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Larry Hadley, RPh
Executive Director, Kentucky Board of Pharmacy
125 Holmes Street, Suite 300
Frankfort, KY 40601

Dear Mr. Hadley and Kentucky Board of Pharmacy leadership,

The Kentucky Society of Health-System Pharmacists (KSHP) appreciates your efforts to solicit feedback from pharmacists and other health care providers as it relates to the handling of hazardous medications and implementation of USP <800>. On behalf of KSHP members, please find our official response to the "Comments on the HDC Committee recommendations" document posted on the Board's web page.

KSHP agrees with the following recommendations in Option 1 and Option 2:

- Option 1
  - 1st bullet point: Delayed implementation
  - 2nd bullet point: Waivers for low volume chemotherapy generators, as long as the term *chemotherapy* is changed to *sterile and non-sterile compounding of Tier 1 Hazardous drugs,* that low volume is defined, and that sterile compounding requires the minimum use of an unvented CACI, BSC with the use of a CSTD when dosage form allows.
  - 3rd bullet point: Waivers for discrepancies between the two chapters
  - 6th bullet point allowing for an SOP for decontamination and deactivation
- Option 2
  - 1st bullet point: Delayed implementation
  - 2nd bullet point
    - #2 – Decontamination per SOP when CSTDs are used
    - #3 – Low Volume exemption as described above
    - #4 – Discrepancies between USP <800 and <797>

KSHP disagrees with the following in Option 1 and Option 2:

- Option 1, bullet points 4 and 5 and Option 2, bullet point 2.1
  - We disagree with a blanket approval allowing pharmacies to compound Table 2 and 3 API using their own SOPs. For non-sterile compounding of Table 1, 2 and 3 medications, the only facility requirements to meet USP <800> are a PEC within a negative pressure room that is externally vented with at least 12 ACPH. This should be a reasonable investment for pharmacies that handle large, bulk powders of hazardous drugs. For example, we do not feel comfortable allowing pharmacy employees to handle large amounts of testosterone using safeguards that are ambiguously agreed upon by their managers.

- We believe there is some confusion regarding the definition of an API. If the Board's interpretation is that an API is *any* tablet or capsule that is broken or split, then we do not believe this warrants a PEC within a negative pressure room. However, our interpretation is that this is bulk powders used for compounding purposes, as alluded to in the USP <800> Glossary and FDA:
    - An active pharmaceutical ingredient (API) is defined in ICH Q7 as "any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
    - Currently, other terms such as "drug substance", "bulk pharmaceutical chemical"(BPC), and API are used interchangeably by the FDA and industry.

General Comments:
KSHP finds it concerning that both Option 1 and Option 2 promote the ability to manage API outside the scope of <800>, meaning that if either option is chosen, it will allow for this exception. We suggest that this recommendation be removed if the Board specifically chooses one of the two options.

We also ask the Board to clarify the waiver process that would be implemented if one of these options is implemented. Both options mention waivers for specific items, but then go on to suggest that other items may also be waived. We also believe that both options are difficult to interpret. When one, a mix, or neither of them are adopted, we encourage the Board to provide education regarding what is to be enforced and not enforced. KSHP also believes that several additional recommendations should have been included in the HDC recommendations. These include:

- The negative pressure window of -0.01 to -0.03 inWP will be extremely difficult to adhere to when compounding Table 1 and API medications. Per USP, this range was randomly chosen and lacks any scientific or clinical data behind it. Also, USP <797> currently allows for 12 hour beyond use dates (BUD) for Compounded Sterile Products compounded in an ISO Class 5 environment in non-certified air. The same concept should be applied to HD compounding, allowing for shorter BUDs. For example, if a hospital pharmacy has a USP <797> and <800> compliant negative pressure room, and the pressure bumps up to -0.05 inWP, the pharmacy should not, in good conscious, stop compounding and risk patient's missing their cancer treatment. Instead, a shorter expiration date should be given, which allows the patients to receive their treatment without any possible harm coming to the patient through a contamination risk, as proposed by USP <797>.
- Gowns that are not contaminated may be worn 4-6 hours instead of 2-3.

KSHP Final Comment:
While both options are very similar, KSHP feels the waiver Option 2 is more consistent with how other USP Chapters are enforced in KY and would allow pharmacies the ability to request waivers as needed, and be approved by the Board based upon the perceived risk to employees handling these medications. If the Board is able to adopt neither of these options, we recommend adopting USP <800> as is, with the ability to request waivers for certain areas that do not cause risk to patients or employees.

Respectfully submitted,

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President, Kentucky Society of Health-System Pharmacists