LOS ANGELES GENERAL MEDICAL CENTER POLICY

Subject: **HAZARDOUS MEDICATIONS**	Original Issue Date: 12/1/17	Policy # **947**
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Policy Owner(s): Directory of Pharmacy Services
Executive Sponsor(s): Chief Medical Officer

Departments Consulted:	Reviewed & approved by:	Approved by:
P&T Committee Pharmacy Department Nursing Department Engineering Department	Attending Staff Association Executive Committee Senior Executive Officer	Chief Medical Officer Chief Executive Officer

PURPOSE

A. Hazardous medications must be managed appropriately to minimize potential harm to humans and the environment.

B. This policy establishes procedures for appropriate handling of hazardous medications, in compliance with relevant laws and regulations.

POLICY

A. Guided by NIOSH recommendations, the Pharmacy Department develops and maintains a list of hazardous medications divided into four groups (Attachment A). The list is reviewed annually, and as new medications or dosage forms are introduced. Investigational and newly approved medications are considered hazardous until data is sufficient to conclude otherwise.

	Manipulation needed:	**No manipulation needed:**
Antineoplastic:	Group 1-A	Group 1-B
Non-antineoplastic:	Group 2-A	Group 2-B

B. Procedures for appropriate handling of hazardous medications are determined by the assigned group. The Pharmacy Department may establish exceptions to the handling requirements for specific hazardous medications or dosage forms by conducting an assessment of risk.

Dispensing for home use of hazardous medications is not subject to this policy.

DEFINITIONS

- Compounding: any manipulation of a hazardous medication prior to dispensing, other than counting of intact tablets and capsules
- C-PEC: containment primary engineering control
- CSTD: closed-system transfer device
- MSDS: material safety data sheet
- NIOSH: National Institute for Occupational Safety and Health
- PPE: personal protective equipment
- RCRA: Resource Conservation and Recovery Act
- SDS: safety data sheet

PROCEDURE

A. **Assessment of Risk**

1. An assessment of risk may be used to establish exceptions to the handling requirements for any specific hazardous medications or dosage forms in Group 2-A or Group 2-B, or for specific hazardous medications or dosage forms in Group 1-A or 1-B that do not require compounding prior to administration.
2. An assessment of risk must consider the type, dosage form, risk of exposure, packaging, manipulation, and other exceptional characteristics or likely situations of use.
3. When the assessment of risk concludes there is an absence of significant risk of direct occupational exposure, alternative procedures for appropriate handling will be explicitly stated and followed (Attachment B).

B. **Handling of Hazardous Medications**

1. **General Personal Protective Equipment Use.** Requirements for PPE are described under each type of handling activity below. In addition, the following conventions must be observed:
   a. Chemotherapy gloves must be changed at least every 30 minutes and whenever torn, punctured, or visibly contaminated
   b. Chemotherapy gowns must be long-sleeved, tied closed, and changed at least every 3 hours and whenever torn, punctured, or visibly contaminated
   c. PPE worn in hazardous medication handling areas must not be worn to other areas

2. **Receipt.** Personnel unpacking hazardous medications must wear a single pair of chemotherapy gloves. Hazardous medications must be unpacked from external shipping containers in a designated area that is neutral or negative in pressure relative to the surrounding areas. When an external shipping container containing hazardous medications appears damaged, the container must be sealed without opening and the supplier must be contacted for further instructions.
3. **Storage.** Sterile and non-sterile hazardous medications may be stored together.
   a. *Groups 1-A, 1-B*
      i. Antineoplastic hazardous medications that require compounding prior to administration must be stored separately from non-hazardous medications.
      ii. Antineoplastic hazardous medications that do not require compounding prior to administration may be stored with non-hazardous medications.
   b. *Groups 2-A, 2-B*

      Non-antineoplastic hazardous medications may be stored with non-hazardous medications.
4. **Compounding**
   a. *General engineering controls*
      i. All sterile and non-sterile compounding of hazardous medications must be performed in a C-PEC located within a buffer area.
      ii. A CSTD must be employed when such a device is available for the hazardous medication being compounded.
      iii. Non-hazardous medications compounded in the same C-PEC as hazardous medications must be labeled as hazardous.
   b. *Primary engineering control for sterile compounding*
      i. The C-PEC must be a Class II or Class III biological safety cabinet or a compounding aseptic containment isolator and must be operated continuously.
      ii. If there is any loss of power or other concern affecting the operation of the C-PEC, sterile compounding must be suspended immediately. Once normal operation of the C-PEC returns, sterile compounding may resume only after the C-PEC has been deactivated, decontaminated, cleaned, and disinfected and after the C-PEC has been operated for at least 30 minutes.

iii. The C-PEC must be certified by a qualified technician every 6 months.

c. *Primary engineering control for non-sterile compounding*

i. The C-PEC must be a Class I, Class II, or Class III biological safety cabinet, a compounding aseptic containment isolator, or a containment ventilated enclosure.

