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# USP <797> and USP <800>

## Revisions and Impact of Updates in ASCs

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ASC Pharmacist Consultants, Inc.

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<h1>USP &lt;797&gt;</h1> <p><b>Pharmaceutical Compounding Sterile Preparations</b></p>	<h1>USP &lt;800&gt;</h1> <p><b>Hazardous Drugs Handling in Healthcare Settings</b></p>
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## Goals & Learning Objectives

- Describe the background of USP, the history and purpose of USP revisions
- Review USP Chapters <797> and USP <800> standards and guidelines
- Identify and understand new revisions and updates to USP Chapters <797> Immediate Use Provision and USP <800> in ASCs
- Understand the complexities of USP <800> and awareness of any medications covered by USP <800> present in the facility
- Recognize best practices in immediate use sterile preparation
- Discuss implementation date of new revisions of provisions and how to prepare for success
- Assess the impact of revisions of USP Chapters <797> and <800> to ASCs



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## USP

### United States Pharmacopeia

An independent, scientific nonprofit organization that sets standards for the identity, purity, manufacturing, and handling of medications that are legally recognized in the US and 140+ countries



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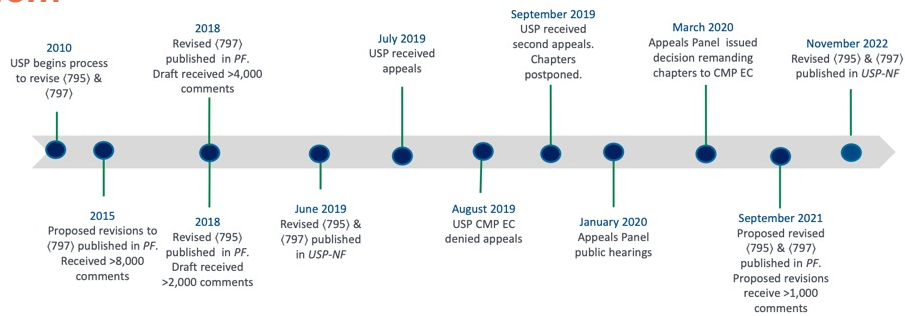
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# USP | History of Revisions

## PURPOSE OF REVISIONS

To clarify, and resolve confusion and workflow disruptions that healthcare workers have faced many years regarding all conditions and standards of pharmaceutical compounding and handling sterile preparations (USP <797>)

**Last USP Revision:  
2008**



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# USP <797>


## Pharmaceutical Compounding Sterile Preparations



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## USP <797>

### Pharmaceutical Compounding Sterile Preparations



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## STERILE COMPOUNDING

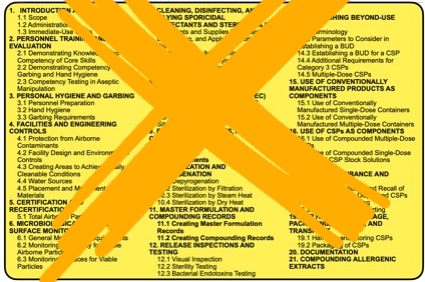
Defined as **any** of the following:

- Combining
- Admixing
- Diluting
- Pooling
- Reconstituting
- Repackaging
- Altering a drug or bulk drug substance to create a sterile preparation

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## USP <797> Sterile Preparation Requirements Hospitals vs. ASCs

**USP <797> 2023 – CSPs in Hospitals**  
Standard Requirements of an IV Compounding Facility



**USP <797> November 2023 Immediate Use Provision**  
IV and Ophthalmic Preparations in the ASC

**Asptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or Compounded sterile products.**

**The preparation involves not more than 3 different sterile products.**

**The Compounded sterile product must be labeled with**  
•Date and Time of draw,  
•Initials of the person drawing  
•Medication Name  
•Medication Strength  
•Beyond-use Date  
•4-h time period within which administration must begin.

