



Georgia Department of Behavioral Health  
& Developmental Disabilities

## Policy # 03-524

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**Chapter:** Hospital Operations  
**Subject:** Adverse Drug Reaction Reporting and Intensive Review of Serious or Lethal Adverse Drug Reaction

**Applicability:**  
DBHDD State Hospitals

**References:**  
See last page of policy

**Attachments:**  
Attachment A – Adverse Drug Reaction Report  
Attachment B – Intensive Review of Serious or Lethal Adverse Drug Reaction

**Effective Date:** October 1, 2010

**Full Implementation Date:** January 5, 2011

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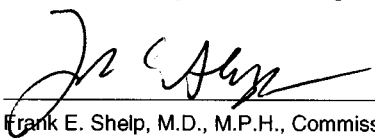
**Approved:**

  
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9.14.10  
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9-15-2010  
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## ADVERSE DRUG REACTION REPORTING AND INTENSIVE REVIEW OF SERIOUS OR LETHAL ADVERSE DRUG REACTION

### 1. POLICY

- A. Georgia DBHDD Hospitals, in keeping with established hospital, state, and federal guidelines, investigate any suspected adverse drug reaction (ADR) in order to:
- i) Help determine when ADRs occur;
  - ii) Determine the types of ADRs that occur (e.g. allergy, dose related, drug-drug interaction, drug-food interaction, withdrawal, idiosyncratic, etc.);
  - iii) Determine outcomes associated with ADRs (e.g. minor, moderate, serious, lethal);
  - iv) Perform an intensive review of any ADR with outcome equal to serious or lethal in order to:
    - a) Identify system issues that may have led to a serious or lethal ADR; and
    - b) Define measures taken to help ensure that such ADRs do not occur in the future;
  - v) Report any ADR with an outcome of serious or lethal to the United States Food and Drug Administration (FDA).

### 2. DEFINITIONS

- A. Adverse Drug Reaction (ADR)
- i) The term “noxious” means: physically harmful or destructive to living beings.

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- ii) According to the World Health Organization, an adverse drug reaction is any noxious unintended, and undesired effect of a drug that occurs at doses used in humans for prophylaxis, diagnosis, or therapy, and it implies a causal relationship between the use of the drug and the noxious event<sup>(i)</sup>.

### 3. PROCEDURE

#### A. Electronic Format of ADR Report

- i) The **ADR Report (Attachment A)** form may be converted to electronic format so that the process flow may occur electronically, provided that the Clinical Director signs each form, and maintains hard copy files of all completed forms.
- ii) For an ADR Report form that is processed electronically, the person completing Section 1, and the person completing Section 2 may type their name and date in the signature lines. However, the Clinical Director will need to print out the completed ADR to sign, date, and then file the completed ADR Report.

#### B. Process flow of the ADR Report

- i) Whenever a suspected ADR is discovered, Section 1 of the ADR Report form, titled *Description of Suspected ADR*, is completed by the discovering practitioner (nurse, pharmacist, or physician), or by the practitioner to whom the suspected ADR is first reported.
- ii) Section 2 of the ADR Report form (*Physician's Investigation of Reaction*) is completed by the discovering physician or APRN.
- iii) Section 3 of the ADR Report form (*Clinical Review*) is completed by the Clinical Director.
- iv) The Clinical Director maintains hard copy files of all completed ADR reports.
- a) When an ADR Report is complete, the Clinical Director will send one (1) copy to the Pharmacy and Therapeutics Committee, and one (1) copy to the Hospital Medical Executive Committee.

#### C. Process flow of the Intensive Review

- i) If an ADR outcome is serious or lethal, then the Clinical Director initiates an Intensive Review.
- ii) The Clinical Director appoints a medical reviewer, nurse reviewer and pharmacy reviewer to participate in the Intensive Review.
- iii) The Clinical Director designates the time and place of a meeting at which the Clinical Director, medical reviewer, nurse reviewer, and pharmacy reviewer will work together to fill out and complete the **Intensive Review of Serious or Lethal Adverse Drug Reaction (Attachment B)** form.
- iv) The Clinical Director maintains hard copy files of all completed Intensive Review report forms.

