UP FOR ADOPTION: A KANSAS COMPOUNDING UPDATE

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KPhA works with the Kentucky Pharmacy Education and Research Foundation, Inc. to certify its courses. KPERF is accredited by ACPE as a provider of continuing pharmacy education.

ACPE UAN 0143-9999-26-060-L07-P/T

DISCLOSURES

Faculty

Katie Allen, faculty for this activity, has no relevant financial relationship(s) with ineligible companies to disclose.

Katie has been a KPhA board member since August 2025. The opinions expressed in this presentation are those of the presenter and not necessarily those of the KPhA.

Planners

None of the planners for this activity have any relevant financial relationships with ineligible companies to disclose.

PRE-TEST QUESTION 1

What standards apply to patient specific sterile compounding performed in Kansas pharmacies?

A. USP 797, CGMP, Section 503A of FDCA, Section 503B of FDCA
B. USP 797 and CGMP
C. USP 797 and Section 503A of FDCA
D. USP 797 and Section 503B of FDCA

PRE-TEST QUESTION 2

The Kansas Board of Pharmacy has fully adopted the USP 795 & 797 with no exemptions effective July 1, 2026

A. True
B. False

PRE-TEST QUESTION 3

You dispense a prescription for a conventionally manufactured topical cream requiring reconstitution of powder and mixing using a pre-supplied stirring tool. Following the directions contained in the manufacturer approved labeling is not subject to USP 795.

A. True

B. False

OBJECTIVES

PHARMACISTS AND TECHNICIANS:

Recognize the compounding standards that apply to Kansas pharmacies

Identify resources and methods to complete USP 795 or 797 gap analysis

Develop standard operating procedures meeting basic compounding standard requirements

BACKGROUND

June 1, 2019

Revised <795> & <797> published in USP-NF

March 12, 2020

Appeals panel issues decisions

May 14, 2022

Compounding Expert Committee status update – received >1400 comments from 350 organizations

Sept 23, 2019

Revised <795> & <797> postponed

May –Nov 2020

USP stakeholder engagement & open forums

BACKGROUND

USP <795> and <797>

- Updates made final and published November 1, 2022 with November 1, 2023 effective date
- Kansas compounding regulations **not** aligned

EXAMPLE: USP 797 VS. KANSAS REG

1.3 Immediate-Use CSPs

Administration begins within 4 h following the start of the preparation.

68-13-4 Sterile Preparations

Immediate use means… a sterile preparation is compounded pursuant to an order in a medical care facility for administration to the patients within one hours of the start of compounding…

BACKGROUND

USP 795 & 797

- Kansas Compounding Coalition formed late 2024
  - Convened experts from across the state in all practice settings
- Recommended adopting USP 795, 797, and 825 by statute

KANSAS HOSPITAL ASSOCIATION COMPOUNDING SURVEY

Developed with input from:

Kansas Compounding Coalition

Kansas Board of Pharmacy

Kansas Council Health System Pharmacy

KHA Member Hospitals

125 hospitals/health systems

November 19 – December 1, 2025

104 respondents

30% indicated concern about Kansas BOP adopting USP chapters 795, 797, and 825

KHA COMPOUNDING SURVEY THEMES

KHA COMPOUNDING SURVEY

Resources that would be helpful

1. Minimum requirements
2. Toolkit or checklist
3. Workflow/pathway template
4. Mini-gap analysis template

HOUSE BILL 2068

K.S.A. 65-1637e Compounding of drugs and distribution of compounded drugs amended to read:

- *(a) The compounding standards established by the general chapters 795 pharmaceutical compounding-nonsterile preparations; 797 pharmaceutical compounding-sterile preparations; and 825 radiopharmaceuticals…published by the United States pharmacopeia and its referenced companion documents in effect on the effective date of this section are hereby adopted.*

HB 2068

K.S.A. 65-1637e amended to read:

- *(b) The board may adopt rules and regulations governing proper compounding practices and distribution of compounded drugs by pharmacists and pharmacies and establishing exemptions or waivers from the requirements set forth in subsection (a).*

HB 2068

K.S.A. 65-1637e amended to read:

- *(c) This section shall be a part of and supplemental to the pharmacy act of the state of Kansas.*
- *(d) This section shall take effect and be in force on and after July 1, 2027.*

NOW WHAT?

AN ACT concerning health and healthcare; relating to pharmacy; adopting the United States pharmacopeia compounding standards under the pharmacy act of the state of Kansas; amending K.S.A. 65-1637e and repealing the existing section.

Be it enacted by the Legislature of the State of Kansas:

Section 1. K.S.A. 65-1637e is hereby amended to read as follows: 65-1637e. (a) *The compounding standards established by the general chapters 795 pharmaceutical compounding - nonsterile preparations; 797 pharmaceutical compounding - sterile preparations; and 825 radiopharmaceuticals - preparation, compounding, dispensing and repackaging published by the United States pharmacopeia and its referenced companion documents in effect on the effective date of this section are hereby adopted.*

(b) The board ~~shall~~ *may* adopt rules and regulations governing proper compounding practices and distribution of compounded drugs by pharmacists and pharmacies *and establishing exemptions or waivers from the requirements set forth in subsection (a).*

~~(b)~~*(c)* This section shall be *a* part of and supplemental to the pharmacy act of the state of Kansas.

