

Subject:		Issued By:	
MEDICATION ERROR REPORTING		IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA's President & CEO	
Policy #:	Issue Date:	Revised Date:	Effective Date:
2019	November 1, 2006	April 24, 2007	May 1, 2007

Reference: Original Medication Errors policy dated 4-12-2006 and 2007 California Board of Pharmacy Lawbook located here: http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf.

PURPOSE

To ensure that any IDS-Pharmacy-related medication errors are properly documented and reported and that corrective actions are implemented to prevent the reoccurrence of the same error in the future.

POLICY

1. **STRICTLY FOLLOW PROCEDURES:** IDS Staff will strictly follow the procedures outlined in this document for reporting medication errors;
2. **IMPLEMENT CORRECTIVE ACTIONS PROMPTLY:** Systemic corrective actions must be implemented and evaluated in order to minimize future, similar errors.

GUIDELINES & PROCEDURES

1. **DOCUMENTATION REQUIREMENTS:** All medication errors that are the responsibility of IDS Staff must be documented and described in detail. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error was discovered. If more than one patient was affected by the same medication error, multiple reports for the same incident must be completed. Such documentation must be promptly forwarded to the Principal Investigator (PI), the study's sponsor, HRA's President & CEO, and the IRB. In addition, a copy of such documentation should be included in the protocol-specific study binder. Documentation must include ALL of the following:
 - a. Date and time of event;
 - b. Protocol name and number;
 - c. The initials of any patients involved;
 - d. Documentation of any patient contact;
 - e. A complete and thorough description of the event;
 - f. The outcome of the event;
 - g. A description of any immediate corrective actions that were taken;
 - h. Details of any systemic corrective action plans to prevent reoccurrence;

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- i. The names of all IDS Staff-Members involved in the medication error;
 - j. The date, location and participants in the quality assurance review;
2. **PATIENT NOTIFICATION:** The staff of the IDS Pharmacy at HRA never have direct patient contact. Therefore, the IDS Pharmacy will notify the study coordinator, the study's sponsor, and the PI of any medication errors according to the terms of the contract. It is the responsibility of the PI and/or their staff to notify any patients involved in medication errors;
 3. **ADDITIONAL REPORTING REQUIREMENTS:** All medication error reports must be regularly compiled and reported to the Office for the Protection of Research Subjects (OPRS) by e-mailing oprs@usc.edu or calling (213) 821-1154. In addition, USC's Institutional Biosafety Committee must be notified by calling (323) 442-2200;
 4. **IDS STAFF NOTIFICATION:** The Pharmacist-in-Charge will inform all IDS Staff-Members of any changes to pharmacy policies, procedures, systems or processes that are made as a result of recommendations generated in any quality assurance program undertaken as a result of a medication error;
 5. **RETAIN MEDICATION ERROR RECORDS ONSITE FOR AT LEAST ONE YEAR:** Any records of quality assurance reviews based upon medical errors must be immediately retrievable within the IDS Pharmacy for at least one year from the date that the review was undertaken.

RESPONSIBILITY

Pharmacist-in-Charge
All IDS Staff