

TITLE: MEDICATION PREPARATION, HANDLING, and STORAGE		
EFFECTIVE DATE: 3/14/06	Policy #: PN.07b	PAGE: 1 OF 5
REVIEW/REVISION DATE: 5/08, 1/10, 7/10,1/11,2/15, 8/16	CREATED BY: R. Thelin, Pharm.D. REVISED BY: K. Kamenetsky, RPh; V. Anselmo, RPh.	DISTRIBUTION: Nursing; Pharmacy

A. MEDICATION PREPARATION & EXPIRATION DATING:

TOPICAL PREPARATIONS	AREA	BEYOND USE DATING	NOTES
Sterile Irrigation Solutions	Sterile use	24 hours	OR, ED irrigations
	Non-Sterile use	6 months	Including preparations, contingent on chemical stability
Povidone Iodine solution and scrub, 70% Isopropyl Alcohol, Hydrogen Peroxide	All	Manufacturer's expiration date	No dating necessary (non-sterile preps)
Bulk chemicals for pharmaceutical compounding, Creams, Ointments, Gels.	All	Manufacturer's expiration date	If container has no expiration date, expires 12 months from date opened
	All	12 months from date opened.	Any product withdrawn or compounded.

PRODUCTS COMPOUNDED IN PHARMACY

Non-Aqueous Liquid or Solid with manufactured drug as source	All	6 Months	OR not more than 25% of time remaining until expiration of product used to compound, whichever is earlier
Non-Aqueous Liquid or Solid with USP or NF drug as source	All	6 months or less	
Water Containing Product (Prepared from solid ingr.)	All	Not more than 14 Days	Must be Refrigerated
All other Formulations	All	Earlier of 1 & 2	1. Intended duration of therapy 2. 30 Days

ORAL MEDICATIONS

Opened bulk liquid packages	Pharmacy Only	12 months from date opened	Or manufacturer's expiration date (if earlier). Including water (distilled/sterile) used for dilution.
Unit dose Solid: packaged in pharmacy	All	12 months	Or manufacturer's expiration date (if earlier)
Unit dose Liquid: packaged in pharmacy	All	12 months	Or manufacturer's expiration date (if earlier)

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INJECTABLE MEDICATIONS	AREA	BEYOND USE DATING	NOTES
Ampules	ALL	Use within 1 hour	Opened single-dose ampules are not to be stored for any time period. Utilize filter straw.
Single Dose Containers (vials, bags, bottles, syringes) Contain no preservatives Opened or Needle Punctured	Opened Outside IV Hood (< ISO Class 5)	Compounded: use within 1 hour Premix medication-containing bags (out of overwrap: product dependent)	Discard remaining contents. All meds with overwraps will be labeled with exp date by pharmacy. If from Pyxis, immediately date/time by nurse required.
Plain IV fluids (LR, NaCl, Dextrose)	All areas	30 days (Once removed from overwrap) Date immediately.	
Multiple Dose Containers (e.g. vials, MDV) Containing preservatives After initial needle puncture	All	28 Days	Unless otherwise specified by manufacturer
Medication drawn into Syringe (USP 797 Low Risk)	Prepared Outside IV Hood (< ISO Class 5)	Use within 1 hour	Discard remaining contents.
Compounded Sterile Product (CSP): (syringe, piggyback, large vol) USP 797 Low Risk: Only sterile ingredients. Simple measure & transfer only. Not > 3 sterile nonhazardous commercial ingredients, including infusion or diluent solution. Into one sterile container.	Prepared Inside IV Hood (≥ ISO Class 5)	Room Temp: 48hrs Refrig: 14 days Frozen*: 45 days	Unless chemical stability dictates a shorter Expiration. *Frozen = < -20F
	Prepared Outside IV Hood (< ISO Class 5)	Administration must begin no later than 1 hour following start of preparation	Preparation must occur without interruption and must be properly labeled. If administration does not begin within 1 hour from start of preparation, discard.
Compounded Sterile Product: (syringe, piggyback, large vol) Medium Risk: As described in USP 797	Prepared Inside IV Hood (≥ ISO Class 5)	Room Temp: 48hrs Refrig: 14 days Frozen:: 45 days	OR as specified by manufacturer, whichever is less.
	Prepared Inside IV Hood (≥ ISO Class 5)	Room Temp: 30hrs Refrig: 9days Frozen:: 45 days	
Hazardous Drugs as CSPs Including, but not limited to: chemotherapeutic agents and other cytotoxic drugs.	As per USP 797, all hazardous drugs shall be prepared in a Class II or III biological safety cabinet (BSC) or a compounding aseptic isolator (CAI) in an ISO Class 5 environment, according to the standards set forth in the chapter. Reference list of Hazardous Drugs in Appendix A of NIOSH Publication No. 2004-165 @ www.cdc.gov/niosh/docs/2004-165 . Beyond Use Dating will be in accordance with above.		

