmacologic or other treatment, admission to the hospital, or lengthens hospital stay by equal to or less than 2 days.
      c. **Severe** – Reaction resulted in death or had the potential to cause death if not treated; caused emergent hospitalization or lengthened hospital stay by greater than 2 days, caused ongoing greater than 2 weeks) disability or impairment, resulted in a congenital anomaly, or required intervention to prevent permanent impairment or damage.
   2. ***Reportable Adverse Drug Reactions*** - all suspected ADRs are reportable. However, the greatest emphasis should be placed on reporting those involving new drugs or product formulations or those judged to be of moderate or severe intensity. Suspected ADRs involving a medication being given as part of a formal drug study should be reported to the Principal Investigator or their representative.
   3. ***Formal Drug Studies*** are studies that have an Institutional Review Board (IRB) approval; these studies may involve investigational or commercially available medications.

POLICY:

A. Personnel who are responsible for administering medications shall be knowledgeable about the medications and able to recognize the possible occurrence of an adverse drug reaction (ADR).

B. Upon discovery or notification of a Suspected Adverse Drug Reaction (SADR), the health care professional shall perform the following:
   1. Review the medication profile and medical record, if necessary, to determine other medications the patient was receiving at or shortly before the SADR was noted.
   2. Review the immediately available literature regarding the association of the medication with the SADR and communicate pertinent findings as appropriate.

C. Personnel who observe a SADR shall report the reaction to the physician, advanced practice provider, pharmacist, and/or nurse responsible for the patient.

D. The professional observing the reaction shall document the suspected adverse drug reaction in the following manner.
   1. Medical Record information to include:
      a. Medication given.
      b. Description of drug reaction.
      c. Notification of physician or advanced practice provider responsible for the patient's care.
      d. Corrective action taken.
      e. Patient response to corrective action.
      f. Submit a suspected adverse drug reaction electronically via the *Web-Based Incident Reporting System* (TrendTracker system). The system can be accessed from any computer logged into the Hospital or HSF network by clicking the TrendTracker (TT) icon. A password is not required to access the system.

E. Using the web-based system the Drug Information Service shall review all SADR reports on a regular basis and perform the following actions:
   1. Assure the accuracy and completion of appropriate fields, if necessary.
   2. Assess the intensity of the SADR according to the established definitions.
   3. Determine the probability that the suspected medication caused the SADR in the patient (if necessary).
   4. Report the SADR to the Food and Drug Administration and/or the manufacturer, as appropriate.
   5. Summarize the findings from significant SADRs and report these data to the Pharmacy and Therapeutics Committee on a quarterly basis.

F. The Pharmacy and Therapeutics Committee shall evaluate the summary report of SADR's and, any individual reactions considered significant or important on a quarterly basis and take action as appropriate.
   1. These activities and any resulting actions shall be recorded in the minutes of the Pharmacy and Therapeutics Committee. As part of Continuous Quality Improvement (CQI) activities, these actions shall be communicated, in writing, to appropriate parties/departments/divisions.

REFERENCES: None			
CMS:	**§482.23(c)(5), §482.25(b)(6)**	**TJCH:**	**MM.07.01.03**
Cross-References (CR):			
** Incident Report Program (CR)*			

ATTACHMENTS: None

INTERDISCIPLINARY COLLABORATION

Pharmacy and Therapeutics Committee	*4/07/21*
Physician / Medical Committees	Endorsement Date
None	
Committee(s)/Council(s)	Endorsement Date
None	
Hospital Department(s)	Endorsement Date

Tracking Record

Supersedes:	Suspected Adverse Drug Reaction Reporting, 11/09/93; 15:15:30, 052225; 03/07/00, 12/02/02, 11/07/05, 10/06/08, 07/4/11, merged Adverse Drug Reaction Reporting TKC58r3 (03/08/12); 05/05/14, 01/20/17, 06/22/18, 02/25/19, 5/29/19, 05/19/20
File Name:	Suspected Adverse Drug Reaction Reporting I#33r12
REVISIONS: Consistent with Joint Commission and URAC Standards, this policy is to be reviewed every 3 years and/or as practice changes.	