Harbor-UCLA MEDICAL CENTER

LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES
HARBOR-UCLA MEDICAL CENTER

SUBJECT: HANDLING OF HAZARDOUS DRUGS (HDs) **POLICY NO.** 325L

CATEGORY: Provision of Care	**EFFECTIVE DATE:** 4/15
POLICY CONTACT: Jennie Ung, PharmD	**UPDATE/REVISION DATE:** 10/21
REVIEWED BY COMMITTEE(S): Pharmacy and Therapeutics, Medication Safety	

PURPOSE:
To provide guidelines for handling of hazardous drugs (HDs): receiving, storing, prescribing, preparing, delivering, administering, disposing, management, and accidental exposure of hazardous drugs (HDs).

POLICY:
At Harbor-UCLA Medical Center, the departments that handle HDs will provide guidelines and a training program relevant to the tasks performed by their workforce members. These guidelines should be easily accessible to the involved workforce members. These departments are Pharmacy, Medicine, Nursing, Employee Health, Environmental Services, and Environmental Health and Safety.

Preparation of all HDs, including oral and injectable, shall be performed by the Pharmacy Department using a Class II biological safety cabinet exhausted to the exterior of the building, unless risk assessment deems otherwise. Workforce members involved in handling of antineoplastic medications shall take appropriate steps to minimize self-contamination and exposure. Hospital workforce members who routinely prepare or administer parenteral antineoplastic agents shall be enrolled in an annual medical surveillance program. See DHS Policy 925.350.

Workforce members actively trying to conceive, are pregnant, or breastfeeding, may elect to refrain from preparing/administering Group 1 (antineoplastic agents). Also, workforce members who have other medical reasons that prohibit exposure to antineoplastic agents may elect to refrain from preparing/administering these agents or caring for patients during their treatment. Workforce members who are trying to conceive, pregnant, or breastfeeding, must utilize the personal protective equipment (PPE) detailed in appendix B when preparing or administering Group 2 and 3. The workforce member has the responsibility of notifying the employer of the specific situations.

DEFINITIONS:
Hazardous Drugs (HDs):
Hazardous drugs are agents that exhibit one or more of the following characteristics: carcinogenicity, teratogenicity, and other developmental toxicity, reproductive toxicity, organ toxicity at low dose, genotoxicity

REVISED: 4/15, 9/17, 1/19, 10/21
REVIEWED: 4/15, 9/17, 1/19, 10/21

APPROVED BY:

Anish Mahajan, MD
Chief Executive Officer

Anish Mahajan, MD
Chief Medical Officer

Joy LaGrone, RN, MSN
Interim Chief Nursing Officer

and structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria (National Institute of Occupational Safety and Health (NIOSH) revision of American Society of Hospital Pharmacy (ASHP) definition [1990]).

Groups of Hazardous Drugs:
Three groups of HDs were categorized by NIOSH in 2016 based on antineoplastic properties and reproductive risk. See **Appendix A** for the HUMC formulary HD list. The lists will be reviewed and revised annually by the Pharmacy Department.

- Group 1: Antineoplastic drugs. Note that many of these drugs may also pose a reproductive risk for susceptible population. Refer to Appendix A, Table 1.
- Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a HD. Note that many of these drugs may also pose a reproductive risk for susceptible population. Refer to Appendix A, Table 2.
- Group 3: Drugs that pose a reproductive risk to men and women who are actively trying to conceive. Also includes women who are pregnant or breast feeding, because some of these drugs may be present in the breast milk. Refer to Appendix A, Table 3.

Hazardous Waste:
Waste(s) that contain properties that are dangerous or potentially harmful to human health or the environment when it is improperly treated, stored, transported, disposed, or managed. Any item that comes in contact with a hazardous drug during its preparation or administration is considered potentially contaminated and must be disposed of as hazardous waste. Such items include needles, syringes, empty drug vials, ampules, blister packs, equipment(s) used to administer oral/enteral route, IV tubing, IV bags or bottles, connecting devices, gauze, alcohol wipes, paper drapes, medication cups, medication packages, and personal protective equipment (PPE).

PROCEDURE:

I. PRESCRIBING OF HD Group 1 MEDICATIONS
- **Refer to Hospital Policy 325 (Medication Prescribing)**

II. REVIEWING AND PROCESSING OF HD AGENTS

1. Group 1

a. The oncology pharmacists are responsible for reviewing and processing all orders which are part of chemotherapy regimen (Group 1); a second pharmacist shall double check all chemotherapy orders for accuracy and appropriateness.

b. The following situations and indications may be processed by any pharmacist and independently double checked by a second pharmacist. Once the pharmacist performs the independent double check, they will document it on the order in EHR.

i. Injectable chemotherapies for non-oncology indications after hours only.
   a. Methotrexate for ectopic pregnancy
   b. Methotrexate for Rheumatoid Arthritis flare
   c. Rituximab/cyclophosphamide for glomerular nephritis
   d. Mitomycin for bladder irrigation or glaucoma
   e. Bevacizumab for macular degeneration

ii. Non-oncology indication of oral chemo medications can be processed anytime.

iii. Oral chemo medications for continuation of therapy (from home or transfer from one unit to another).

c. A warning message will show on the drug label and MAR as "ALERT: Chemotherapy" and another warning sticker label on the plastic bag as "CAUTION: Chemotherapy".

