

**MINUTES UTAH BOARD OF PHARMACY
ELECTRONIC MEETING
JULY 28, 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: 2:48 P.M.

DOPL STAFF PRESENT ELECTRONICALLY

Bureau Manager: Jennifer Falkenrath
Bureau Manager: Larry Marx
Board Secretary: Lisa Martin
Pharmacy/Health Program Specialist:
Jim Garfield

Chief Investigator: David Furlong
CSD Admin: Ron Larsen
Management Analyst: Carolyn Dennis
Investigator: Dan Briggs

BOARD MEMBERS PRESENT ELECTRONICALLY:

Chair: Carrie Dunford, PharmD
Vice Chair: Christopher Sheard, PharmD
Carl "Trip" Hoffman, PharmD,
Karen Gunning, PharmD

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

BOARD MEMBERS NOT PRESENT:

GUESTS ATTENDED ELECTRONICALLY

Dustin Grant- Roseman
University
Nathan Hagen- UofU
Health
RJ Evans
Samaya Shuput
Donelle Perez
Greg Jones- Harmons
Cliff Holt
Trevor Hawkins

Jeremy Olson
Ademola Are
Jared Memmott
Jennifer Healey
Joseph Miner- DOH
Matthew Higley
Tina Posey-Itubia
Richard Bowman, Smiths
Derek Monson
Hali O'Malley

Mark Brinton, UMA
Nathan Checketts
Marc Babitz- DOH
Rich Lakin- DOH
Michelle Neo-Itubia
Jaime Montuoro, Smith's Pharmacy
Erik Jorvig- Roseman University
Erin Johanson- Roseman University
Lorri Walmsley- Walgreens

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

**AMINISTRATIVE BUSINESS: Audio Pt 1
CALL MEETING TO ORDER**

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

READ AND APPROVE JUNE 23, 2020 MINUTES (0:05)

**Mr. Ligorini made a motion to approve the minutes with revisions as discussed.
Dr. Sheard seconded the motion.
The Board motion passed unanimously.**

INVESTIGATION REPORT (0:12)

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

CONTROLLED SUBSTANCE DATABASE (CSD) UPDATE (0:16)

Mr. Larsen provided updates regarding the CSD Database Mr. Larsen stated pharmacy techs and interns should be able to access the account. Mr. Larsen provided contact information for DTS for login issues.

DTS phone numbers are 801-538-5770 801-538-5440

CSD phone contacts are 801-530-6628 option 3 and csd@utah.gov

Dr. Dunford asked if the slides that were presented in the June meeting are available on the Division's website.

Mr. Larsen stated the goal is to have the presentation available however there are current programming issues that have delayed the ability to post the information. Mr. Larsen stated the RX gov has also found a technology issues with transferring the information to the CSD. Mr. Larsen stated a full-time programmer has been assigned to correct the issue.

DISCUSSION ITEMS:

SB 23 (0:28 & Audio Part 2)

Dr. Dunford welcomed Ms. Dennis to the meeting.

Ms. Dennis stated SB 23 allows the Division to license individuals via endorsement with certain provisions. Ms. Dennis stated Board discussion at the last meeting determined to keep the Utah MPJE. Ms. Dennis stated pass rate documentation has been received which supports the Board's decision to keep the exam as a requirement.

Dr. Dunford stated first time ACPE graduates have a steady pass rate of approximately 81%. Dr. Dunford stated there is a 52% pass rate for reinstatement or endorsement applicants. Dr. Dunford stated concerns of creating different standards for new graduates and endorsement applicants.

Dr. Gunning stated the report provided shows that the Utah MPJE should continue to be required.

Dr. Sheard stated based upon the numbers of the report it would appear the majority of new graduates would be from Utah schools and the box which shows applicants other than new graduates at such a lower rate supports maintaining the MPJE requirement.

