COMPOUNDING: PAST, PRESENT AND FUTURE

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COMPOUNDING COMPETENCY

WHERE DO I START?

- **Be well informed**
  - Understand the evolution of pharmacy compounding
- **Have increased awareness**
  - Be aware of how a national standard of practice evolved
- **Have thorough understanding of patient risks**
  - Those associated with non-compliance with USP Chapters
- **Cultivate practical abilities**
  - Developing your compounding skill set will help you minimize the risk of contaminated or improperly prepared compounded sterile preparations (CSPs)

APPLICABLE USP CHAPTERS

- Compounding Specific
  - <795>Pharmaceutical Compounding – Nonsterile Preparations
  - <797> Pharmaceutical Compounding – Sterile Preparations
  - <800> Hazardous Drugs – Handling in Healthcare Settings
  - <71> Sterility Testing
  - <85> Bacterial Endotoxins Test
  - <659> Packaging and Storage Requirements
  - <788>, <789> Particulate Matter

WHAT IS COMPOUNDING?

- An ESSENTIAL element of pharmacy
- Preparing customized medications that are not otherwise commercially available.
- Performed by or under the supervision of a pharmacist
- Pursuant to an order from a licensed prescriber for an individual

WHAT IS STERILE COMPOUNDING?

- **Preparing sterile medications in aseptic environment**
  - Intravenous
  - Intrathecal
  - Ophthalmic
  - Irrigating solutions
- **Administered in the hospital or home**
  - Replacing fluids and electrolytes
  - Providing nutrition
  - Other medications
    - Antibiotics
    - Hydration
    - Chemotherapy

WHAT IS NONSTERILE COMPOUNDING?

- **Creating a medication in a clean environment**
  - Orally
    - Capsules and Tablets
    - Solutions and Suspensions
  - Topically
    - Ointments and Creams
  - Inserted Rectally
    - Suppositories
- **Have a much lower risk causing infection**
  - Sterile techniques are not required

HISTORY OF COMPOUNDING

Prior 20th Century AD

- *Traditional* extemporaneous *compounding*

1945 – 1970s

- *Increase* in industrial *pharmaceutical manufacturing*
- *Academic instruction* slowly *decreased* in pharmacy schools
- *FDA* became *concerned* about *injury and death* of patients

1980s – 2000s

- A *resurgence* of extemporaneous *compounding*
- *Several incidents* of injury and deaths occurred from *contaminated CSPs*
- *Inadequate* quality control *standards*

2001 - Present

- Many schools still *do not offer any didactic or practical education* in sterile and non-sterile compounding
- Primarily *knowledge* introduced during *on the job training*
- Sterile and nonsterile compounding *standards enforced*
  - *December 1, 2019*

REGULATORY COMPLIANCE

New England Compounding Center

- Tainted steroid injections
- 750 fungal infections
- 64 deaths
- Causes

USP 797

USP 800

FDA

Board of Pharmacy

Drug Quality and Security Act

USP <795> Non Sterile Preparations

ROLE OF UNITED STATES PHARMACOPEIAL (USP)

- Scientific non profit organization that ***sets standards for identity, strength, quality and purity of medications, food ingredients and dietary supplements manufactured, distributed and consumed*** worldwide

- ***No enforcement or regulatory authority***

- Guidelines are ***enforceable*** under the law
  - State Boards of Pharmacy
  - The FDA
  - The Joint Commission (TJC)

ROLE OF THE FOOD AND DRUG ADMINISTRATION (FDA)

- Has regulatory authority over ***manufacture, distribution and labeling*** of drugs, medical devices and foods
- ***Enforces*** USP's drug standards in the US
- Regulates compounding under the adulteration and misbranding provisions of the 1***938 Food, Drug & Cosmetic Act***, but usually defers to State Boards of Pharmacy
- Inspect sterile and nonsterile compounding pharmacies