2. **Group 2 & 3**
   a. A second pharmacist check is not required for Groups 2 & 3 HDs.
   b. A warning message will show on the drug label and MAR as "ALERT: Hazardous Drug" and another warning sticker label on the plastic bag as "CAUTION: Hazardous Drug" with the instructions for handling.

III. RECEIPT OF HDs

1. Don a single pair of chemo gloves when unpacking HDs from shipping containers.
2. Inspect all HD containers for signs of damage, breakage, or leaks prior to opening. If HD container, package of shipping cartons is damaged, follow procedures as described under Spill Management in Section X.
3. All HDs listed on the NIOSH list must be unpacked (removal from external shipping containers) and transported directly to appropriate designated storage area.
4. HDs must not be unpacked from their shipping containers in sterile compounding areas or in positive pressure areas.

IV. STORAGE OF HDs

1. HDs must be stored in a manner that prevents spillage or breakage from the container. Do not store HDs on the floor.
2. Group 1: HDs in powder or liquid formulation requiring manipulation must be stored separately from other inventory in a manner that prevents contamination and personnel exposure.
3. Refrigerated Group 1 HDs: regardless of dosage formulation, must be stored in a dedicated refrigerator.
4. All Group 2 & 3, and final dosage forms of Group 1: may be stored with other inventory based on risk assessment.

V. PREPARATION/COMPOUNDING OF HDs

1. **Engineering controls**
   a. Sterile and nonsterile Group 1 and some Group 2 HDs (refer to **Appendix B**) shall be prepared in a containment primary engineering control (C-PEC) such as Class II Biological Safety Cabinet (BSC) or compounding aseptic containment isolator (CACI), located in containment secondary engineering controls (C-SEC).
   b. C-SEC must be externally vented through high-efficiency particulate air (HEPA) filtration.
   c. C-SEC must be physically separated from other preparation areas.
   d. C-SEC must have a negative pressure between 0.01 and 0.03 inches of water column.
   e. C-PEC must operate continuously if used for sterile compounding or if the C-PEC supplies the negative pressure air.
   f. C-PEC shall be cleaned with the approved hospital cleaning agent before and after preparing the medication.
2. **Non-sterile compounding**
   a. A C-PEC is not required if manipulation is limited to handling of final dosage forms (e.g., tablets and capsules) that do not produce particles, aerosols, or gases.
   b. A C-PEC used for sterile compounding may be used for occasional nonsterile HD compounding if decontaminated, cleaned, and disinfected before resuming sterile compounding in that C-PEC.
   c. C-PEC used for sterile and non-sterile preparation must be at least 1 meter (3.28 feet) a part.

d. C-PEC used for manipulation of nonsterile HDs must be either externally vented or redundant-HEPA filtered in series.

3. **Containment supplemental engineering controls**
   a. Closed system transfer devices (CSTDs) provide adjunct controls to offer additional levels of protection during compounding and administration.
   b. Some CSTDs have been shown to limit the potential of generating aerosols during compounding.
   c. CSTDs must not be used as a substitute for a C-PEC when compounding:
   d. CSTDs must be used when compounding HDs when the dosage form allows.
      i. CSTDs must be used when administering Group 1 and 2 HDs when the dosage form allows. CSTDs known to be physically or chemically incompatible with a specific HD must not be used for that HD.

VI. OTHER SPECIAL INSTRUCTIONS FOR PHARMACY

1. The hood shall be cleaned with the approved hospital cleaning agent before and after preparing the medication. See **Appendix C**.
2. Hand hygiene shall be performed with soap and water or alcohol-based foam before handling, but use only soap and water after handling of HDs.
3. The work surface of the C-PEC must be decontaminated between compounding of different HDs.
4. Agents used for deactivation, decontamination, and cleaning should be applied through the use of wipes wetted with appropriate solution and not delivered by a spray bottle to avoid spreading HD residue. Workforce member who prepare antineoplastic medications shall wear disposable chemo gloves with the outer one covering the gown cuff; a disposable mask; and a disposable gown of the proper design (long sleeves, closed fronts, and closed cuffs).
5. Chemo gloves should be changed every 30 mins when performing sterile compounding unless otherwise recommend by manufacturer's documentation.
6. When compounding IV Group 1 & 2, all IV bags shall be spiked and primed before HDs are added.

VII. DELIVERY OF HDs

1. Group 1 HDs (oral liquid, topical cream/ointments, injectable, and IV solutions) will be double-bagged and labeled with "Caution: Chemotherapy" label before delivering to the approved chemotherapy care areas (refer to section VIII 2a). If the Group 1 is for a non-oncology indication, any RN can pick up the drug from the pharmacy (e.g. Methotrexate for ectopic pregnancy).
2. Group 2 and 3 HDs (oral liquid, topical cream/ointments, injectable, and IV solutions) will be double-bagged and labeled with "Hazardous Drug" label before delivering to patient care area.
3. Pneumatic tubes must not be used to transport any liquid HD (i.e. oral liquid, topical creams/ointments, gels, IV syringe or solution) or any dosage forms of Group 1 or 2 due to the potential for leakage and contamination.

VIII. ADMINISTRATION OF HDs

1. Only chemotherapy certified RNs and approved physicians may administer Group 1 HDs following standard guidelines for each drug (refer to **Appendix A**).
   Exceptions:
   a. Group 1 HDs can be administered in other areas such as Operating Room (OR), Urology Clinic, Eye Clinic and Emergency Department by a registered nurse and/or provider trained in proper handling and disposal of HDs when using for a non-oncology indication(s) (i.e. Methotrexate IM/SQ for ectopic pregnancy or Mitomycin intravesical administration for bladder irrigation). Refer to Appendix A, Table 1.

b. Oral chemotherapy agent can be administered by any registered nurse following high alert medication policy. **Refer to Hospital Policy 396**. Oral chemotherapy agents shall be ordered by a licensed independent provider using the EHR orderable or on a chemotherapy/biotherapy order form.