Ms. Dennis stated the information provided by the Board will be included in the full Division report. Ms. Dennis asked if the Board would like to discuss pharmacy

technician endorsement map which has been created. Ms. Dennis stated there are several states that required an educational component which require the national exam; this exceeds Utah's current hour requirement. Ms. Dennis stated the second set of states do not require the national exam or a training program; however, those states have a requirement to show verification of current licensure and passing exam. Ms. Dennis stated the next set of states would need to hold the license for at least one year or present the lower tier license type and documentation of passing the national exam. The last set of states do not have a pharmacy technician license.

Dr. Dunford stated the provided information makes sense and is comfortable with the breakdown of requirements depending on which state the applicant is coming from.

Dr. Sheard stated that the on-the-job training is being phased out to help ensure all individuals are provided the same level of training. Dr. Sheard asked if the expectation will be upheld with this new provision of endorsement.

Ms. Dennis stated this will not change requirements for and Utah trained technicians; however, for those that are trained outside of Utah instead of requiring 1000 hours of training they will need to have at least one year of experience with a full license.

Dr. Sheard asked if there is a requirement for employment for the year that they have held a license in a different state.

Ms. Dennis stated SB 23 says "licensed practice for a year" however it doesn't define what that year is or an amount of required hours. Ms. Dennis stated typically we do not require documentation of employment as it is an attestation within the application; however, if there are questions or concerns about an individual's experience a request can be made for that information.

Dr. Dunford stated there is a provision in the rule that requires repeating the program if a license hasn't been obtain within 2 years of completing the training program.

Ms. Dennis read from SB 23 which doesn't indicate when the experience must be completed. Ms. Dennis stated as there isn't an endorsement provision for technician in Utah statute SB 23 will be the default requirement. Ms. Dennis stated the Board's concerns can be included in the report. Ms. Dennis stated other professions have stated similar concerns about the time-frame the year experience was obtained. Ms. Dennis stated she will speak with Ms. Blackburn about possible rule authority in correlation with this bill.

TECHNICIAN IMMUNIZATION TRAINING (Audio Part 2 0:21 & Audio Part 3)

UNIVERSITY OF UTAH

Mr. Hagen stated this program is similar to other programs that have been approved by the Board. Mr. Hagen stated the program will provide training in immunizations under the direction of a pharmacist. Mr. Hagen stated this program involves several modules and each module provides a completion certification which is required prior to moving forward to the next module. Mr. Hagen stated an annual review of skills will be required.

Mr. Hale asked if there have been any technicians that have provided immunizations.

Dr. Sheard stated his employer has had several technicians successfully provide immunizations

Mr. Ligori made a motion approving the immunization training program as presented.

Mr. Hale seconded the motion.

The Board motion passed unanimously.

SMITHS

Mr. Bowman reviewed the provided program stating training will include a blood-borne pathogens training, BLS course, storage, handling and administration. Mr. Bowman stated the pharmacy will maintain files with all training of each individual.

Dr. Sheard asked if the PIC will be training at each location or if there is a central training location.

Mr. Bowman stated training will be at each location under direction of the pharmacy manager to avoid large groups of trainees.

Mr. Hale made a motion approving the immunization training program as presented.

Dr. Hoffman seconded the motion.

The Board motion passed unanimously.

Mr. Hale made a motion to take a break.

Mr. Ligori seconded the motion.

The Board motion passed unanimously.

The meeting closed at 9:56 am.

The meeting opened at 10:01 am.

COVID-19 VACCINE (Audio Part ?)

Dr. Dunford reviewed the vaccine protocol and recommended adding allowance for Covid-19 or pandemics which would require compliance with procedures as determined by the CDC.

Dr. Babitz stated if a vaccine is provided by the federal government it would be administered by health department. Dr. Babitz stated once there is mass production of a vaccine then pharmacies should be part of the team for public administration. Dr. Babitz stated there are several vaccines being researched with questions such as how many doses would be required and how many vaccines will be approved.

Mr. Lakin stated the CDC anticipates a possible vaccine will be available in December; however, it is probable that the supply will be limited at that time. Mr. Lakin stated some assumptions of the vaccine include limited doses and initial efforts will be directed to the critical workforce; which is undefined at this time. Mr. Lakin stated providers must enroll with jurisdiction's immunization program; a process is being developed which provides a link to register.

