WELCOME

GINA GAMBARO

Director, Marketing &

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Housekeeping notes

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Safe Handling of Hazardous Drugs

OSHA Requirements and How They Affect Long-Term & Residential Care

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Forum Extended Care Services

Learning objectives

- Understand the requirements for USP 800
- Identify what qualifies as a Hazardous Drug (HD)
- Learn the importance of risk assessment and staff training related to your facility's HDs
- Understand what is needed to create a plan to manage the handling and disposal of HDs in your facility
- Know how your pharmacy partner can help with USP 800 adherence

What is USP 800?

- Provides standards for safe handling of hazardous drugs to minimize exposure risk to healthcare personnel, patients, and the environment
- Covers both sterile and non-sterile products
- Applies to any personnel who may be exposed to HDs

How does this affect long-term care?

- USP Chapter 800 went into effect Dec 1, 2019
- Currently it is only “compendially applicable”
  - Once appeals to other related Chapters are resolved & successfully adopted, USP 800 will also become an official “standard”
- Certain entities can already enforce USP 800 for organizations within their jurisdiction
  - State regulators
  - Federal regulators (including OSHA and FDA)
  - Accrediting bodies
- Preparing for compliance with USP 800 is not a short process

USP <800> requirements — a summary

Each facility must have a management system and documentation for HDs

- ❑ A list of HDs specific to the facility
- ❑ Facility and engineering controls
- ❑ Safe work practices & use of personal protective equipment (PPE) for:
  - Receipt
  - Storage
  - Manipulation/mixing
  - Administration
  - Deactivating, decontaminating, cleaning & disinfecting
  - Disposal
- ❑ Personnel responsibilities & training
- ❑ Medical surveillance

What are hazardous drugs (HDs)?

- The National Institute for Occupational Safety and Health (NIOSH) defines HDs as any drug that exhibits ≥1 toxic characteristic in humans or animals:
  - Carcinogenicity
  - Teratogenicity or developmental toxicity
  - Reproductive toxicity
  - Organ toxicity at low doses
  - Genotoxicity
  - Structure and toxicity profiles of new drugs that mimic existing hazardous drugs

- NIOSH maintains a list of antineoplastic & HDs used in healthcare settings
- Includes any drugs with manufacturer safe-handling guidelines

	Table 1: Antineoplastics	Table 2: Non-Antineoplastics	Table 3: Non-Antineoplastics with Adverse Reproductive Effects
Cytotoxic	✓		
Level of hazard	Represent an occupational hazard to HC workers; the majority are hazardous to males or females actively trying to conceive, women who are pregnant or may become pregnant & women who breast feed	Some may represent an occupational hazard to males or females actively trying to conceive, women who are pregnant or may become pregnant & women who breast feed	Represent a potential occupational hazard to males or females actively trying to conceive, women who are pregnant or may become pregnant & women who breast feed
May be present in breast milk	✓	✓	✓
Always use recommended engineering controls & PPE, regardless of formulation (IV, SC, topical, tab, or cap)	✓		
Unopened, intact tablets and capsules may not pose same degree of risk as injectable drugs, which usually require extensive preparation	✓	✓	✓
Cutting, crushing, or otherwise manipulating tablets & capsules will increase risk of exposure	✓	✓	✓

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Risperdal is no longer considered an HD as of 2019

Some of the more common HDs in LTC

Azathioprine*	Finasteride	Raloxifene (Evista)
Cyclosporine	Fluconazole	Spironolactone
Carbamazepine	**Ganciclovir***	Temazepam
Chloramphenicol*	**Hormones*** (androgens, estrogens, progestins)	Topiramate
Clonazepam	**Methotrexate†**	Isotretinoin/Tretinoin
Cyclosporine*	Misoprostol	Valproate/Valproic acid
Divalproex	Paroxetine	**Valganciclovir***
Dutasteride	Phenytoin	Warfarin