2. All chemotherapy orders must be independently double checked by another registered nurse prior to administration for drug name, dose, route, indication, current weight/height, body surface area (BSA), dosage calculation, ensuring appropriate time intervals between scheduled treatment, reviewing and documenting laboratory values and other factors that may be required for the treatment.
3. The chemotherapy provider order form and the MAR must reflect the signature of two RN's confirmation of dose verification.
4. The same principle is applicable for all written protocols for combination chemotherapy, and/or investigational study medications:
   a. Investigational drugs may also be administered when approved as part of a study by the Institutional Review Board (IRB) of Harbor-UCLA, the respective medical division and the Department of Nursing.
   b. The names of chemotherapy certified RNs may be confirmed from the Unit Manager or Clinical-Professional Development.
   c. Requirements of the chemotherapy certified nurse include:
      i. Education and Training: Completion of the "Chemotherapy Certification" course (didactic portion).
      ii. Completion of the clinical portion of the certification process, which must be completed onsite at Harbor-UCLA within four months of course completion.
      NOTE: "Record of Chemotherapy Drug Administered" shall serve as proof of completion of the clinical practicum.
      iii. A minimum of six months clinical experience in acute care or in infusion therapy is preferred.
      iv. Annual Maintenance of Competency by successful completion of the annual chemotherapy recertification.
5. The preferred locations for the administration of chemotherapy are as follows:
   a. **In-patient:** 5 East Ward/PCU, 5 West RTU, 5 West ICU (Adults), 6 East Ward/PCU, and 6 East PICU.
      i. When chemotherapy is ordered in 6E PICU and a chemotherapy certified RN is not available in the PICU, the chemotherapy RN from 6 East Ward may initiate administration of chemotherapy in 6E PICU. The 6E PICU RN is responsible for monitoring the patient.
      ii. When chemotherapy is ordered in 5 West ICU and a chemotherapy RN is not available in 5 West ICU, the Infusion Clinic RN or 5E Chemotherapy Certified RN may initiate administration of chemotherapy in 5 West ICU. The 5 West ICU RN is responsible for monitoring the patient.
      iii. If any chemotherapy needed to be administered to any non-chemotherapy area such as 6WICU, 3 East etc., the nurse manager/house supervisor must make arrangement with a chemotherapy certified nurse from 6East, 6EPICU, 5E, 5WICU, or Infusion clinic for administration ahead of time to avoid delay. A chemotherapy certified nurse must pick up the HD Group 1 from inpatient pharmacy.
   b. **Out-patient:** 5 East Infusion Clinic (Adults), Pediatric Clinic, and PACU

6. Nursing Instructions

a. Group 2 & 3 HDs may be administered by nursing in accordance to Hospital Policy 325Q, following the personal protective equipment (PPE) requirements. Refer to Appendix B.
b. The nurse must never crush, break, open or alter capsules and oral HDs.
c. If the delivered oral HD cannot be administered in its original form, the nurse shall contact the pharmacy to request for that particular agent to be prepared and dispensed as a suspension or in an intravenous form.
d. The IV site shall be monitored for signs and symptoms of drug infiltration and/or extravasation.
e. If infiltration/extravasation of a vesicant is suspected or confirmed, notify physician to enter an order for *Extravasation Management Provider Order Form* which shall be used to determine the appropriate antidote, method of administration and compress measures.
f. The *Chemotherapy Extravasation/Infiltration Nursing Documentation Form* shall be completed as well as a Safety Intelligence entry.

7. **Intrathecal (IT)/Intraventricular**
   a. Trained provider from restricted service(s) shall administer intrathecal/intraventricular chemotherapy.
   b. Vinca alkaloids should never be given intrathecally because of the potential lethal neurotoxicity.

8. **Intravitreal**
   a. Trained provider from restricted service(s) shall administer intravitreal chemotherapy.

9. **Intravesicular**
   a. Trained provider/nursing staff from restricted service(s) shall administer intravesicular chemotherapy.

IX. SAFE HANDLING AND DISPOSAL OF HDs

1. All workforce members who prepare, administer, care for patients receiving HDs must follow the following Personal Protective Equipment (PPE), which provides worker protection to reduce exposure from HD aerosols and residues. Refer to **Appendix B**.
2. Situations requiring PPE. Refer to Appendix B.
   a. During preparation of HDs;
   b. Transporting
   c. Administration by any route;
   d. Spiking and priming of IV bags and tubings;
   e. Handling leakage from tubing, syringes, and connection sites;
   f. Disposing of HDs or contaminated items;
   g. Handling the body fluids of a patient who received HDs in the past 48 hours; and
   h. Cleaning a spill.
3. **Pharmacy /Nursing/Physicians/ Environmental Services**
   a. Group 1 HD waste contaminated with trace (i.e. all PPE, chemo pads, empty bottles, tubing, IV bags and tubing that have no moving liquid) shall be discarded in a bag which must be placed in a solid, lidded container labeled "Chemotherapy Waste" for disposal by Environmental Services and/or outside approved vendor.
   b. Group 1 HD waste including all bottles and tubing with moving liquid shall be discarded in a bag which must be placed in a solid, lidded container labeled "RCRA". A Hazardous Waste Container" for disposal by Environmental Services and/or outside approved vendor.