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- v) When an Intensive Review report form is complete, the Clinical Director will send one (1) copy to the Pharmacy and Therapeutics Committee, and one (1) copy to the Hospital Medical Executive Committee.
- D. The Clinical Director is responsible for notifying the FDA of ADRs as required by this procedure and as required by FDA policy (discussed below). The following notes are current as of this writing. If FDA changes policy in the future, this portion of this procedure will be updated accordingly.
- a) As of this writing, the FDA states that it is purely voluntary for hospitals to notify the FDA of ADRs with the following exception:
- If an Investigational New Drug (IND) is being used in a study at the hospital, and the IND is found to be associated with an ADR, then the hospital is required to notify the sponsor, and the sponsor then notifies the FDA of the ADR<sup>(iv)</sup>.
- b) To clarify: the FDA states that even the reporting of serious or lethal ADRs to the FDA Medwatch program is voluntary, unless an IND is involved<sup>(iv)</sup>. However, Georgia DBHDD hospitals via the associated Clinical Director will report any ADR with an outcome of serious or lethal to the FDA.
- c) Forms used to report ADRs to the FDA may be printed from the following web source:  
<http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>

#### 4. REFERENCE MATERIALS

- i) World Health Organization. International Drug Monitoring: The Role of the Hospital. Technical Report Series No 425. Geneva, World Health Organization, 1996. In Dipiro et al *Pharmacotherapy: A Pathophysiologic Approach* 6<sup>th</sup> ed. Pp 119 McGraw Hill (Available electronically at [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_425.pdf](http://whqlibdoc.who.int/trs/WHO_TRS_425.pdf))
- ii) Naranjo CA, Busto U, Sellers EM, et al. A method for estimating the probability of adverse drug reactions. *Clin Pharmacol Ther.* 1981; 30:239-245. (Available electronically at <http://www.nature.com/clpt/journal/v30/n2/index.html>)
- iii) United States Department of Health and Human Services: Food and Drug Administration. Web capture 02-04-10. (Available electronically at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>)
- iv) Shepard, David. Clinical Pharmacist. Central State Hospital, Milledgeville Georgia. Personal Communication with the United States Food and Drug Administration Medwatch Program: 1-800-332-1088. 02-04-2010.

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**ADVERSE DRUG REACTION REPORT**

**Identification (Name, Unit, Visit ID)**

1. **Description of Suspected ADR** (by discovering practitioner (nurse, pharmacist or physician) or practitioner to whom reaction is reported).

A. Date and time when the reaction was first observed: \_\_\_\_\_

B. Describe the suspected ADR:

\_\_\_\_\_

C. Describe intervention(s) made immediately before medical, pharmaceutical and nursing staff intervention(s):

\_\_\_\_\_

D. Describe intervention(s) made by medical, pharmaceutical and nursing staff:

\_\_\_\_\_

E. List medication(s) suspected of causing the reaction (attach separate sheet if needed)

Medication 1: \_\_\_\_\_ Medication 2: \_\_\_\_\_ Medication 3: \_\_\_\_\_

F. Complete Section F if the discoverer is not a physician/APRN, (physician/APRN must be notified of any suspected adverse drug reaction):

Name of Physician/APRN Notified: \_\_\_\_\_ Date and Time of Notification: \_\_\_\_\_

G. Section 1 Completed By: (may type in data if this is an electronic form)

Signature	Printed Name/Title	Date
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2. **Physician/APRN Investigation of Reaction** (To be completed by physician) (attach separate sheet if needed).

A. Summarize symptoms of the reaction:

\_\_\_\_\_

B. Describe facts or circumstances surrounding the reaction:

\_\_\_\_\_

C. Describe additional information such as possible drug-drug or food-drug interactions, or pre-existing conditions that could have led to the ADR.

