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USP <800> Hazardous Drugs Is Here:

What Needs To Happen at the Retail and LTC Pharmacy?

R. Jeffrey Hedges
President & CEO

Where is USP <800>?

The best way to describe the status of USP <800> Hazardous Drugs as of today

Confusion

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History of USP <800>

USP <800> originally was posted with the General Chapter on February 1, 2016

UPS postponed the implementation January 1, 2018 on September 29, 2017

USP <800> was updated on June 1, 2019 with an implementation date of December 1, 2019

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Interpretations of USP <800>

September 23, 2019, Rockville, MD

USP published a Notice of Intent to Revise. This effected:

- Delaying USP <795> Non-Sterile Compounding
- Delaying USP <797> Sterile Compounding
- **USP <800> is unchanged and will become official on December 1, 2019**

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Interpretations of USP <800>

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

Section I states: "Tablet and capsule forms of **hazardous drugs** should not be placed in automated counting machines, which subject them to stress and may introduce powdered contaminants into the work area."

USP <800> Section 12 states: Tablet and capsule forms of **antineoplastic HDs** must not be placed in automated counting or packaging machines, which subject them to stress and may create powdered contaminants.

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Interpretations of USP <800>

USP followed up with their updated FAQs in November.

FAQ 68 - USP states that “Tables and capsule forms of **antineoplastic HDs** must not be placed in automated counting or packaging machines…

Now the question – Whose right?

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Automated Counting or Packaging Machines

NIOSH is the most restrictive and is highest precedence rule.

Remove **All** Hazardous Drugs from Automated Counting Machines and Pill Counters

Exceptions:

- RxSafe 1800® the tablet and capsule never leaves the manufacturer's stock bottle
- EyeCon® is a scanner with no mechanical mechanism to create powder or dust

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What does a Retail and LTC Pharmacy need to be compliant?

Start with identifying all hazardous drugs in the pharmacy inventory

Create an inventory of these hazardous drugs

- Name of the hazardous drug
- What form? Tablet, capsule, liquid, cream, gel, injection
- Is the HD in a stock bottle or manufacturer's packaging?
- What is the NOISH List Table?

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What does a Retail and LTC Pharmacy need to be compliant?

The Assessment of Risk must, at a minimum, contain the following:

1. Type of Hazardous Drug (e.g., antineoplastic, non-antineoplastic, reproductive risk only)
2. Dosage form
3. Risk of exposure
4. Packaging
5. Manipulation

A normal pharmacy will have **140 Assessments**

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What does a Retail and LTC Pharmacy need to be compliant?

Designated Counting Tools

Segregate Hazardous Drugs

- This is an operational process
- However some states are mandating in their regulations

Spill Kit with requirements for Hazardous Drugs

Access to Safety Data Sheets (SDS)

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What does a Retail and LTC Pharmacy need to be compliant?

We have identified these 12 policies and procedures for which are required in a Retail & LTC operation:

- Compounding
- Dispensing Final Dosage Forms
- Disposal
- Documentation & Standard Operating Procedures
- Hazard Communication Program
- List of Hazardous Drugs
- Non-Sterile Compounding
- Personnel Qualifications – Training, Evaluation and Requalification
- Responsibilities of Personnel Handling Hazardous Drugs
- Safe Glove Procedures
- Spill Control
- Types of Exposure

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Who is Regulating USP <800>

FDA is conducting on-site no-notice inspections of non-sterile compounding pharmacies

Accreditation Organizations have added USP <800> to their standards to achieve their accreditation

EPA and OSHA will if a situation warrants their involvement

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Who is Regulating USP <800> Individual States

Almost half of the states have stated they will not enforce or will delay implementation of USP <800>

- Even though the state environmental departments are inspecting their portions
- States like DE, IL, NC and SC who started enforcement have seemed to backed off their inspections on hazardous drugs

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Who is Regulating USP <800> Individual States

What are these inspectors asking for when they enter a pharmacy?

1. Assessment of Risks
2. Storage of Hazardous Drugs
    a. Separate storage area
    b. Are there any HDs in the robots
3. Separate and marked HD Counting Tools
4. Policies and Procedures

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What can Industry Do?

The biggest item is making the Hazardous Drugs more identifiable.

- Pharmacy Software are indicating a drug is HD as it is being dispense.
- Wholesalers have different methods for identifications, but usually Table 1, Antineoplastic Drugs
    - All three (3) Tables are Hazardous Drugs, not just Table 1

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What can Industry Do?

The biggest item is making the Hazardous Drugs more identifiable.

- Manufacturers can mark their bottles containing Hazardous Drugs with a distinguishing color
  - Blue is the color used by OSHA, US DOT, IATA and EPA
- A standardize Hazardous Drug Label would also make for easy recognition through out the distribution chain.

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Where is USP <800> going?

Prevent the Confusion

Three things industry can do make it easier for the individual pharmacy

1. Pharmacies need to implement USP <800> as they are going to be inspected tomorrow because tomorrow may be the day
2. Stop mis-interpatations, challenge for sources
3. Industry can help through ease of identification of HD and wholesalers identifying all HDs

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Questions

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We're here to help you stay stress-free and in compliance! ™

R.J. HEDGES
& ASSOCIATES

724-357-8380

SALES@RJHEDGES.COM

WWW.RJHEDGES.COM

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