

DRAFT MINUTES
UTAH BOARD OF PHARMACY
August 23, 2022 | 8:30 A.M.
North Conference Room
160E 300 S Salt Lake City UT
Hybrid Meeting- In Person and Electronic

DUE TO COVID 19, Electronic attendance was available.

CONVENED 8:34 A.M.

ADJOURNED: 12:51 P.M.

DOPL STAFF PRESENT:

Bureau Manager: Lisa Martin
Board Secretary: Maree Christensen
Lead Investigator: Camille Farley
Pharmacy Prgrm Specialist: Jim Garfield
Outreach Specialist: Ashley Beyer
Investigator: Silmara Charleworth

Investigator: Kalia Silcox
Investigator: Johnathan Evans
CSD Admin: Jeff Henrie
Compliance Specialist: Jennifer Johnson
Assistant Director: Deborah Blackburn

BOARD MEMBERS PRESENT:

Chair: Carrie Dunford, Pharm-D
Karen Gunning, Pharm-D, 10:30am
Sepidah Daeery, Pharm-D

Gary Hale, R.Ph.
Autumn Hawks, Pharmacy Technician
Shaun Curran, PA CS, Public Member

BOARD MEMBERS NOT PRESENT:

Vice Chair: Christopher Sheard, Pharm-D

GUESTS IN ATTENDANCE ELECTRONICALLY

Adam Gee
Adam Jones – Utah Pharmacy Association
Ben Berertt – Utah Family Pharmacies
Brian Bothwell
Bryan Holt
Chad Moss
Chris Christensen – Stapley Pharmacy
Cliff Holt
Crystal Grimes - Lees Pharmacy
Dave Davis - Utah Retail Merchants
Association
Donelle Perez – Peterson’s Fresh Market
Elizabeth Miller
Erin Johnson – Roseman University
Greg Jones – Harmons Pharmacy
Hali O’Malley - MedQuest Pharmacy
Jennifer Healey

Jennifer Strohecker – Department of Health
and Human Services
Jessie Leyva
Kathryn Simpson
Kathy Varley
Kelly Barland – University of Utah
Redstone Pharmacy
Kirsann Humpreys Bacon - Department of
Health and Human Services
Laura Gifford
Lindsey Kisielewski
Mark Brinton – Utah Medical Association
Mark Johnston
Michael Kiley
Michael Kiley
Michelle Wood
Nicole Laughton
Rich Bishop – Smith’s Food & Drug

RJ Evans – MedQuest Pharmacy
Roxana Hedges - University of Utah
Redstone Pharmacy
Ryker Blair – MedQuest Pharmacy

Sara Watson
Shane Gurley
Trenton Petersen

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

ADMINISTRATIVE BUSINESS:
CALL MEETING TO ORDER

Dr. Dunford called the meeting to order at 8:34 A.M.

REVIEW AND APPROVE JULY 26, 2022 MINUTES *(Audio 00:05:24)*

Ms. Hawks made a motion to approve the minutes with revisions as discussed.

Dr. Hale seconded the motion.

The Board motion passed unanimously.

VOTE CHAIR & VICE CHAIR *(Audio 06:34)*

Dr. Hale made a motion to defer vote Chair & Vice-Chair until the September Meeting.

Ms. Hawks seconded the motion.

The Board motion passed unanimously.

DISCUSSION ITEMS:

INVESTIGATIVE REPORT—CAMILLE FARLEY *(Audio 00:07:13)*

Lead Investigator Farley presented the pharmacy report for July, as provided.

Dr. Dunford expressed concern due to the increased amount of letters of concern.

Ms. Farley explained that the letters of concern were mostly related to violations from random compounding inspections.

Ms. Farley still hasn't seen the NABP newsletter.

Ms. Martin stated she will follow up with this.

CSD UPDATE—JEFF HENRIE *(Audio 00:11:53)*

Mr. Henrie presented the CSD update.

Utah hosted a regional PDMP (prescription drug monitoring program) closed door meeting, with 23 PDMP administrators in attendance. Utah's PDMP is more similar to other states, than originally thought. Mr. Henrie stated the CSD webpage had been updated to include icons for help & external links, with medical cannabis being integrated into the CSD database and multifactor authentication has now be activated. Mr. Henrie stated the electronic prescriptions are gradually increasing.

DOCUMENT STORAGE *(Audio 00:28:45)*

Dr. Dunford asked how DOPL viewed the inventory record term 'readily available', in relation to a physical copy and an inventory list stored electronically at a pharmacy.