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B. MEDICATION HANDLING (Transport):

1. Access to medications:
 - a. Access is limited to nurses, physicians, respiratory care practitioners, pharmacy staff and other professionals/technicians responsible for medication management.
 - b. Unauthorized access to unattended medications is not permitted.
2. Pharmacy Medication Delivery to Patient Care units:
 - a. When delivering medications to patient care units, pharmacy personnel will insure medications are secure at all times. This includes, but is not limited to, moving delivery carts and other transportation devices (bins, baskets, etc) into medication rooms.
 - b. Chemotherapy & biohazard medications are transported separate from other medications. Injectable chemotherapy must be accompanied with a 'spill kit' for transport.
3. From Medication Storage to Patient:
 - a. All drugs removed from a medication storage area are removed just prior to administration.
 - b. Once removed, the drug must remain with the individual at all times and should not be left unattended.
 - c. If not administered or used, the drug should be returned to the original storage area within 30 minutes.
 - d. The drug should not be left on or in any area exceeding 86° F, including clothing pockets
4. Disposition of unused medications:
 - a. Medications that are not administered are returned to the locked medication cart, locked medication cabinet, locked/secured refrigerator or locked medication room.
 - b. Medications that have been opened/tampered, or waste required, should be discarded appropriately. Controlled medication waste is required to be witnessed and documented. (see chemotherapy & biohazard policies for meds that require special disposition)
 - c. Pharmacy personnel will reconcile returned medications to detect potential diversion.

C. MEDICATION STORAGE: Room temperature

1. Delivery area:
 - a. All medications are delivered to a locked medication room (including locked/secured Pyxis, locked medication cart, or directly to the Nurse and stored as per standards detailed below.
 - b. Emergency medications are stored in crash carts or sealed boxes with break away locks
 - c. Controlled Dangerous Substances CII-CIV are stored as described in the Controlled Dangerous Substance Policy.
2. No products are allowed to be left in the patient room.
3. Access is limited to nurses, physicians, respiratory care practitioners, pharmacy staff and other professionals/technicians responsible for medication management.
4. Proper temperature and prevention of exposure to light are maintained for all medication storage areas as per manufacturer's labeling instructions. The following temperature ranges are observed:
 - i. a. Controlled Room Temperature = 20 to 25° C, 68 to 77° F
(allows for brief deviations to Room Temperature: 15 to 30° C, 59 to 86° F)

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D. MEDICATION STORAGE: Refrigerated or Frozen

1. **Temperature:** For all refrigerators or freezers containing medication, temperature ranges observed:
 - a. Refrigerator Temperature = 2 to 8° C, 36 to 46° F
 - i. All medications that are stable unrefrigerated will be dated upon dispensing from pharmacy with a 'use by' expiration date (i.e. Insulin products)
 - b. Freezer Temperature = -20 to -10° C, -4 to 14° F

2. **Frequency of monitoring:**

The temperature of each refrigerator and freezer in the hospital where medications are stored is recorded every 15 minutes by the wireless remote temperature monitoring system.

E. Criteria for preparation of compounded sterile products (CSPs) outside of the Primary Engineering Control (PEC) in the Pharmacy IV Room:

1. The need exists for **emergency or immediate** patient administration of a CSP on the Nursing Unit.
2. The primary engineering control (PEC) in the Pharmacy IV Room which provides ISO Class 5 air is not operational.

In these instances, compounded sterile product (CSP) will be prepared under the following Immediate-Use restrictions:

- A. **Compounding Restrictions for Immediate-Use CSPs prepared outside of the PEC**
 1. No hazardous products may be compounded outside of the chemotherapy aseptic compounding isolator.
 2. Not more than 3 commercially manufactured packages of sterile products may be transferred from their original, manufacturer's containers to the final product.
 3. Not more than 2 entries may be made into any one container or package of sterile infusion solution or administration container/device.
 - 4.

- B. **Compounding Requirements for Immediate-Use CSPs:**
 1. Preparation will be done:
 - a. By a registered nurse, pharmacist, or pharmacy technician
 - b. According to the requirements of USP Chapter 797 and N.J.A.C. 13:39, Subchapter 11, as outlined in this policy.
 - c. In a designated spot on the nursing unit, or in the pharmacy, that has been disinfected by application of an appropriate disinfectant, including 70% alcohol, Cavicide, and PDI Germicide disinfecting wipes, immediately before the preparation begins.
 - d. As a continuous process.*
 - e. In one hour or less*
 - f. Using aseptic technique.
 2. The finished CSP must remain under continuous supervision until administration begins.

*Unless a longer time is required for the preparation of a particular ingredient.

C. Administration of Immediate-Use CSPs

1. Begins not later than 1 hour after the start of preparation of the CSP.
2. Should be completed immediately, by the person who prepared the CSP, when possible.
3. If C.2. is not possible, the immediate and complete administration should be witnessed by the person who prepared the CSP

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4. If neither C.2., nor C.3., is possible, the CSP must be labeled with the following information
 - i. Date & Time prepared
 - ii. Patient identifying information
 - iii. Names and amounts of all ingredients, including name & volume of any diluent, vehicle, or base solution
 - iv. Directions for use
 - v. Name and initials of person who prepared it
 - vi. The exact 1 hour BUD and time, written as "use by" followed by date & time
5. **Immediate-use CSPs may not be stored for later use.** If administration has not begun within 1 hour of the start of preparation, the Immediate-use CSP, will be promptly, properly, and safely discarded.

NOTE: attachment of an Advantage™ or Mini-Bag Plus bag™ to a vial constitutes preparation of a sterile product. If such preparation takes place outside of ISO Class 5 air (i.e. outside of the laminar flow hood or glovebox), all of the stipulations of this policy apply.