ii. For occasional non-sterile compounding of hazardous medications, a C-PEC used for sterile compounding may be used for non-sterile compounding if the following criteria are met:

- During non-sterile compounding, no sterile compounding may occur in any C-PEC located within the same buffer area
- Following non-sterile compounding, the C-PEC must be deactivated, decontaminated, cleaned, and disinfected before sterile compounding resumes

iii. The C-PECs for sterile and non-sterile compounding may be located in the same buffer area if the following criteria are met:

- The C-PECs are placed at least 1 meter apart
- During non-sterile compounding, no sterile compounding may occur in any C-PEC located within the same buffer area

iv. The C-PEC must be certified by a qualified technician every 6 months.

d. *Personal protective equipment*

i. Personnel who perform sterile and non-sterile compounding of hazardous medications must don a single pair of shoe covers, a hair cover, a face mask, a chemotherapy gown, and a single pair of chemotherapy gloves before entering the ante area, a second pair of shoe covers before entering the buffer area, and a second pair of chemotherapy gloves before handling hazardous medications.

ii. De-garbing must occur so that PPE worn for handling hazardous medications does not contaminate other areas.

5. **Dispensing.** Hazardous medications must be dispensed by pharmacy staff as a final product that minimizes or eliminates the requirement for further manipulation by nursing staff. Splitting, crushing, and opening dosage forms of hazardous medications is described in Section 3, "Compounding."

a. *Groups 1-A, 1-B*

i. Antineoplastic hazardous medications that are cytotoxic must bear a yellow label with the words "Chemotherapy – Dispose of Properly."

ii. Antineoplastic hazardous medications that are not cytotoxic must bear a yellow label with the words "Hazardous – Dispose of Properly."

b. *Groups 2-A, 2-B*

Non-antineoplastic hazardous medications must bear a yellow label with the words "Hazardous – Dispose of Properly."

6. **Transport.** Hazardous medications must be transported in an external container such as a bin or bag and must be transported in a manner that minimizes potential for falls and spills. Personnel must wear a single pair of chemotherapy gloves when placing hazardous medications into or removing hazardous medications from an external container for transport. A chemotherapy spill kit must accompany hazardous medications in liquid dosage forms during transport.

a. *Groups 1-A, 1-B*

i. The pneumatic tube system must not be used to transport antineoplastic hazardous medications.

ii. Antineoplastic hazardous medications must be transported in a sealed plastic bag bearing a distinctive warning including one of the terms "Antineoplastic," "Chemotherapy," or "Cytotoxic."

b. *Groups 2-A, 2-B*

Non-antineoplastic hazardous medications must be transported in a sealed plastic bag.

7. **Administration.** Hazardous medications must be administered while observing universal precautions. For injectable hazardous medications, a CSTD must be employed when such a device is available. Splitting, crushing, and opening dosage forms of hazardous medications is described in Section 4, "Compounding." Following administration of a hazardous medication, all patient body fluids must be treated as hazardous for at least 48 hours.

a. *Group 1-A*

Personnel administering antineoplastic medications requiring dosage form manipulation must:

- Be certified in cytotoxic medication use and advanced infusion care as described in Section C, "Training of Personnel Handling Hazardous Medications," though the Pharmacy Department may waive this requirement for non-cytotoxic antineoplastic hazardous medications
- Wear full PPE (chemotherapy gown and a double pair of chemotherapy gloves)

b. *Group 1-B*

Personnel administering antineoplastic medications requiring no dosage form manipulation must:

- Be certified in cytotoxic medication use as described in Section C, "Training of Personnel Handling Hazardous Medications," though the Pharmacy Department may waive this requirement for non-cytotoxic antineoplastic hazardous medications
- Wear a single pair of chemotherapy gloves

c. *Group 2-A*

Personnel administering non-antineoplastic medications requiring dosage form manipulation must wear full PPE (chemotherapy gown and a double pair of chemotherapy gloves. Pentamidine for inhalation must be administered following policies and procedures of the Respiratory Department.

d. *Group 2-B*

Personnel administering non-antineoplastic medications requiring no dosage form manipulation must wear a single pair of chemotherapy gloves.

e. *Group 3*

A list of non-hazardous medications that require advanced infusion care is provided in Section 3 of Addendum. Personnel administering these medications must be certified in advanced infusion care as described in Section C, "Training of Personnel Handling Hazardous Medications."