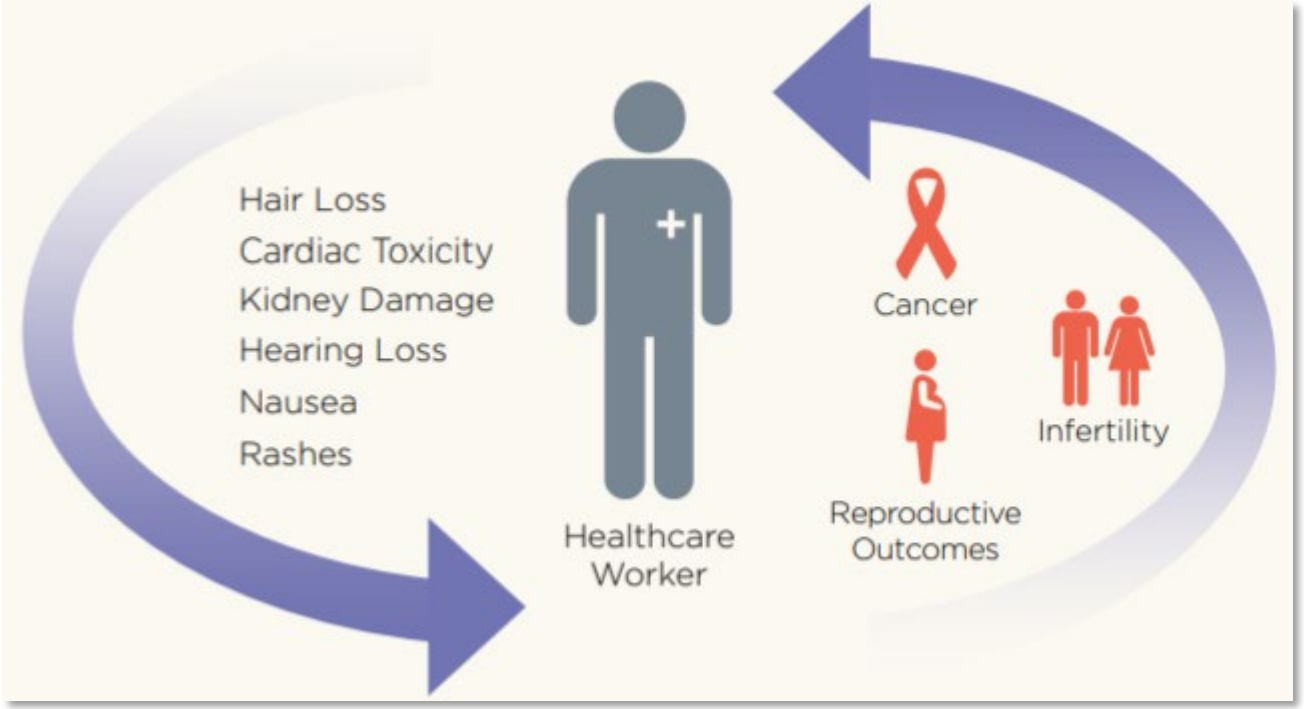
*** Items identified as Table 1 as of the 2020 NIOSH draft list.**

† Items identified as Table 1 in the 2016 NIOSH published list.

Note: The Environmental Protection Agency (EPA) considers any pharmaceutical waste to be hazardous if it is corrosive, ignitable, reactive, or toxic

Why is risk assessment & training so important?

- >8 million U.S. healthcare workers are exposed to HDs each year[1]
- > 12 billion doses of HDs are handled each year[2]
- HDs can have acute[3] and long-term effects[4-5]



1. https://www.cdc.gov/niosh/topics/hazdrug/
2. IMS Data 2016 data and analysis.
3. Valanis BG, et al. Am J Hosp Pharm. 1993 Mar;50(3):455-62. 4. Hansen J, Olsen JH. Scand J Work Environ Health. 1994 Feb;20(1):22-6. 5. Connor TH, et al. *J Occup Environ Med*. 2010 Oct;52(10):1019-27.

Risk assessment & staff training requirements

- Identification of HDs in <u>your</u> facility
- Appropriate training for staff who handle these items in all areas

Creating a plan for HDs in your facility

1 Appoint an on-site compliance leader (the “designated person”)

- Each facility must have a “DP” who develops, implements, and maintains USP 800 compliance
  - Single point of contact for accountability & dissemination of information
  - Oversees training of personnel
  - Reports hazardous situations to management
  - Required to review assessment of risk and P&Ps annually

Creating a plan for HDs in your facility

Your pharmacy can help

2 Identify which HDs are used at your location

2016 Published NIOSH List	https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf?id=10.26616/NIOSHPUB2016161
2020 Proposed NIOSH List	https://www.cdc.gov/niosh/docket/review/docket233c/pdfs/DRAFT-NIOSH-Hazardous-Drugs-List-2020.pdf

