

MINUTES
UTAH ADVISORY PHARMACY COMPOUNDING EDUCATION COMMITTEE
ELECTRONIC MEETING
JUNE 24, 2021 | 9:00 A.M.
HEBER M. WELLS BUILDING
SALT LAKE CITY, UT 84114

**DUE TO COVID-19, NO PUBLIC ANCHOR LOCATION WAS PROVIDED.
PUBLIC ATTENDANCE BY PHONE**

CONVENED: 9:05 A.M.

ADJOURNED: 10:41 A.M.

DOPL STAFF PRESENT ELECTRONICALLY:

Bureau Manager: Jennifer Falkenrath

Board Secretary: Jennifer Johnson

Pharmacy Inspector: Sharilee Scheller

Pharmacy Inspector: Travis Drebing

Pharmacy Investigator: Jennifer Healey

COMMITTEE MEMBERS PRESENT ELECTRONICALLY:

Chair: Matthew Higley, PharmD.

Hali O'Malley, PharmD.

Christopher Kane, PharmD

Casey Sayre, PharmD

Jeremy Olsen, PharmD

COMMITTEE MEMBERS NOT PRESENT:

Vice Chair: Chris Cox, PharmD.

Adam Taintor, MD

BOARD OF PHARMACY MEMBERS PRESENT ELECTRONICALLY:

Dr. Carrie Dunford, Chair – Board of Pharmacy

GUESTS ATTENDED ELECTRONICALLY:

Natalia Nino

A. Hansen

Note: Others may have attended but were not identified.

ADMINISTRATIVE BUSINESS:

CALL MEETING TO ORDER

Dr. Higley called the meeting to order at 9:05 A.M.

APPROVE MARCH 25, 2021, MEETING MINUTES

Refer to audio for specifics (Audio) (00:03:00 – 00:04:20)

The Committee reviewed the minutes.

Dr. O’Malley made a motion to approve the minutes with corrections

Dr. Sayre seconded the motion.

The Committee motion passed.

DISCUSSION ITEMS:

FDA MOU DISCUSSION

<https://www.fda.gov/media/91085/download>

Refer to audio for specifics (Audio) (00:03:00 -00:42:30)

Dr. Higley stated NABP has issued a letter requesting the FDA pushback their deadline for those to sign the FDA MOU. NABP cited multiple reasons for the request including the COVID-19 Pandemic. Currently, the deadline is set for October 27, 2021.

Dr. Higley and Dr. O’Malley stated they believe New Hampshire is the only state that has signed the FDA MOU.

Ms. Falkenrath stated the Division has received a lot of public inquiries regarding whether or not Utah plans to sign the FDA MOU. Ms. Falkenrath stated NABP is also putting information on their website and stated they are a great resource for up to date information regarding the FDA MOU.

The Committee stated they were not ready to make a decision at this time due to very little information being provided.

Ms. Falkenrath stated there is still time for review consideration. Ms. Falkenrath stated the Advisory Pharmacy Compounding Education Committee (APCEC) will have their next Board meeting on September 30, 2021, and the Board of Pharmacy (BOP) will also meet on September 28, 2021, and again on October 26, 2021. This would still allow for a response by the October 27, 2021, deadline.

Dr. Olsen stated where the APCE Committee has already discussed and expressed their recommendation to the BOP, he wanted to know what the BOP’s plans were.

Ms. Falkenrath stated the BOP is waiting for the official recommendation from the APCE Committee in order to move forward.

The APCE Committee stated at this time their recommendation is they would rather sign than not, but they would like to see if there are going to be any changes to the document or if the date to sign is pushed out before signing.

The APCE Committee stated they have concerns with having a decision made at the last minute and asked who would be involved in signing.

Ms. Falkenrath stated this could be discussed at the September 28, 2021, BOP meeting and have the Committee attend. Ms. Falkenrath stated this would still allow the Division Director time to review and sign before the October 27, 2021, deadline.