c. Group 2 &3 HD waste (i.e. unused medications, empty bottles, tubing, IV bags) shall be discarded in the pharmaceutical waste bin.
d. All equipment, supplies, and receptacles in contact with Bacillus Calmette Guerine (BCG) vaccine should be handled and disposed of as biohazardous waste.
e. All HDs/supply waste shall be transported according to medical waste procedures within the Medical Waste Management Plan.
f. Upon reaching the medical waste holding area, Environmental Services and/or outside approved vendor will segregate all HD waste in designated holding areas marked for such waste.
g. HD waste will be disposed by a contracted disposal service using recommended procedures of the Department of Health Services.

X. Spill Management

1. HD spills: Spill kits should be available wherever HDs are stored, transported, prepared, or administered. Workforce member who work with HDs should be trained in spill cleanup. Cytotoxic spill is divided into two categories; Small spill and large spill.

a. **Small Spills:** The ASHP considers small spills to be less than 5 mL. The 5-mL volume of material should be used to categorize spills as large or small. In the Pharmacy, spills less than 5 mL or 5 gm outside a BSC should be cleaned up immediately by the Pharmacy staff. If the small spill occurs in a nursing unit, the nursing staff is responsible for cleaning up the spill. In case there is a small spill, the following steps must be taken:
   i. Remove patient(s) form the area if possible and/or provide safety to the patient(s).
   ii. Immediately post a sign or signs that warn others of the presence of a hazardous spill. This will prevent others from being exposed.
   iii. Don two pair of chemo gloves, a disposable gown, and a face shield.
   iv. Wear NIOSH approved respirator.
   v. Use appropriate items in the spill control kit to contain the spill.
   vi. Notify Environmental Service ((424) 306-8370) and Environmental, Health and Safety Department ((424) 306-7700) of the location of the spill. Provide the name of the drug, approximate amount, room number and the location of the spill occurred.
   vii. Clean up the spill according to the instructions on the spill kit.
   viii. Immediately report and document the spill, input information in the Safety Intelligence (SI) system, and contact the Environmental, Health and Safety Department at ext. 67700. Reporting includes the name of the drug and the approximate volume spilled, how the spill occurred, spill management procedure followed, the names of the personnel, patients, and others exposed to the spill, and the list of personnel notified of the spill.
   ix. Complete the report though the medication event reporting and Safety Intelligence (SI) systems.

b. **Large Spills:** When a large spill occurs, the area should be isolated and aerosol generation should be avoided. For spills larger than 5 mL, limit liquid spread by gently covering with absorbent sheets or spill-control pads or pillows. If a powder is involved, use damp cloths or towels. Trained individuals from Environmental/Biohazard Department shall clean up the large spill. In case there is a large spill, the flowing steps must be taken:
   i. Remove patient(s) from the area if possible and/or provide safety to the patient(s).
   ii. Immediately post a sign or signs that warn others of the presence of a hazardous spill. This will prevent others from being exposed.

iii. Don two pair of chemo gloves, a disposable gown, and a face shield.
iv. Wear a NIOSH approved respirator.
v. Use appropriate items in the spill control kit to contain the spill.
vi. Notify Environmental Service ((424) 306-8370) and Environmental, Health and Safety Department ((424) 306-7700) of the location of the spill. Provide the name of the drug, approximate amount, room number and the location of the spill.
vii. Follow the instructions from the Environmental Service and Environmental, Health and Safety Department for any assistance.
viii. If larger than 500 mL, contact North State Environmental (approved outside vendor) at (909) 875-9288 for containment and clean-up of the spill. If possible and safe, contain the area after the removal of workforce members, patients and/or visitors.
ix. Report and document the spill immediately and input information in the Safety Intelligence (SI) system and immediately contact the Environmental, Health and Safety Department at ext. 67700. Reporting includes the name of the drug and the approximate volume spilled, how the spill occurred, spill management procedure followed, the names of the personnel, patients, and others exposed to the spill, and the list of personnel notified of the spill.
x. Complete the report though the medication event reporting and Safety Intelligence (SI) systems.

XI. Accidental Exposures/First Aid Measures

Immediately, but calmly, notify others in the room/unit that a spill has taken place. Specify whether or not you need help.

1. Allergic Reaction:
   a. Emergency medications shall be available in the immediate area of chemotherapy administration.
   b. When a severe allergic reaction occurs in the clinics, activate hospital's Medical Rapid Response Team, notify the physician, and wait for instructions.
2. Skin exposure:
   a. Remove any contaminated gloves and/or gown.
   b. Wash contaminated skin with soap and water immediately.
   c. Refer to the Safety Data Sheet (SDS) for agent specific interventions (all departments/areas must contain their own SDS)
3. Eye exposure:
   a. Flush the affected eye immediately with saline solution or water for at least 15 minutes.
   b. If the area has an eyewash station, use the eyewash for irrigation of the affected eye.
4. Seek emergency treatment from Employee Health Services or Emergency Department always.
5. Inhalation exposure:
   a. Move away from the area of exposure as quickly as possible.
   b. Seek emergency treatment from Employee Health Services or Emergency Department always.
   c. Refer to the SDS for agent specific interventions.
      - Keep your department's and/or unit's SDS binder in a visible and reachable location for workforce members.
6. Needle stick:
   a. If the drug has been injected into the tissue through a needle stick, do not immediately remove the needle, draw back on the syringe plunger and remove the drug.
   b. If the needle has been removed after accidental injection, treat as an extravasation.
   c. Seek emergency treatment from Employee Health Services or Emergency Department immediately and always.

d. Refer to the SDS for agent specific interventions.
e. All accidental exposures shall be reported by the employee to the immediate supervisor and entered in the medication event reporting and Safety Intelligence (SI) systems.