\_\_\_\_\_

D. Describe associated treatment(s) ordered:

\_\_\_\_\_

E. Using the **Individual's MAR**, review all medications the individual was receiving at the time of the reaction. (Attach a copy of the MAR to this form)

MAR reviewed

F. Is a medication suspected of causing the reaction?  Yes  No  Unsure

i. If "no", proceed directly to section 2M, sign and date, and forward to the Clinical Director.

G. List Suspected Medication(s) and Rate the ADR probability for each medication

List suspected Medication(s) →												
Question	Yes	No	Don't Know/NA	Score	Yes	No	Don't Know/NA	Score	Yes	No	Don't Know/NA	Score
Are there previous conclusive reports on this reaction?	+1	0	0		+1	0	0		+1	0	0	
Did the adverse reaction occur after suspected drug was administered?	+2	-1	0		+2	-1	0		+2	-1	0	
Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0		+1	0	0		+1	0	0	
Did the adverse reaction reappear when the drug was re-administered?	+2	-1	0		+2	-1	0		+2	-1	0	
Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0		-1	+2	0		-1	+2	0	
Did the reaction appear when placebo was given?	-1	+1	0		-1	+1	0		-1	+1	0	
Was the drug detected in the blood (or other bodily fluids) in concentrations known to be toxic?	+1	0	0		+1	0	0		+1	0	0	
Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0		+1	0	0		+1	0	0	
Did the patient have similar reaction to the same or similar drugs in any previous exposure?	+1	0	0		+1	0	0		+1	0	0	
Was the adverse event confirmed by any objective evidence?	+1	0	0		+1	0	0		+1	0	0	
Total Score:												
Write <b>ADR Probability Rating</b> → "Definite" (Total Score ≥ 9) "Probable" (Total Score = 5, 6, 7, or 8) "Possible" (Total Score = 1, 2, 3, or 4) "Doubtful" (Total Score = 0)												

- H. Is ADR still expected? (circle one) YES NO UNSURE  
 i. If "No" skip to section 2N signatures and forward form to Clinical Director.  
 ii. If "Unsure" please explain \_\_\_\_\_
- I. Based on the ratings in Item H and on clinical judgment, which medication most likely caused the ADR? \_\_\_\_\_  
 i. Medication classification:  **Medical** (non-psychotropic)  **Anticonvulsant** (non-psychotropic)  
 **Psychotropic**:  Antidepressant  Antiparkinson  Antipsychotic  Benzodiazepine  Mood Stabilizer  Other: \_\_\_\_\_  
 ii. Route:  P.O.  Per Tube  Topical  Rectal  Subcutaneous  I.M.  Vaginal  Other
- J. Type of reaction:  
 i.  Allergy  Dose-Related  Drug-drug interaction  Drug-food interaction  Withdrawal  Idiosyncratic  Unknown  
 Other (explain): \_\_\_\_\_
- K. Does the drug need to be added to individual's allergy list?  Yes  No (If "Yes", submit an order to pharmacy stating "individual is allergic to (drug)")
- L. Outcome of the reaction  
 Not yet known  
 Minor: An ADR that is insignificant or is secondary to a coexisting condition or reaction  
 Moderate: An ADR that is non life-threatening but requires non-emergent intervention  
 Serious: An ADR that presents a life-threatening circumstance, results in temporary or permanent harm, requires medical intervention to prevent or minimize harm, or results in hospitalization  
 Lethal: An ADR that results in death
- M. Part 2 Completed By: (may type in data if this is an electronic form)

Signature	Printed Name/Title	Date
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**Part 3. Clinical Review:** To be completed by the Clinical Director.

