KENTUCKY BOARD OF PHARMACY
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

Special Meeting Notice and Agenda

Hazardous Compounding Committee

August 13, 2018
9:00 a.m.

I. Call to Order

II. Minutes – July 9, 2018

III. Review :
1. Hazardous Drugs
2. Wholesalers
3. Negative Pressure Ventilation
4. Deactivating Agent
5. Waivers/differences between USP 800 and USP 797
6. How to adopt USP General Chapter if sections are not harmonized with USP General Chapter?
   A. Segregated Compounding Area
   B. 'Low Volume' Hazardous Drug

IV. Next meeting – TBD

V. Adjournment

Kentucky Board of Pharmacy

Hazardous Drug Compounding Committee

125 Holmes Street
Frankfort KY 40601

August 13, 2018

MINUTES

Chair Matt Martin called the meeting to order at 9:08 a.m. Members present: Barb Jolly, Jennifer Grove, Trenika Mitchell and Paul Daniels. Members absent: Chris Harlow, Alyson Roby and John Carver. Staff: Darla Sayre, Executive Staff Advisor. Guests: Jason Lyddane, St. Joseph Hospital and Robin Walters, Pikeville Medical Center.

On motion by Dr. Mitchell, seconded by Professor Jolly, the minutes of the July 9, 2018 meeting were approved.

Dr. Martin thanked everyone for their attendance. Dr. Martin provided a list of outstanding issues found in previous meetings and tabled until the entire chapter had been discussed. Those issues are:

1. Hazardous Drugs
2. Wholesalers
3. Negative Pressure Ventilation
4. Deactivating Agent/Decontamination
5. Waiver/differences between USP <800> and USP <797>
6. How to adopt USP General Chapter if sections are not harmonized with USP General Chapter?
    A. Segregated Compounding Area
    B. 'Low Volume' Hazardous Drug

At the request of the committee, Ms. Cheryl Lalonde, Board Counsel joined the meeting. Mr. Daniels questioned Ms. Lalonde on the options of the committee concerning recommendations to the Board. Ms. Lalonde identified two paths the committee could take. One option would be to provide proposed changes to the wording of USP <800>. The other option would be to recommend the adoption of USP <800> but establishing a waiver process for compliance issues. Ms. Lalonde informed the committee that any legal steps the Board may take would have to be taken after USP <800> takes effect.

After much discussion, the committee decided to submit both options to the Board. Dr. Mitchell moved to rescind the decision from the March 12, 2018 meeting adopting the following language concerning hazardous drugs:

> Hazardous drugs.
>
> (1) The pharmacist-in-charge shall be responsible for determining which drugs will be included on the pharmacy's list of HDs. The pharmacy's list of HDs shall include any drugs identified as Category 1 drugs on the most current list of drugs established by the National Institute for Occupational Safety and Health (NIOSH) that the pharmacy handles.
>
> (2) Drugs identified in Categories 2 and 3 on the most current list of drugs established by NIOSH, and final dosage forms of conventionally manufactured drugs that do not require any further manipulation

other than counting or repackaging are not required to be handled as specified in this section if the pharmacy performs a risk assessment for the drug(s). The pharmacy shall maintain documentation of any risk assessments of such drugs.

(3) For a drug that enters the market after the most recent version of the NIOSH list is established, the pharmacy shall evaluate the drug using the criteria found in the NIOSH list to determine whether the drug is to be added to the pharmacy's list of HDs. If the information available on a drug is deemed insufficient to make an informed decision, the drug shall be considered hazardous until more information is available.

Mr. Daniels seconded and the motion passed unanimously.

Professor Jolly moved to accept the following options [proposed changes and waiver process] and present these recommendations to the Board.

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

Dr. Mitchell seconded, and the motion passed unanimously.

On motion by Professor Jolly, seconded by Mr. Daniels and passed unanimously, Dr. Martin adjourned at 11:55 a.m.