**Must follow all conditions!**

**The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability and compatibility studies).**

**Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.**

**Single-dose containers must not be used for more than one patient. Any unused starting component from a single-dose container must be discarded after preparation is complete.**

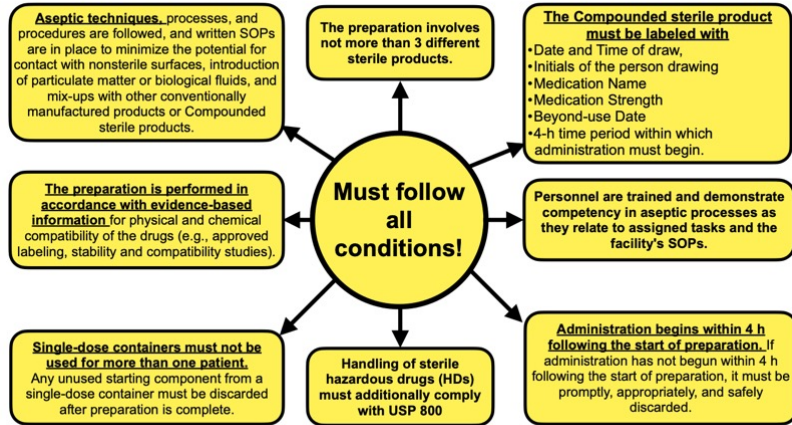
**Handling of sterile hazardous drugs (HDs) must additionally comply with USP 800**

**Administration begins within 4 h following the start of preparation. If administration has not begun within 4 h following the start of preparation, it must be promptly, appropriately, and safely discarded.**

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# USP <797> Immediate Use Provision in ASCs

**How to get your IV and Ophthalmic Sterile Preparations to 4 Hours?**  
**All conditions must be met:**



## USP <797> Immediate Use Provision in ASCs

**Condition #1**  
Aseptic Techniques and Defined SOPs/Competencies must be put in place.



**Aseptic techniques, processes, and procedures** are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or Compounded sterile products.




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Immediate Use Provision in ASCs

Condition #2


Maximum of 3 Sterile Products



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The preparation involves **not more than 3** different sterile products.




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USP <797>

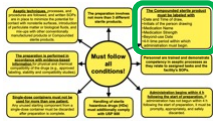
Immediate Use Provision in ASCs

Condition #3

Meet All Labeling Requirements



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The Compounded sterile product **must be labeled with:**

1. Date and Time of draw
2. Initials of the person drawing
3. Medication Name
4. Medication Strength
5. Beyond-use Date
6. 4-hour time period within which administration must begin\*

\*NEW USP labeling requirement = 4-hour BUD

If medication administration doesn't begin within 4 hours of initial preparation, ***it must be discarded***

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Provision in ASCs

Condition #4

Team Members must  
be Properly Trained  
AND  
Demonstrate  
Competency in  
Aseptic Processes



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Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.


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Immediate Use  
Provision in ASCs

Condition #4

Team Members must  
be Properly Trained  
AND  
Demonstrate  
Competency in  
Aseptic Processes



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USP **does not define** how frequent the competencies for aseptic technique processes should be assessed

- CA Board of Pharmacy: **“Best practice is every 12 months”**
- **ASC’s responsibility** to determine competency assessment frequency and associated specific tasks – outlined in ASC SOP


USP recommends training include **didactic education** and **knowledge-based demonstration competencies**


- All team members who compound sterile preparations, including anesthesia, require competency training
- Core Competencies defined by USP <797> include:
  - ✓ Hand hygiene, garbing, cleaning / disinfecting, measuring/mixing, aseptic technique, BUD, labeling

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**USP <797>**  
Immediate Use  
Provision in ASCs


**Condition #5**  
Administration must be *within 4 hours* of initial start time of sterile preparation





**Administration begins within 4 hours following the start of preparation.**

If administration has not begun within 4 h following the start of preparation, it must be promptly, appropriately, and safely discarded.



