

**MINUTES
UTAH BOARD OF PHARMACY
ELECTRONIC MEETING
DECEMBER 15, 2020- 8:30 A.M.
HEBER M. WELLS BUILDING
SALT LAKE CITY, UT 84114**

**DUE TO COVID-19, NO PUBLIC ANCHOR LOCATION WAS PROVIDED.
PUBLIC ATTENDED ELECTRONICALLY**

CONVENED: 8:30 A.M.

ADJOURNED: 2:53 P.M.

DOPL STAFF PRESENT ELECTRONICALLY

Division Director: Mark Steinagel
Bureau Manager: Larry Marx
Bureau Manager: Jennifer Falkenrath
Board Secretary: Jennifer Johnson
CSD Admin: Ron Larsen

Investigator: Dan Briggs
Chief Investigator: David Furlong
Compliance Specialist: Sicily Hill
Compliance Manager: Tracy Naff

BOARD MEMBERS PRESENT ELECTRONICALLY:

Chair: Carrie Dunford, PharmD
Vice Chair: Christopher Sheard, PharmD
Sepideh Daery, PharmD
Karen Gunning, PharmD

Gary Hale, R.Ph
Autumn Hawks, Pharmacy Technician
Joseph Ligori, Public Member

BOARD MEMBERS NOT PRESENT: N/A

GUESTS ATTENDED ELECTRONICALLY

Jaime Montuoro
RJ Evans
Kristie Fitzgerald
Greg Jones, Harmon's
Ademola
Lauren Paul, CVS Health
Cliff Holt
Donelle Perez
Dave Davis, URM
Denise Frank
Mark Brinton, AMA

Christopher Christensen
Travis Drebing, Pharmacy Inspector
Jennifer Healey, Pharmacy Investigator
Jim Garfield, Pharm/Health Prgrm Specialist
Jared Memmottt
Hali O'Malley, Advisory Pharmacy Compounding
Education Committee
Mathew Higley, Advisory Pharmacy Compounding
Education Committee
Chris Kane, Advisory Pharmacy Compounding
Education Committee

Note: Other guests may have been in attendance electronically but were not identified

ADMINISTRATIVE BUSINESS:

CALL MEETING TO ORDER

Refer to audio for specifics (Audio 1_01) (00:00 – 00:04:44)

Dr. Dunford called the meeting to order at 8:30 A.M.

READ AND APPROVE NOVEMBER 17, 2020 MINUTES

Refer to audio for specifics (Audio 1_01) (00:04:44 – 00:06:40)

Mr. Ligori made a motion to approve the minutes a written.

Ms. Hawks seconded the motion.

The Board motion passed unanimously.

INVESTIGATION REPORT

Refer to audio for specifics (Audio 1_01) (00:06:44 – 00:15:00)

Dan Briggs, Investigation Supervisor, reviewed the investigation report as provided.

Questions and comments were discussed.

CONTROLLED SUBSTANCE DATABASE (CSD) UPDATE

Refer to audio for specifics (Audio 1_01) (00:15:00 - 00:43:48)

Mr. Larsen provided a CSD update.

Mr. Larsen stated the new data transmission system is working as well as expected.

Mr. Larsen stated the system is doing what it was designed to do. It's identifying the information being submitted and providing feedback. Pharmacies are reporting their data or submitting their zero reporting.

Mr. Larsen stated pharmacies are being notified of any issues with the data provided and are being asked to correct and resubmit. The system is also identifying those that should be reporting and aren't or the pharmacies that are not submitting their zero reporting.

Mr. Larsen stated he expects to hear feedback from the pharmacy community regarding additional responsibility placed on them to correct data errors and resubmit.

Mr. Larsen stated starting January 1, 2021, all pharmacies are required to adhere to current requirements for submitting data electronically to the CSD. They will either be required to submit their data or have a waiver. Those not in compliance will have administrative action taken.

Questions and comments were discussed.