- No further action  Additional information requested  Hold until outcome is known  Determined that no ADR occurred  
 Add to individual's allergies list  Incident/injury report completed  Intensive Review indicated (required for all serious/lethal ADRs)  
 Report to FDA (required for all serious/lethal ADRs)  Additional Comments \_\_\_\_\_

Signature of Clinical Director	Clinical Director Printed Name/Title	Date
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Georgia Department of Behavioral Health and Developmental Disabilities

**Policy: Adverse Drug Reaction and Intensive Review  
of Serious or Lethal Adverse Drug Reaction****INTENSIVE REVIEW OF SERIOUS OR LETHAL  
ADVERSE DRUG REACTION****Identification (Name, Unit, Visit ID)**

**1. The purpose of this report is to identify system issues that may have led to a serious or lethal ADR. This report form is completed by a team composed of a medical reviewer, a pharmacy reviewer, a nursing reviewer and the Clinical Director.**

**2. Classification of this ADR**

- Serious      An ADR that presents a life-threatening circumstance, results in temporary or permanent harm, requires medical intervention to prevent or minimize harm, or results in hospitalization
- Lethal        An ADR that results in death

**3. Did the individual have any pre-existing diseases/conditions which could have contributed to the ADR?  Yes** **No**

If yes: please check all that apply

- The order writer was aware of the pre-existing diseases/conditions.
- The order writer was aware as to how the pre-existing diseases/conditions could have contributed to ADR with this medication.
- The order writer took reasonable care to have the individual appropriately monitored for potential ADR.
- The nurse(s) administering the associated medication were aware of the pre-existing disease/conditions.
- The nurse(s) administering the associated medication had orders to appropriately monitor the individual for potential ADR(s).
- The nurse(s) administering the associated medication had appropriate orders and training as to how to proceed if associated complications arose.

**4. Was this an allergic reaction?  Yes  No**

If yes: please check all that apply.

- The allergy was listed in patient data base (AVATAR) as an active allergy for this individual.
- The Allergy was listed in the allergy section of the very order form used to order the medication.
- The Allergy was listed in the allergy section of the individual's Medication Administration Record.
- The order writer was aware of the allergy at the time of writing the order for the medication.
- The nurse administering the medication was aware of the allergy at the time of administering the medication.
- The nurse(s) administering the associated medication had appropriate orders and/or training as to how to proceed if associated complications arose.

**5. Was drug-drug interaction associated with this ADR?  Yes  No**

If yes: please check all that apply

- The associated pharmacist(s) was aware of the potential medication interaction.
- The associated pharmacist(s) informed the order writer of the potential medication interaction in a timely manner.
- The associated order writer was aware of the potential medication interaction(s) at the time of the ADR.
- The nurse(s) administering the associated medication had orders to appropriately monitor the individual for potential ADR(s).
- The nurse(s) administering the associated medication had appropriate orders and training as to how to proceed if associated complications arose.

**6. Was drug-food interaction associated with this ADR?  Yes  No**

If yes: please check all that Apply

- The associated dietician was aware of potential drug-food interaction(s).
- The associated order writer was made aware of potential drug-food interaction(s).

- The order writer was aware of the potential drug-food interaction(s).
- The nurse(s) administrating the associated medication had orders to appropriately monitor the individual for potential ADR(s).
- The nurse(s) administrating the associated medication had appropriate orders and training as to how to proceed if associated complications arose.

**7. Was the drug dose associated with this ADR?**  Yes  No

If yes: please check all that Apply

- The associated pharmacist was aware of the potential for the dose to cause the ADR.
- The associated pharmacist discussed this dose with the nurse, order writer, and/or Clinical Director.
- If the medication was an antipsychotic, the associated order writer had access to CSH maximum dose information.
- The order writer was aware of the potential for the dose to cause the ADR.
- The Clinical Director was aware of the potential for the dose to cause the ADR
- The nurse(s) administrating the associated medication had appropriate orders and training as to how to proceed if associated complications arose.

**8. Given the above information (Items 2-8), please describe: A) what, if anything, could have been done to have prevented this ADR from occurring; and B) what measures are being/ have been taken to help ensure that this ADR does not occur in the future?**

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**9. Signatures**

Signature of Medical Reviewer:	Printed Name:	Date:
Signature of Nurse Reviewer:	Printed Name:	Date:
Signature of Pharmacy Reviewer:	Printed Name:	Date:
Signature of Clinical Director:	Printed Name:	Date: