AGENDA
USP CHAPTER 800 TASK FORCE

University of Kentucky College of Pharmacy
789 South Limestone
Lexington, KY 40506
September 12, 2017
1 pm to 3 pm EST

I. Call to Order
II. Introductions
III. Minutes from August 8, 2017 meeting
IV. Discussion of possible recommendations
V. Next meeting, if necessary

MINUTES
USP CHAPTER 800 TASK FORCE MEETING
August 8, 2017

CALL TO ORDER: The first meeting of the USP Chapter 800 Task Force was held at the Seelbach Hotel Ballroom, 500 South 4th Street, Louisville, Kentucky. Katie Busroe, Chair, called the meeting to order at 1 pm EST.

Members present: Katie Busroe, Chair; Jeff Akers, ARH; Ann Albrecht, Lexington Clinic Pharmacy; Holly Byrnes, KSHP President-elect; John Carver, Baptist Health; Gina Guarino, Kroger; Amanda Harding; Kentucky Board of Pharmacy staff; Chris Harlow, KPhA President; Stephanie Huff, University of Louisville Hospital; Daniel Jones, Strawberry Hills Pharmacy; Barb Jolly, Sullivan University College of Pharmacy; Leslie Kenney, KSHP President; Matt Martin, PCCA; Trenika Mitchell, University of Kentucky College of Pharmacy; Anne Marie Megibben, Compound Care Pharmacy; Chris Palutis, C&C Pharmacy; Adam Parrish, Walmart; Ron Poole, Kentucky Board of Pharmacy Board Member; Phillip Schwieterman, University of Kentucky Hospital; Kent Shelton, Lexington Compounding; Robin Walters, Pikeville Medical Center Oncology Infusion Center Pharmacy; Brian Yarberry, Norton Children's Hospital; and Ex-Officio members: Mark Glaser, KPhA Executive Director; and Anne Policastri, KSHP Executive Vice President. Task force members Seth Depasquale, BET Pharmacy; Michelle DeLuca Fraley, Ephraim McDowell Cancer Support Clinic; and Joel Thornbury, Nova Pharmacy were unable to attend.

There were approximately 75 guests present.

DISCUSSION: At the July 12, 2017, Kentucky Board of Pharmacy Board Meeting, the Kentucky Board of Pharmacy charged this Task Force to make a recommendation to the Board regarding USP Chapter 800, Hazardous Drugs – Handling in Healthcare Settings. Several options for a recommendation were discussed, including but not limited to: adoption of USP Chapter 800, adoption of parts of USP Chapter 800 and no adoption of USP Chapter 800. Chair Busroe will summarize the options to present at the next Task Force Meeting.

NEXT MEETING: The next USP Chapter 800 Task Force Meeting will be September 12, 2017, from 1 pm to 3 pm EST, at a site to be determined.

ADJORNMENT: On motion by Matt Martin, seconded by Ron Poole, and passed unanimously, the meeting adjourned at 3 pm EST.

Respectfully submitted,
Katie Busroe, Chair

POSSIBLE RECOMMENDATIONS

1. **Adopt USP Chapter 800, with implementation date of July 1, 2018**
    a. Following the Federal standard
2. **Adopt USP Chapter 800, with delayed implementation date of January 1, 2020**
    a. Allowing more time for compliance
3. **Adopt USP Chapter 800, with implementation date of July 1, 2018 but allow a waiver**
    a. Mirror 201 KAR 2:076, with USP Chapters 795 and 797
4. **Adopt USP Chapter 800, with delayed implementation date of January 1, 2020 but allow a waiver**
    a. Mirror 201 KAR 2:076, with USP Chapter 795 and 797
    b. Allowing more time for compliance and completing a waiver
5. **Adopt portions of USP Chapter 800 (see additional information, next document)**
    a. **Products in their final dosage form requiring no manipulation other than counting**
    b. **Nonsterile compounded preparations**
        i. Antineoplastic drugs (Group 1)
        ii. Non-antineoplastic drugs (Group 2) and reproductive hazards (Group 3)
        iii. APIs
    c. **Sterile compounded preparations**
        i. Antineoplastic drugs (Group 1)
        ii. Non-antineoplastic drugs (Group 2) and reproductive hazards (Group 3)
        iii. APIs
6. **Do not adopt USP Chapter 800**

ADOPT PORTIONS OF USP CHAPTER 800

1. **Adopt USP Chapter 800 for sterile and non-sterile compounding of antineoplastic drugs:**
    - **a.** Implementation date of July 1, 2018
    - **b.** Implementation date of January 1, 2020
    - **c.** Implementation date of July 1, 2018 or January 1, 2020 with a waiver process consistent with 201 KAR 2:076 for USP Chapters 795 and 797
2. **Adopt USP Chapter 800 for sterile compounding of all hazardous drugs:**
    - **a.** Implementation date of July 1, 2018
    - **b.** Implementation date of January 1, 2020
    - **c.** Implementation date of July 1, 2018 or January 1, 2020 with a waiver process consistent with 201 KAR 2:076 for USP Chapters 795 and 797
3. **Adopt USP Chapter 800 for:**
    - **a. drugs in their final dosage form not being manipulated other than counting,**
    - **b. all sterile compounding of hazardous drugs,**
    - **c. non-sterile compounding of antineoplastic drugs (Group 1),**
    - **d. non-sterile compounding of non-antineoplastic drugs (Group 2) and reproductive hazard drugs (Group 3) APIs having a Kentucky regulation:**
        - **i.** Implementation date of July 1, 2018
        - **ii.** Implementation date of January 1, 2020
        - **iii.** Implementation date of July 1, 2018 or January 1, 2020 with a waiver process consistent with 201 KAR 2:076 for USP Chapters 795 and 797
        - **iv.** Nonsterile compounding of Group 2 and Group 3 APIs:
            1. Require a separate room (not vented, not negative pressure)
            2. Powder containment hoods
            3. Personal protective equipment (PPE)
                - **a.** Chemotherapy gloves
                - **b.** Protective gown
                - **c.** Shoe covers
            4. Compounding personnel informed of risks of working with APIs
            5. Medical surveillance of compounding personnel
            6. Notice to the public hazardous drugs being compounded
            7. Policies for:
                - **a.** Receiving
                - **b.** Storage
                - **c.** Compounding
                - **d.** Use of PPE
                - **e.** Use of powder containment hoods
                - **f.** Training
                - **g.** Cleaning
                - **h.** Designation of hazardous drug areas
                - **i.** Disposal
                - **j.** Medical surveillance

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Kentucky USP <800> Implementation
Talking Points

- National implementation of USP<800> was purposefully delayed to allow pharmacies necessary time to stand up compliance. An early adoption will leave many locations with the inability to stand up USP<800> compliance which will result in the abandonment of compounding service. This ultimately will negatively impact patients and their access to necessary medications.

- The recently finalized USP Ch. <800> outlines standards for handling hazardous drugs in healthcare settings to minimize exposure to these medications and to promote patient safety, worker safety, and environmental protection. These standards address requirements for the receipt, storage, compounding, dispensing, administration, and disposal of medications that are on the National Institute for Occupational Safety and Health (NIOSH) list of hazardous drugs in healthcare settings.

- Depending on the type of hazardous drug being handled, USP Ch. <800> establishes different requirements for different medications, which has varying implications for the pharmacy community.

- While USP Ch. <800> provides flexibility for pharmacies that do not "manipulate" hazardous drugs to perform a risk assessment and then implement appropriate strategies to mitigate risk exposure, this undertaking would be a lengthy process and would be extremely difficult to comply with in the near future. For pharmacies that opt to perform a risk assessment, clinical teams need time to complete risk assessments and then document both the process and the strategy to contain that risk for every drug product on the NIOSH list that is in their stock. Additionally, pharmacies need time to work through distribution logistics both in their own distribution centers and with vendor wholesalers. Given that wholesale distributors are not subject to the requirements of USP Ch. <800>, it's unclear whether wholesalers are familiar with the new requirements of Ch. <800> and/or whether different wholesalers are prepared to implement practices to help pharmacies identify the hazardous drugs within shipments being provided to pharmacies.