DISCUSSION ITEMS:

STANDING ORDERS

Refer to audio for specifics. (Audio 1_01) (00:43:48 – 00:44:36) & (Audio 1_02) (00:00 – 00:44:28)

Ms. Falkenrath stated with Dr. Miner retiring from the Department of Health (DOH) there has been discussion regarding who would take over signing off on the Standing Orders that are in place with the DOH. Ms. Falkenrath stated Dr. Angela Dunn has agreed to sign the Naloxone Standing Order. This will be posted to the Divisions website.

Ms. Falkenrath stated the Division has asked if Dr. Dunn would be willing to sign off on the Standing Order for COVID-19 Testing. Ms. Falkenrath stated if Dr. Dunn is able to sign off on this it will be posted to the Division website once it's been signed.

Ms. Falkenrath stated for the Standing Order for the Hormonal Contraceptive Questionnaire there is a physician who is willing to sign it and is currently working with the DOH on how to implement. Ms. Falkenrath stated as soon as the Division has received the information to move forward at that time the physicians name will be released so we are able to get the word out so the program can continue to be utilized.

Ms. Falkenrath stated the Vaccine Administration Protocol requires a physician be used for each pharmacy.

Ms. Falkenrath stated after speaking with the DOH each school that wants to use the Albuterol and Epinephrine Standing Order is required to get a participating physician to sign the Standing Order. Ms. Falkenrath stated, this is the only way we can get this Standing Order going for the State.

Ms. Falkenrath provided the Board with a copy of the Standing Order language the DOH had reviewed and agreed with. Ms. Falkenrath stated both Dr. Miner and Dr. Babitz have reviewed and approved the draft.

Questions and comments were discussed.

The Board discussed additional language they would like added to provide clarification.

Dr. Gunning made a motion to submit the Standing Order draft to DOH for a final review.

Mr. Hale seconded the motion.

The Board motion passed unanimously.

MOU DISCUSSION

Refer to audio for specifics. (Audio 1_02) (00:44:28 -45:21) & (Audio 1_03) (00:00 – 00:06:09)

The Board reviewed the FDA MOU.

Dr. Dunford asked Director Steinagel if he had any specific questions for Dr. Higley regarding the FDA MOU besides how many pharmacies would be affected.

Director Steinagel stated at this time his main question was if everyone wanted to do it.

Director Steinagel stated all his other questions have been answered. He does not have any concerns regarding the legal side or the workload side.

Director Steinagel stated he understands this will be discussed at the Advisory Pharmacy Compounding Education Committee meeting and anticipates another discussion with the Pharmacy Board before making a determination.

Dr. Gunning stated based on the conversation from the last Board meeting by not signing it, it would significantly impact compounding pharmacies in the state with the inability to ship to other states.

Dr. Higley stated the compounders that ship out of state would have the greatest impact.

Dr. Gunning stated she feels there are more that would be affected by this than what we are aware of and suggested sending out a pharmacy alert.

Dr. Higley stated he is leaning towards signing the FDA MOU so that there is not an impact on compounding pharmacies but agrees additional conversations are needed to make a final determination.

The Board made recommendations for information to be included in the pharmacy alert.

Dr. Dunford stated there is still plenty of time to discuss this since the MOU does not need to be signed until later in 2021, but she wanted to make sure it was discussed in case any changes to legislation were needed.

FINE AMOUNT DISCUSSION 58-17b-502(1)(p)

Refer to audio for specifics. (Audio 1 _ 03) (00:06:25 – 00:15:04)

Ms. Falkenrath stated during the last legislative session there was a new Rule that allowed for fine amount authority. Ms. Falkenrath stated she needs to implement in the Rule a fine amount for Utah Code 58-17b-502(1)(p), Unprofessional Conduct.

Ms. Falkenrath stated she needs the Boards feedback on what their recommendation would be for a fine amount. Ms. Falkenrath stated the fine amounts range from \$100 - \$10,000.