Ms. Farley stated the DEA pharmacist manual states, 'shall be maintained in a written, typed written or printed form at the registered location'.

Dr. Dunford asked if any of the letters of concern were due to not having a physical copy of the inventory record at the time of inspection.

Ms. Farley clarified that the letters of concern were due to not having any inventory records at the time of the inspection. The investigation team sent out a pharmacy alert at the end of July that indicated a pharmacy must have inventory lists readily available as per the DEA pharmacist manual. Ms. Farley stated the DEA required 2 years of a physical copy whereas DOPL required 5 years.

Dr. Dareey asked if it would be acceptable for a pharmacy to store 2 years of inventory records in the pharmacy and the rest electronically.

Ms. Farley clarified the term readily available was to have an inventory list that a pharmacy could produce to investigations at the time of inspection.

Mr. Davis queried why DOPL required 5 years whereas DEA only required 2 years of inventory records.

Ms. Farley clarified that it had been 5 years for as long as she can recall. Ms. Farley also commented that Medicaid and insurances could possibly require 7 – 10 years of inventory records.

Dr. Dunford recommended the switch from the DOPL 5 year inventory retention to 2 years.

Dr. Hale recommended record retention of 2 years in a pharmacy and 3 years electronic; due to endless paperwork.

Mr. Davis, commented the need for DOPL to be in sync with the DEA.

The Board discussed an update for rule language R156-17b-603 (2)(b)- Operating Standards - Inventory Requirements, to include the wording electronically available.

Dr. Dunford recommended to discuss this language in further detail at the next Board meeting.

ULIPRISTAL GUIDANCE (*Audio 01:30:23*)

Dr. Dunford shared Oregon's guidance document and requested the Board's feedback with the previous model drafted at last month's meeting, compared to Oregon's model.

Dr. Dunford discussed Dr. Sheard's concerns that Ulipristal is a category X classification in regards to pharmacists not needing to complete a pregnancy test to prescribe.

Dr. Gunning discussed that all contraception are category X and it isn't really an issue.

Dr. Gunning stated the advantages associated from using Oregon's guidance model; limited update requirements and pharmacists would be in a position of guidance to the patient. Dr.

Gunning stated the Utah Ulipristal guidance document will need to include a limitation of patients being at least 18 years old to comply with the minor consent laws.

Dr. Hale stated that he is in agreement with the Oregon's guidance language that include 18 years or older, which in turn, will increase the access.

Mr. Brinton from UMA (Utah Medical Association) commented on the potential dangers for pregnant women, when prescribing Ulipristal; as it has not been studied in pregnancies and suggested to have a red flag, when prescribing.

Dr. Gunning stated the Ulipristal guidance document is an addendum to the current hormonal standing order, therefore the pharmacist would know not to prescribe to women who could be pregnant, it is common practice for the pharmacist to ask standard of care questions when prescribing. Dr. Gunning stated that Ulipristal is not handled any differently than other emergency contraceptives such as levonorgestrel.

Dr. Dunford requested Board members look at the Ulipristal questionnaire to see if it could be consolidated. Dr. Dunford requested this be discussed at the next Board meeting.

RULE UPDATES (*Audio 00:51:41*)

Ms. Blackburn provided updates for the rule changes as discussed in previous meetings and due to the legislative session.

The Board discussed and gave feedback and concerns as needed.

R156-17b-608 –Delivery Via United States Postal Service, Licensed Common Carrier, or Supportive Personnel.

The Board had no concerns with this section.

R156-17B-612(b) – Operating Standards - Insulin Prescriptions and Diabetic supplies.

Ms. Blackburn stated the rule could include the Divisions pharmacy webpage address for additional information relating to therapeutic supplies in addition to the supply list.

Dr. Dunford asked for feedback regarding the idea of the webpage being included on the rule update section. Dr. Dunford stated she much preferred the list without the webpage address.

Dr. Hale agreed with Dr. Dunford's statement.

R156-17b-610.6 – Hospital Pharmacy Dispensing Prescription Drugs to Patients at Discharge to Meet a Patient's Immediate Needs.

The Board had no concerns with this section.

58-17b-901 –Operating Standards – Charitable Prescription Drug Recycling Program.

Ms. Blackburn stated there are no changes to this section; however, she wanted to bring it before the Board in relation to the section (5) (a)-controlled substances.

Dr. Dunford stated controlled substances cannot be accepted back from a patient except for destruction and there are requirements to be an approved location to accept those returns.

Dr. Dunford requested the language in this section remain as it is currently written.