- Pharmacies that are not eligible to comply with Ch. <800> by doing an assessment of risk face bigger compliance challenges. Notably, pharmacies that provide patients with certain anti-cancer drugs, pharmacies that compounded hazardous drugs, and even pharmacies that perform tablet splitting or otherwise manipulate dosage forms of hazardous drugs, are likely to need extensive and costly renovations, special equipment, and will need to implement stringent operating procedures to minimize exposure to these medications if such pharmacies are to continue to provide these types of medications to their patients.

- Recognizing the significant changes may be necessary in many pharmacy facilities, USP opted to delay the effective date of USP Ch. <800> until July 1, 2018. However, particularly for pharmacies that are subject to the more stringent requirements of USP Ch. <800>, compliance with the 2018 deadline may not be workable.

- There are a limited number of vendors capable of performing the extensive facilities updates (which include construction of a negative pressure room) that will be necessary for many pharmacies under USP Ch. <800>. It is unlikely that this small number of vendors will able to meet the demand of the many institutional, compounding, LTC, and community pharmacies that will require facilities updates by the July 2018 implementation date.

- It is important to note that lease and landlord agreements for pharmacies are many times subject to terms which will not allow for physical modifications and construction enhancements. As a result, sites need ample time to gain approvals and permits or change physical locations to implement USP<800> physical construction requirements.

- Given the broad impact and extensive scope of USP Ch. <800>, the pharmacy community needs adequate time to evaluate their individual operations, determine their compliance pathway, and implement any necessary facilities, operations and practice changes, or relocate. Where extensive and costly renovations and other facilities changes are needed, pharmacies also need time work these costs into their budget. In some cases, this will be a multi-step, multi-year process that is subject to review by numerous organization stakeholders.

- To ensure that pharmacies can continue to provide patients with access to needed medications while working to comply with the requirements of this new standard, we request that Boards of Pharmacy that opt to require compliance with USP Ch. <800> delay the compliance date until 2021.

-----Original Message-----
From: Micah Benford [mailto:mbenfordrx@gmail.com]
Sent: Saturday, September 9, 2017 7:46 AM
To: Angela Gibson
Subject: USP 800

I am the pharmacy manager for a long term care pharmacy serving the ID/DD population. I cannot imagine having the USP 800 standards applying to the handling of common medications such as risperidone, or the simple act of pouring megestrol into a dosing bottle. Pharmacies cannot stop and change the entire workflow for all of these "hazardous" substances. If compounding with hazardous powders, etc, then yes, these standards should apply. But not to the every day dispensing of medication.

I would also like to add that I understand the safety of personnel precedes worrying about the workflow of the pharmacy, but we already require gloves to be worn when handling all medications for sanitary purposes. Pharmacies have to develop efficient workflows to serve patients timely, and adding unnecessary barriers will negate those efficiencies. I feel USP 800 should apply to sterile and non-sterile compounding only.

-Micah Benford

From: Randy Stiles <acepharmer@yahoo.com>

Date: 9/11/17 3:14 PM (GMT-05:00)

To: Angela Gibson <agibson@kphanet.org>

Subject: USP 800

I am against the adoption USP regs by the KYBOP. From my research, the mission of the USP was initially to eliminate unsafe and impure drugs from the market, and then to create best practices for the manufacture of medications. I see these regulations as overreach and mission shift from the purpose of USP. I cannot find any mechanism of oversight of USP by Congress or any other elected legislative body, to ensure that USP is staying within its scope.