(d) This section shall take effect and be in force on and after July 1, 2027.

Sec. 2. K.S.A. 65-1637e is hereby repealed.

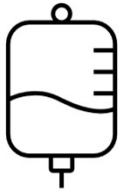
Sec. 3. This act shall take effect and be in force from and after its publication in the statute book.

COMPOUNDING REQUIREMENTS

- Compliance with chapters 797, 795, and 825 is enforceable by the FDA as cited in the FDCA, section 503A
- USP vs CGMP
  - Not subject to CGMP if the following conditions are met as a 503A:
    - Compounding for patient-specific prescriptions
    - Using bulk drug that has a USP/NF monograph, is FDA approved, or appears on the FDA 503A bulk drug list
    - Not regularly compounding drugs that are essentially copies of commercially available drug product

MINIMUM STANDARDS

USP 797 CATEGORIES



Immediate Use
- No more than 3 sterile products, 4 hour beyond use date

Category 1
- Typically segregated compounding area
- 12 hour BUD

Category 2
- Cleanroom suite
- Extended BUDs

Category 3
- Sterility & endotoxin testing
- Extended BUDs

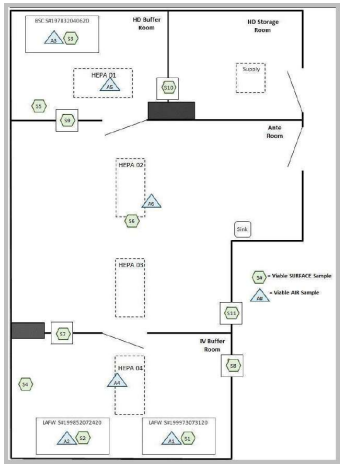
	Cleanroom Suite*	Segregated Compounding Area	Immediate Use Counter
Primary Engineering Control	Yes	Yes	No
Secondary Engineering Control	Yes	No	No
Max BUD Refrigerated	10 days	24 hours	N/A
Max BUD Room Temp	4 days	12 hours	4 hours

*No sterility testing and only sterile components

	Cleanroom Suite*	Segregated Compounding Area	Immediate Use Counter
Primary Engineering Control	Yes	Yes	No
Secondary Engineering Control	Yes	No	No
Max BUD Refrigerated	10 days	24 hours	N/A
Max BUD Room Temp	4 days	12 hours	4 hours

*No sterility testing and only sterile components

OLATHE HOSPITAL CLEANROOM



IMMEDIATE USE COMPOUNDING REQUIREMENTS

Aseptic Technique Training & Competency
- SOPs

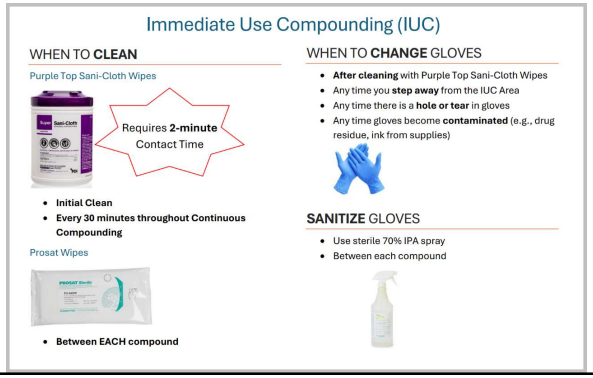
Not more than 3 sterile products
- Multiple vials of the same medication = 1 product

Administration must begin within 4 hours
- Appropriate labeling required if not administered by preparer

No hazardous drugs
- USP 800

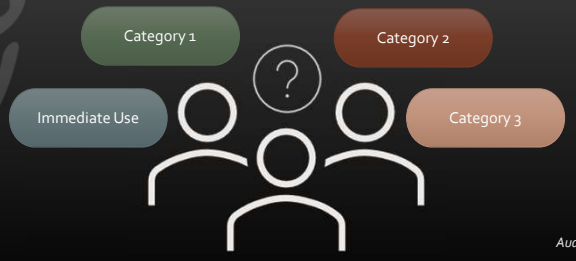
OLATHE HOSPITAL 'STAT COUNTER'

OLATHE HOSPITAL PHARMACY JOB AID



RECONSTITUTION PER PACKAGE-INSERT INSTRUCTIONS

- This is NOT considered immediate-use compounding and is NOT subject to USP requirements
- Caution!
  - IV push antibiotics



Audience Survey

USP 795

In Scope

All persons who prepare compounded nonsterile preparations and all places where CNSPs are prepared.