Dr. Olsen stated the recommendation is that Utah will sign if there is no other option, but would prefer not to if they don't have to. Dr. Olsen stated he does not want Utah pharmacies affected if Utah did not sign the FDA MOU.

The APCE Committee stated they would like to hold the September APCE Committee meeting prior to the September BOP meeting. This would allow for the APCE Committee to make the recommendation for signing or have further discussion prior to the BOP meeting on September 28, 2021.

Ms. Falkenrath stated an official motion will need to be made in order to move the APCE Committee meeting from September 30th to September 23rd

Dr. Olsen made a motion move the APCE Committee meeting to September 23, 2021.

Dr. O'Malley seconded the motion.
The Committee motion passed

Dr. Olsen stated when the APCE Committee presents to the BOP in September, he would like to identify the concerns the APCE Committee has with the FDA MOU.

The APCE Committee reviewed the letters the APCE Committee sent to the FDA regarding the concerns Utah has regarding the FDA MOU.

Ms. Falkenrath stated a response has been received from the FDA and they indicated questions can be found on the FDA's website as well as NABP's website. And indicated the FDA would be happy to schedule a meeting with the Committee if they would like. FDA stated there were responses to the FAQ that were provided.

The APCE Committee stated at this time they feel Utah's concerns as well as the other States concerns have been relayed to the FDA and they know where everyone stands.

Additional questions, comments, and concerns were discussed.

The APCE Committee discussed the questions they had on what the implementation timeframe is once signed as well as getting the information out to the pharmacy community.

Ms. Falkenrath stated information could be put in the November Pharmacy Newsletter, pharmacy alert could be sent out, and links to NABP's website could be provided.

Dr. Higley stated he would like to include information in place on how to proceed after the October 27, 2021, deadline to prepare those how to move forward.

The APCE Committee stated they would like to have together for the September Committee meeting.

The APCE Committee discussed concerns with information needing to be added to Rule to require those to report.

Ms. Falkenrath stated she will review to see if a legislative change and rule update require reporting.

Dr. O'Malley stated she understands at this time reporting is voluntary, but would need to check with the BOP to determine if rules need to be drafted to require reporting.

Ms. Falkenrath stated for Utah, it's required you follow state laws and rules for requirements. Ms. Falkenrath stated she would look into rule writing and will plan to have a draft ready to go if needed.

INSANITARY CONDITIONS

Refer to audio for specifics (Audio) (00:42:30 – 1:14:15)

Dr. Higley stated the Committee has gone back and forth several times with the BOP regarding the FDA Guidance on Insanitary Conditions and the conflicting information with USP Guidance. Dr. Higley stated the FDA Guidance is non-binding.

Ms. Falkenrath stated previously the APCE Committee mentioned sending a letter to FDA regarding their concerns with the FDA guidance and asking for clarification since there is conflicting information based on FDA guidance and state adopted USP Guidance that is identified in Statute and Rule.

Dr. Higley stated he has been drafting a guidance document for consideration.

Dr. Higley stated there are not set recommendations for pharmacies. This leaves pharmacies at risk with the state, FDA, and USP due to the differences. Dr. Higley stated Pharmacies are concerned on whose guidelines they need to follow when there are discrepancies.

Dr. Olsen stated he wants to make sure people do not take the guidance document to insanitary conditions as legal advice. Dr. Olsen stated it needs to be clear the purpose of the document is for guidance only and people still need to follow USP <795> & <797>.

Dr. Dunford stated the BOP cannot tell people to disregard the FDA's guidance document to insanitary conditions. Dr. Dunford stated there is a grey ambiguity with non-binding guidance and understanding they really can become binding. The FDA can inspect at any time and can cite based on their requirements. The BOP does not have any control over what FDA inspects to and cites to. Pharmacies are responsible to be compliant with all.

Dr. Dunford stated there has been some hesitation with the letter. Want to make sure the intent of the letter is to indicate this is what the Utah BOP inspectors will inspect to and cite to for Utah. Also, we do not want it to come across as the Utah BOP is dismissing the FDA's guidance or recommendations.

