Q: What is Utah’s statute and rule regarding non-sterile compounding and sterile compounding?

Pharmacy Practice Act

58-17b-102. Definitions.

(18) (a) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a limited quantity drug, sterile product, or device:
   (i) as the result of a practitioner's prescription order or initiative based on the practitioner, patient, or pharmacist relationship in the course of professional practice;
   (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or
   (iii) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

   (b) "Compounding" does not include:
   (i) the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to another pharmacist or pharmaceutical facility;
   (ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner; or
   (iii) the preparation of a prescription drug, sterile product, or device which has been withdrawn from the market for safety reasons.

(51) "Pharmacy" means any place where:
   (a) drugs are dispensed;
   (b) pharmaceutical care is provided;
   (c) drugs are processed or handled for eventual use by a patient; or
   (d) drugs are used for the purpose of analysis or research.

(57) "Practice of pharmacy" includes the following:
   (a) providing pharmaceutical care;
   (b) collaborative pharmacy practice in accordance with a collaborative pharmacy practice agreement;
   (c) compounding, packaging, labeling, dispensing, administering, and the coincident distribution of prescription drugs or devices, provided that the administration of a prescription drug or device is:
      (i) pursuant to a lawful order of a practitioner when one is required by law; and
      (ii) in accordance with written guidelines or protocols:
(n) prescribing and dispensing a self-administered hormonal contraceptive in accordance with Title 26, Chapter 64, Family Planning Access Act.

(72) "Unlawful conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-501.

(73) "Unprofessional conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-502 and may be further defined by rule.

**Pharmacy Practice Act Rule**

R156-17b-502. Unprofessional Conduct.

"Unprofessional conduct" includes:

(2) failing to comply with the USP-NF Chapters 795 and 797 if such chapters are applicable to activities performed in the pharmacy;

**What is USP 797? And why do I need to follow it?**

General Chapter <797> Pharmaceutical Compounding – Sterile Preparations
Millions of medications are compounded each year in the US to meet the unique needs of patients. Compounding provides access to medication for patients who may not be able to use commercially available formulations due to dosing requirements, allergies or rare diseases. Medications that are required to be sterile include those administered through injection, intravenous infusion (IV), intraocular (injection in the eye) or intrathecal (injection in the spine). Understanding the risks inherent in sterile compounding and incorporating established standards are essential for patient safety. Compounded drugs made without the guidance of standards may be sub-potent, super potent or contaminated, exposing patients to significant risk of adverse events or even death.

USP develops standards for preparing compounded sterile drugs to help ensure patient benefit and reduce risks such as contamination, infection or incorrect dosing.

USP General Chapter <797> describes a number of requirements, including responsibilities of compounding personnel, training, facilities, environmental monitoring, and storage and testing of finished preparations.

USP-NF 797 was first published in 2004. The chapter was last revised in USP31–NF26 2nd Supplement, which became official on June 1, 2008. The revised USP General Chapter <797> is expected to be published in USP 42-NF 37 Second Supplement on June 1, 2019 and become official on December 1, 2019. Sections of the revised <797> may have longer implementation dates that will allow time for adoption of the standard.

What is USP-NF 795? And why do I need to follow it?

USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations

Millions of medications are compounded each year in the US to meet the unique needs of patient, including vulnerable populations such as seniors and children. Compounding provides tailored therapy to patients who may not be able to use commercially available formulations due to dosing requirements, allergies or rare diseases.

Compounded drugs made without the guidance of standards may be sub-potent, super potent or contaminated, exposing patients to significant risk of adverse events or even death.

USP develops standards for compounding nonsterile drugs to help ensure patient benefit and reduce risks such as contamination, infection or incorrect dosing. USP General Chapter <795> provides standards for compounding quality nonsterile preparations. The chapter describes requirements for the compounding process, facilities, equipment, components, documentation, quality controls and training. General Chapter <795> also provides general guidelines for assigning beyond-use dates to nonsterile preparations.

Who’s responsibility is it to follow USP-NF 795? And what items are considered to be non-sterile compounded preparations?
PHARMACEUTICAL COMPOUNDING—NONSTERILE PREPARATIONS

INTRODUCTION

The purpose of this chapter is to provide compounders with guidance on applying good compounding practices for the preparation of nonsterile compounded formulations for dispensing and/or administration to humans or animals. Compounding is an integral part of pharmacy practice and is essential to the provision of healthcare. This chapter and applicable monographs on formulation help define good compounding practices. Furthermore, this chapter provides general information to enhance the compounder's ability in the compounding facility to extemporaneously compound preparations that are of acceptable strength, quality, and purity. Pharmacists, other healthcare professionals, and others engaged in the compounding of drug preparations should comply with applicable state and federal compounding laws, regulations, and guidelines.