If there is a severe health risk posed to pharmacists or the public, there are other agencies that may have jurisdiction. The proposed 800 regulations are onerous and will be expensive to comply with. These issues should be addressed by either the state legislature, or at least improved best practices can be created from within the pharmacy profession and taught in our pharmacy schools. This will allow pharmacies and pharmacists to make changes to their procedures when they feel it is appropriate and affordable.

sincerely,

Randy Stiles, R.Ph

Pikeville, Ky

From: caseither@fuse.net [mailto:caseither@fuse.net]
Sent: Friday, September 8, 2017 4:50 PM
To: Angela Gibson
Subject: USP 800

To Task Force,

Here is my 2 cents on USP 800. I think the requirements for USP 800 will cause many pharmacies to exit compounding limiting scope of practice. Consequently, with less competition in compounding, prices will increase for patients. While the intent of USP is noble, it is my belief that many personnel that work in pharmacy are currently being exposed to these hazardous drugs. Specifically, USP 800 does not address exposure to commercially available products where there is exposure from opened bottles. There is powder in these bottles, that can end up on counting trays, spatulas, counting machines (Eyecon), robotics, etc. If USP 800 was not trying to penalize compounding pharmacy and truely cared about exposure, then all of these products would be blistered packaged, eliminating any possiblity for exposure. It is my belief that Manufacturer's are behind USP 800, for the purpose of reducing scope of practice for pharmacists. Personally, if KY adopts all aspects of USP 800 I will comply, but there will be a surchage for any Rx that requires special handling, resulting in higher expenses for patient. The build out for compliance will be costly, but ultimately, the increase in compounding business due to others exiting compounding hopefully will justify the investment. Another thought is that why don't insurance companies seem concerned at all when obtaining personal life insurance. There are no questions regarding working in a high risk environment like a compounding pharmacy. In closing, I think it would great to see KY take a stand and NOT adopt USP 800. Allow individual pharmacies to adopt policies and procedures that fit their own model, where ultimately, the patient will benefit.

Sincerely,

Craig Seither, R.Ph.
Fort Thomas Drug Center
26 North Fort Thomas Avenue
Fort Thomas, KY 41075

September 12, 2017

Katie Busroe, RPh
Inspections and Investigations Supervisor
Kentucky Board of Pharmacy
125 Holmes St #300
Frankfort, KY 40601

Re: Adoption of USP 800 as Regulatory Requirements

As the Task Force deliberates its recommendations to the Kentucky Board of Pharmacy regarding the adoption of USP 800 Standards as regulatory requirements in Kentucky, the Kentucky Pharmacists Association, based on input received from members and other pharmacists from diverse practice settings across the Commonwealth, makes the following recommendation:

> **Delay the discussion of adoption of USP 800 as regulatory requirements until additional information is available from early adopters.**

Much can be learned from the experiences in other states that have adopted USP 800 standards as regulatory requirements. We believe a pragmatic approach to USP 800 from all perspectives seems prudent at the present time. Unlike USP 795 and USP 797, which had considerable history before they were adopted into regulation, USP 800 is a new chapter with no similar history or background.

Sincerely,

Chris Harlow, Pharm D
KPhA President

96 C. Michael Davenport Blvd. | Frankfort, KY 40601 | Phone 502-227-2303 | Fax 502-227-2258

From:	Busroe, Katie (Brd of Pharmacy)
To:	Sayre, Darla (KY Board of Pharmacy)
Subject:	FW: Thoughts about USP 800
Date:	Wednesday, September 13, 2017 6:50:42 AM
Attachments:	image002.png image003.png image004.png

Can you add this to the USP 800 Task Force September 12 information, please?

Thanks!

Katie Busroe, RPh

Inspections and Investigations Supervisor

Kentucky Board of Pharmacy

Cell 859-619-5477

Fax 502-696-3806

From: Mark Glasper [mglasper@kphanet.org]
Sent: Tuesday, September 12, 2017 9:28 AM
To: Hart, Steve (KY Board of Pharmacy); Busroe, Katie (Brd of Pharmacy)
Subject: FW: Thoughts about USP 800

Wanted to be sure you received this letter as well for the USP 800 Task Force meeting. Thought it had previously been sent to the Board by the sender.

