



PRISONS
Health and Wellness Services
Policies and Procedures

Title	USP <800> Hazardous Drugs-Handling in Healthcare Settings			
Section	TX II-24	Issue Date September 22, 2020	Supersedes Date November 2019	Next Review Date September 2021

References

Performance-Based Standards and Expected Practices for Adult Correctional Institutions, 5th Edition 5-ACI-6A-43 (M); USP<800> Hazardous Drugs-Handling in Healthcare Settings; Kienle PC. <800> Answer Book. American Society of Health-System Pharmacists, Bethesda, MD. 2017; American Society of Health-System Pharmacists. ASHP guidelines on Handling Hazardous Drugs. *Am J Health-Syst Pharm* 2018; 63:1172-1193; North Carolina Board of Pharmacy, Guidance on USP<800> Assessment of Risk and Other Educational Information. June 12, 2019; Occupational Safety and Health Administration (OSHA); NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, CDC, DHHS (NIOSH) Publication No. 2016-161 (Supersedes 2014-138)

I. PURPOSE

To establish policy and procedures for all employees who work in healthcare areas where Hazardous Drugs (HDs) are handled to ensure requirements are met for the *USP <800> Hazardous Drugs-Handling in Healthcare Settings* standard which promotes patient safety, worker safety, and environment protection.

II. POLICY

All employees who work in facility healthcare areas where HDs are handled shall comply with the *USP <800> Hazardous Drug-Handling in Healthcare Settings* standard.



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III. DEFINITIONS

- (a) Assessment of Risk (AOR) – An evaluation of risk to determine alternative work practices and/or containment strategies.
- (b) Entity – The DPS facility where HDs are handled, not limited to pharmacies, and includes any other place where healthcare is provided.
- (c) Final Dosage Form – Any form of a medication that requires no further manipulation before administration.
- (d) Hazardous Drug (HD) – Any drug identified by at least one of the following NIOSH criteria: carcinogenicity, teratogenicity/developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, or new drugs that mimic existing HDs.
- (e) HD1 (NIOSH Table 1 HD), HD2 (NIOSH Table 2 HD), HD3 (NIOSH Table 3 HD). These abbreviations will appear on medication prescription labels for hazardous drugs.
- (f) Incidental spill – Defined by OSHA as “release of a hazardous substance which does not pose a significant safety or health hazard to employees in the immediate vicinity or to the worker cleaning it up, nor does it have the potential to become an emergency” within a short time frame.
- (g) NIOSH – National Institute for Occupational Safety and Health, a federal agency under the CDC responsible for ensuring safe and healthy working conditions for all individuals.
- (h) Personal Protective Equipment (PPE) – Items such as gloves, gowns, goggles, respirators, face shields and other equipment that protect individual workers from hazardous physical or chemical exposure.
- (i) Safety Data Sheet (SDS) – An information document that provides written or printed material concerning a hazardous chemical.
- (j) Spill kit – A container of supplies and related material used to contain an HD spill.



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- (k) USP – United States Pharmacopeia, the reference that sets quality, purity, strength, and identity standards for medicines, food ingredients, and dietary supplements.

IV. PROCEDURE

(a) Responsibilities of Personnel Handling Hazardous Drugs

- (1) Designated Person (DP) – A specific individual at each facility who is responsible for overseeing facility compliance, ensuring competency of personnel, and implementing the requirements of the DPS USP <800> HD policy and facility specific SOPs.
- (2) All personnel who handle HDs are responsible for understanding the fundamental practices and precautions and for continually evaluating these procedures to prevent harm to patients, minimize exposure to personnel and minimize contamination of the work and patient-care environment.

(b) Hazardous Drugs (HD), Safety Data Sheet (SDS) and Assessment of Risk (AOR) Lists

- (1) HD, SDS and AOR lists will be available to staff on the Health and Wellness internal website.
- (2) The HD list must include any items on the current NIOSH list that facility personnel handle.
- (3) The HD list, SDSs and AORs will be reviewed annually and updated whenever a new HD agent or dosage form is used.

(c) Personnel Training

- (1) All personnel who handle HDs must be trained based on their job functions (e.g., receipt, storage, dispensing, administration, disposal).
- (2) Training must occur before an employee independently handles HDs, and annually thereafter. All training and competency assessments must be



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documented.

- (3) Follow-up is the responsibility of the facility’s Designated Person and documentation will be kept on file in accordance with all state and federal requirements.
- (d) Receipt of Hazardous Drugs
 - (1) HDs must be delivered from the supplier to the DPS Pharmacy Services dedicated HD area then delivered to storage immediately after receiving and unpacking.
 - (2) A single pair of chemotherapy gloves must be worn when unpacking HDs. A spill kit must be accessible in the receiving area.
 - (3) The shipping container must be visually examined for signs of breakage and damage.
- (e) Dedicated Hazardous Drug Area
 - (1) The designation of an HD area within a DPS Pharmacy Services non-compounding pharmacy setting can be limited to an area where final dosage forms are counted, repackaged and labeled.
 - (2) The HD area should be clearly marked, have dedicated equipment for use and a procedure for deactivation, decontamination and cleaning.
- (f) Storage of Hazardous Drugs
 - (1) Store HDs in a manner that prevents spillage or breakage. Do not store on the floor.
 - (2) Antineoplastic final dosage form (Table 1), non-antineoplastic (Table 2) and reproductive only (Table 3) HDs may be stored with other inventory or in a separate HD area.



