ADVERSE DRUG REACTIONS (ADRs) AND ALLERGIES TO MEDICATIONS

1. **Policy:** Confirmed diagnosis of allergy or any adverse drug reaction to medication shall be made by the attending physician, and shall be documented by him/her in the resident's medical record on admission and thereafter when appropriate.

2. **Purpose:**
   a. To ensure an accurate diagnosis of adverse drug reactions and/or allergy to medication.
   b. To ensure communication between the resident and the attending physician regarding the type of adverse drug reaction diagnosed.
   c. To ensure that the resident understands any past or potential adverse medication effects, and that the resident's consent to receive a medication is based on complete knowledge and information concerning such effects.
   d. To ensure that identified allergies and adverse drug reactions are reported and documented in the resident’s chart.

3. **Training Requirements:** Medical and nursing staff will be trained on this operating procedure upon hire into the position during Discipline-Specific Training and by their supervisor each time the operating procedure is revised.

4. **References:**
   b. Florida State Hospital Operating Procedure 150-34, “Psychotherapeutic Medication Prescription Standards.”

5. **Background:**
   a. Quality resident care requires that adverse drug reactions, and allergies to medications are assessed and diagnosed accurately, documented correctly, and communicated to the resident in a manner to ensure that he/she understands the type of adverse reaction or allergy experienced. Accurate, timely communication and proper documentation improve resident care and safety. Also, resident cooperation and compliance with taking their medications is enhanced when the resident understands the difference between a true allergic response versus an adverse drug reaction.
b. There are many ways in which drugs may react in the body to produce unpredictable, harmful, and sometimes unexplained responses. No drug is totally safe and absolutely free of side effects. Sometimes these effects are immediately apparent. At other times, they may take weeks or months to develop. Reactions to drugs range from relatively mild to fatal. With the increasing numbers of drugs being utilized, the incidence of adverse reactions has increased and is presently a significant problem in medical therapeutics. An unpredictable and sometimes unexplainable drug response that has not been optimally, clearly, and distinctly defined is referred to as an adverse drug reaction.

6. Definitions:

a. **Drug allergy** is an altered state or reaction to a drug resulting from previous sensitizing exposure and the development of an immunologic mechanism. Substances foreign to the body act as antigens to stimulate the production of antibodies or immunoglobulins. Later, when a previously sensitized individual is again exposed to the foreign substance, the antigen reacts with the antibodies in ways that are damaging to body tissues. The antigen-antibody complex is not directly responsible for the manifestations of allergy. Rather, the complex reacts with various tissues, and cells of the body, by processes not clearly understood, and causes them to release certain substances (e.g., histamine) which then provoke the systems of allergy. Allergic reactions may manifest themselves in a variety of symptoms ranging from minor skin rashes to fatal hypotension. Reactions may be localized or widespread, and the symptoms may appear immediately or within hours to days following drug administration.

   (1) Immediate allergic reactions occur within minutes of exposure to the chemical to which the person has been previously sensitized. Immediate and severe reactions are called anaphylactic reactions and are frequently fatal if not recognized and treated quickly. Signs and symptoms are severe, occur suddenly, and produce shock. The most dramatic form of anaphylaxis is sudden, severe bronchospasm, vasospasm, severe hypotension, and rapid death. Signs are largely caused by contraction of smooth muscles and may begin with irritability, extreme weakness, nausea and vomiting, and may proceed to dyspnea, cyanosis, convulsions and cardiac arrest. Antihistamine drugs, epinephrine, norepinephrine, and bronchodilators are indispensable in the treatment of anaphylactic shock.

   (2) Mild allergic reactions may be characterized by the development of a rash, angioedema, rhinitis, fever, asthma, and pruritus. Some allergic reactions are delayed and may appear anywhere from 7 to 14 days after initial administration of the drug. Delayed reactions are frequently analogous to “serum sickness” and are characterized by angioedema, arthralgia, fever, lymphadenopathy, and splenomegaly. Contact dermatitis, which results from direct skin contact with the eliciting drug, is also a delayed allergic response. An individual who has had a mild allergic response to a particular drug should avoid exposure to that drug and, optimally, should have skin tests performed in order to more definitely diagnose his response. Reinstitution of therapy with the same drug is always dangerous to residents who manifest allergic reactions, since an anaphylactoid reaction may occur.

b. **Hypersensitivity** is frequently used synonymously with allergy, and is appropriate because it is frequently confused with other kinds of adverse drug reactions. Since there is a lack of precision of defining hypersensitivity, it may be wisest to avoid usage of the term.

c. **Idiosyncrasy** is any abnormal or peculiar response to a drug that may manifest itself by:

   (1) over response of abnormal susceptibility to a drug;
(2) under response, demonstrating abnormal tolerance;

(3) a qualitatively different effect from the one expected, such as excitation after the administration of a sedative; or

(4) unpredictable and unexplainable symptoms.

