Virginia Board of Pharmacy

COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

Virginia Code § 54.1-3410.2 and 18VAC110-20-321 require pharmacies performing sterile or non-sterile compounding to comply with USP Standards. USP standards for sterile and non-sterile compounding may be found in the current editions of the USP-NF. In accordance with 18VAC110-20-170, the Board requires a pharmacy to maintain references consistent with the pharmacy's scope of practice and with public safety.

USP Chapter 795 lists the requirements for non-sterile compounding including information about the compounding environment, equipment, stability criteria and beyond-use dating and records. USP Chapter 797 lists requirements for policies and procedures, training and evaluation of personnel performing sterile compounding, determining risk levels and the physical standards for the sterile compounding area. The Board expects that the requirements of Chapters 795 and 797 will be found in compliance at time of inspection. USP Chapter 800 describes practice and quality standards for handling hazardous drugs to promote patient safety, worker safety, and environmental protection. While full compliance with Chapter 800 is encouraged, only those requirements related to compounding are legally required.

USP often updates and adds to their Frequently Asked Questions site for the general chapters. Please visit the following links to the USP website for frequently asked questions on the listed chapters:

Chapter 795: https://go.usp.org/USP_GC_795_FAQs
Chapter 797: https://go.usp.org/USP_GC_797_FAQs
Chapter 800: https://go.usp.org/General-Chapter-800-FAQ
Chapter 825: https://go.usp.org/frequently-asked-questions/radiopharmaceuticals

1. ***Where may information regarding USP-NF standards for compounding be located?***

   A subscription to the current version of USP-NF Chapters may be purchased at https://store.usp.org/usp-nf-online/category/USP-3110.

2. ***Does the law require compliance only with Chapter <797>?***

   No, the law requires compliance with all applicable chapters within USP-NF. Regarding sterile compounding, pharmacists should pay particularly close attention to General Chapters: <1> Injections, <71> Sterility Testing, <85> Bacterial Endotoxin Testing, <659> Packaging and Storage Requirements, and <797> Pharmaceutical Compounding- Sterile Preparations.

3. Should compounding personnel who work in multiple pharmacies, to include pharmacy interns on rotations, pass a media-fill test, gloved fingertip test, and garbing test at each pharmacy where they will prepare CSPs?

Yes, all compounding personnel working in multiple pharmacies, to include pharmacy interns on rotations, should pass a media-fill test, gloved fingertip test, and garbing test at each pharmacy prior to performing sterile compounding.

4. Must a compounding pharmacy using Schedule II powders comply with the perpetual inventory requirements of Regulation 18VAC110-20-240?

Yes.

5. May a pharmacist provide a compounded drug to another pharmacy or veterinarian who will then dispense the drug to his client?

Virginia Code § 54.1-3410.2 indicates pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place; however, a pharmacist may distribute to a veterinarian in accordance with federal law.

Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian. Virginia Code § 54.1-3301 indicates a veterinarian shall only be authorized to dispense a compounded drug, distributed from a pharmacy, when (i) the animal is his own patient, (ii) the animal is a companion animal as defined in regulations promulgated by the Board of Veterinary Medicine, (iii) the quantity dispensed is no more than a seven-day supply, (iv) the compounded drug is for the treatment of an emergency condition, and (v) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian.

Of note, Virginia Code § 54.1-3410.2 does authorize pharmacists to provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients. Pharmacists who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (v) the name and address of the pharmacy; and (vi) the quantity. Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a

veterinarian for either further distribution or sale to his own patient or administration to his own patient with (a) the name and strength of the compounded medication or list of the active ingredients and strengths; (b) the facility's control number; (c) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (d) the name and address of the pharmacy; and (e) the quantity.

6. May a prescriber or patient obtain a patient-specific compounded sterile product from an out-of-state pharmacy that is not registered by the Virginia Board of Pharmacy as a nonresident pharmacy?

No, only nonresident pharmacies registered by the Virginia Board of Pharmacy may ship compounded sterile products into Virginia. Verification of registration may be determined at DHP's License Lookup site by searching the business name and choosing "nonresident pharmacy" as the occupation.

7. May a pharmacy or prescriber obtain a compounded sterile product from an out-of-state outsourcing facility that is not registered by the Virginia Board of Pharmacy as a nonresident outsourcing pharmacy?

No, only nonresident outsourcing facilities registered by the Virginia Board of Pharmacy may ship compounded sterile products into Virginia. Verification of registration may be determined at DHP's License Lookup site by searching the business name and choosing "nonresident outsourcing pharmacy" as the occupation.

8. Does USP consider flavoring to be compounding?

Yes, but the Board will exercise enforcement discretion of USP compounding standards for flavoring.

9. If a pharmacy has one pharmacist (A) that supervises compounding and verifies the compounding of the product but has a separate pharmacist (B) who does NOT supervise compounding and is only responsible for verifying the prescription/order data entry and dispensing of the previously verified compounded drug, is that second pharmacist (B) required to do media-fill testing, gloved fingertip testing, and evaluation?

Per USP Chapter <797>, Table 2, pharmacists who do not have oversight of compounding but only perform final verification of the dispensed drug whose compounding has already been verified (pharmacist B) need only perform initial training and competency as defined per the facility standard operating procedures. Garbing and media-fill competency are not required for pharmacist B.

10. May a pharmacist use camera technology to verify accuracy of a compounded drug product?

USP does not have guidance for when a pharmacist may use a camera to verify accuracy of a compounded product. However, the Board's longstanding position is that audio-visual technology may be used by the pharmacist physically present in the pharmacy to directly supervise compounding.

11. When will the Board begin enforcing USP's revised Chapters <795> and <797> that become effective November 1, 2023?

Virginia Code § 54.1-3410.2 states that "pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding." Therefore, pharmacies must comply with revised USP Chapters <795> and <797> upon the effective date of those revisions, which is November 1, 2023. Operationally, inspectors will begin citing deficiencies for noncompliance of USP revised standards as of November 1, 2023, but the Board will exercise enforcement discretion for the first 6 months, i.e., through April 30, 2024, and not take disciplinary action unless egregious in nature. Staff will consult with a committee of the Board for direction regarding possible disciplinary action for deficiencies that appear egregious.