R156-16b-628 – Operating Standards – Prescriptions Issued Within the Public Health System.

Ms. Blackburn stated a guidance document needs to be drafted in relation to 58-31b, Nurses Practice Act.

Ms. Blackburn discussed topics that could be included in the draft guidance document including; labeling, record keeping, patient counseling, purchasing and distribution, operating, treatment, quality of care and storage requirements.

Dr. Dunford stated the Board would need to partner with the Department of Health to draft the document.

The Board had no concerns.

Ms. Blackburn stated that she could compose the initial draft the document.

R156-17b-303(a) – Qualifications for Licensure –Pharmacist, Pharmacy Intern, and Pharmacy Technician – Education Requirements.

Dr. Dunford stated a resident or fellow that have graduated with a pharmacy degree are licensed pharmacists. Dr. Dunford stated the language is outdated and suggested to remove 303(2)(b).

Dr. Hale agreed with Dr. Dunford's statement.

R156-17b-601 & 102(1)(a)(b) - Operating Standards – Pharmacy Technician and Pharmacy Technician Trainee. & Definitions.

Dr. Dunford asked if the wording Pharmacy Technicians University should be left in.

Ms. Hawks stated that she remembers it was discussed in a previous meeting leave it in until after the date had past.

Dr. Dunford stated to leave the language as is.

Ms. Hawks made a motion to approve the rule updates with revisions as discussed.

Dr. Hale seconded the motion.

The Board motion passed unanimously.

Dr. Dunford requested rule sections R156-37-603(10) and 58-37-22(3) be removed.

Dr. Hale made a motion to remove sections R156-37-603(10) and 58-37-22(3) as discussed.

Ms. Hawks seconded the motion.

The Board motion passed unanimously.

EXTENSION REQUEST GUIDELINES (*Audio 01:53:00*)

Ms. Martin discussed with the Board a drafted DOPL extension request form; to ensure best information is obtained to determine if an extension should be granted.

Dr. Hale commented that the form seems streamlined enough to make an educated decision.

Ms. Martin stated that DOPL will use this form going forward.

OUTREACH TOPICS (*Audio 2:13:27*)

Dr. Dunford requested topics for outreach that will assist in educating pharmacists and the public.

Dr. Hale stated he would like to draft out a formal letter that pharmacists can send to physicians as a reminders to e-prescribe.

Dr. Dunford reviewed the topics of e-prescriptions, insulin emergency refills, and oral contraception.

Ms. Grimes from Lee's Marketplace Pharmacy, queried about the injunction relief, regarding communication going out to the physicians; as they are not really be aware of the requirements of pharmacists from the DEA.

Dr. Dunford clarified that the Board had previous discussions on the injunction relief and have not had any communication regarding this; maybe this should go to the Physicians Board first.

Dr. Hale stated prescribers are not aware of the ICD-10 codes that pharmacies are having to follow; which is tied into the injunction relief. Dr. Hale discussed the issues surrounding the ICD-10 code between the pharmacies and the prescribers; a pharmacy refuses to fill the prescription, prescribers are sending it again to a different pharmacy; the situation needs to be addressed appropriately.

Dr. Dunford stated that this topic should be addressed at the Physician, Dental and Controlled Substance Advisory Board meetings.

Dr. Dunford discussed the need for educating the public, pharmacies, and prescribers on certain topics that were discussed previously with Ms. Beyer DOPL's Outreach Specialist.

Ms. Beyer discussed the ways that outreach could assist including; press releases, social media, online resources, emails, and free educational courses.

Dr. Gunning commented that BYU women's health group may be willing to work with Ms. Beyer.

Mr. Jones from Harmon's pharmacy, discussed the need for pharmacists to be informed prior to any press releases being sent out to the public.

The Board discussed prioritizing the previously discussed outreach topics; oral contraceptives, insulin emergency refills and e-prescribing for Ms. Beyer to focus the outreach on.

INSULIN EMERGENCY FILLS *(Audio 01:56:05)*

Dr. Dunford discussed the emails received from advocacy groups, which stated insulin emergency refills being made available OTC (over the counter) and pharmacy prescribing requirements adjusted. Dr. Dunford stated the FDA has authority to change insulin availability to OTC.

Dr. Gunning raised concerns that pharmacists wouldn't have time to provide the same standard of care as a physician does when refilling the prescription; and that making all insulin OTC may not be the best solution as more evaluation and patient care should be given to these patients.

Dr. Dunford stated in order for the Board to move to an insulin prescribing program like Pep and Prep they would need to work with the Department of Health to identify if there is a need for this, and a guidance document would need to be drafted that would include a thorough evaluation similar to a physician.