Idiosyncratic reactions are generally thought to result from genetic enzymatic deficiencies that lead to abnormal mechanism of metabolizing drugs. This term has been used rather vaguely to describe drug reactions that are qualitatively different from the usual effects obtained in the majority of residents and that cannot be attributed to drug allergy.

d. Side effects are defined as actions or effects of a drug other than the therapeutic effect it is prescribed for whether it is intrinsically harmful or not. It may be common and minor annoyances, expected and benign, or unexpected and potentially harmful. Some side effects are usually listed on the drug label and go away when the drug is discontinued. A side effect may be tolerated for the drug's therapeutic effect, or it may be so unacceptable or hazardous that the drug may be discontinued. Onset may be sudden or take days to develop.

e. Adverse drug reaction or serious side effect is an undesired or unexpected side effect, allergy, or toxicity that occurs with the administration of medication. Adverse drug reactions may be rare and can be potentially life threatening. Onset may be sudden or take days to develop. Adverse drug reactions may require discontinuation of the medication, modification of the dosage, hospitalization, and/or supportive treatment.

f. Cumulation or Toxic Reactions occur when the body cannot metabolize one dose of drug before another dose is administered. In other words, when drugs are excreted more slowly than they are absorbed, each new dose adds more to the total quantity in the blood and organs than is lost in the same amount of time by excretion. Unless drug administration is adjusted, sufficiently high concentrations can be reached to produce toxic effects.

7. Procedure:

a. On admission, the physician(s), nurse(s), nurse practitioner, and physician assistant shall interview/examine the resident and review all documents which accompany the resident, to determine if the resident has experienced any adverse responses to medication, including allergic reactions, prior to admission.

b. If at any time the resident and/or family member advises any staff member that resident has an allergic or adverse response to any medication, this shall be noted on the progress note and reported to the physician(s).

(1) The physician who is first aware of the adverse response to medication shall assess the circumstances/symptoms and determine if the condition should be diagnosed as an allergic reaction or as another type of adverse response.

(2) The physician will discuss with the resident his/her symptoms and explain whether the symptoms represent an allergic reaction or another type of adverse response. Documentation of this discussion shall be written in the progress notes.

(3) Documentation of a diagnosed allergy or adverse response to medication shall be entered in the Recovery Record as follows:
(a) problem list by the physician;

(b) AXIS III of the DSM IV diagnosis (Form 207, Diagnosis Sheet) by the physician, nurse practitioner or a pharmacist (Addendum if identified after admission);

(c) Medication History section of the Comprehensive Admission and Annual Psychiatric Evaluation (Form 259) by the attending physician, nurse practitioner or a staff pharmacist (Addendum if identified after admission);

(d) the past history section and the concluding diagnostic impression of the Medical History/Physical Examination/Neurological Examination form by the physician or nurse practitioner (Addendum if identified after admission);

(e) front of chart--Allergy tags;

(4) Information on All Allergies must be input into the Computer Database. All allergy information must be received by Pharmacy Services before medication can be continued or new medications dispensed. Strictly following this procedure is necessary to prevent adverse and/or allergic reactions.

c. When a resident displays any symptoms which may be interpreted as an allergy or an adverse response to medication, the person observing the symptoms shall report to the assigned nurse, nurse practitioner, physician or physician assistant, and document the symptoms on the progress note. The nurse or physician assistant shall report the resident’s condition to the physician or nurse practitioner, who shall assess the condition to determine if the diagnosis is an allergic reaction or another type of adverse response to medication.

d. When a diagnosed allergy or adverse response to medication is documented on the problem list or any other of the above, it shall be called to the attention of the registered nurse as soon as possible, and the registered nurse shall:

   (1) note the allergy on the current Physician’s Order sheet;

   (2) note all allergies on the front outside cover of the ward chart using a commercially prepared label, or a piece of tape with the allergy written in bold red letters.

 e. The first person starting a blank Physician’s Order form shall transfer any previous notations of allergy from the previous Physician’s Order form.

 f. Adverse drug reactions carry a special reporting requirement of Form 160, Adverse Drug Reaction Report. All adverse reactions must be reported to Risk Management. It may be necessary for the Director of the Pharmacy to notify drug carriers, suppliers, manufacturers and the Federal Government.

(Signed original on file in Central Health Information Services)

DIANE R. JAMES
Hospital Administrator
SUMMARY OF REVISED, ADDED OR DELETED MATERIAL
This procedure was reviewed and revised to reflect change from Discipline Specific Education to Discipline Specific Training; and to spell out abbreviations/acronyms.