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## Batch Compounding...

Allowable

?

Recommended


?

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## Is Batch Compounding Allowable?

2008 (Current)	2022 (Revised)*
USP <797> Immediate Use Provision not intended for batch compounding	Allowed for multiple doses, and/or multiple patients*
Not intended for storage of anticipated needs	If all conditions are met*
<b>Compounding Documentation Not Addressed</b>	<b>Compounding Record (CR) is required if preparing immediate use CSPs for more than 1 patient</b>
 <p>ASC Pharmacist Consultants</p>	<p><b>Per CA Board of Pharmacy:</b>  <b>All CRs must be readily retrievable</b></p> <ul style="list-style-type: none"> <li>• May be stored electronically</li> <li>• May be in the form of prescription or medication order, compounding log, or label</li> </ul>
	<p><b>2022 Revision</b>            ASCs should have all conditions met and policies implemented by 11-1-2023</p>

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## We do not recommend Batching...

**WHY?** **Batching causes the ASC confusion and further imposes infection control risks**

### Most ASCs are Medicare Certified

- **Batching makes it more difficult in following CMS infection control rules and the USP <797> Immediate Use Provision rules**
- **CMS Standards + CMS Infection Control Program (One and Only Campaign):**
  - “MDVs should be dedicated to a single patient whenever “possible”
  - “MDVs that are kept or accessed in an **immediate patient treatment area**, (i.e. anesthesia cart, OR, patient bay) **should be dedicated to that patient only** and discarded after use to prevent inadvertent contamination of the vial through direct/indirect contact with potentially contaminated surfaces or equipment that could lead to infections to subsequent patients”
- **Medication sterile preparation area?**
  - Not all ASCs have one
- **New revision allows batching of immediate use CSPs if all conditions are met, but batching is strongly not recommended as best practice as the goal is for our anesthesia providers to create a culture of prepping for single patient only**


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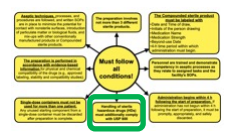
Immediate Use Provision in ASCs

Condition #6

Handling of Sterile Hazardous Drugs is now in USP Chapter <800>



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Handling of sterile hazardous drugs (HDs) must **additionally comply with USP 800.**


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Condition #7

Single Dose Containers are for one, single patient only.



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**Single-dose containers must not be used for more than one patient.**

Any unused starting component from a single-dose container must be discarded after preparation is complete.

Not a new requirement.


CDC: "Questions about Single-dose/Single-use Vials"

[https://www.cdc.gov/injectionsafety/providers/provider\\_faqs\\_singlevials.html](https://www.cdc.gov/injectionsafety/providers/provider_faqs_singlevials.html)


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**USP <797>**  
Immediate Use Provision in ASCs

**Condition #8**  
All Sterile Preparations must be from Evidence-Based Information



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**The preparation is performed in accordance with evidence-based information** for physical and chemical compatibility of the drugs (e.g., approved labeling, stability, and compatibility studies).

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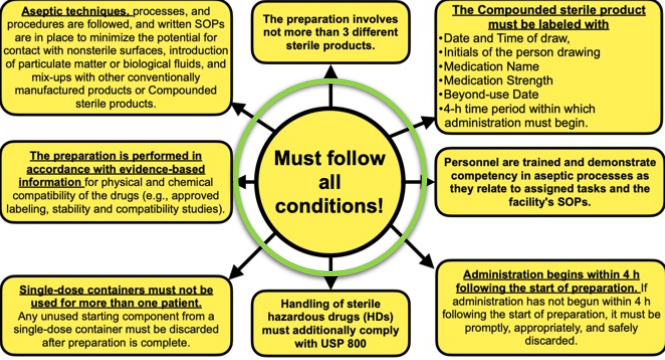
## USP <797> Immediate Use Provision in ASCs

Have you met all 8 Conditions?

You can successfully prepare IV and Ophthalmic Sterile Preparations at your ASC and expect survey success.