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(g) Dispensing of Hazardous Drug Final Dosage Forms

- (1) HDs that do not require further manipulation, other than counting and repackaging of final dosage forms, may be prepared for dispensing without further requirements for containment unless required by the manufacturer or if there are visual indicators of exposure. A single pair of chemotherapy gloves should be used.
- (2) Equipment (e.g., counting trays and spatulas) dedicated for HDs will be used. HD equipment should be decontaminated after each use and the dispensing area cleaned after completion of HD dispensing.
- (3) HD prescription labels will be marked with HD1, HD2, and HD3 (see definitions) for identification purposes.

(h) Administering Hazardous Drugs

- (1) A single pair of chemotherapy gloves is required for administering intact tablets, capsules, and final dosage forms, unless otherwise documented on the Assessment of Risk (AOR) for a specific HD and dosage form.
- (2) A single HD dose can be crushed with a tablet crusher provided a plastic pouch is used to contain the medication and appropriate PPE is worn.
- (3) All other administration activities require appropriate PPE based on the Assessment of Risk (AOR) for each HD medication and dosage form.

(i) Transport of Hazardous Drugs

- (1) Pneumatic tubes must not be used to transport any antineoplastic (NIOSH Table 1) or liquid HDs, due to the potential for breakage and contamination.
- (2) Transportation of HDs from receipt to storage; storage to dispensing area; finished preparation to off-site/on-site administration areas; finished preparation to holding areas for pick-up by patient; shall be in a container that minimizes the



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risk of breakage and leakage. No further containment is needed unless required by the manufacturer.

(j) Personal Protective Equipment (PPE) AND Hand Hygiene

- (1) Appropriate PPE, e.g., gloves, gowns, must be worn when handling HDs. This includes handling during receipt, storage, dispensing, administration, deactivation, decontamination, cleaning, disinfection, spill control and waste disposal.
- (2) Chemotherapy gloves must meet the American Society for Testing and Materials (ASTM) standard D6978. A single pair of gloves must be used for all job functions unless two pairs of chemotherapy gloves are required based on the AOR.
- (3) All employees must wash hands thoroughly using soap and water before and after handling HDs, HD waste or contaminated PPE. The use of antiseptic hand sanitizer alone is not an acceptable form of hand hygiene.

(k) Deactivation, Decontamination, Cleaning and Disinfection

- (1) All areas and reusable equipment used when handling HDs must be deactivated, decontaminated, and cleaned after handling is complete. Appropriate PPE must be worn during deactivation, decontamination and cleaning activities.
- (2) HD residue removal by deactivation (render an HD inactive) and decontamination (remove HD residue) can be completed using peroxide or sodium hypochlorite (bleach) formulations. Disinfection (destroy organisms) must be done in areas intended for sterile compounding.
- (3) Clean the affected surfaces with a facility approved germicidal detergent to remove contamination other than HD residue. No cleaning agents should be sprayed in the HD area.



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(l) Spill Control for Hazardous Drugs

- (1) Each facility must assign specific individuals to spill control. All HD spills must be contained and cleaned immediately by trained workers. The size and scope of the spill should first be assessed to determine if it requires outside assistance and a coordinated spill response.
- (2) Incidental spills (e.g., an HD tablet dropping on the floor, small liquid spills) do not pose a significant safety or health hazard to employees in the immediate vicinity or to the employee cleaning it up, nor does it have the potential to become an emergency.
- (3) Incidental spills may be cleaned up with approved cleaning agents, e.g., sodium hypochlorite or bleach wipes, or hydrogen peroxide wipes. Incidental spills may be cleaned up using a single pair of chemotherapy gloves. No gown or mask is required.
- (4) Spill kits must be readily available in all areas where HDs are handled and must contain all necessary cleaning supplies. All spill materials must be disposed of as hazardous waste in an appropriate disposal container.

(m) Hazardous Drug Waste Disposal

- (1) All employees who dispose of HDs, HD waste, or materials presumed to have trace contamination must wear appropriate PPE and follow established hand hygiene requirements.
- (2) Hazardous drugs, trace waste and contaminated PPE must be placed in an appropriate approved waste disposal bin.
- (3) Disposal of all HD waste, including but not limited to, unused HDs and trace-contaminated PPE and other materials, must comply with all applicable federal, state and local regulations. If sorting is problematic, all NIOSH HDs should be managed as hazardous waste.



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(n) Hazardous Communication Program

- (1) Facilities must have SDS sheets for each hazardous drug readily available to employees during each work shift and when they are in their work area.
- (2) Personnel who handle hazardous drugs must be provided with information and training before their initial work assignment and when the hazard changes. Training and competency must be evaluated annually and documented.
- (3) All facility staff who handle HDs or their contaminants, particularly personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs.
- (4) The HD Hazard Communication program will follow the Hazard Communication Standard in DPS Safety, Occupational and Environmental Health, Section E- Policy E-11.

(o) Occupational Safety Program

- (1) The Occupational Safety Program must be a collaborative effort, with input from all affected areas, such as Pharmacy, Nursing, Medical, Environmental Services, Maintenance, Risk Management, Industrial Hygiene, Custody and Safety.
- (2) Safety, Occupational and Environmental Health Office standards for Occupational Health will be followed by facilities and staff regarding the handling of hazardous drugs.
- (3) SDSs will be monitored and updated by Central Pharmacy with information provided by the three DPS pharmacies: Central Pharmacy, CPHC and NCCIW.

Todd E. Ishee

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