Greetings,

The Advisory Pharmacy Compounding Education Committee (APCEC) is working on recommendations for adopting the 2022 revisions to USP <797>, USP <795>, and USP <800> into Utah State Regulation.

The Committee is requesting input about how to best adopt these new recommendations. Additional information about changes can be found on the USP website: https://go.usp.org/2022_Revisions_795_797.

These chapters will become official on November 1, 2023; however and importantly, they will not be enforced in Utah until they are adopted into Utah Pharmacy regulation. Until that time, the previously published versions will continue to be enforceable.

If you have comments on the implementation of the chapters, please attend the next APCEC meeting or send feedback to pharmacy@utah.gov. Our timeline allows for feedback up to the next committee meeting and then our proposal will be submitted to the Utah Board of Pharmacy for new regulations.

Next Scheduled Meeting: **September 14, 2023**

USP <797> Highlighted Updates

- Immediate-use compounded sterile products (CSPs) changes will allow up to 4-hours for administration, but additional training requirements are now required.
- USP added new provisions around preparation according to approved labeling and when that process is out of scope for USP <797>.
- USP has updated the risk categories from Low-Risk, Medium-Risk, and High-Risk to Category 1, Category 2, and Category 3 with new beyond use dates (BUDs)

Training

- There are new training requirements for personnel who have direct oversight of compounding every 12 months as well as personnel who may only restock, clean, and disinfecting according to facility SOPs.
- Personnel who compound Category 1 or 2 CSPs must complete competencies in garbing, hand hygiene, aseptic manipulation initially every 6 months, and those who compound Category 3 CSPs must complete this initially and every 3 months.

Personal Hygiene and Garbing

- USP now allows the designated person to evaluate whether individuals with high risk of contaminating CSPs or environment due to rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections should be allowed to compound and permit accommodations.
- Compounding Category 3 CSPs will require additional garbing including no exposed skin.

Facilities and Engineering Controls

- Only Category 1 CSPs may be compounded in a segregated compounding area (SCA).
- Temperature and humidity monitoring will now be required in compounding spaces.

Microbiological Air and Surface Monitoring

- Surface sampling for sites compounding Category 1 and 2 CSPs must be conducted monthly.
- Identification of recovered microorganisms must be to the genus level for any overages in counts.

Cleaning and Disinfecting

- Sporicidal disinfection will now be required at certain intervals based on risk category.

Master Formulation and Compounding Records

- USP added a new section on these master formulation and compounding records.

Beyond Use Dates (BUDs)

- Category 1 CSPs will be limited to ≤ 12 hours at controlled room temperature and ≤ 24 hours under refrigeration.

- Category 2 CSP BUDs will depend on whether they are terminally sterilized, whether sterility testing is performed, if all starting components are sterile, and the temperature they are stored. This can range from 1 day to up 90 days.
- Category 3 CSP BUDs will depend on whether they are terminally sterilized, and if they have passed additional testing. They BUDs can range from 60 to 180 days.

Compounding Allergenic Extracts

- USP has added additional information on compounding allergenic extracts

USP <795> Highlighted Updates

- Adding components (such as flavors) not stipulated in the labeling to conventionally manufactured products is compounding.
- Clarify nasal and sinus preparations for local application are non-sterile as well as otic preparations (excluding perforated eardrums).

Training

- Designated Person(s) - One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CNSP (compounded non-sterile prep).
- Knowledge AND competency demonstration every 12 months in hand hygiene, garbing, cleaning & sanitizing, handling and transporting, measuring and mixing, proper use of equipment, and documentation of the compounding process .

Garbing

- Gloves must be worn for all compounding. Other garb must be appropriate for the type of compounding performed; However, garbing requirements and frequency of changing garb must be determined by the facility and outlined in facility SOPs.

Compounding Area

- Space must be specifically designated for compounding and other activities must not be occurring in the space at the same time as compounding.
- There SHOULD NOT be carpet in the compounding area. (Floors should be easily cleanable and should not be porous or particle generating).
- Weighing, measuring, or otherwise manipulating components that could generate airborne particles must be evaluated to determine if these activities must be performed in a closed-system processing device.

Cleaning and Sanitizing

- Outlines cleaning and sanitizing of areas and equipment.

Beyond Use Dates (BUDs)

- Use of water activity to aid in assessing the susceptibility of CNSPs to microbial contamination and potential for API degradation due to hydrolysis. Available water to react, not the water content.
    - aw > than or equal to 0.60
        - Non-preserved aqueous dosage forms - 14 days refrigerated
        - Preserved aqueous dosage forms - 35 days room temp or fridge
    - aw < 0.60
        - oral liquid (non-aqueous) - 90 days
        - other non-aqueous dosage forms - 180 days

Extending BUDs

- CSNPs with stability information: if there is a stability study using a stability-indicating analytical method for the API(s), CNSP formulation, and material of composition of the container closure that will be used, then the BUD indicated by the study may be used in lieu of the BUDs specified in the tables provided for aqueous and nonaqueous dosage forms, up to max of 180 days.
    - If BUD is extended, aqueous CNSP must be tested for antimicrobial effectiveness. Antimicrobial effectiveness testing can be bracketed (high concentration and low concentration).