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**Implementation Date:**  
**November 1st, 2023**

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## USP <800>

### Hazardous Drug Handling in Health Care Settings



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## What is the exposure?

More than

8 million



**U.S. healthcare workers** are exposed  
to hazardous drugs every year<sup>1</sup>

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## What is the exposure?



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## What is the exposure?

Drugs are classified as **hazardous** when they possess any of **these characteristics**<sup>1</sup>:

- ✓ Impact or damage DNA/genes
- ✓ Cause cancer
- ✓ Contribute to infertility
- ✓ Impact a developing embryo or fetus
- ✓ Cause developmental abnormalities
- ✓ Cause organ damage
- ✓ Have a similar structure or function to drugs that are determined to be hazardous

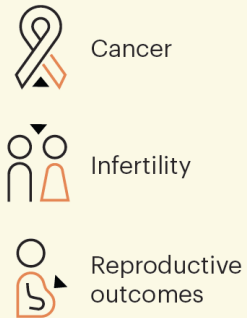
<https://www.cdc.gov/niosh/topics/hazdrug>

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## What are the potential risks?

Acute<sup>3</sup> and long term effects<sup>4,5</sup>

Hearing loss  
 Cardiac toxicity  
 Kidney damage  
 Hair loss  
 Nausea  
 Rashes



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## Who is at risk?

Anyone handling hazardous drugs is at risk of exposure<sup>1</sup>

- ▶ Pharmacists
- ▶ Pharmacy Technicians
- ▶ Nurses
- ▶ Physicians
- ▶ Surgeons
- ▶ Physician Assistants
- ▶ Respiratory Therapists
- ▶ Home Health Aides
- ▶ Nurses' Aides
- ▶ Housekeeping
- ▶ Janitorial Services
- ▶ Environmental Services
- ▶ Veterinarians
- ▶ Veterinarian Technicians
- ▶ Veterinarian Assistants



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## Where can exposure occur?

Exposure can take place in any healthcare setting<sup>1,6</sup>



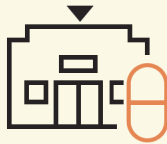
Hospitals



Surgical centers



Veterinary hospitals and clinics



Pharmacies



Home health care



Skilled nursing facilities

## How can exposure occur?

Every aspect of handling hazardous drugs may result in exposure if proper precautions are not taken<sup>1,6</sup>



## USP <800> in the ASC | Meds

**Ask yourself:**  
*Do we have any of these meds?*

### National Institute for Occupational Safety and Health

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




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## USP <800> in the ASC | Meds

**Ask yourself:**  
*Do we have any of these meds?*

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

GROUP 1	GROUP 2	GROUP 3
<p>Antineoplastic drugs</p> 	<p>Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug</p>	<p>Drugs that primarily pose a reproductive risk to men and women who are actively trying to conceive and women who are pregnant or breast feeding, because some of these drugs may be present in breast milk</p>

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## USP <800> in the ASC | Meds

**Ask yourself:**  
*Do we have any  
of these meds?*

### GROUP 1

Antineoplastic drugs\*



Generic Name	Trade Name
Fluorouracil	Fluoroplex
Gemcitabine	Gemcitabine
MitoMYcin	MitoMYcin

\* Not a complete list

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## USP <800> in the ASC | Meds

**Ask yourself:**  
*Do we have any  
of these meds?*

### GROUP 2

Non-antineoplastic drugs  
that meet one or more of  
the NIOSH criteria for a  
hazardous drug



Generic Name	Trade Name
Chloramphenicol	Chloromycetin
Estrogen Conjugated 25mg	Premarin
Estrogen Vaginal Cream	Premarin Vaginal Cream

\* Not a complete list

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## USP <800> in the ASC | Meds

**Ask yourself:**  
*Do we have any of these meds?*

### GROUP 3

Drugs that primarily pose a reproductive risk to men and women who are actively trying to conceive and women who are pregnant or breast feeding, because some of these drugs may be present in breast milk

Generic Name	Trade Name
Fluconazole	Diflucan
Methylergonovine	Methergine
miSOPROStol	Cytotec
Oxytocin	Pitocin
Temazepam	Restoril
Warfarin	Coumadin

\* Not a complete list

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## USP <800> in the ASC What you need to do...