8. **Waste.** Waste related to medications listed under RCRA will be disposed according to RCRA regulations. A list of medications listed under RCRA is provided in Section 4 of addendum. As used below, "empty" means holding no pourable or scrapable pharmaceutical material.

a. *Medications under RCRA*

Containers holding pharmaceutical material, empty containers, and obviously or potentially contaminated items such as PPE are disposed as RCRA waste (black bins). Empty containers assessed by pharmacy personnel as not previously holding p-listed pharmaceutical material may be disposed as pharmaceutical waste (blue bins).

b. *Group 1-A, 1-B other than medications under RCRA*

Containers holding pharmaceutical material are disposed as pharmaceutical waste (blue bins). Empty containers and obviously or potentially contaminated items such as PPE are disposed as trace chemotherapy waste (yellow bins).

c. *Group 2-A, 2-B other than medications under RCRA*

Containers holding pharmaceutical material and empty containers are disposed as pharmaceutical waste (blue bins). Obviously or likely contaminated items such as PPE are disposed as pharmaceutical waste (blue bins). Likely non-contaminated items such as PPE are disposed as non-classified waste (trash bins).

9. **Spills.** Hazardous medication spills will be managed according to Medical Center Policy 957, "Hazardous Medication Spills."

10. **Exposure.** Any personnel who is exposed to a hazardous medication via dermal or mucosal contact, injection, ingestion, inhalation, or other means must immediately take steps to minimize the severity and duration of exposure (e.g. wash or rinse, needle aspiration, removal of saturated materials) and report to an immediate supervisor for evaluation at the employee health center. All unintentional exposures to hazardous medications must be reported to the medical center Safety Intelligence system as soon as possible.

C. **Training of Personnel Handling Hazardous Medications**

1. **Pharmacy Staff**

a. Pharmacy staff who will handle hazardous medications must be fully trained in the handling of hazardous medications and successfully complete a written competency exam to ensure the effectiveness of training.

b. Personnel knowledge and ability must be re-assessed through written competency exam every 12 months and whenever a new or significantly changed equipment or procedure is implemented.

c. Training records must be maintained for at least 3 years.

d. Training for pharmacy staff who will handle hazardous medications in any capacity must include:
   - Review of this policy and the medical center list of hazardous medications
   - Proper use of PPE, engineering controls, and other safety devices
   - Management of hazardous medication spills
   - Response to known or suspected hazardous medication exposures

e. Additional training for pharmacy staff who will handle antineoplastic hazardous medications during compounding must include:
   - The American Society of Health-System Pharmacist video "Safe Handling of Hazardous Drugs"
   - The Chemotherapy Pharmacy compounding written competency exam

2. **Nursing Staff**

a. Registered nurses and other ancillary staff who will handle hazardous medications, including all personnel authorized by the medical center to transport or administer medications, must be fully trained in the handling of hazardous medications and successfully complete a written competency exam to ensure the effectiveness of training.

b. Personnel knowledge and ability must be re-assessed through written competency exam every 12 months and whenever a new or significantly changed equipment or procedure is implemented.

c. Training for registered nurses and other ancillary staff who will handle non-antineoplastic hazardous medications must include:
   - Review of this policy and the medical center list of hazardous medications
   - Proper use of PPE and safety devices
   - Management of hazardous medication spills
   - Response to known or suspected hazardous medication exposures

d. A certification program will be established to provide registered nurses who will handle certain hazardous and non-hazardous medications (Sections 1 and 3 of Addendum) with additional, focused training in cytotoxic medication use and advanced infusion care. This program must include:

- Clinical and pharmacologic properties of medications that require such certification for administration
- Management of hypersensitivity and extravasation
- Monitoring of response to antineoplastic hazardous medications
- Experiential training under a certified registered nurse for a minimum of 24 hours
- The Oncology Nursing Society/Oncology Nursing Certification Corporation Chemotherapy-Biotherapy Certificate Course

D. **General Requirements**

1. **Communication Plan.** The medical center maintains a file containing the SDS or MSDS for each hazardous medication in use. This file must be readily accessible to personnel during each work shift and at each work area.
2. **Pregnancy.** Personnel who are actively trying to conceive, pregnant, or breastfeeding must collaborate with their supervisor to minimize handling of hazardous medications.
3. **Medical Surveillance.** Medical surveillance for personnel handling hazardous medications at Los Angeles General Medical Center will be governed by the Health Services of Los Angeles County policy 925.350, Hazardous and Anti-Neoplastic Drug Medical Surveillance.

RESPONSIBILITY

Pharmacy Staff
Nursing Staff

REFERENCES

- Institute for Safe Medication Practice (ISMP) International Medication Safety Self Assessment for Oncology, 2012
- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016
- Occupational Safety and Health Administration (OSHA) Hazard Communication standard 29 CFR 1910.1200
- United States Pharmacopeia (USP) Chapter <797>: Pharmaceutical Compounding – Sterile Preparations
- USP Chapter <800>: Hazardous Drugs – Handling in Healthcare Settings

ATTACHMENTS

Appendix A – Hazardous Medications

Appendix B – Hazardous Medications

REVISION DATES

August 13, 2018; November 18, 2019; February 2, 2023; December 9, 2023