



**Hazardous Drugs  
USP 800**



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**Hazardous Drugs  
USP 800**

USP's newest regulation and how  
it affects healthcare facilities

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**Who is Your Speaker?**



**Eric Lintner, RPh, BCPS**

Clinical Projects Director  
Consonus Pharmacy Services

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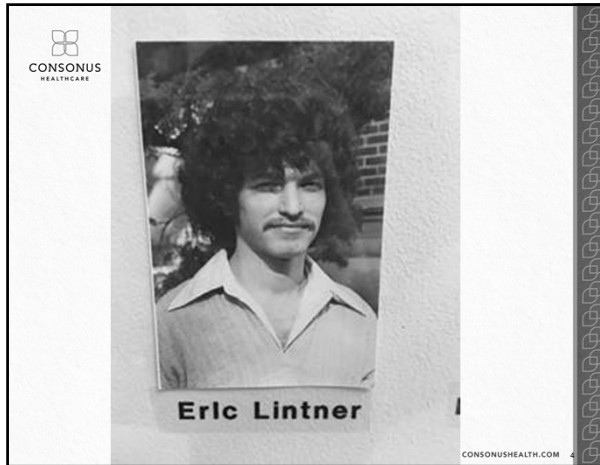
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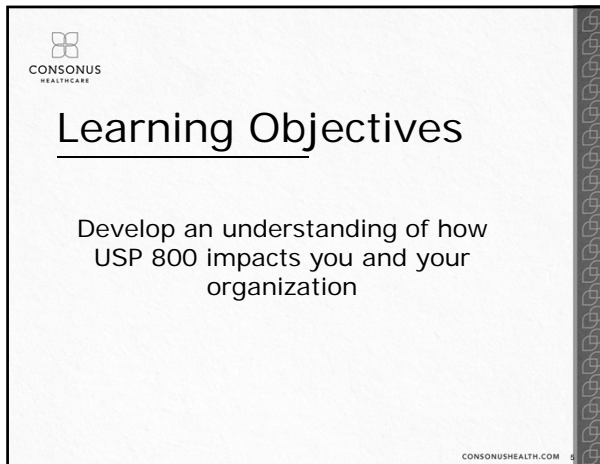
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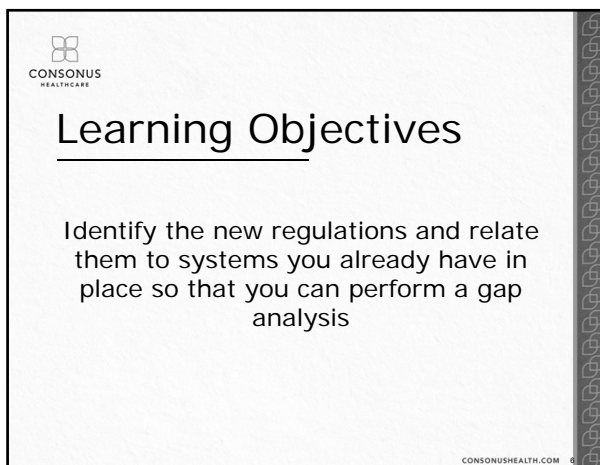
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## Learning Objectives

Assist you in developing strategies to mitigate risk and increase resident and staff safety

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## What is USP 800?

New regulation covering hazardous drug:

- Receiving
- Labeling
- Compounding
- Packaging
- Storing
- Transport
- Administration
- Disposal

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## What is USP 800?

New regulation covering hazardous drug:

- Labeling
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- Storing
- Transport
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- Disposal

**In all healthcare settings**

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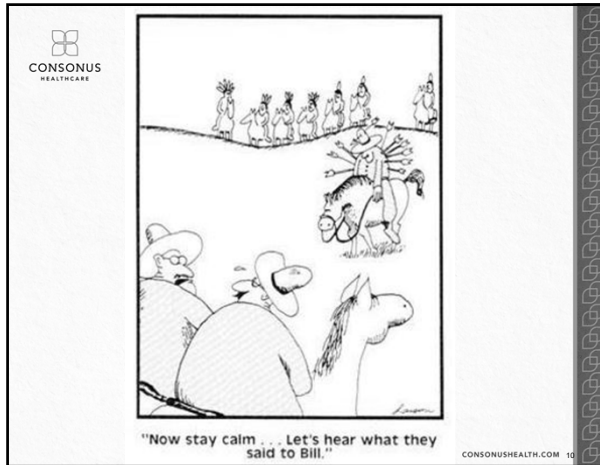
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## Why is This Timely?

- Numerous studies demonstrate the dangers of handling hazardous drugs
- Hazardous drug rules have been very difficult to understand
- We all want to adhere to the highest standards to protect our staff

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## Why is This Timely?