1

Identify all Hazardous Drugs in the facility

2

Assess risk of each medication and dosage form

3

Policies and Procedures

4

Train personnel to oversee and monitor compliance

5

Complete risk assessment for each Hazardous Drug

6

Reassess at least every 12 months

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## USP <800> in the ASC

**Risk Assessment:** *Identify risks at each step*



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## USP <800> in the ASC

**Risk Assessment:** *Identify risks at each step*

### EXAMPLE 1

Generic Name	Trade Name
<b>Phenytoin</b>	<b>Dilantin</b>



#### Questions to Ask:

What Purpose? Emergency Cart

- Is it necessary on the Emergency Cart?
- Can it be removed from the formulary?

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## USP <800> in the ASC

**Risk Assessment:** *Identify risks at each step*

### EXAMPLE 2 - MitoMYcin

Generic Name	Trade Name
MitoMYcin	MitoMYcin



#### Questions to Ask:

What Purpose? Urology

- Will we continue this type of case?
- Complete risk assessment...

## USP <800> in the ASC

**Risk Assessment:** *Identify risks at each step*

### EXAMPLE 2 - MitoMYcin

RECEIVING	STORING	TRANSPORT	COMPOUNDING
<p>Full chemo PPE and 2 pair chemo gloves</p> <p>Place in facility ziplock package</p>	<p>Engineering</p> <p>Negative pressure room with chemo dedicated refrigerator</p>	<p>Chemo gloves not required due to facility ziplock package</p>	<p>Requires Biologic Safety Cabinet (BSC)</p> <p>Order from 503b compounding pharmacy</p>



## USP <800> in the ASC

**Risk Assessment:** *Identify risks at each step*

### EXAMPLE 2 - MitoMYcin

#### DISPENSING

ASCs do not dispense

#### ADMINISTRATION

Impermeable gown, mask, goggles/face shield, double chemo gloves and Closed System Transfer Device (CSTD) if dosage form allows

#### DISPOSAL

Addresses prevention of accidental exposures or spills, personnel training response to exposure, and use of a spill kit.

PPE must be placed in an appropriate waste container

**Cleaning:** Do reusable devices need additional care prior to sterilization?

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## USP <800> in the ASC

**Risk Assessment:** *Identify risks at each step*

### EXAMPLE 2 - MitoMYcin

#### PATIENT CARE

Risk of additional exposure during patient care?

#### MANAGING WASTE

Storage requirements of Chemotherapy waste?

#### SPILLS

Design a spill kit, and a spill response guideline

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## USP <800> in the ASC

**Risk Assessment:** *Identify risks at each step*

### EXAMPLE 3 - Mitosol® Kit (MitoMYcin), For Ophthalmic Preparations

Generic Name	Trade Name
MitoMYcin	Mitosol® Kit



#### The Mitosol Kit for Ophthalmic Preparation Meets The New USP <800> Rules

- Implementation of Mitosol Successfully by 11/1/2023?
- Risk Assessment?
- Each step of Risk Assessment addressed in Detail and Defined in SOP?