Revision USP-NF 795 (update eta Dec 2019)

1.1 Scope

13 COMPOUNDED NONSTERILE PREPARATIONS AFFECTED

14 CNSPs that may be affected by this chapter include but are not limited to

15 the following dosage forms:

16 Solid oral preparations
17 Liquid oral preparations
18 Rectal preparations
19 Vaginal preparations
20 Topical preparations (i.e., creams, gels, irrigations for non-internal and non-surgical body cavities)
22 Nasal and sinus preparations intended for local application
23 Otic preparations

27 AFFECTED PERSONNEL AND SETTINGS

28 This chapter applies to all persons who prepare CNSPs and all places where CNSPs are prepared. This includes but is not limited to pharmacists, technicians, physicians, veterinarians, dentists, naturopaths, chiropractors, and nurses, in all places including but not limited to pharmacies, hospitals, and other healthcare institutions, patient treatment sites, and physicians' or veterinarians' practice sites.

34 The compounding facility's leadership and all personnel involved in preparing, storing, packaging, and transporting CNSPs are responsible for 1) ensuring that the applicable practices and quality standards in this chapter are continually and consistently applied to their operations, and 2) proactively identifying and remedying potential problems within their operations. Personnel engaged in the compounding of CNSPs must also comply with applicable laws and regulations of the regulatory jurisdiction. The compounding facility must designate one or more individuals (i.e., the designated person) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs. The responsibilities of the designated person include but are not limited to:
45 Developing and implementing a training program
46 Routinely monitoring and observing compounding activities and taking
47 immediate corrective action if deficient practices are observed
48 Demonstrating the procedures for personnel and observing and
49 guiding personnel throughout the training process
50 Evaluating whether individuals with certain conditions, such as rashes
51 or respiratory illnesses, will be allowed to work in compounding areas
52 before their conditions are resolved because these conditions carry
53 the risk of contaminating the environment and CNSPs
54 Ensuring that standard operating procedures (SOPs) are fully
55 implemented. The designated person must ensure that follow-up is
56 carried out if problems, deviations, or errors are identified
57 Establishing, monitoring, and documenting procedures for the handling
58 and storage of CNSPs and/or components of CNSPs
59 If the compounding facility has only one person responsible for all the
60 compounding in the facility, then that person will become the designate.

Who's responsibility is it to follow USP-NF 797? And what items are considered to be sterile preparations?

<797> PHARMACEUTICAL COMPOUNDING—STERILE PREPARATIONS

Change to read:

INTRODUCTION
The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial endotoxins, (3) variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles (see “official” and “article” in the General Notices and Requirements) or 10% for nonofficial articles, (4) unintended chemical and physical contaminants, and (5) ingredients of inappropriate quality in compounded sterile preparations (CSPs). Contaminated CSPs are potentially most hazardous to patients when administered into body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs and tissues. When CSPs contain excessive bacterial endotoxins (see Bacterial Endotoxins Test <85>), they are potentially most hazardous to patients when administered into the central nervous system.

Despite the extensive attention in this chapter to the provision, maintenance, and evaluation of air quality, the avoidance of direct or physical contact contamination is paramount. It is generally acknowledged that direct or physical contact of critical sites of CSPs with contaminants, especially microbial sources, poses the greatest probability of risk to patients. Therefore, compounding personnel must be meticulously conscientious in precluding contact contamination of CSPs both within and outside ISO Class 5 (see Table 1) areas.

To achieve the above five conditions and practices, this chapter provides minimum practice and quality standards for CSPs of drugs and nutrients based on current scientific information and best sterile compounding practices. The use of technologies, techniques, materials, and procedures
other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein. The standards in this chapter do not pertain to the clinical administration of CSPs to patients via application, implantation, infusion, inhalation, injection, insertion, instillation, and irrigation, which are the routes of administration. Four specific categories of CSPs are described in this chapter: low-risk level, medium-risk level, and high-risk level, and immediate use. Sterile compounding differs from nonsterile compounding (see Pharmaceutical Compounding—Nonsterile Preparations <795> (CN 1-May-2016)) primarily by requiring the maintenance of sterility when compounding exclusively with sterile ingredients and components (i.e., with immediate-use CSPs, low-risk level CSPs, and medium-risk level CSPs) and the achievement of sterility when compounding with nonsterile ingredients and components (i.e., with high-risk level CSPs). Some differences between standards for sterile compounding in this chapter and those for nonsterile compounding in Pharmaceutical Compounding—Nonsterile Preparations <795> include, but are not limited to, ISO-classified air environments (see Table I); personnel garbing and gloving; personnel training and testing in principles and practices of aseptic manipulations and sterilization; environmental quality specifications and monitoring; and disinfection of gloves and surfaces of ISO Class 5 (see Table I) sources.