Dr. Dunford stated it is worth sending a letter to FDA regarding the concerns Utah has and indicate FDA's recommendations go against USP and did they intend for that. Also, that there are conflicts with individual recommendation from FDA, BOP, State, & USP.

Dr. Higley stated he would like to send a letter to the FDA and hope they will respond. If they do, the APCE Committee and BOP will be able to provide the community information on what FDA's response was.

Dr. Higley providing the APCE Committee with a copy of the draft letter identifying conflicts and concerns. The APCE Committee reviewed and provided feedback.

Dr. Olsen stated the Committee's responsibility is to educate and stated he wants to make sure the letter is carefully drafted so that it shows the attempt to address the issues and not pushing it off to someone else to address.

Questions, comments, concerns, and recommendations for changes were discussed.

Dr. Higley stated he will make the updates and send out for final review.

Ms. Falkenrath stated the final draft will need to be placed on committee letterhead in order to be sent out.

ESSENTIAL COPY GUIDANCE

Refer to audio for specifics (Audio) (1:14:15 – 1:18:30)

The APCE Committee reviewed the Essential Copy Guidance Dr. Cox drafted.

Dr. Higley stated he was not sure if any recent updates had been made but stated the APCE Committee wanted to have an FAQ document or information available to cover those areas that were grey or ambiguous and not clearly defined in law or rule. Also, because the law and rule were not going to be updated to cover essential copies.

Dr. Higley stated once approved he was hoping to have it featured in the newsletter and posted on the DOPL website.

Questions, comments and concerns were discussed.

The APCE Committee stated they would like to review and make sure there wasn't additional information or updates made or that Dr. Cox had drafted something different.

Dr. Olsen asked if this was something the Committee would like to have wrapped up by the end of the year.

Dr. Higley stated there are two more Committee meetings left in 2021 and he would like to have areas wrapped up where they can be.

Dr. Higley stated he would check with Dr. Cox to see if he had any updates regarding the Essential Copy Guidance and stated the Committee would plan to review at their next meeting.

FDA BULK DRUG SUBSTANCE LIST

https://www.fda.gov/advisory-committees/updated-agenda-information-june-9-2021-meeting-pharmacy-compounding-advisory-committee-meeting?utm_medium=email&utm_source=govdelivery#event-materials

Refer to audio for specifics (Audio) (1:18:30 – 1:22:00)

Dr. Higley stated the FDA is looking at bulk product and identifying what is okay to compound with and what will not be.

Dr. Higley stated the FDA did hold a meeting to discuss this but not everyone was able to attend.

Dr. O'Malley provided a summary to the Committee and reviewed products that were recommended to the FDA. Dr. O'Malley stated the FDA will have the final say.

Dr. O'Malley stated once the FDA has updated the bulk list she will provide an update to the Committee.

Before closing the meeting Dr. Higley stated at the next Committee meeting he would like to discuss areas and topics of discussion the Committee would like to complete before the end of 2021. This would include the FDA MOU, Insanitary Conditions, etc.

Dr. Sayre stated a lot of this information appears to be close to being resolved and the Committee should discuss what they would like to accomplish in the upcoming year.

Dr. Higley stated there are consistent questions regarding the new USP <795> & <797>.

Dr. O'Malley stated the situation with USP is a slow process and it could take a few years for appeals to be resolved.

Dr. Olsen discussed the information provided to him regarding USP. And discussed having info provided for the newsletter.

Ms. Falkenrath stated newsletter information is due July 1 for the August release.
Ms. Falkenrath stated she needed to know as soon as possible if the Committee wanted to have information regarding USP provided in the newsletter, if so she can request for an extension date on the newsletter with NABP.

Dr. Higley adjourned the meeting.

NEXT SCHEDULED MEETING: Thursday, September 23, 2021

ADJOURNED: Meeting adjourned at 10:41 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.

9-23-2021

Date Approved

(ss)



Dr. Matthew Higley, Chairperson
Advisory Pharmacy Compounding Education
Committee

23 September 2021

Date Approved

(ss)



Jennifer Falkenrath, Bureau Manager
DOPL