

# Virginia Board of Veterinary Medicine

## FAQs about USP and Compounding

October 31, 2019

### What is USP?

USP stands for United States Pharmacopeia. USP works with more than 900 scientists, practitioners and regulators to develop standards that help protect public health. The organization is internationally recognized and globally focused. USP standards have been adopted in 140+ countries.

Information can be found on the USP website (<https://www.usp.org/>)

### What is the role of USP?

As independent non-profit organization, USP has shared a close relationship and collaborative history with the Food and Drug Administration (FDA) and the states for more than a century. USP standards are recognized in federal law (1938 Federal Food, Drug, and Cosmetic Act, 1997 FDA Modernization Act, and 2013 Drug Quality and Security Act). In addition to recognition in federal law, many states, of which Virginia is one, have adopted USP standards.

### What is a USP chapter?

General Chapters establish procedures, methods, and practices to help ensure the quality of medicines including compounded preparations.

### What are the USP Chapters related to compounding?

[Non-sterile compounding: Chapter 795](#)

[Sterile Compounding: Chapter 797](#)

[Handling of Hazardous Drugs: Chapter 800](#)

### What is the effective date of these chapters?

The revised versions of USP Chapters 795 and 797 are postponed indefinitely with the earliest possible effective date of June 1, 2020. In the meantime, the current versions of these chapters remain in effect.

While Chapters 795 and 797 undergo further revisions, Chapter 800 cannot be fully implemented because of reference to these chapters. However, hazardous drugs categories exist without the implementation of Chapter 800.

### **Is there a list of hazardous drugs?**

The Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH) have issued the following publication:

[NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016](#)

This list does not contain any “veterinary use only” drugs. However, the list contains human drugs that are also prescribed by veterinarians.

Table 5 found in the list provides information on personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings.

### **How does a ventilation hood system get certified to ensure protection?**

This link explains CETA (Controlled Environment Testing Association) standard CAG - 003:

<https://elsmar.com/elsmarqualityforum/attachments/cetaasepticcompoundingcertificationguide1-pdf.6706/>. Note the standard provided in this link was updated in May 2015. The updated version is only available only to CETA members. You may wish to contact CETA for more information.

The USP recommends choosing a certifier who is accredited by the CETA National Board of Testing (CNBT). The CETA website contains search engine to help locate a registered certifier: <https://www.cetainternational.org/cnbt>

### **Who will enforce the compounding chapters?**

USP has indicated that the mechanism of enforcement is in the hands of the states. However, the FDA may take over if the states fail to address the issue of appropriate standards for compounding. For the most updated information issued by the Board related to compounding, please review **150-5** [Use of compounded drugs in veterinary practice](#). This guidance document will be updated as information becomes available.

### **Does the USP need veterinary practitioners to participate on standards-development committees?**

The USP Call for Candidates’ application for membership on an expert committee is available at <https://callforcandidates.usp.org/node>. Currently, USP needs veterinarian participation on expert committees as there are only two across 26 committees.