

<b>Title:</b> <b>High Risk Medication Management</b>	<b>Policy Number:</b> C – MED - 0008 <b>Policy Type:</b> Clinical Operations <b>Effective Date:</b> 01/11
<b>Replaces (supersedes):</b>  N/A	<b>Policy Chronicle:</b>  Date Original Version of Policy was Effective: 09/06 Most Recent Review: 12/07  Reviewer _____ Date: 01/18/11 Helen Gibbons, Medication Safety Officer  Previous Reviews:
<b>Area of Operation(s):</b>  Inpatient and Ambulatory Care	
<b>Regulatory Agency / Standards:</b>  TJC MM.01.01.03	<b>This Policy has been Reviewed and Approved Electronically:</b>  Steven Cano _____ Sr. Director / Chief Pharmacy Officer  Elizabeth Cadigan, R.N. _____ Sr. Vice President of Patient Care Services / Chief Nursing Officer  Allison Bayer _____ Chief Operating Officer  Somava Stout, M.D. _____ Chair, Medical Executive Committee
<b>Keywords(s):</b>	High Risk Medication, Investigational Medication

**I. Purpose:**

To proactively employ various additional safety measures to protect patients from harm related to high-risk medications.

**II. Personnel:**

Medical staff, nursing staff, pharmacy staff, and other ancillary care providers.

**III. Policy:**

Special, standardized procedures and processes shall be employed to minimize the potential for serious adverse events related to the use of high-risk medications.

**IV. Definitions:**

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**High-Risk Medication** - A medication that has an inherent narrow therapeutic index and/or has the potential to cause serious adverse events when not used appropriately.

**Investigational Medication** – A medication that is in the process of legitimate clinical study [with or without approval from the U.S. Food and Drug Administration (FDA) for marketing].

## V. Procedures:

### A. Criteria for the Identification of High-Risk Medications

High-risk medications shall be identified through a variety of means including but not limited to:

- published *ISMP Newsletter* alerts
- published *Joint Commission Sentinel Event Alerts*
- internal sentinel event reports
- other criteria as determined by the Pharmacy & Therapeutics (P&T) Committee.

### B. High-Risk Medications List / Management Process

A list detailing the medications assigned "high-risk" status by the P&T Committee, as well as the special management processes required and the reference bases for topic selection, will be reviewed at least annually and made available on Staff.Net.

Special management processes shall fall into one or more of the following areas that describe the medication use process:

- Procurement
- Storage
- Ordering
- Transcribing
- Preparing (Compounding)
- Dispensing
- Distribution
- Administering
- Monitoring

### C. Investigational Medication Control and Administration

Investigational medications may be brought into the hospital and administered, assuming that the patient is enrolled in an approved clinical research trial. A physician order for the investigational medication initiates the process.

Upon receipt of the order for an investigational medication, the Pharmacist will contact the prescribing physician to secure copies of the signed informed consent and approved research protocol. Once the legitimacy of the order for the investigational drug has been established, the Pharmacist will return the copy of the informed consent to the patient chart. The study protocol will be filed in the Pharmacy with a second copy going to the patient care area for reference by nursing personnel.

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Storage of investigational medications will be controlled by the Pharmacy. The Pharmacist shall take possession of the investigational medication for the duration of the hospitalization. The drug shall be dispensed in a manner consistent with the existing drug distribution system. Ambulatory storage and dispensing shall be coordinated between the Pharmacist and the principal investigator / study coordinator.

An Investigational Drug Accountability Record shall be initiated by the Pharmacist to document the dispensing process.

Investigational medications shall be labeled in a standard manner, and will include the following information:

- Patient name or initials and patient identification number (if applicable)
- Name of medication
- Strength and dosage form
- Prescribing investigator's name
- The words "FOR INVESTIGATIONAL USE ONLY"