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Pharmacy 101

Objectives

Regulations

- CDC
- USP 797
- Exhibit 351

Greatest Issues

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

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Pharmaceutical Services 416.48

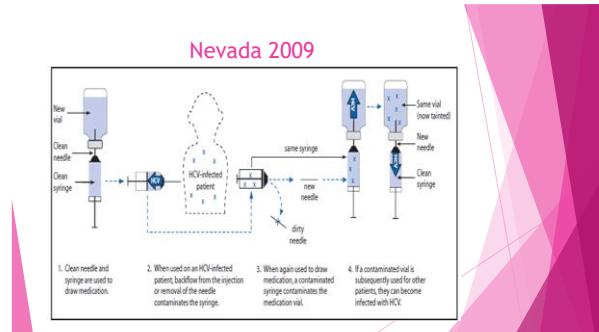
Provided in a safe and effective manner... in accordance with ethical and professional practice.



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

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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.

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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.

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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.

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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

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1 Hour Rule.....

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



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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.

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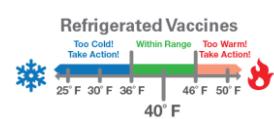
► How many times may individual single-dose or single-use vials be entered for a single patient?

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.

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Monitoring of Temperature



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FDA Extends Outdates

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



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Institute for Safe Medication Practices



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

 Institute for Safe Medication Practices

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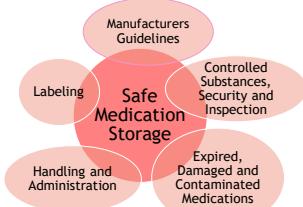
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www.SafeMedicationSolutions.com

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Safe Injection Practices



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Conclusions



- ▶ 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.

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