Mark A. Glasper
Executive Director/CEO
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-------- Original message --------
From: "Matthew J Buderer, R.Ph. FIACP" <matt@budererdrug.com>
Date: 9/8/17 11:08 AM (GMT-05:00)
To: Angela Gibson <agibson@kphanet.org>
Subject: Fwd: Thoughts about USP 800

Dear Kentucky Board of Pharmacy,

I am a Kentucky licensed pharmacist with a licensed pharmacy from Ohio. I just participated in a meeting at the Ohio Pharmacists Association yesterday where we discussed USP 800 with the Chief Pharmacist of the Board and Cameron McNamee. At the present time, we were told that Ohio is not going to enforce USP 800, rather just the sections on hazardous drugs referenced in USP 795 and 797.

Below are some of the thoughts I presented to the Board for their consideration. I hope this is helpful for your consideration, as well.

Best regards,

Matt

Matthew J Buderer, R.Ph., FIACP

Buderer Drug Company

Sandusky/Perrysburg/Avon, Ohio 800-318-3408

-------- Original Message --------

Subject: Thoughts about USP 800
Date:08/14/2017 09:23
From:"Matthew J Buderer, R.Ph. FIACP" <matt@budererdrug.com>
To: Cameron.McNamee@pharmacy.ohio.gov, "Zapadka, Sheri" <Sheri.Zapadka@pharmacy.ohio.gov>

Dear Cameron and Sheri,

I recently participated in a teleconference call about USP 800. The presenter was AJ Day from PCCA. He was one of the members of the USP 800 task force for the Texas Board of Pharmacy. I would like to relay some of the things discussed in the teleconference as I hope it may be helpful in your decision making on USP 800 rules for Ohio, if any.

Its likely that you know most of this information already, but it may be helpful to know the thoughts of our pharmacy on the matter, as well. Some of the points/concerns discussed:

- Indiana and South Carolina have decided not to enforce USP 800 as it is not about public safety, rather employee safety. They defer to OSHA. It is my understanding

that Texas is adopting, or has adopted the same based on the information given to them by the task force.

- There is data on the occupational hazards of NIOSH Group 1 antineoplastic drugs but there is insufficient data or no data associated with the occupational hazards associated with the drugs listed in the other groups. So, Group 1 drugs should be prepared in a negative pressure environment but a risk assessment or study should be conducted on the drugs listed in the other groups. As such, AJ Day was part of a research study examining the exposure to the preparation of estradiol capsules. He is willing to discuss the results of this study and is awaiting it to be published in a peer reviewed journal. In short, the results showed that particulate was below analytic detection.
- Due to a lack of evidence for non-Group 1 drugs, there was concern about the liability of the Board if they had adopted USP 800 and whether they could win a lawsuit if challenged.
- Rules enforcing USP 800 create an a non-competitive business environment, where only the large pharmacies prevail and small business is likely to be unable to make the costly adjustments.

It is my suggestion that the Ohio State Board of Pharmacy, based on the above considerations, take a similar stance as Texas, Indiana and South Carolina and not enforce USP 800. Otherwise, I think it would be reasonable to postpone the adoption or enforcement of USP 800 until 2021 and observe what other states adopt and what evidence is published on the risk of exposure. Being that it is still early and research is now only beginning, a decision could be made once more evidence is presented.

The decision of the Board greatly affects the investment that we need to initially make and the monthly investment that we continue to have to make to maintain compliance. Initially, we predict that we will need to spend $850,000 to refit our 3 pharmacies to be compliant with USP 800 as written. It will then cost an additional $5000 per pharmacy each year in just utilities for the maintenance of heating and cooling the number of air turns in the space designated for hazardous compounding. This investment is made in a business environment where insurance companies will not pay more for a drug compounded in compliance with USP 800. For this reason, the extent to which the Board enforces all or some of USP 800 will determine our investment.

Additionally, many smaller compounding pharmacies in Ohio will discontinue business. Adoption of USP 800 will have an impact on small business. While this might be beneficial for those of us who remain, it may not serve the economy well and more importantly, it will limit patient's access to compounded medications.

Thank you for your consideration of the above comments and suggestions.

Best regards,

Matt

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Matthew J Buderer, R.Ph., FIACP

Buderer Drug Company

Sandusky/Perrysburg/Avon, Ohio 800-318-3408