Mr. Brinton stated what the advocacy groups have recommended isn't supported by state law; for this to happen the state law would need to be changed.

Dr. Dunford suggested future communication with the advocacy groups should be directed to the Department of Health to assist in providing resources for the patients.

Dr. Dunford asked if pharmacists are comfortable filling the 60 day emergency insulin request.

Dr. Gunning stated the issue with a pharmacist being uncomfortable in filling the request could be in relation to audits and other ramifications.

Dr. Hale stated the way the rule is written it seems to be working and solving the issue.

Dr. Dunford suggested to include the insulin emergency refill as an outreach topic in order to communicate relevant information to pharmacists and the public.

MPJE/NABP *(Audio 02:07:49)*

Dr. Dunford stated NABP is seeking pharmacists that are on the Board to attend the MPJE/NABP discussion in Chicago or online on September 7th and 8th.

Dr. Dunford stated she is able to attend on the 9th.

Dr. Hale stated that he is available on the 7th.

Dr. Daery stated she may be available on the 8th.

Dr. Dunford requested resolutions from the Board to take to the National NABP meeting.

Dr. Dunford stated any topics can be emailed to her.

EMERGENCY HORMONAL CONTRACEPTION

This topic was included with the Ulipristal guidance.

NEWSLETTER TOPICS *(Audio 03:40:06)*

Dr. Dunford stated that she and Dr. Gunning will bring back topics from the NABP for newsletter topics. This item will be discussed at the September meeting.

APPOINTMENT ITEMS:

COMPLIANCE REPORT—JENNIFER JOHNSON *(Audio 03:15:46)*

Ms. Johnson presented the Compliance report for July as provided.

Super Drug & Herbal Store fine \$10,425 to be paid by November 9, 2022, remains unpaid.

Spence's North Pharmacy issued a 5 year probation, last met with the Board August 2021, new PIC – Bryan Holt and have submitted corrected documentation.

SUPER DRUG & HERBAL STORE, PROBATIONARY INTERVIEW *(Audio 03:21:11)*

Dr. Hale conducted the interview asking Mr. Fitzgerald, representing Super Drug & Herbal Store for an update.

Mr. Fitzgerald updated the Board as to his staffing situation with three main employees resigning last month and he was unaware that the required CE's were due at this meeting, Mr. Fitzgerald provided an update as to a new employee who recently completed 16 hours of compounding continuing education.

Dr. Hale made a motion to accept the 16 hours of continuing education completed by Super Drug & Herbal Store's new employee; and required Mr. Fitzgerald to complete the required 4 hours of compounding continuing education by the September 27th meeting.

Dr. Daeery seconded the motion.

The Board motion passed unanimously.

An appointment was made for Mr. Fitzgerald to meet with the Board on September 27, 2022 meeting.

SPENCE'S NORTH PHARMACY, PROBATIONARY INTERVIEW *(Audio 03:30:02)*

Dr. Hale conducted the interview asking Mr. Holt, representing Spence's North Pharmacy for an update.

Mr. Holt informed the Board that he was hired October 2021. The pharmacy is under new management. The pharmacy is a non-sterile compounding site. Mr. Holt expressed interest in early termination.

Dr. Hale stated the 3 year early termination option would be a possibility after October 21, 2022 with submission of a second non-sterile inspection.

Dr. Dunford requested Mr. Holt submit a written letter to request the early termination, including an explanation for future maintenance of compliance.

An appointment was made for Mr. Holt to meet with the Board on October 25, 2022 meeting.

COORESPONDANCE (Audio 03:42:14)

NACDS; DEA policies

Dr. Dunford discussed the letter from NACDS (National Association of Chain Drugs Stores) concerning a conversation with the DEA. The letter stated no changes may be made on schedule 2 prescriptions.

Ms. Martin commented that the way Utah statutes are written, any allowance for prescription changes excluded schedule 2 prescriptions.

Ms. O'Malley from MedQuest pharmacy, stated that the letter that was sent out from NABP including information that they are working on communication with the DEA for clarification.

Mr. Jones from Harmon's pharmacy, stated he had received an email from NACDS; stating if information is omitted from a patient's prescription then it is not a valid prescription.

MEETING ADJOURNED: 12:51 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.

NEXT SCHEDULED MEETING: Tuesday, September 27, 2022

**2022 Board Meeting Tentatively Scheduled:
Oct 25, Nov 29, Dec 13**

Chairperson

Date

Bureau Manager

Date