MINUTES
UTAH ADVISORY PHARMACY COMPOUNDING EDUCATION COMMITTEE
DECEMBER 08, 2022 | 9:00 A.M.
ROOM 474, 4th Floor
160 E 300 S Salt Lake City UT
Hybrid Meeting- In Person and Electronic

Electronic attendance was available.

CONVENED: 9:01 A.M. **ADJOURNED: 10:57 A.M.**

DOPL STAFF PRESENT ELECTRONICALLY:
Bureau Manager: Larry Marx
Board Secretary: Maree Christensen
Investigator: Travis Drebing
Pharmacy/Health Program Specialist: Jim Garfield

COMMITTEE MEMBERS PRESENT ELECTRONICALLY:
Chair: Matthew Higley, Pharm D
Vice Chair: Chris Cox, Pharm D
Hali O'Malley, Pharm D
Christopher Kane, Pharm D
Casey Sayre, Pharm D
Jeremy Olsen, Pharm D

COMMITTEE MEMBERS NOT PRESENT:
Adam Taintor, Pharm D

GUESTS ATTENDED ELECTRONICALLY:
Ryan Ball
Pejman Mesdaghi

Note: Others may have attended, but were not identified.

ADMINISTRATIVE BUSINESS:
CALL MEETING TO ORDER
Dr. Higley called the meeting to order at 9:01 A.M.

APPROVE SEPTEMBER 22, 2022, MEETING MINUTES (*Audio 00:01:50*)
Dr. Cox made a motion to approve the minutes with revisions as discussed.
Dr. O'Malley seconded the motion.
The Board motion passed unanimously.

DISCUSSION ITEMS:
USP <797> AND <795> UPDATES (*Audio 00:04:20)*
Dr. Higley stated the final revision of USP <797> and <795> is now available, however there is a USP paywall requirement to view the document. Dr. Higley stated there are free USP <797> and

<795> fact sheets on the USP website. Dr. Higley stated an additional category was created; category three CSP (compound sterile preparation), which has added additional requirements to the BUD (beyond-use date) of 180 days.

Dr. O'Malley stated due to the USP updates not becoming official until November 2023, everyone is still held to the current version. Dr. O'Malley stated the new version of USP <795> would allow for carpeting in the compound area of the pharmacy. Dr. O'Malley stated the change could affect the smaller compounding pharmacies.

Dr. Higley suggested the Committee make recommendations to the pharmacy Board on how to adopt the new official version to ensure it is in line with state laws and the Pharmacy Practice Act. Dr. Higley discussed the proposed rules for USP <800>.

Dr. O'Malley asked if there were foreseeable issues relating to USP <797> for pharmacies.

Dr. Higley stated the issue would be, in relation to category three; sterility testing and gowning. Dr. Higley asked Dr. Olsen and Dr. Cox if there were potential issues for pharmacies in relation to sterile compounding.

Dr. Olsen expressed he thought it was wrong for pharmacies to pay for the subscription, just to see what law they will be held to. Dr. Olsen stated isolators would no longer be used with the new version, and current USP compounding guideline language has also been amended.

Dr. Higley asked if DOPL staff had thoughts on the subscription requirement.

Mr. Marx stated if the new version is incorporated into the rules it must be made available to the public by the Divsion. Mr. Marx stated the subscription requirement seems problematic. Mr. Marx stated the division would need to communicate with the Attorney General's office to see if there is a way around the copyright issue.

Dr. Higley stated USP had communicated they are not the enforcement body, therefore rules would need to be adopted into each states' law or rule. Dr. Higley stated if USP <797> is adopted outright, the document would need to be made available to the public at the same time as the proposed draft rules are published to the pharmacy website.

Dr. O'Malley stated the first step is, to decide if the Committee would recommend adopting the USP <797>document outright or write each requirement into the Utah Pharmacy rules; which would be far more time consuming. Dr. O'Malley stated the paywall issue would be the same problem with USP <800> and<825>.

Dr. Higley stated he would contact USP to discuss the paywall issue; then provide the Committee with feedback.

Dr. Higley suggested to send out an alert to pharmacies in relation to the new version of USP <797> and <795>. Dr. Higley stated he would draft a summary for USP <797>.

Mr. Marx stated it would be a great idea to send out the information and request feedback from pharmacies.

Dr. Higley asked for a volunteer to draft a summary for USP <795>.

Dr. O'Malley stated she would draft a summary for USP <795>. Dr. O'Malley stated there would be issues with adopting USP <800> out right, such as; negative pressure rooms.

Dr. Cox stated he agreed with Dr. O'Malley with the issues surrounding USP <800>, such as; financial impact on independent pharmacies and small chain pharmacies.