Creating a plan for HDs in your facility

3 Perform an initial "assessment of risk" (AoR)

- ❑ For every Table 2 & 3 HD used in your facility
- ❑ Identify exposure **risk and routes** for all HDs by type & dosage form:
  - How are they handled throughout the facility?
  - Receiving/storage/packaging
  - **Handling/manipulation/crushing/mixing**
  - **Administration/patient care activities**
  - Movement (**spills**, transport & **waste**)
- ❑ Identify **types** of potential exposure based on staff responsibilities & activity
- ❑ Identify ALL staff members who may encounter HDs

About your assessment

3

- AoR not required for Table 1 drugs because all containment requirements must be followed
- Tables 2 & 3 HDs that do not have to follow all the containment requirements if AoR is performed & implemented:
  - Final dosage forms of compounded HD preparations and conventionally manufactured HD products (including antineoplastic dosage forms) that do not require any further manipulation other than counting or repackaging, unless required by the manufacturer
- For dosage forms of other HDs, the facility may perform AoR to determine alternative containment strategies and/work practices

AoRs must be conducted for each HD

3

- Each dosage form
- When/how it is handled (crushing, admin, cleaning, etc)
- What is the level of risk for each of the above
- What PPE &/or other risk-mitigating measures will be taken for each

Activity	Types of Exposure in LTC
Receipt	▪ Contacting HD residue on drug containers, individual dosage units, outer containers, work surfaces, or floors
Dispensing	▪ Counting or repackaging tablets & capsules
Manipulations	▪ Crushing or splitting tablets or opening capsules ▪ Pouring oral or topical liquids from one container to another ▪ Weighing or mixing components ▪ Constituting or reconstituting powdered or lyophilized HDs ▪ Withdrawing or diluting injectable HDs from parenteral containers ▪ Expelling air or HDs from syringes ▪ Contacting HD residue present on PPE or other garments ▪ Deactivating, decontaminating, cleaning, and disinfecting areas contaminated or suspected to be contaminated ▪ Maintenance activities for potentially contaminated equipment and devices
Administration	▪ Generating aerosols during administration (injection, irrigation, oral, inhalation, or topical application) ▪ Priming an IV administration set
Patient-care activities	▪ Handling body fluids (urine, feces, sweat, or vomit) or body-fluid-contaminated clothing, dressings, linens & other materials
Spills	▪ Spill generation, management & disposal
Waste	▪ Collection & disposal of hazardous waste and trace contaminated waste

3

Creating a plan for HDs in your facility

4 Establish processes & update policies & procedures

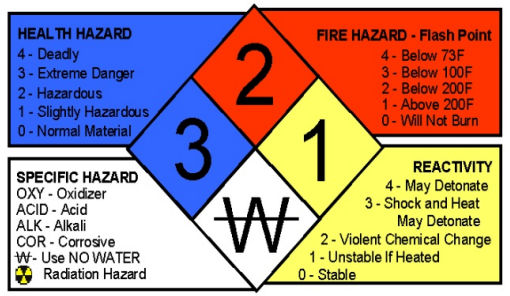
- Designated person review of AoRs and P&Ps at least every 12 months; review must be documented
- Revisions made as needed & communicated to all personnel handling HDs
- SOPs for safe handling of HDs for all situations must include all sections listed in Chapter 800
- Best practices for managing risks associated with HDs:

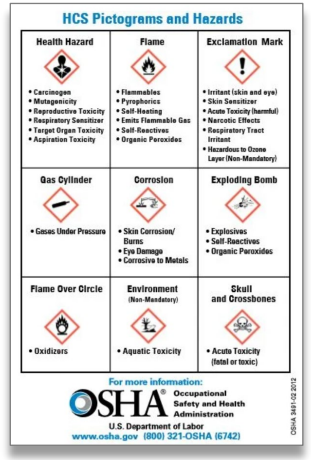
  https://www.cdc.gov/niosh/topics/hazdrug/riskmanagement.html

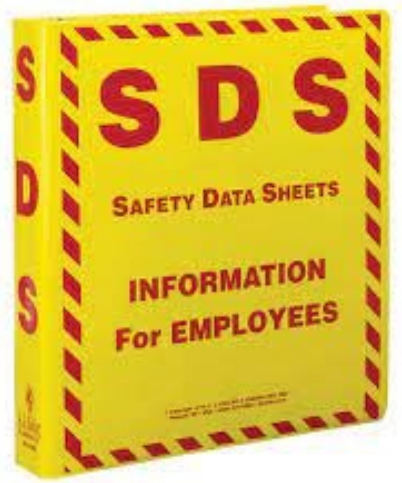
P&Ps: Maintain a list of all HDs used in the facility