7. All exposed workforce members should complete an Industrial Accident (IA) form and be followed by the designated agency after receiving immediate treatment at Employee Health Services or Emergency Department.
8. All exposed employees will report to Employee Health on weekdays from 7:00 a.m. – 4:30 p.m., excluding weekends and holidays. Employee Health will make the determination to treat and/or seek expert consultation as necessary. During non-business hours, the employee will report to the Emergency Department Triage Area. The employee will be seen immediately in the Emergency Department and will initiate any necessary treatment related to exposure. The workforce member must report to Employee Health Service for follow-up on the following business day.
9. Environmental Health and Safety Department (424-306-7700) must be notified of any employee exposure.

Note: *Currently, no National Institute of Occupational Safety and Health (NIOSH) recommended exposure limits (RELs), Occupational Safety and Health Administration (OSHA) permissible exposure limits (PELs), or American Conference of Governmental Industrial Hygienist threshold limit values (TLV®) have been established for hazardous drugs in general.*

XII. MEDICAL SURVEILLANCE PROGRAM – See DHS Medical Surveillance Policy 925.350

XIII. PERSONNEL TRAINING

Any and all workforce members handling HDs must receive training that is specific to their job function.

1. Workforce members training includes at least the following:
   a. HDs handled at the facility and the risk of each
   b. Review of P&P as related to all aspects of HD handling
   c. Proper use of PPE equipment and devices (CSTDs)
   d. Response to known or suspected exposure to HDs
   e. Spill management
   f. Proper disposal of HDs and trace-contaminated materials
2. Training must be documented before workforce member handle HDs, before introducing a new HD, and before any new equipment is used in the handling of HD.
3. Specific competencies must be developed and should include psychomotor skills and actions workers must take.

Recordkeeping:

Hazardous drug medical surveillance records shall be maintained for the duration of workforce member/assignment plus thirty (30) years, in accordance with 29 CFR 1910.1020 and §3204 of the General Industry Safety Orders.

Medical Surveillance is only recommended by NIOSH, OSHA, American Society of Health-System Pharmacists (ASHP) but not mandated. Providing a medical surveillance program for hazardous drug handlers is recognized as the standard of occupational health practice for hazardous drug handlers.

SUBJECT: HANDLING OF HAZARDOUS DRUGS (HDs) **POLICY NO.** 325L

Reviewed and approved by:
Medical Executive Committee on date 10/2021

Beverley A. Petrie, M.D.
President, Professional Staff Association

Appendix A:

Table 1. Group 1: Antineoplastic

Generic Name	AHFS* Medication Classification	Route
Only Chemo Certified Registered Nurses and Approved Providers may administer		
Ado-trastuzumab emtansine	Antineoplastic agents	Intravenous
Arsenic trioxide	Antineoplastic agents	Intravenous
Azacitidine	Antineoplastic agents	Intravenous
Bleomycin	Antineoplastic agents	Intravenous
Bortezomib	Antineoplastic agents	Intravenous
Carboplatin	Antineoplastic agents	Intravenous
Carmustine	Antineoplastic agents	Intravenous
Cisplatin	Antineoplastic agents	Intravenous
Cladribine	Antineoplastic agents	Intravenous
Cyclophosphamide	Antineoplastic agents	Intravenous
Cytarabine	Antineoplastic agents	Intravenous, Intrathecal
Cytarabine (liposomal)	Antineoplastic agents	Intravenous
Dacarbazine	Antineoplastic agents	Intravenous
Dactinomycin	Antineoplastic agents	Intravenous
Daunorubicin	Antineoplastic agents	Intravenous
Daunorubicin (liposomal)	Antineoplastic agents	Intravenous
Docetaxel	Antineoplastic agents	Intravenous
Doxorubicin	Antineoplastic agents	Intravenous
Doxorubicin (liposomal)	Antineoplastic agents	Intravenous
Epirubicin	Antineoplastic agents	Intravenous
Etoposide	Antineoplastic agents	Intravenous
Fludarabine	Antineoplastic agents	Intravenous
Fluorouracil	Antineoplastic agents	Intravenous
Gemcitabine	Antineoplastic agents	Intravenous
Gemtuzumab ozogamicin	Antineoplastic agents	Intravenous
Idarubicin	Antineoplastic agents	Intravenous
Ifosfamide	Antineoplastic agents	Intravenous
Irinotecan	Antineoplastic agents	Intravenous
Mechlorethamine	Antineoplastic agents	Intravenous
Methotrexate	Antineoplastic agents	Intravenous, Intrathecal
Mitomycin	Antineoplastic agents	Intravenous
Mitoxantrone	Antineoplastic agents	Intravenous
Oxaliplatin	Antineoplastic agents	Intravenous
Paclitaxel	Antineoplastic agents	Intravenous
Pemetrexed	Antineoplastic agents	Intravenous
Pertuzumab	Antineoplastic agents	Intravenous
Streptozocin	Antineoplastic agents	Intravenous