The standards in this chapter are intended to apply to all persons who prepare CSPs and all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment clinics, pharmacies, physicians' practice facilities, and other locations and facilities in which CSPs are prepared, stored, and transported). Persons who perform sterile compounding include pharmacists, nurses, pharmacy technicians, and physicians. These terms recognize that most sterile compounding is performed by or under the supervision of pharmacists in pharmacies and also that this chapter applies to all healthcare personnel who prepare, store, and transport CSPs. For the purposes of this chapter, CSPs include any of the following: (1) Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants. (2) Manufactured sterile products that are either prepared strictly according to the instructions appearing in manufacturers' approved labeling (product package inserts) or prepared differently than published in such labeling. [NOTE—The FDA states that “Compounding does not include mixing, reconstituting, or similar acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling” [21 USC 321 (k) and (m)]. However, the FDA-approved labeling (product package insert) rarely describes environmental quality (e.g., ISO Class air designation, exposure durations to non-ISO classified air, personnel garbing and gloving, and other aseptic precautions by which sterile products are to be prepared for administration). Beyond-use exposure and storage dates or times (see General Notices and Requirements and Pharmaceutical Compounding—Nonsterile Preparations <795>) for sterile products that have been either opened or prepared for administration are not specified in all package inserts for all sterile products. Furthermore, when such durations are specified, they may refer to chemical stability and not necessarily to microbiological purity or safety.]

1. INTRODUCTION AND SCOPE (update eta Dec 2019)
This chapter describes the minimum practices and quality standards to be followed when preparing compounded sterile human and animal drugs (compounded sterile preparations, or CSPs). These practices and standards must be used to prevent harm, including death, to human and animal patients that could result from 1) microbial contamination (nonsterility), 2) excessive bacterial endotoxins, 3) variability from the intended strength of correct ingredients, 4) chemical and physical contaminants, and/or 5) use of ingredients of inappropriate quality.

9.1.1 Scope

10 CSP AFFECTED

The requirements and standards described in this chapter must be used to ensure the sterility of any CSP. Although the list below is not exhaustive, the following must be sterile:

14 Injections
15 Aqueous bronchial inhalations
16 Baths and soaks for live organs and tissues
17 Irrigations for internal body cavities (i.e., any space that does not freely communicate with the environment outside of the body)
19 Ophthalmics
20 Implants

For the compounding of hazardous drugs, see Hazardous Drugs—Handling in Healthcare Settings 800.

23 PERSONNEL AND SETTINGS AFFECTED

This chapter applies to all persons who prepare CSPs (e.g., pharmacists, pharmacy technicians, physicians, veterinarians, and nurses) at all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment sites, infusion facilities, pharmacies, and physicians' or veterinarians' practice sites).

28 The compounding organization's leadership and all employees involved in preparing, storing, and transporting CSPs are responsible for 1) ensuring that the applicable practices and quality standards in this chapter are continually and consistently applied to their operations, and 2) proactively identifying and remedying potential problems within their operations.

33 SPECIFIC PRACTICES

34 Administration of medications: This chapter is not intended to address administration of sterile medications. Administration of sterile medications should be performed in accordance with the Centers for Disease Control and Prevention's Safe Injection Practices and the manufacturer's or compounder's labeling of the sterile medication.

39 Proprietary bag and vial systems: Docking and activation of proprietary bag and vial systems (e.g., ADD-Vantage®, Mini Bag Plus®, addEASE®) strictly in accordance with the manufacturer's instructions for immediate administration to an individual patient is not considered compounding. However, aseptic technique must be followed when attaching the proprietary bag and vial system.

44 Docking of the proprietary bag and vial systems for future activation and administration is considered compounding and must be performed in accordance with this chapter, with the exception of 12. Establishing Beyond-Use Dates and In-Use Times.
use dates (BUDs) for proprietary bag and vial systems must be assigned in accordance
with the manufacturer’s instructions provided in product labeling.

Reconstitution or dilution: Reconstituting or diluting a conventionally manufactured
sterile product with no intervening steps strictly in accordance with the manufacturer’s
labeling for administration to an individual patient is not considered compounding.
However, aseptic technique must be followed during preparation, and procedures must
be in place to minimize the potential for contact with nonsterile surfaces and introduction
of particulate matter or biological fluids.
Any other reconstitution or dilution of a conventionally manufactured sterile product is
considered compounding and must be performed in accordance with this chapter.
Repackaging: Repackaging of a conventionally manufactured sterile product from its
original primary container into another primary container must be performed in
accordance with the requirements in this chapter for CSPs, including assignment of
BUDs and in-use times as described in 12. Establishing Beyond-Use Dates and In-Use
Times.

What is the solution/alternative to still being able to treat patients in office?

1. Comply with USP 797 regulations
2. Have a third party compound patient specific medications
3. Purchase premade sterile compounded medications