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## USP <800> in the ASC

**Risk Assessment:** *Identify risks at each step*

### EXAMPLE 3 - Mitosol® Kit (MitoMYcin), For Ophthalmic Preparations

RECEIVING	STORING	TRANSPORT	COMPOUNDING
No chemo-tested gloves or PPE needed to open box.	Can be Stored with Other Medications at room temperature, as long as labeled as HD, clearly	PPE is not needed to transport the kit Mitosol is a Closed Transfer System Device (cTSD)	Not Applicable Mitosol is a ready to use format by Mobius Therapeutics

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## USP <800> in the ASC

**Risk Assessment:** *Identify risks at each step*

### EXAMPLE 3 - Mitosol® Kit (MitoMYcin), For Ophthalmic Preparations

<p><b>DISPENSING</b></p> <p>ASCs do not dispense</p>	<p><b>ADMINISTRATION</b></p> <p><b>Surgeon:</b> Impermeable gown, mask, goggles/face shield, <u>double</u> chemo gloves during administration; single chemo gloves allowable after administration during surgery (monitor for exposure and holes)</p> <p>Closed System Transfer Device (CSTD) is included as part of the kit</p>	<p><b>DISPOSAL</b></p> <p>Addresses prevention of accidental exposures or spills, personnel training response to exposure, and use of a spill kit.</p> <p>PPE must be placed in an appropriate waste container</p> <p><b>Cleaning:</b> Do reusable devices need additional care prior to sterilization?</p>
<p><b>PATIENT CARE</b></p> <p>Risk of additional exposure during patient care?</p>	<p><b>MANAGING WASTE</b></p> <p>Storage requirements of Chemotherapy waste?</p>	<p><b>SPILLS</b></p> <p>Design a spill kit, and a spill response guideline for on and off the sterile field</p>

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**Sign up for updates**  
to USP <797> and USP <800>  
and other topics related  
to USP Healthcare Quality  
and Safety Standards:



**Questions**



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MEDICATION MANAGEMENT: MEDICATION SAFETY

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USP GENERAL CHAPTER <800> HAZARDOUS DRUGS

**USP General Chapter <800>** provides standards for safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients and the environment. This may impact your facility if you are using a hazardous drug, like Mitomycin C. The official date for implementation is 12/1/19. PSS has developed a policy for implementation – it must be customized to your facility (see link below). Mitomycin C can no longer be utilized in the way it has been previously – ordered from a compounding pharmacy; received in a syringe; stored in a freezer; defrosted and poured into medicine cup on back table; etc. Mitosol, from Mobius Therapeutics, is really the only option as it comes in a closed system device. Please read the policy in detail for all the necessary details that need to be implemented with the use of hazardous drugs.

Download a free education resource from [Mobius Therapeutics\\*](#) on USP 800 Handling of Hazardous Drugs using the link below. Included in this material is a risk assessment to be incorporated with your facility policy.

- [Policy: Handling of Hazardous Drugs \(requires customization\)](#)
- [Hazardous Drug \(HD\) Acknowledgement of Reproductive Risk](#)

[FREE Educational Resource on USP 800 Handling of Hazardous Drugs: Mobius Therapeutics](#)

**MEDICATION MANAGEMENT**

- Medication Management Overview
- Compounding
- Controlled Substances
- Eye Drops
- Formulary
- Infection Control
- Medication Labeling
- Medication Safety**
- CA Board of Pharmacy Resources

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attendee



Complete Course  
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for processing your  
certificates



Any questions  
regarding CE Credit,  
contact

Jenna@pss4asc.com



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## Upcoming Webinars

DATE	CE	WEBINAR TOPIC	SPEAKER
JUL 24	20	Managing your ASCs Ancillary Service Contracts	Vanessa Sindell Nancy Stephens
AUG 24	60 RN, CASC	Piecing Together the Talent Puzzle: 6 Truths about Finding and Keeping Talent	Trinet
SEP 25	20	Credentialing Review	Cyndi Krause
OCT 27	60 RN, CASC	ASC Billing 101	Jessica Macias
NOV 27	20	Annual Survey Watch Report 2023	Crissy Benze
DEC 18	60 RN, CASC CAIP	Steam Sterilization	Delores O'Connell

[www.ProgressiveSurgicalSolutions.com/webinars](http://www.ProgressiveSurgicalSolutions.com/webinars)

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<https://www.usp.org/usp-chapter-800-download>



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