Temsirolimus	Antineoplastic agents	Intravenous
Teniposide	Antineoplastic agents	Intravenous
Thiotepa	Antineoplastic agents	Intravenous
Topotecan	Antineoplastic agents	Intravenous
Vinblastine	Antineoplastic agents	Intravenous
Vincristine	Antineoplastic agents	Intravenous
Vinorelbine	Antineoplastic agents	Intravenous
Registered Nurse/Provider Trained to handle HDs may Administer		
Bacillus Calmette Guerin	Vaccine	Intravesical
****Bevacizumab**	Antineoplastic agents	Intravitreal
Fulvestrant	Antineoplastic agents	Intramuscular
Leuprolide	Antineoplastic agents	Intramuscular
Methotrexate	Antineoplastic agents	Intramuscular, Subcutaneous
Mitomycin	Antineoplastic agents	Intravesical, Subconjunctival
Register Nurse may administer following High Alert Policy/Procedure (Hospital Policy 396)		
Anastrozole	Antineoplastic agents	Oral
Busulfan	Antineoplastic agents	Oral
Capecitabine	Antineoplastic agents	Oral
Chlorambucil	Antineoplastic agents	Oral
Crizotinib	Antineoplastic agents	Oral
Cyclophosphamide	Antineoplastic agents	Oral
Dasatinib	Antineoplastic agents	Oral
Erlotinib	Antineoplastic agents	Oral
Estramustine	Antineoplastic agents	Oral
Etoposide	Antineoplastic agents	Oral
Everolimus	Antineoplastic agents	Oral
Exemestane	Antineoplastic agents	Oral
Fluorouracil	Antineoplastic agents	Topical
Flutamide	Antineoplastic agents	Oral
Hydroxyurea	Antineoplastic agents	Oral
Imatinib	Antineoplastic agents	Oral
Lomustine	Antineoplastic agents	Oral
Megestrol	Antineoplastic agents	Oral
Melphalan	Antineoplastic agents	Oral
Mercaptopurine	Antineoplastic agents	Oral
Mitotane	Antineoplastic agents	Oral
Procarbazine	Antineoplastic agents	Oral
Sorafenib	Antineoplastic agents	Oral
Sunitinib	Antineoplastic agents	Oral
Tamoxifen	Antineoplastic agents	Oral
Temozolomide	Antineoplastic agents	Oral
Thioguanine	Antineoplastic agents	Oral

Toremifene	Antineoplastic agents	Oral
*AHFS: American Hospital Formulary Service *Medications listed are per DHS formulary and does not include all medications listed in NISOH* *** HUMC staff shall handle as Group 1 (not listed on NIOSH 2016 Group 1 list)*		Last update: September 2016

Table 2. Group 2: Non-antineoplastic Drugs that meet one or more of the NIOSH criteria for a HD

Generic Name	AHFS* Medication Classification	Route
Abacavir	Nucleoside and reverse transcriptase inhibitor	Oral
Azathioprine	Immunosuppressant agents	Intravenous, Oral
Carbamazepine	Anticonvulsants, miscellaneous	Oral
Chloramphenicol	Chloramphenicols	Intravenous, Oral
Cidofovir	Nucleosides and Nucleotides	Intravenous, Intravitreal
Cyclosporine	Immunosuppressant agents	Intravenous, Oral
Dexrazoxane	Protective agents	Intravenous
Divalproex	Anticonvulsants, miscellaneous	Oral
Entecavir	Nucleosides and Nucleotides	Oral
Estradiol	Estrogens	Oral, Topical
Estrogen/progesterone combinations	Contraceptives	Oral
Estrogen, conjugated	Estrogens	Oral, Intramuscular, Topical
Estrogen, esterified	Estrogens	Oral
Fingolimod	Biologic Response Modifiers	Oral
****Fosphenytoin**	Hydantoins	Intravenous
Ganciclovir	Nucleosides and Nucleotides	Intravenous
Leflunomide	Disease-modifying antirheumatic agents	Oral
Liraglutide Recombinant	Incretin Mimetics	Subcutaneous
Medroxyprogesterone acetate	Progestins	Oral, Intramuscular
Methimazole	Antithyroid agent	Oral
Mycophenolate mofetil	Immunosuppressive agents	Oral, Intravenous
Nevirapine	Non-nucleoside reverse transcriptase inhibitors	Oral
Oxcarbazepine	Anticonvulsants, miscellaneous	Oral
Paliperidone	Atypical antipsychotic	Intramuscular
Phenoxybenzamine	Non-selective alpha-adrenergic blocking agent	Oral
****Phenytoin**	Hydantoins	Oral, Intravenous
Progesterone	Progestins	Vaginal, Intramuscular, Oral
Propylthiouracil	Antithyroid agent	Oral
Raloxifene	Estrogen agonist-antagonist	Oral

Risperidone	Atypical anti-psychotics	Oral
Sirolimus	Immunosuppressive agent	Oral
Spironolactone	Mineralocorticoid receptor antagonist	Oral
Tacrolimus	Immunosuppressive agents	Oral, Topical
Thalidomide	Biologic response modulators	Oral
Valganciclovir	Nucleosides and Nucleotides	Oral
Zidovudine	Antiretroviral agents	Oral, Intravenous
*AHFS: American Hospital Formulary Service *Medications listed are per DHS formulary and does not include all medications listed in NISOH* *** Group 2 HDs follow all Group 3 HDs handling procedures listed in appendix B*		Last update: September 2016

