

Excellencia University Infection Prevention Conference

1

---

---

---

---

---

---

---

---

## Pharmacy 101

### Objectives

#### Regulations

- CDC
- USP 797
- Exhibit 351

#### Greatest Issues

- 1 hour rule
- MDV
- Labeling of syringes
- Anesthesia Providers

Excellencia University Infection Prevention Conference

2

---

---

---

---

---

---

---

---

## Pharmaceutical Services 416.48

Provided in a safe and effective manner... in accordance with ethical and professional practice.



3

---

---

---

---

---

---

---

---



Pharmacy  
101

Most frequent cited tags

Historically the most dangerous area of concern

Excelsior University Infection Prevention Conference



4

---

---

---

---

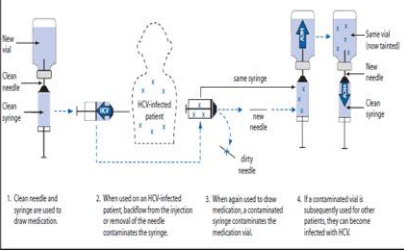
---

---

---

---

Nevada 2009



1. Clean needle and syringe are used to draw medication.
2. When used on an HIV-infected patient, backflow from the injection or removal of the needle contaminates the syringe.
3. When again used to draw medication, a contaminated syringe contaminates the medication vial.
4. If a contaminated vial is subsequently used for other patients, they can become infected with HIV.

5

---

---

---

---

---

---

---

---

Steps to Safety for Your Patients

1. Wash hands, prepare the work area, wash hands
2. Wipe all vials, even if new, with alcohol prep
3. Don't share needles or syringes
4. Proper placement of the labeled syringe if not using immediately
5. IV fluids are labeled and intended for single patient use

6

---

---

---

---

---

---

---

---



**USP-NF General Chapter <797>**  
Pharmaceutical Compounding—  
Sterile Preparations

Excellentia University Infection Prevention Conference

7

---

---

---

---

---

---

---

---

**USP 797**

The purpose of USP 797 is to describe conditions and practices that prevent harm, including death, to patients that could result from compounded sterile preparations due to microbial contamination, excessive bacterial endotoxins. Variability in intended strength of the product, unintended chemical and physical contaminants, or ingredients of inappropriate quality.

8

---

---

---

---

---

---

---

---

**USP 797 SDV**

Open or needle-punctured single dose containers, such as bags, bottles, syringes, and vials of sterile products and CSP's shall be used within 1 hour if opened in worse than ISO Class 5 air quality and any remaining contents must be discarded.

9

---

---

---

---

---

---

---

---

### USP 797 UPDATE

- ▶ On July 27, 2018, the Compounding Expert Committee of the United States Pharmacopeia Convention published proposed revisions to USP chapter <797> Pharmaceutical Compounding - Sterile Preparations. The proposed chapter was open to public comments until November 30, 2018, and is expected to become official on December 1, 2019. We anticipate a June 2019 publish date.

Excellentia University Infection Prevention Conference

10

---

---

---

---

---

---

---

---

### USP 797 UPDATE

- ▶ Current description is Low, Medium, High Risk
- ▶ Proposed description is Category 1 vs Category 2
- ▶ Staff training:
  1. Prior, annual training
  2. Hand Hygiene
  3. Cleaning & Disinfection
  4. Calculations, measuring, & mixing
  5. Aseptic technique
  6. Achieving and /or maintaining sterility
  7. Use of equipment
  8. Documentation

11

---

---

---

---

---

---

---

---

### 1 Hour Rule.....

- ▶ USP 797
- ▶ CDC
- ▶ APIC
- ▶ AAAHC
- ▶ TJC
- ▶ IMQ



12

---

---

---

---

---

---

---

---

### CDC Q&A's

► **What are examples of the “immediate patient treatment area”?**

Examples of immediate patient treatment areas include operating and procedure rooms, anesthesia and procedure carts, and patient rooms or bays.

Excellentia University Infection Prevention Conference

13

---

---

---

---

---

---

---

---

► **How many times may individual single-dose or single-use vials be entered for a single patient?**

The safest practice is to enter a single-dose or single-use vial only once so as to prevent inadvertent contamination of the vial and infection transmission. Single-dose or single-use vials should be used for a single patient and a single case/procedure/injection. Therefore, they should require only a single entry into the vial.

Excellentia University Infection Prevention Conference

14

---

---

---

---

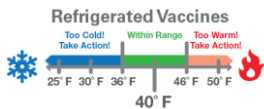
---

---

---

---

### Monitoring of Temperature



15

---

---

---

---

---

---

---

---

## FDA Extends Outdates

<https://www.fda.gov/drugs/drugsafety/drugshortages/ucm563360.htm>



16

---

---

---

---

---

---

---

---

## Institute for Safe Medication Practices

- ▶ High Alert Drug List
- ▶ Look Alike - Sound Alike
- ▶ Confused Drug Names
- ▶ Tall Man Lettering



Excellencia University Infection Prevention Conference

17

---

---

---

---

---

---

---

---



[www.SafeMedicationSolutions.com](http://www.SafeMedicationSolutions.com)  
Gregory Tertes, R.Ph.  
Consultant Pharmacist, President

18

---

---

---

---

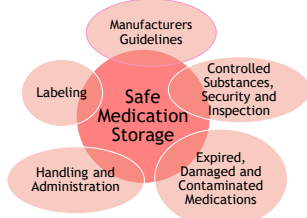
---

---

---

---

## Safe Injection Practices



19

---

---

---

---

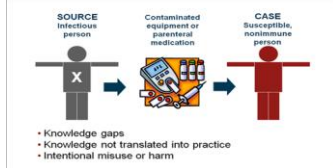
---

---

---

## Conclusions

### Where Are We Dropping the Ball?



- ▶ Injection safety is a basic expectation in patient safety
- ▶ Safe practices should not be sacrificed in efforts to save time or money
- ▶ If you have to justify or qualify your injection practices, you might be doing something wrong

20

---

---

---

---

---

---

---