4

- Update as new HDs introduced & review annually
- Completed risk assessment including HD type, dosage form, exposure risk, packaging & manipulation
- Safety Data Sheets (SDS)







P&Ps: Facilities, engineering controls & storage

4

- Processes to limit contamination
- Do you need specific areas for activities?
  - HD storage separate from break rooms & refreshment areas
- Methods to prevent spillage & breakage

P&Ps: Personal protective equipment (PPE)

4

- PPE should be appropriate to the specific activity, based on risk of exposure, to protect against:
  - Direct contact (Table 1 HDs: double chemo gloves, impermeable gowns)
  - Spills or splashes (goggles, face mask/shield)
  - Inhaled exposure to HDs (specific respirators)
  - Incidental contact with HD residue (head, hair, shoe, sleeve covers?)
- Specifications for disposable vs reusable PPE, including disinfection or proper disposal after each use or contamination

P&Ps: Receiving hazardous drugs

4

- PPE for unpacking all HD
- Processes to address residue on:
  - Drug containers
  - Individual dosage units
  - Outer containers
  - Work surfaces
  - Floors

P&Ps: Labeling, packaging, transport & disposal

4

- Dispensed separately (cannot be co-mingled with other meds)
- All staff who perform routine waste removal & cleaning in HD handling areas must be trained in appropriate procedures to protect themselves & prevent HD contamination
- Disposal of all HD waste (including unused HDs & trace-contaminated PPE and other materials) must comply with all applicable federal, state, and local regulations, including:
  - HD trace waste containers for point of administration
  - HD waste containers & storage for preparation & disposal areas

P&Ps: What kind of manipulation takes place?

4

- Weighing or mixing components
- Constituting or reconstituting powdered or lyophilized HDs
- Withdrawing or diluting injectable HDs from parenteral containers
- Expelling air or HDs from syringes
- Contacting HD residue present on PPE or other garments
- Maintenance of potentially contaminated equipment & devices

P&Ps: Crushing, splitting or opening capsules in LTC

4

- Table 1 HDs cannot be split, crushed, or otherwise manipulated
- Avoid crushing tablets or opening capsules if possible
- Request orders for liquid formulations if solid oral dosage forms are not appropriate
- If HD dosage forms do require this type of manipulation for a dose, personnel must:
  - AoR must include this manipulation & determine proper PPE/handling, specifically donning appropriate PPE & using a plastic pouch to contain any dust or particles generated

P&Ps: Administering HDs

4

- Staff must be specifically trained on minimizing exposure risk when administering HDs
- Appropriate PPE must be worn
- Use compliant protective medical devices & techniques (needleless & closed systems)

- After use: PPE must be removed and disposed of in a waste container approved for trace-contaminated HD waste at the site of drug administration
- Equipment (tubing, needles) & packaging materials must be disposed of properly, such as in HD waste containers, after administration

P&Ps: Cleaning & disinfecting where HDs are handled

4

- ❑ All personnel who clean in HD handling areas must be trained to minimize risk & prevent HD contamination
- ❑ Includes all reusable equipment & devices used with HDs
- ❑ Appropriate PPE requirements
  - 2 pairs chemo gloves
  - Impermeable disposable gowns resistant to chemicals used

- ❑ Monitor effectiveness, including resident administration areas
- ❑ Separate steps to deactivate, decontaminate, clean & disinfect

P&Ps: Exposure response

4

- Spill kits must be readily available in all areas where HD are routinely handled
- Staff must be trained on procedures for containing accidental exposures/spills & the use of a spill kit
- Qualified personnel wearing appropriate PPE must contain & clean HD spills immediately
- Follow-up plan for exposure

P&Ps: Medical surveillance

4

- Designed to minimize adverse health effects in personnel potentially exposed to HDs
- Assessment & documentation to determine whether there is a deviation from the expected norms
  - Symptom complaints
  - Physical findings
  - Laboratory values (such as a blood count)

- Healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program

Creating a plan for HDs in your facility

5 Train anyone who handles HDs

- ❑ All staff handling HDs must be trained based on job function, before independently handling any HDs
- ❑ Assess competency across the facility every 12 months
- ❑ Staff can download USP's <800> HazRx™ Mobile App
  - Minimize on-the-job risk
  - Select any drug & your activity to access handling instructions

How can your pharmacy partner help?