The Board reviewed the fine table in Utah Admin. Code R156-17b402 and stated this falls in the highest level of unprofessional conduct and poor ethics and recommended applying the highest tier amount is appropriate. The proposed tier would be \$2,500 - \$5,000 for the first offense and \$5,500 - \$10,000 for a subsequent offense

Mr. Ligori made a motion to accept the proposed fine schedule of \$2,500 - \$5,000 for the first offense and \$5,500 - \$10,000 for a subsequent offense for Utah Code 58-17b-502(1) (p).

Dr. Gunning seconded the motion.

The Board motion passed unanimously.

UTAH ADMIN. CODE R156-17b-612 (5) (a)

Refer to audio for specifics. (Audio 1 _ 03) (00:15:11 – 00:39:04)

Ms. Falkenrath stated this was a discussion item Greg Jones had requested for a topic of discussion.

Ms. Falkenrath stated the request is in regard to the communication of a transfer of a prescription between a pharmacist, pharmacy intern, or DMP's as authorized. Does it need to be communicated verbally over the phone, or is a fax sufficient?

Ms. Falkenrath stated the Division has received calls and faxes regarding prescription transfers or the transfer of an entire patient profile from one pharmacy to another pharmacy. Ms. Falkenrath stated there is a question of whether the patient requested to have all of their medication information transferred or just one medication.

Questions and comments were discussed.

The Board stated they do not feel receiving a fax is determined to be the final communication. The Board stated if there are any questions regarding a transfer it should not be an issue if the pharmacy follows up with the patient and or transferring pharmacy to confirm and verify a prescription transfer.

Ms. Hawks asked if the language allowed for a pharmacy technician to follow up, even though they are not able to do the transfer, they can still confirm what needs to be transferred.

Ms. Falkenrath stated additional language can be crafted to add the pharmacy technician.

The Board discussed additional recommendations for changes or updates to the language.

Ms. Hawks made a motion to approve the current proposed language changes.

Mr. Ligorì seconded the motion.

The Board motion passed unanimously.

Mr. Hale made a motion for a break.

Dr. Gunning seconded the motion.

The Board motion passed unanimously.

The Board took a break at 10:40 A.M.

The meeting resumed 10:50 A.M.

FLAVORING DISCUSSION

Refer to audio for specifics. (Audio 1 _ 03) (00:40:17 – 00:45:06) & (Audio 1 _ 04) (00:00 – 00:15:47)

Dr. Dunford stated this has been a continued discussion regarding flavoring and cutting out the addition of flavoring in certain circumstances from the compounding definition.

Dr. Dunford stated it has previously been discussed when using less than 5% of the total volume did not make a clinically significant change in the product.

Dr. Dunford stated Ms. Falkenrath has recommendations for draft language and take the information out of the definition of compounding.

Ms. Falkenrath stated the information is in the definition and she has drafted two different options for language changes based on information provided during the Rule hearing as well as previous Board meeting discussions.

The Board reviewed information provided by Ms. Falkenrath for proposed changes to the language for R156-17b-102.

Dr. Gunning stated the second draft is clearer and distinctly separates the flavoring agents. Dr. Gunning stated flavoring does not include reconstitution or other actions that are performed within accordance to manufacturer directions
Questions and comments were discussed.

The Board discussed additional language changes.

The Board recommended the Advisory Pharmacy Compounding Education Committee review the draft language at their December 15, 2021, electronic meeting.

Dr. Higley stated this could be added to the Advisory Pharmacy Compounding Education Committee agenda and bring any recommendations back to the next meeting. Dr. Higley stated he feels the addition of flavoring should not be added to the definition of compounding.

TECH IN TRAINING RATIO DISCUSSION

Refer to audio for specifics (Audio) ((Audio 1 _ 04) (00:15:47 – 00:37:57) & (Audio 2) (00:00 – 00:16:55)

Dr. Daery stated with all the issues pharmacies are currently facing with COVID-19 and beyond there has been a recommendation to increase the ratio of technicians in training during an emergency situation.

Dr. Daery stated she would like to make the recommendation to adjust the ratio from one to two technicians in training for one pharmacist. And include language that does not dismiss the pharmacist, pharmacy intern, pharmacy technician, or other employees from their legal duty of creating a safe work environment for the pharmacy.