USP <800> Information

- USP <800> has not undergone any revisions as part of these updates but are referenced within USP <797> and USP <795> and therefore may be required if these chapters are adopted into Utah law.
- Below is language that was proposed to implement USP <800> in Utah prior to USP pushing back implementation date. We proposed implementing a modified version of the chapter based on previous feedback. Please let us know if there is additional feedback on this proposal as well.

Proposed Rule Changes

While the Pharmacy Practice Act requires the legislator to create changes, the Pharmacy Board can update the Pharmacy Practice Act Rule via recommendations.

R156-17b-614e. Operating Standards- Compounding.

(1) A person engaging in sterile or nonsterile compounding shall practice in accordance with {~~all~~} applicable federal and state laws and rules, and in accordance with the USP-NF, including:
   a. USP General Chapter <797> Pharmaceutical Compounding - Sterile Preparations;
   b. USP General Chapter <795> Pharmaceutical Compounding Nonsterile Preparations; and
   c. USP General Chapter <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging.

(2) These operating standards shall apply:
   a. to any person licensed under Title 58, Chapter 17b, Pharmacy Practice Act, that engages in compounding; and
   b. to the compounding of all sterile or nonsterile compounded pharmaceuticals, antineoplastic drugs, or non-antineoplastic drugs, no matter where the patient is located.

(3) A person engaging in sterile or nonsterile hazardous drug compounding with antineoplastic drugs, according to the NIOSH list under USP <797>and <795>, shall practice in accordance with all applicable federal and state laws and rules, and in accordance with the requirements of USP General Chapter <800> Hazardous Drugs - Handling in Healthcare Settings.

(4) A person engaging in sterile or nonsterile hazardous non-antineoplastic drug compounding, according to the NIOSH list under USP<797> and <795>, shall practice in accordance with applicable federal and state laws and rules, and in accordance with the following requirements as found in USP General Chapter <800> Hazardous Drugs - Handling in Healthcare Settings:
   a. compound sterile or nonsterile hazardous non-antineoplastic drugs in:
      i. a double-HEPA filtered or externally ventedcontainment ventilated exposure (CVE);
      ii. a class II biological safety cabinet (BSC); or
      iii. a compounding aseptic containment isolator (CACI)
   b. clearly mark and identify hazardous API, and store it in designated area separate from all other medications. The designated area does not require a separate room.
   c. Adhere to the requirements in the following USP <800>sections:
      i. Section 2: LIST OF HAZARDOUS DRUGS;

ii. Section 4: RESPONSIBILITIES OF PERSONNEL HANDLING HAZARDOUS DRUGS;
iii. Section 7: PERSONAL PROTECTIVE EQUIPMENT, except that only one pair of chemotherapy gloves is required for compounding with non-antineoplastic drugs;
iv. Section 8: HAZARD COMMUNICATION PROGRAM;
v. Section 9: PERSONNEL TRAINING;
vi. Section 10: RECEIVING;
vii. Section 11: LABELING, PACKAGING, TRANSPORT AND DISPOSAL; (viii) Section12:
viii. DISPENSING FINAL DOSAGE FORMS;
ix. Section 13: COMPOUNDING;
x. Section 15: DEACTIVATING, DECONTAMINATING, CLEANING, AND DISINFECTING; and
xi. The following provisions of Section 17: DOCUMENTATION AND STANDARD OPERATING PROCEDURES:
A. Hazard communication program;
B. Occupational safety program;
C. Designation of HD areas
i. storage;
ii. Compounding
iii. Use and maintenance of proper engineering controls (e.g., c-PECs, C-SECs, and CSTDs);
D. hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, administration, spill, and disposal);
E. Deactivation, decontamination, cleaning, and disinfection;
F. Dispensing;
G. Transport;
H. Administering;
I. Disposal; and
J. Spill control.

(5) A person that is not in compliance by December 1, 2019, with an operating standard for hazardous drug compounding that is based on a new or revised USP-NF requirement that became official December 1, 2019, shall:
a. have in place by March 31, 2019, a written plan with timelines that details how the person will become compliant on or before December 1, 2020;
b. comply with requirements from previous versions of the USP-NF that are the same as the official December 1, 2019, requirements; and
c. on or before December 1, 202x, be in compliance with USP-NF operating standards in accordance with their written plan.