According to the CDC, about 8 MILLION healthcare workers are exposed to HDs each year due to improper handling precautions

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Antineoplastic Drug Administration by  
Pregnant and Nonpregnant Nurses  
An Exploration of the Use of Protective Gloves  
and Gowns

AJN Jan, 2019

Many nurses reported  
not wearing protective  
gloves and gowns

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Did not always wear gloves:

- 20% of nonpregnant
- 14% of pregnant nurses



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Did not always wear  
gowns:

- 59% of nonpregnant
- 48% of pregnant nurses



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## Just Who is USP?

- **USP** stands for United States Pharmacopoeia
- State and federal agencies rely on USP/NF for drug standards

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## Just Who is USP?

Enforced by:

- State Boards of Pharmacy
- OSHA
- CMS
- Health Department Surveyors

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## Enforceable vs Safety

Recent changes by USP:

- Limit Scope
- Compounding only
- What about administration of meds?

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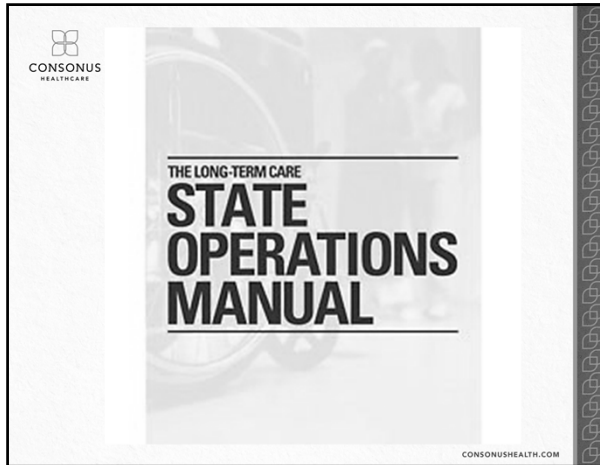
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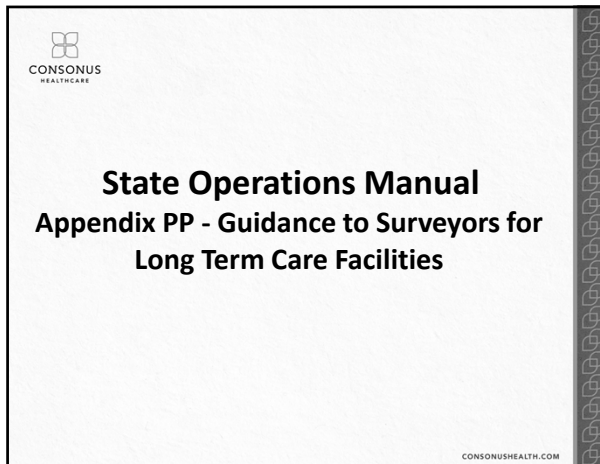
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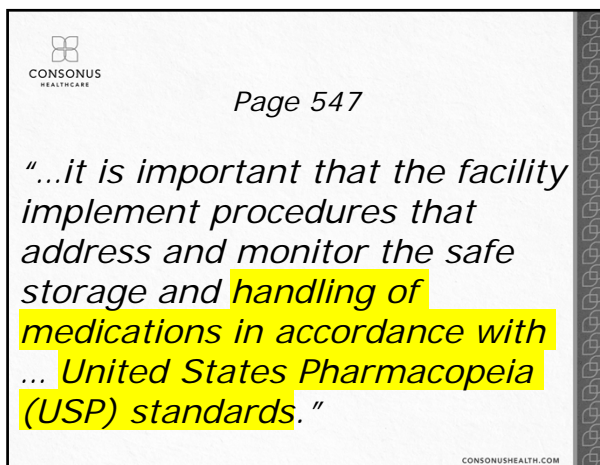
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## When is USP 800?

- Currently in final form
- Full implementation planned for  
**12/01/2019**

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## What is USP 800?

Why?

- Promote patient safety, worker safety, and environmental protection.
- Negative effects of handling HD's without proper care.

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## USP 800?

We've discussed:

- Why it's needed
- Who it applies to
- Enforceability

Now, let's talk about what drugs are HAZARDOUS

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## What is a Hazardous Drug?

**NIOSH** = National Institute for Occupational Safety and Health (a part of the Centers for Disease Control and Prevention or **CDC**)



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## What is a Hazardous Drug?

NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH



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## What is a Hazardous Drug?

They have defined and created 3 lists or Categories of HD's:

- ➔ Antineoplastic
- ➔ Non-antineoplastic (with hazards)
- ➔ Non-antineoplastic (primarily adverse reproductive effects)

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## What is a Hazardous Drug?

6 characteristics (Must have at least one of the following):

- ☐ Carcinogenicity
- ☐ Teratogenicity or developmental toxicity
- ☐ Reproductive Toxicity in humans
- ☐ Organ Toxicity at low doses
- ☐ Genotoxicity
- ☐ New drugs that mimic characteristics of HDs

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## Does USP 800 Affect Me?

Recommended for:  
All healthcare workers in all settings who  
handle hazardous drugs

Required for:  
Those who compound hazardous drugs

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## Does USP 800 Affect Me?

