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**NABP Annual Meeting**  
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**USP General Chapter <797>:  
Legal/Regulatory Update**

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# Presentation Objectives

**At the end of this presentation, participants will:**

- Understand the legal impact of USP's general chapters on compounding,
- Understand the role of state boards with regard to general chapter <797>, and
- Have gained understanding about what some states are doing regarding general chapter <797> ,
- Understand some of the challenges for the future.



- **FDA's role:**
  - Authority over drugs
    - Definition under Federal law includes compounded preparations
  - All "drugs" must meet applicable *USP-NF* requirements or state the difference
  - In theory, FDA can use <797> in enforcement actions if the preparation is covered by a USP-NF monograph
    - This would be highly unusual



- **State Role**

- States generally have authority over professional practice
- Compounding may occur in the practice of several different professions
  - Pharmacy
  - Medicine (oncology, allergy)
  - Veterinary Medicine
  - Nursing



- **Some state Pharmacy Boards require compliance with *USP-NF* generally**
  - Meet all standards of *USP*
  - Observe “the current” *USP*
  - Meet the “intent and guidelines” of *USP*
  - Ensure compliance with “*USP-NF* standards for sterile and non-sterile compounding”



- **Some state Pharmacy Boards require compliance with <797> specifically**
  - “Must follow USP chapter <797> standards”
  - SOPs consistent with chapter <797> standards
  - Qualifying pharmacist responsible for compliance with USP standards related to sterile compounding



# State Examples

- **Some state Pharmacy Boards incorporate provisions of <797> or are similar to <797>**
  - Use of risk level definitions



# Challenges

- What about the other professionals involved in compounding?
  - Virginia
- How to help pharmacies and others understand the benefits, and support the requirements
- How to help pharmacies and others understand how to implement the requirements



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*Thank You!*