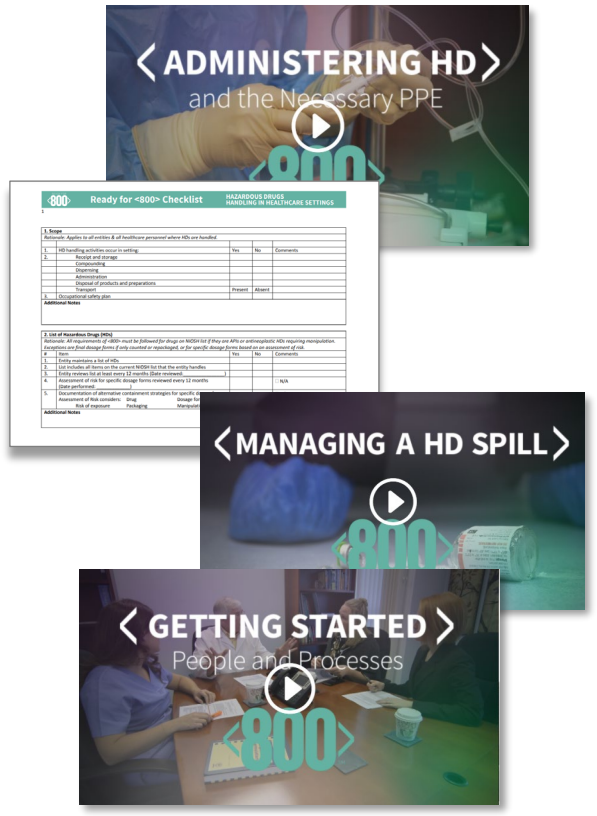
- Custom reporting for HDs used in your facility
- Expertise in distinguishing risk among HDs
- Special preparation of HDs:
  - Containment packaging
  - HD identification
  - Pharmacy preparation

- Consultation when orders to crush HD meds are issued
- Training on appropriate medication administration & PPE for HDs

Things to consider

Utilize a tool kit or online staff training?

- ✓Resources for risk assessments
- ✓Policy templates
- ✓Training materials



Consult your contracted waste vendor

- ✓Experts in hazardous drug handling
- ✓May have their own training & resources

Resources

Description	URL
USP 800: Standard	https://go.usp.org/l/323321/2020-03-09/3125jw
USP 800: FAQ	https://go.usp.org/General-Chapter-800-FAQ
USP 800: 2020 Revision Bulletin on Handling of HDs in Healthcare Settings	https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-800-rb-notice-20200626.pdf
USP 800: App	https://www.usp.org/hazrx-app
OSHA: HD Information	https://www.osha.gov/hazardous-drugs#background
NIOSH: 2016 Published List of HDs in Healthcare Settings	https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf?id=10.26616/NIOSHPUB2016161
NIOSH: 2020 Draft List of HDs in Healthcare Settings	https://www.cdc.gov/niosh/docket/review/docket233c/pdfs/DRAFT-NIOSH-Hazardous-Drugs-List-2020.pdf
NIOSH: Risk Management for HDs	https://www.cdc.gov/niosh/topics/hazdrug/riskmanagement.html
NIOSH: Updates	https://www.cdc.gov/niosh/topics/hazdrug/

Online HD Safety Data Sheets

MSDSonline	https://www.msdsonline.com/msds-search/
SDS Search	https://www.msds.com/
Chemical Safety Software	https://chemicalsafety.com/sds-search/
SDS Pro	https://sdspro.com/free-trial/

Vendor information & toolkits

Description	URL
Attorney Summary: Understanding USP 800: A Resource for LTC Providers	https://www.agg.com/news-insights/publications/understanding-usp-800-a-resource-for-long-term-care-providers/
Toolkits	▪ https://www.readyfor800.com ▪ https://medtrainer.com/usp/ ▪ https://cpnp.org/medication/usp800
Education	▪ https://www.inmar.com/blog/resources/2020-epa-hazardous-drugs-and-usp-800-handling-webinar ▪ https://www.stericycle.com/en-us/resource-center/topics/pharmaceutical-waste `

Questions?

About CE credit

Administrator credit

This program has been approved for one hour of continuing education by the National Continuing Education Review Services (NCERS) of the National Association of Long-Term Care Administrator Boards (NAB) – Approval # 20220619-1-A75649-DL.

Nursing credit

This program has been approved for one clock hour of continuing education credit by The Illinois Board of Nursing, an approved sponsor of continuing education by the Illinois Department of Professional Regulation.

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July: *Transformation: Key Takeaways from the LeadingAge Illinois Annual Meeting & Expo*

Aug: *A Fireside Chat with Senior Care Pharmacy Coalition on Initiatives Supporting Long-Term Care*

THANK YOU!