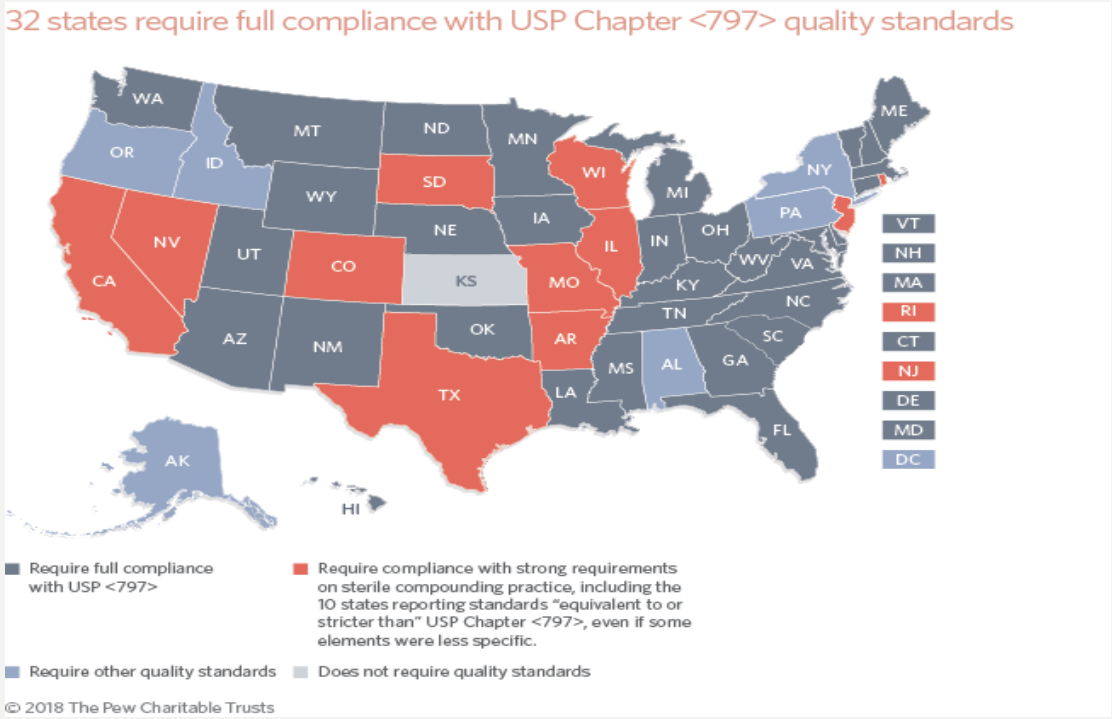
STATE BOARDS OF PHARMACY REGULATORY OVERSIGHT

- USP <797> (2004), first enforceable national compounding standard of practice, revised 2008
- USP <795> (2011), revised 2014
- All states license pharmacists to compound
- All states have adopted USP 795 as the baseline for safe and legal nonsterile compounding. In short, adhering to USP 795 standards puts pharmacists and technicians on the right sides of health care practice and the law.
- Varying degrees of regulations, oversight and enforcement of compounding practices exists among the states for sterile compounding
  - 32 states require full compliance with USP 797
  - 11 states have strong standards with 10 classified as "equivalent to or stricter than"
  - 6 states and District of Columbia require other compounding quality standards
    - Includes Pennsylvania, for example, traditional pharmacies must adhere to compounding quality standards, though the standards do not specify minimum equipment or facility requirements for compounding, a key component of Chapter
  - 1 state, Kansas, does not impose any particular compounding quality standards.

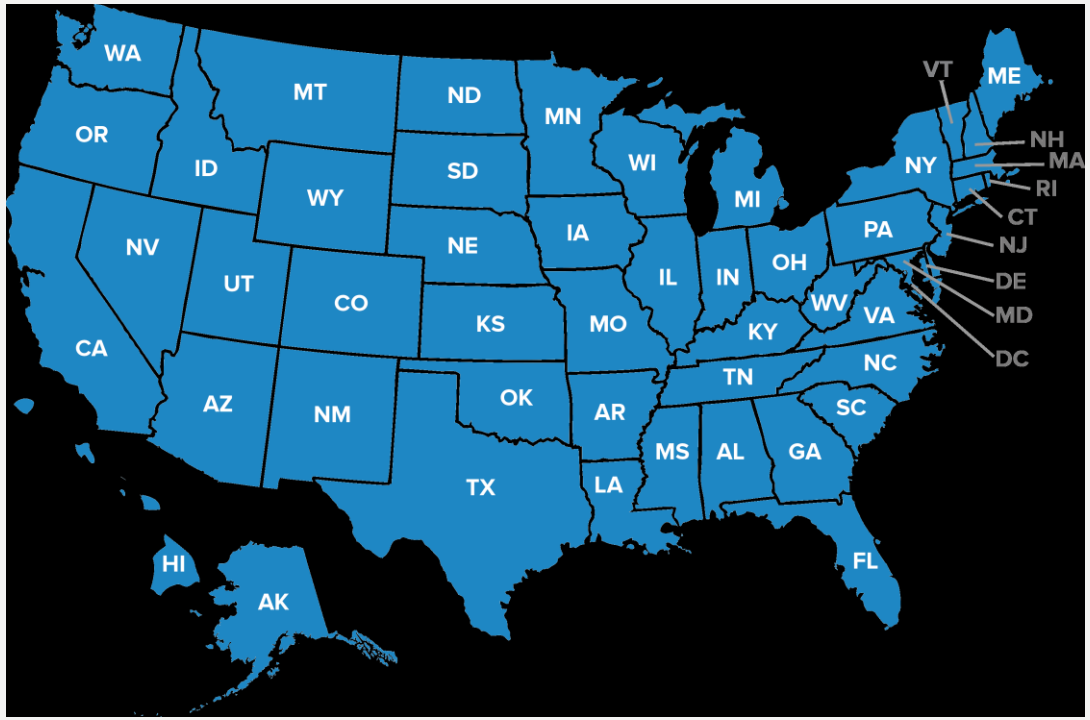
The Pew Charitable Trusts, "Best Practices for State Oversight of Drug Compounding" (2018), http://www.pewtrusts.org/~/media/assets/2018/02/best_practices_for-state_oversight_of_drug_compounding.pdf

COMPLIANCE WITH COMPOUNDING STANDARDS STERILE AND NONSTERILE

STERILE



NON-STERILE



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ENSURING PROPER NONSTERILE COMPOUNDING TECHNIQUES

- Properly identifying all nonsterile compounding being done
- Categorizing nonsterile compounds
  - Simple, Moderate, or Complex
- Personnel requirements
  - Supervisor and compounders
- Facility requirements
  - Nonhazardous or Hazardous
- Component Selection
  - USP-NF Compendium
- Compounding practices
  - Selecting, storing, compounding, dispensing, monitoring the patient
- Packaging and Storage
  - Meet USP requirements
- Documentation
  - Policies and procedures
  - Safety data sheets
  - Master formulation records
  - Compounding records
- Quality Assurance Plan

RISKS ASSOCIATED WITH NONSTERILE COMPOUNDING

- Patient Safety
- Accuracy
- Appropriate dosage forms
- Drug efficacy
- Compounder safety

QUESTIONS ANYONE . . .