Out of Scope

- Splitting tablets
- Reconstitution of conventionally manufactured nonsterile product following approved labeling
- FDA approved compounding kits following PI

USP 795 KEY CHANGES

Compounding Categories

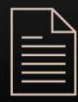
Simple, moderate, and complex compounding categories have been **eliminated**

BUDs

Dosage form, compounding conditions, and water activity

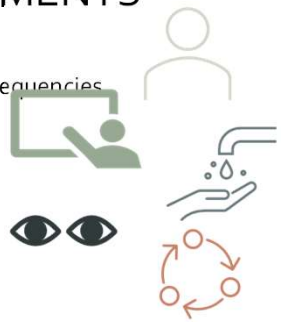
Master Formulation Records & Compounding Records

Must be created for all CNSPs



USP 795 NEW REQUIREMENTS

- Designated person
- Training & competencies with defined frequencies
- Hand hygiene and garbing
- Designated compounding area
- Visual inspection prior to release
- Standard operating procedures



READY TO ADOPT?

WHERE TO START

Gap Analysis

- Current state vs. where to go
- Identify risks and set priorities
- Excellent student project!

EXAMPLE GAP ANALYSIS

ashp Inpatient Care Practitioners

USP <797> Gap Analysis Tool

Date Completed		Compliance Status [Yes, No, N/A]	SOP	Comments
Section	**Audit Criteria**			
1. Introduction and Scope	USP 797 describes the **minimum standards** for compounded sterile preparations (CSPs) for human and animal drugs.			
1. Introduction and Scope	Provide personnel with stated objective of USP 797 as the minimum sterile compounding requirements to minimize harm from six listed sources that may result in harm, including death to human and animal patients: 1) microbial contamination [nonsterility], 2) excessive bacterial endotoxins, 3) variability from the intended strength of correct ingredients, 4) physical and chemical incompatibilities, 5) chemical and physical contaminants, and/or 6) use of ingredients of inappropriate quality.			
1.1.1 CSPs Affected	Understand definition of sterile compounding to determine in scope versus out of scope as applicable to practices that apply to the facility.			
1.1.1 CSPs Affected	Evaluate and define compounding practices to bring in-scope/revised activities to compliance for the requirements of compounding of CSPs for human and animal drugs [see USP 797 definition of sterile compounding listed box 7.]			

STANDARD OPERATING PROCEDURES

USP 797 REQUIRED SOPS

Personnel

Garbing & hand hygiene

Competency assessments

Media fill & gloved fingertip testing

Aseptic technique

Facilities & Engineering Controls

Cleanroom operations

Pressure differential checks

Hood certification and use

Environmental monitoring

USP 797 REQUIRED SOPS

Compounding Activities

Receiving & storing components
Use of hoods
Aseptic manipulations
Labeling, documentation, and BUD assignment
Final verification and release

Quality & Cleaning

Cleaning and disinfecting schedules
Incident reporting and corrective actions
Equipment maintenance
Validation of processes

USP 795 REQUIRED SOPS

Personnel

Garbing & hand hygiene
Training
Competency assessments

Compounding

Designated area
Storage & temperature control
Equipment
Components, receipt, and disposal
Master formulation record
Labeling

USP 795 REQUIRED SOPS

Quality Assurance & Control

Complaint handling
Adverse event reporting

Packaging & Transporting

Describe packaging
Modes of transportation, special handling, and temperature monitoring required

STANDARD OPERATING PROCEDURES

POST-TEST

1. What standards apply to patient specific sterile compounding performed in Kansas pharmacies?
   A. USP 797, CGMP, Section 503A of FDCA, Section 503B of FDCA
   B. USP 797 and CGMP
   C. USP 797 and Section 503A of FDCA
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POST-TEST

1. What standards apply to patient specific sterile compounding performed in Kansas pharmacies?
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   C. USP 797 and Section 503A of FDCA
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POST-TEST

2. The Kansas Board of Pharmacy has fully adopted USP 795 and 797 with no exemptions effective July 1, 2026.
   - True
   - False

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POST-TEST

2. The Kansas Board of Pharmacy has fully adopted USP 795 and 797 with no exemptions effective July 1, 2026.
   - True
   - **False**

POST-TEST

3. You dispense a prescription for a conventionally manufactured topical cream requiring reconstitution of powder and mixing using a pre-supplied stirring tool. Following the directions contained in the manufacturer approved labeling is not subject to USP 795.

- True
- False

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POST-TEST

3. You dispense a prescription for a conventionally manufactured topical cream requiring reconstitution of powder and mixing using a pre-supplied stirring tool. Following the directions contained in the manufacturer approved labeling is not subject to USP 795.

- **True**
- False

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REFERENCES

1. United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding – sterile preparations. USP-NF 2023, Issue 1, November 1, 2022, official as of November 1, 2023.
2. United States Pharmacopeial Convention. General chapter <795> pharmaceutical compounding – nonsterile preparations. USP-NF 2023, Issue 1, November 1, 2022, official as of November 1, 2023.
3. United States Pharmacopeia (USP). (2022, May 14). Previous important updates. https://www.usp.org/compounding/previous-important-797-updates
4. Kansas State Board of Pharmacy. (n.d.). Kansas pharmacy practice act. https://www.pharmacy.ks.gov/home/showpublisheddocument/8094/639196574843070000

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THANK YOU!

Questions?
You can reach me at

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