Ms. Falkenrath stated the Division Director has the authority to grant waivers under the declared emergency for a temporary change. For something permanent the Board would need to make recommendations to change the Rule.

Questions, comments, and concerns were discussed.

Mr. Hale made a motion for the Board of Pharmacy recognizes that a pharmacy may have two technicians in training per pharmacist per shift during the pandemic.

Dr. Daery seconded the motion.

Mr. Ligori voted in favor.

Dr. Sheard, Dr. Gunning opposed.

Ms. Hawks abstained.

Dr. Dunford stated that puts the Board at a tie.

Additional questions, comments, and concerns were discussed.

Ms. Falkenrath stated Dr. Dunford can vote and make the final decision.

Dr. Dunford stated based on the current motion she would vote no. Dr. Dunford stated she would agree to an amended proposal identifying who else can be on staff to support the pharmacy technicians in training.

Dr. Sheard stated he understands the need and even with the amendment he is still concerned with the safety of the pharmacy with too many new members.

Dr. Sheard stated even though he know it happens the pharmacy technicians responsibility is not to supervise pharmacy technician in training.

Ms. Hawks made a motion to amend the previous motion to increase the pharmacy technician in training ratio to two per pharmacist per shift, provided there is also a licensed pharmacy technician or pharmacy intern on staff and only during the duration of the pandemic.

Dr. Daery seconded the motion.

Mr. Hale, Mr. Ligor, and Dr. Gunning voted in favor.

Dr. Sheard opposed.

The Board motion passed.

Dr. Dunford stated this recommendation will be forward to Director Steinagel for review and approval for a waiver during the pandemic.

Dr. Dunford stated this will continue to be a topic of discussion

E-PRESCRIBING DISCUSSION

Refer to audio for specifics (Audio) Part 2 (00:17:00 – 00:27:27)

Dr. Dunford stated there is a law change in the Controlled Substances Act requiring Controlled Substances be E-Prescribed starting in 2022. Dr. Dunford stated Medicare Part D and the Support Act have the requirement that all controlled substance paid for by Medicare Part D also be E-prescribed by 2022.

Dr. Dunford stated she has been approached about some waivers that may be allowed in certain circumstances as indicated in Statute. Dr. Dunford also stated that because this information is in the Controlled Substances Act, it affects all professions that prescribe controlled substances.

Dr. Dunford asked Mr. Marx which Board will be making the final recommendations for E-Prescribing exceptions and waivers.

Mr. Marx stated except for emergency situations, there is not a plan to allow any exceptions or waivers.

Mr. Marx stated specific defined exceptions or waivers will be defined in the Controlled Substances Act Rule.

Mr. Marx stated he would like to have the Boards most affected by this change

weigh-in before the Division makes the final decision.

Mr. Marx stated the BOP is the most proactive Board when it comes to Rules. Where this is going to impact pharmacists substantially and by involving the BOP Mr. Marx stated he feels we will get the best possible Rule.

Mr. Marx stated the whole purpose with this is to reduce fraud.

Dr. Dunford asked what the BOP needs to do to keep this moving forward.

Mr. Marx stated the plan is to keep this in front of the BOP and the Physicians Board as things move forward.

Dr. Dunford stated the BOP will need to continue to discuss having software available to pharmacies that allow for electronic transfer of a controlled substance prescription since this will be a barrier to this requirement of E-Prescribing controlled substances.

Dr. Dunford stated this will be discussed at the next meeting.

NEWSLETTER (FEBRUARY, MAY, AUGUST, NOVEMBER)

Refer to audio for specifics (Audio) (00:27:50 - 00:35:45)

The Board reviewed and discussed the items to be featured in the next newsletter.

Dr. Dunford reviewed the article Dr. Gunning and Chris Eppich, Pharm D Student provided regarding shoulder injury related to vaccine administration. The Board discussed sending this out in an alert as well as being featured in the next Newsletter.

