The Kentucky Board of Pharmacy is requesting comments regarding the implementation of USP <800>. Below are the options presented to the Board on October 17, 2018 based on the recommendation of the Hazardous Drug Compounding Committee.

Option 1, Proposed Changes

- We recommend a one year delayed implementation of USP <800> from the filing date.
- We recommend the Board consider waivers for low-volume chemotherapy generator facilities.
- We recommend the Board consider waivers for discrepancies between USP <800> and USP <797>.
- Section 2. Box 1. Add '[except Section 5.3.1]' after –Any HD API
- Section 5.3.1. Third paragraph. Add 'for all NIOSH Table 1 API. An assessment of risk can be conducted for NIOSH Tables 2 and 3 APIs and manipulated dosage forms.' after at least 12 ACPH.
- Section 15.2. Second paragraph. Add 'unless a CSTD is used. When a CSTD is utilized a SOP must be established by the facility to outline the decontamination process during compounding.' after must be decontaminated between compounding of different HDs.

Option 2, Waiver Process

- We recommend a one year delayed implementation of USP <800> from the filing date.
- We recommend a waiver process be considered for the following:
  1. Pharmacies should be able to conduct an assessment of risk for requiring a CSEC for manipulation of any dosage form including APIs on Tables 2 and 3 NIOSH list drugs.
  2. Pharmacies should be able to decontaminate based upon SOPs rather than after a different product is compounding IF CSTDs are used.
  3. Low-volume chemotherapy generator facilities.
  4. Discrepancies between USP <800> and USP <797>.
  5. Other

The deadline for submission of comments is March 31, 2019. Submit comments by mail, email or fax.

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