

# FAWK'S NEWS

## USP <797>

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Chapter 797 in the United States Pharmacopeia (USP) that provides enforceable standards for sterile compounding.

### Compounded Sterile Products (CSPs)

Any manipulation of a sterile drug that goes beyond the package insert directions

### Immediate Use CSPs

A CSP that is prepared outside a clean room setting for direct and immediate use.

## What is compounding?

Compounding includes combining, diluting, or repackaging medications. In simple terms, it means any time you mix two or more products together or go beyond what the package insert instructs.

## What are Compounded Sterile Product (CSPs)?

A CSP is created whenever two or more sterile products are combined or a medication is manipulated beyond the package insert.

Examples include:

- Diluting a medication for IV use
- Preparing IV antibiotics
- Mixing medications in a syringe for a block

Since most ASCs do not have a cleanroom for sterile compounding, the CSPs made in this setting almost always fall into the category of “**Immediate Use CSPs**”. These are prepared for a single patient and must be administered within 4 hours of preparation.

## What is NOT Compounding?

Not everything done with a vial counts as compounding. Activities that are considered administration, not compounding, include:



## FAWKS Call to Action!

**If you're mixing, diluting, or altering a medication beyond the package insert, treat it as compounding.**

**This means:**

- 1) Label every syringe with all 5 elements: Medication(s), Concentration(s), Date, Time and Initials**
- 2) Limit compound to 3 sterile products**
- 3) Prepare compound for immediate use (not in anticipation of use)**
- 4) Four (4) hour beyond use date**



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- Withdrawing a single dose from a manufacturer's vial or ampule and giving it right away exactly as the package insert directs.
- Using a prefilled syringe supplied by the manufacturer.
- Reconstituting a drug exactly as described in the package insert and administering it immediately.

## Most Common Immediate-Use CSPs in ASCs

- Preoperative:
  - Cefazolin (Ancef) – reconstituted and diluted for IV infusion
  - Other antibiotics (e.g., clindamycin, vancomycin) prepared for surgical prophylaxis
- Intraoperative:
  - Phenylephrine or ephedrine diluted in saline for IV bolus use
  - Local anesthetic “cocktails” (e.g., ropivacaine with adjuncts) prepared just before a block
  - Lidocaine/ Propofol with epinephrine drawn up for infiltration or sedation/induction