Table 3. Group 3: Non-antineoplastic Drugs that primarily have adverse reproductive effects

Generic Name	AHFS* Medication Classification	Route
Acitretin	Vitamin A	Oral
****Ambrisentan (HUMC Group 2)**	Vasodilating agents, modulating	Oral
Cabergoline	Ergot-derivative dopamine receptor agonists	Oral
Choriogonadotropin	Gonadotropins	Intramuscular
Clomiphene	Estrogen agonist-antagonists	Oral
Clonazepam	Benzodiazepines	Oral
Colchicine	Anti-gout agents	Oral
Dinoprostone	Oxytocics	Vaginal
Finasteride	Alpha reductase inhibitors	Oral
Fluconazole	Azoles	Oral, Intravenous
Methylergonovine	Oxytocics	Oral, Intravenous, Intramuscular
Methyltestosterone	Androgens	Oral
Mifepristone	Oxytocics	Oral
Misoprostol	Prostaglandins	Oral
Nafarelin	Gonadotropins	Intranasal Spray
Oxytocin	Oxytocics	Intravenous
Pamidronate	Bone resorption inhibitors	Intravenous
Paroxetine	Selective serotonin uptake inhibitors	Oral
Ribavirin	Nucleosides and nucleotides	Oral
Temazepam	Benzodiazepines	Oral
****Testosterone (HUMC Group 2)**	Androgens	Intramuscular
Topiramate	Anticonvulsants, miscellaneous	Oral

****Tretinoin (HUMC Group 2)**	Cell stimulants and proliferants	Oral, Topical
Ulipristal	Contraceptives	Oral
Valproate/valproic acid	Anticonvulsants, miscellaneous	Oral, Intravenous
Voriconazole	Azoles	Oral, Intravenous
Warfarin	Coumadin derivatives	Oral
Ziprasidone	Atypical antipsychotics	Oral, Intravenous
Zoledronic acid	Bone resorption inhibitors	Intravenous
*AHFS: American Hospital Formulary Service ** Based on HUMC risk assessment, these group 3 HDs are re-categorized to group 2 *Medications listed are per DHS formulary and does not include all medications listed in NISOH*		Last update: September 2016

Appendix B: PPE Requirements when handling of HD

Activity	HUMC Group 1	HUMC Group 2	HUMC Group 3
Receiving			
Receiving & unpacking	▪ USP 800 PPE: Single chemo gloves *If package/shipping container are damaged follow procedures described under Spill Management		
Storage			
Medications provided in final dosage form ***(i.e. tablets, capsules, gels, topical creams/ointments, patch, manufactured prefilled syringes or unit dose oral solutions, premixed IV solutions)***	▪ Stored along with other (non-HD) pharmacy inventory with a "chemo label" on medication bin ▪ May be stored in Pyxis/Taylst	▪ Stored along with other (non-HD) pharmacy inventory with "hazardous drug label" on medication bin ▪ May be stored in Pyxis/Talyst	
Medications requiring manipulations ***(i.e. Injectables, bulk oral suspensions)***	▪ Stored separately from non-HD pharmacy inventory in chemo area with "chemo drug label" on medication bins	▪ Stored along with other (non-HD) pharmacy inventory with "hazardous drug label" on medication bins	
Refrigerated Medications	▪ Stored in Chemo refrigerator with a "chemo label" on medication bin	▪ Stored in refrigerator along with other (non-HD) pharmacy inventory with "hazardous drug label" on medication bin	
Labeling			
Auxiliary labeling	Labeled "Caution: Chemotherapy"	Labeled "Hazardous Drug"	
Repackaging			
Repackaging, Counting, Pouring	Performed outside of Biologic Safety Cabinet (BSC). Use a chemosorb pad on work surface. USP 800 PPE: Single chemo gloves. If risk of splash wear chemo gown, N95 mask, and face shield.		
Auto repackager	Do NOT use auto repackagers for any chemo/hazardous drugs, MUST use unit dose blister pack system.		

Compounding	HUMC Group 1 HUMC Group 2	HUMC Group 3
Cutting, crushing of tablets/ capsules	▪ MUST be performed in BSC in USP 800 room ▪ USP 800 PPE o Double chemo gloves, o Chemo gown o Head/Hair cover, o Mask o Double shoe cover o Crush tablets using plastic pouch to contain any dust or particles generated	▪ Performed **outside** of USP 800 room ▪ USP 800 PPE o Single chemo gloves o N95 mask o Crush tablets using plastic pouch to contain any dust or particles generated *For Ambrisentan, Tretinoin (NIOSH Group3), handle has HUMC group 2
Withdrawing and/or mixing IV/ IM/ SubQ solution form a vial or ampule **Diluting powder**	▪ Performed in BSC in USP 800 room ▪ USP 800 PPE o Double pair of chemo gloves, o Chemo gown o Head/Hair cover, o Mask o Double shoe cover ▪ Priming IV tubing in BSC ▪ Use CSTD if dosage form permits * Phenytoin and Fosphenytoin (NISOH Group 2) handle following HUMC group 3 procedures	▪ Performed in USP 797 hood ▪ USP 797 PPE ▪ Priming performed by nursing prior to administration ***If pregnant, nursing, or trying to conceive, utilize the following USP 800 PPE:** o Double pair of chemo gloves, o Chemo gown o Head/Hair cover, o N95 mask o Double shoe cover o CSTD if dosage form permits * For Testosterone (NIOSH Group 3) handle as HUMC group 2

