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

Special Meeting Notice and Agenda

Hazardous Compounding Committee

March 12, 2018
9:00 a.m.

I. Call to Order

II. Minutes – February 12, 2018

III. Sections 1, 2, 3, 4, 8 and 9 of <USP>800

IV. Next meeting – April 9, 2018 Manufactured Products

V. Adjournment

Kentucky Board of Pharmacy

Hazardous Drug Compounding Committee

125 Holmes Street
Frankfort KY 40601

March 12, 2018

MINUTES

Chair Matt Martin called the meeting to order at 9:05 a.m. Members present: Barb Jolly, Paul Daniels, Chris Harlow, John Carver and Jennifer Grove. Members absent: Alyson Roby and Trenika Mitchell. Staff: Larry Hadley, Amanda Harding, Rhonda Hamilton, John Romine and Darla Sayre. Guests: Jason Lyddane, St Joseph Hospital; Bob Oakley; Don Kupper, New Vitalis Pharmacy; Adam Parrish, Wal-mart; Robin Walters, Pikeville Medical Center; John Starks, Clark Regional Medical Center and Hilary Lamb, student.

On motion by Dr. Jolly, seconded by Dr. Carver, the minutes of the February 12, 2018 meeting were approved.

Section 1 Introduction and Scope: Dr. Martin questioned why wholesale distributors were excluded from USP 800. The committee believed that wholesale distributors should be included to ensure the safety of all personnel who may come in contact of the hazardous drugs. Dr. Jolly stated that our guidelines should align with other agencies as personnel involved are under the jurisdiction of various agencies. Dr. Harlow and Dr. Grove addressed concerns regarding receipt of pharmaceuticals. Creating separate purchase orders does not correct the issue as they may be shipped in the same container. Treating all received pharmaceutical orders as hazardous drugs creates an undue burden on the pharmacy requiring a larger area for opening shipments. Dr. Harding advised the committee to specify which wholesale distributors they were included. There are different types of wholesale distribution who may or may not be involved in shipment of hazardous drugs. Dr. Martin suggested tabling this section until later in the meeting.

Section 2 List of Hazardous Drugs: Dr. Jolly stated that the NIOSH list in updated regularly. There is a phone application available for individuals to keep up to date with any changes made to the list. Dr. Martin questioned the scientific studies that support the need for negative pressure ventilation for nonvolatile Table 2 and 3 drugs. There should be a difference in how Tables 1,2, and 3 are treated. All hazardous drug APIs are handled the same according to the list. They should be treated differently depending on the characteristics of the specific drug. Dr. Jolly inquired if specific drugs could be handled by a risk assessment. Jason Lyddane stated that risk assessment is allowed by USP 800. Mr. Hadley requested information from guests if individual hospitals were planning to follow the USP 800 guidelines in the future. Dr. Carver stated that Baptist Health is currently planning to follow USP 800 guidelines or whichever is the most stringent. Dr. Jolly asked if this included satellite pharmacies too. Dr. Carver stated that satellite pharmacies were included in compliance with USP 800. Robin Walters, Pikeville Medical Center; John Starks, Clark Regional Medical Center; Bob Oakley and Jason Lyddane, St. Joseph Hospital all indicated that their facilities plan to comply with USP 800. Mr. Daniels stated that currently hospitals will have to file a waiver to comply with USP 800. Bob Oakley questioned if there were any criteria for these waivers and who would monitor them once approved. Dr. Jolly suggested allowing flexibility in the list to allow pharmacies to group similar drugs together under one risk assessment. Dr. Harlow stated that the regulation should be straight forward and not open to interpretation. Dr. Grove agreed. Mr. Daniels informed the committee that USP 795 is now interpreted differently. Many different procedures are used by entities but all are compliant. Dr. Harding stated that compliance is based on the minimum requirements.

Dr. Harlow made a motion to adopt wording from the Texas Hazardous Drug Task Force as follows:

> Hazardous drugs.
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> (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.
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> (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.
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> (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.

Dr. Grove seconded. The motion passed with Mr. Daniels opposing. Mr. Daniels stated his opposition was based the definition of hazardous drugs already exists in USP 795.

Section 3 Types of Exposure: After discussion, the committee agreed to leave Section 3 as is.

Section 4 Responsibilities of Personnel Handling Hazardous Drugs: Dr. Jolly requested specifications for the qualifications for handling hazardous drugs. How do you determine if someone is adequately skilled? Dr. Harding stated that there is no requirement for qualification currently in Kentucky law. Dr. Harlow requested that the designated person be required to be a pharmacist. He advised that Texas has wording that has a list of qualifications. Dr. Martin advised that not all facilities have a pharmacist named as the designated person. Dr. Harding stated that the qualification list can be found in Section 9. After discussion, the committee agreed to leave Section 4 as is.

Section 8 Hazard Communication Program: After discussion, the committee agreed to leave Section 8 as is.

Section 9 Personnel Training: After discussion, the committee agreed to leave Section 9 as is.

Dr. Martin returned to the concerns in Section 1 regarding wholesale distributors. After discussion, the committee agreed to table this until the April meeting to allow the committee to become more familiar with 201 KAR 2:105 and KRS 315.400.

The next meeting will be April 9, 2018 to discuss the wholesale distributor issue and manufactured products. Section 5 will be discussed at the May 14th meeting.

On motion by Dr. Jolly, seconded by Dr. Harlow and passed unanimously, Dr. Martin adjourned at 10:57 a.m.