Dr. Higley stated he would draft a summary for USP <800> as well.

Dr. O'Malley stated there is a proposed USP <800> document on the DOPL pharmacy webpage for public reference.

Dr. Olsen suggested to include in the alerts to pharmacies, the official USP <797> and <795> documents being behind a paywall, as well as a timeline of completion of the adoption of the new version into state law.

Mr. Marx stated the time frame realistically would be around November 2024; if there is no push back or issues.

USP <800> UPDATES (*Audio 01:20:32)*
Dr. Higley stated he had received communication from the pharmacy Board Chair, asking the committee to review if compounding requirements can be applied to other professions.

Mr. Marx stated there are no other professions that have adopted USP <800>, the only professions that would be able to, are physicians and advanced practice registered nurses. Mr. Marx stated DOPL has been witnessing issues in other professions, relating to the compounding of vitamin IV bags.

Dr. O'Malley stated the vitamin IV bags were the top topic at the FDA compounding meeting that was held in November 2022. Dr. O'Malley stated the FDA had concerns with who is regulating the IV bag compounding.

Dr. Olsen stated the FDA had commented that nurses are stepping into medicine and performing the IV's at wellness clinics and spas.

Mr. Marx stated patients are selecting what products go into their IV bags without a medical consultation. Mr. Marx stated a medical consultation is an important part of the standard of care.

Dr. Higley stated USP <797> is not just limited to pharmacies, other medical professions should really look into adopting the compounding USP <797> rules.

Mr. Marx stated he would look into drafting the USP <797> compound language for other professions. Mr. Marx stated he will follow up with Ms. Blackburn for assistance with the draft. Mr. Marx suggested for the Committee to draft a USP <797> rule recommendation to the pharmacy Board.

Dr. Higley stated he would draft a rule recommendation for the pharmacy Board to review.

FDA COMPOUNDING MEETING REVIEW (*Audio 01:36:57)*
Dr. Olsen discussed topics that were presented at the recent FDA Compounding Meeting.
Dr. Olsen discussed the top three FDA 483 section 503 A inspection observations.
Dr. Olsen stated media fill testing's were not performed to the correct standards, Aseptic and ISO-5 classified areas were not in certified conditions, and microbial contamination was found due to improper product evaluation with remedial action.

Dr. Olsen discussed the top three FDA 483 section 503B inspection observations.
Dr. Olsen stated discrepancies were not thoroughly reviewed in environmental monitoring systems, procedures and guidelines for Aseptic and ISO-5 were not followed for sterile drug products, and investigation of discrepancies and failures which involved failure to conduct smoke study. Dr. Olsen discussed the topic of IV hydration clinics presented by the FDA. Dr. Olsen stated the IV hydration topic had the most response and questions by attendees.

Dr. Olsen stated committee had voted on bulk drug substances for inclusion on the 503A bulks list.

Dr. Olsen discussed FDA section 503A, MOU (Memorandum of Understanding); why the MOU is important, developing, and the current status of the MOU.

Dr. Olsen discussed FDA section 105; a state Board of pharmacy may voluntarily submit to the FDA certain information relating to a pharmacy's compounding operations. Dr. Olsen stated FDA section 105 also includes the FDA being tasked with receiving, assessing and disseminating information among other state Boards of pharmacy.

Dr. Olsen discussed the FDA topic, DSCSA (Drug Supply Chain Security Act) the act is currently in the next phase of implementation.

Dr. Higley stated the DSCSA implementation phase is part of a 10 year plan, which is planned for November 2023.

Dr. Higley asked who could attend the pharmacy Board meeting on December 20, 2022 to present to APCEC update.

Most of the Committee members responded that they would be unavailable for the December pharmacy Board meeting.

Mr. Marx suggested to post-pone the APCEC update until the January pharmacy Board meeting.

Dr. Higley asked who could attend the January pharmacy Board meeting.

Dr. Olsen stated he would attend the January pharmacy Board meeting

NEXT SCHEDULED MEETING: Thursday March 23, 2022.

2023 Board Meetings Tentatively Scheduled:
June 22, August 15, September 19, December 14.

ADJOURNED: Meeting adjourned at 10:57 A.M.

Note: These minutes are not intended to be a verbatim transcript but are intended to record the significant features of the business conducted in this meeting. Discussed items are not necessarily shown in the chronological order they occurred.

(ss) Matt Higley (Mar 24, 2023 09:41 MDT) — 03/24/2023

Chairperson
Advisory Pharmacy Compounding Education Committee — Date

(ss) Lisa Martin — 03/27/2023

Bureau Manager — Date