Delivery	**HUMC Group 1**	**HUMC Group 2**	**HUMC Group 3**
Pneumatic tube	No	No	▪ Yes: tablets, capsules, patch ▪ No: oral liquid, topical creams/ointments, gels, IV syringe or solution (or liquid containing products)
Transport to patient care area	▪ Don on single pair chemo gloves before removing HDs from transporting container ▪ Seal in Double bag for: oral liquid, topical creams/ointments, gels, IV syringe or solution (or liquid containing products)		
Administration	**HUMC Group 1**	**HUMC Group 2**	**HUMC Group 3**
Intact tablet or Capsule	USP 800 PPE: Single chemo gloves		
Oral liquid drug or feeding tube **Topical Drug**	USP 800 PPE: ▪ Double chemo gloves ▪ Chemo gown ▪ Eye/face shield if potential to spit up, or liquid could splash		USP 800 PPE: ▪ Single chemo gloves
IV solutions, Injectables, and Intravesical medications	MUST use CSTD if dosage form permits USP 800 PPE: ▪ Double chemo gloves ▪ Chemo gown ▪ Eye/face shield if potential to spit up, or liquid could splash * Phenytoin and Fosphenytoin (NISOH Group 2) handle following HUMC group 3 procedures		USP 800 PPE: ▪ Single chemo gloves ▪ Eye/face shield if potential to spit up, or liquid could splash ***If pregnant, nursing, or trying to conceive, utilize the following USP 800 PPE:** ▪ CSTD if dosage form permits ▪ Chemo gown ▪ Double chemo gloves ▪ Eye/face shield if potential to spit up, or liquid could splash

Disposal/Cleaning	**HUMC Group 1**	**HUMC Group 2**	**HUMC Group 3**
Drug-contaminated waste **Drugs and metabolites in body fluids**	USP 800 PPE when disposing/cleaning: ▪ Double chemo gloves ▪ Chemo gown ▪ N95 mask ▪ Eye/face shield if potential to spit up, or liquid could splash		
Waste container for trace HD (PPE, empty bottles, IV bags and tubing WITHOUT moving liquid)	Discard in a bag which must be placed in a solid, lidded container labeled "Chemotherapy Waste" for disposal by Environmental Services. ***Calmette Guerine (BCG) vaccine**: All equipment, supplies and receptacles in contact with Bacillus should be handled and disposed of as biohazardous waste	Discard empty IV sets and medication vials in pharmaceutical waste bin.	
Waste container for bulk HD (unused medication, vials, IV bags and tubing WITH moving liquid)	Discarded in a bag which must be placed in a solid, lidded container labeled "RCRA". A Hazardous Waste Container" for disposal by Environmental Services	Discard IV sets, vials, and medications in pharmaceutical waste bin.	
Cleaning Spills	**HUMC Group 1**	**HUMC Group 2**	**HUMC Group 3**
Spills (i.e. leaking from tubing, syringes, and connection sites)	Spill kits should be available wherever hazardous drugs are stored, transported, prepared, or administered **Small Spills (<5mL or 5g):** Pharmacy Staff will perform cleaning if in pharmacy and Nursing staff will perform cleaning if in nursing unit. **Large Spills (≥ 5mL):** Environmental, Health and Safety Department and/or the outside approved vendor will perform cleaning Refer to Hospital policy 325L section X: Spill Management for procedural steps ▪ USP 800 PPE o Double pair of chemo gloves, o Chemo gown o Face shield o NIOSH approved respirator		

Compounding Attire	
1.Double shoe covers	Don the 2nd pair upon entering the clean room and remove upon leaving
2.Head cover	
3.Facial hair cover, if applicable	
4. Mask	
5.Disposable chemo gowns made of polypropylene or other laminate materials (should be glossy)	• Must be changed every 2-3 hours or per manufacturer guidance or immediately after a spill or splash • NEVER worn outside the HD handling area. • Must be closed in the back, long-sleeve, closed cuffs that are knit or elastic. • No seams or closures that HDs could pass through.
6.Two pairs of sterile chemo gloves	• Chemo gloves must be ASTM standard 6978 or its successor. • No powder • Inner glove under the gown cuff and outer glove over the cuff. • Must be changed every 30 minutes or when torn, punctured or contaminated
7.Eye/Face shield	• Required when working outside a C-PEC (i.e. for spill cleanup) • When there is a potential for respiratory exposure to HDs during a spill

Prohibited items and individuals

- Visible jewelry
- Piercing with jewelry
- Headphones
- Earbuds
- Personnel electronic devices
- Cosmetics
- Nail polish
- Artificial nails
- False eyelashes (eyelash extensions are permitted)
- Food and drinks

Any objects that shed particles (cardboard boxes, paper towel)

Excluded from ISO7 and ISO 5 spaces until resolved

- Exposed rashes
- Sunburn
- Weeping
- Sores
- Conjunctivitis
- Active respiratory infections
- Communicable diseases

Appendix C: Summary of Cleaning Steps

Cleaning Step	Purpose	Agents
Deactivation	Render the compound inert or inactive	Sodium hypochlorite or other Environmental Protection Agency (EPA) registered oxidizer
Decontamination	Remove inactivated residue	Sterile alcohol, sterile water, peroxide or sodium hypochlorite
Cleaning	Remove organic/inorganic material	Germicidal detergent and sterile water
Disinfection	Destroy organism	Sterile alcohol or other EPA-registered disinfectant appropriate for use