Athens Regional HEALTH SYSTEM

TITLE:	Adverse Drug Reaction Reporting
EFFECTIVE DATE:	*June 2000, updated September 2011*
PERFORMED BY:	*Anticoagulation Management Services (AMS) Clinical Pharmacist*
RELATED DOCUMENTS:	*Pharmacy Medication Errors and Adverse Drug Reaction Reporting*
MANUAL:	*Anticoagulation Management Services (AMS) Coumadin Clinic*
FORMULATED BY:	*Anticoagulation Management Services (AMS) Clinical Pharmacist*

I. Purpose

A. To establish a program for reporting adverse drug reactions for the AMS Clinic.

II. Policies

A. An "Adverse Drug Reaction" is defined as:

1. Any response to a drug which occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease that results in any undesirable and unexpected event requiring discontinuing the drug or modifying the dose; or requires or prolongs hospitalization; or results in disability; or requires treatment with a prescription drug; or is reportable to the FDA; or results in death.

2. The definition of a serious ADR, as described by the FDA, is one in which the patient outcome is death, is life-threatening (real risk of dying), hospitalization (initial or prolonged), disability (significant, persistent, or permanent), congenital anomaly, or required intervention to prevent permanent impairment or damage.

B. All suspected Adverse Drug Reactions (ADRs) will be identified, documented, and reported in the patients AMS record.

C. When a patient is known or suspected to be allergic to a drug(s), it will be listed in the allergy section of the patients chart on IAN and updated in the patient's electronic medical record in Sunrise.

D. All serious ADRs occurring in patients enrolled in the ARMC AMS Clinic will be reported immediately to the referring and/or prescribing physician and to the Department of Pharmacy. Documentation of serious ADRs is completed in e-Variance system of ARMC, in addition to the patients the AMS record.

E. In those cases where the reaction is acute:

1. Notify the referring physician or the physician covering for the referring physician immediately. The clinician will discuss the reaction with the physician. Instructions from the physician can be relayed to the patient, but specific orders for laboratory tests, etc. are the responsibility of the physician.

2. If the referring physician or covering physician is not available, or if the patient requires urgent care, the patient will be advised to go to an emergency room for evaluation and treatment and contact the referring physician as soon as possible. The clinician will contact the emergency room of the patient's choice and give report. A copy of the progress note describing the adverse reaction will be faxed to the referring physician, and a message will be left with the referring physicians service.

3. A progress note describing the situation will be faxed to the referring physician and the Medical Director. Responsibility for further evaluation and treatment lies with the referring physician.

F. Documentation of the signs, symptoms, and the time the physician was notified, as well as any action taken will be in the patient medical record.

G. The Clinician completing the suspected ADR Report will identify the suspected drug and ADR, and send the completed notification to the Department of Pharmacy.

H. All reported serious ADRs will be reviewed by the Medical Director.

Document Owner:	Pharmacy Clinical Manager
Document Approver:	Anticoagulation Management Service Medical Director
Original Issue Date:	06/01/2000
Last Reviewed Date:	01/31/2011
Last Revision Date:	09/01/2011