From pharmacy technicians who receive  
and package medications to the  
medication staff and the C.N.A.'s that  
administer them and housekeeping staff  
that dispose of contaminated waste.

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**Exposure in SNF/ICF**

**Personnel at risk of exposure**

- Nurses, Med Aides, CNAs
- Housekeeping, Dietary Aides, etc.

**Routes of exposure**

- Inhalation
- Dermal absorption
- Accidental injection
- Ingestion when eating if hands contaminated

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**Potential Routes of Exposure**

**Inhalation**

- Breathing contaminated air (aerosols and vapors)

**Dermal Contact**

- Touching contaminated surfaces
- Direct contact with drugs

**Ingestion**

- Chewing gum
- Hand-to-mouth (eating and drinking)

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## Exposure in SNF/ICF

### Effects of exposure

- Cancer risks
- Reproductive risks
- Liver damage
- Short term toxicity

### Exposure situations

- Med pass of HDs, including IV's
- Spills/Bodily fluids
- Laundry
- Waste (human and drug waste)

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## Skin Exposure to Chemotherapy



Photo courtesy of James Tinguely, TycoHealthcare

Dermal exposure from chemotherapy spill. Scarring is likely to occur.

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## Expectations of USP 800

- ☐ Hazard Communication Program
- ☐ Designate a Responsible Person
- ☐ Assessment of Risk
- ☐ Develop a Plan
- ☐ Train Staff/Document Competency
- ☐ Use Proper Protective Garb
- ☐ Medical Surveillance?

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## Hazard Communication

- Written overall program specified by OSHA
- How will you identify and address the hazards?
- Policies and Procedures

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## Hazard Communication (cont')

- What staff is at risk and to what extent?
- Train staff/document competency
- Use of proper protective garb
- Medical Surveillance?

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## Assessment of Risk

- Prepare a list of all HD's in facility
- Update annually
- New items assessed
- Assessment of Risk for each item, dosage form and route of administration

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## Medical Surveillance Program (cont')

- Involves assessment and documentation of symptoms, complaints, physical findings, and laboratory values
- Viewed as a secondary prevention tool that can help with early detection of health problems or maintenance issues

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## Medical Surveillance Program

Facility must gauge the risks in their particular situation and whether it is necessary to enroll and implement.

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## PPE to be Aware of

- PPE
  - Gloves – ASTM tested D6978 or better
    - Double up when administering antineoplastic hazardous drugs.
  - Gowns (close in the back and must resist permeability by HD's)
    - Wear when administering liquid HDs and cleaning
  - N95 (or better) fitted surgical mask, safety goggles, and all the above – Spills that contain a risk of splashing.

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## Other Precautions to be Aware of

- Signage
  - Area restriction signs are needed for display when spill contains at least trace amount of HDs.
  - HD handling areas should be displayed as such

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## Other Precautions to be Aware of

- Waste Disposal
  - EPA just released new federal rules for "Hazardous Waste Pharmaceuticals"
  - Each state has their own DEQ rules
  - EPA/DEQ definitions of "hazardous" are quite different than USP 800
  - NIOSH vs EPA/DEQ

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## Other Requirements to be Aware of

- Waste Disposal
  - ALF/RCF are eligible for "Household exemption"
  - SNF/ICF no longer able to flush any medications
  - Establish a relationship with a competent waste disposal company

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## Key Points

- Who is Impacted?
- Is it Mandatory?
- When Does it Take Effect?

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And no one ever heard from the Anderson brothers again.

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## Key Points

- ☐ Identify Program Coordinator
- ☐ Hazard Communication Program
- ☐ Assessment of Risk
- ☐ Contact Your Pharmacies
- ☐ Training and Assessment of Competency
- ☐ Contact Your Training Providers
- ☐ Policies and Procedures
- ☐ Obtain Personal Protective Equipment (PPE)
- ☐ Contact PPE Suppliers
- ☐ Medical Surveillance?
- ☐ Contact Worker's Comp Provider
- ☐ Contact Your Waste Disposal Company

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- 2016 NIOSH HD Drug List-  
<https://www.cdc.gov/niosh/docs/2016-161/>
- USP Compounding Compendium (available only by purchase)
- USP Chapter 800 Download-  
<http://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>
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<http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings>

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- Gap Analysis Tool  
<https://hazmedsafety.com/en>
- EPA Management of Pharmaceutical Hazardous Waste  
<https://www.epa.gov/hwgenerators/management-pharmaceutical-hazardous-waste>

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## Questions?

For more information and resources, visit the Consonus booth during the tradeshow!

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<https://www.linkedin.com/in/eric-lintner-rph-bcps-099a965/>



LinkedIn Group:

- Long-term Care Industry Professionals
- Specialty Pharmacy, PBM, Home Infusion, Mail Order and Long Term Care Professionals
- Oregon State Pharmacy Association



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