Mr. Ligori will submit an article regarding the Role of the Public Member on the Board of Pharmacy and what the requirements are to be eligible to serve.

LUNCH BREAK

The Board took a lunch break at 12:12 P.M.

The meeting resumed at 1: 30 P.M.

APPOINTMENTS:

COMPLIANCE REPORT – SICILY HILL

Refer to audio for specifics (Audio 3) (00:00 – 00:05:20)

Ms. Hill reviewed the compliance report as provided.

CENTRAL DRUG PHARMACY, LLC, DBA BOUNTIFUL DRUG, PUBLIC REPRIMAND

Out of Order

Refer to audio for specifics (Audio 3_01) (00:17:30 – 00:29:11) & (Audio 3_02) (00:00 -00:03:05)

Dr. Gunning conducted the interview with Mary Eilertsen, the PIC for Central Drug Pharmacy, LLC, DBA Bountiful Drug.

Dr. Eilertsen discussed what brought the pharmacy before the Board and what steps the pharmacy has taken to address and correct.

Comments and questions were discussed.

The Board reviewed the information provided by the pharmacy.

Dr. Gunning made a motion to accept the corrective action plan addressing the issues of Central Drug Pharmacy's Public Reprimand.

Mr. Hale seconded the motion.

The Board motion passed.

The Board found Central Drug Pharmacy, LLC, DBA Bountiful Drug IN COMPLIANCE.

Central Drug Pharmacy, LLC, DBA Bountiful Drug does not need to meet with the Board any further at this time.

ROCK CANYON PHARMACY, PROBATION REVIEW

Out of Order

Refer to audio for specifics (Audio 3_01) (00:06:16 – 00:17:25)

Introductions were made.

Ms. Hawks conducted the interview with Tom Jensen, the PIC for Rock Canyon Pharmacy.

Dr. Jensen met with the Board to request an extension of time for the training requirement. Dr. Jensen discussed recent events that have affected the pharmacy, including the unexpected passing of the owner, that have delayed their progress

Ms. Hawks made a motion to extend timeframe for training to be completed March 31, 2021

Dr. Gunning seconded the motion.

The Board motion passed unanimously.

The Board found Rock Canyon Pharmacy IN COMPLIANCE.

An appointment was made to see Rock Canyon Pharmacy in April.

TIFFANI NELSON, EXTENSION

Refer to audio for specifics (Audio 03_02) (00:11:30 - 00:28:04)

Dr. Daery conducted the interview with Dr. Nelson.

Dr. Nelson met with the Board to request an additional extension of time on her temporary pharmacist license that expires on February 21, 2021. Dr. Nelson stated due to

personal circumstances she is concerned she will not have enough time to complete all her requirements and asked for some additional time on her license.

Dr. Nelson previously met with the Board on October 27, 2020, when the Board granted her approval to retake the NAPLEX exam for the fourth time. Due to the amount of time Dr. Nelson has been out of school the Board requested she complete additional hours of practice in a pharmacy. The Board asked Dr. Nelson to complete all requirements by the time her temp pharmacist license expired.

Based on the information provided at the October meeting, the Board determined Dr. Nelson may have been issued her temporary pharmacist license in error. Because Dr. Nelson needed to complete additional hours her license was left active.

Dr. Daery stated based on the information provided the Board is unable to extend her license any further. The Board advised Dr. Nelson to complete her hours and if she was unable to complete the exams by the time her license expires on February 21, 2021, she would have to discontinue practicing but would still be allowed to take the exams without holding a license.

The Board wished Dr. Nelson good luck on her exams.

Dr. Nelson thanked the Board for their time.

NEXT SCHEDULED MEETING: Tuesday, January 26, 2021

ADJOURN: Meeting adjourned at 2:53 P.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.

January 29, 2021
Date Approved

(ss) *Carrie B. Dunford*
Carrie Dunford, Chairperson
Utah Board of Pharmacy

29 Jan 2021
Date Approved

(ss) *Jennifer Falkenrath*
Jennifer Falkenrath, Bureau Manager
DOPL