Dr. Gunning stated she would like to see an addition to the protocol specific to covid-19 and not any possible pandemic.

Dr. Dunford stated she would like to work on an update to the protocol now due to the requirements of approving changes and getting each pharmacy to update and obtain required signatures.

Dr. Miner supported pursuing vaccine protocols now to be ready for when a vaccine becomes widely available.

Mr. Jones requested clarification for which program pharmacies would need to register with to receive the vaccine. Mr. Jones asked if the registration is through Vaccine for Children program (VFC).

Mr. Lakin stated registration would be through the flu only provider with VFC. Mr. Lakin stated this status will convert to Covid-19 vaccine provider. Mr. Lakin stated the intent of having pharmacies enroll now through the flu only system is to assist in preparedness. Mr. Lakin stated any pharmacy that is not already enrolled through the system at the time the Covid-19 vaccine is available will be delayed in obtaining the vaccine.

Dr. Dunford suggested including this enrollment information in the Newsletter.

Dr. Dunford asked what they should name the allowed Covid-19 vaccine in the protocol under approved vaccines.

Dr. Miner suggested listing Covid-19 as this is the commonly understood term for this specific disease.

Dr. Gunning made a motion to add Covid-19 to the vaccine protocol.

Mr. Hale seconded the motion.

The Board motion passed unanimously.

COVID-19 WEBSITE (Audio Part ?)

Dr. Dunford referred to the Covid-19 page of the Division's website. Dr. Dunford asked if there are any items that need to be updated or removed.

Ms. Falkenrath stated the state emergency licenses section should be removed as the Division is not currently offering this license type. Ms. Falkenrath stated one reason for this is there has not been a shortage of pharmacists in Utah at this time.

Dr. Dunford asked about the guidance for hydroxychloroquine that is still on the website.

Mr. Hale suggested removing this item as there isn't a shortage of the medication at this time.

Mr. Hale made a motion removing the hydroxychloroquine section from the Division's website.

Ms. Hawks seconded the motion.

The Board motion passed unanimously.

Dr. Dunford asked about the BLS and CPR requirement.

Ms. Falkenrath stated the live component of the training is not available at this time; however, she will reach out to the providers for an update.

Mr. Marx stated several courses are offering limited mannequin testing in-person.

Dr. Gunning suggested adding a link to the CDC's recommendations on immunization administration during the pandemic.

Dr. Dunford suggested adding links to CDC and Utah Department of Health. Dr. Dunford suggested updating guidance to refills during the pandemic.

Ms. Falkenrath requested the Board provide wording for the updated guidance.

INSPECTIONS (Audio Part 4 0:11)

Dr. Dunford stated there has been discussion concerning inspections during Covid-19.

Mr. Furlong stated self-inspections have been completed in the past and may be useful on a randomized basis. Mr. Furlong stated self-inspections allows an opportunity for training within the pharmacies.

Dr. Gunning asked about the idea of requiring self-inspections on an annual basis which could then be used by investigators.

Mr. Furlong stated support for the suggestion however, the requirement might need to be included in the rule. Mr. Furlong stated the inspection list could be provided on the Division website.

Dr. Gunning stated this might be helpful especially when there is a new pharmacist in charge (PIC).

Ms. Falkenrath stated surrounding states are allowing remote inspections. Ms. Falkenrath stated Nevada is requiring self-inspections which are then sent to a state investigator; however, in Utah requiring a self-inspection would need to be added to the rule.

Mr. Furlong stated there may be a higher success rate if the pharmacies are doing a self-inspection prior to an investigator conducting an onsite or remote inspection.

Mr. Hale stated support of self-inspections and remote inspections to ensure all requirements are being met.

Ms. Montuoro stated their facilities are accustomed to completing self-assessments and are doing electronic reviews presently.

Mr. Jones stated their facilities require PICs to complete an inspection once a year to assist with awareness of current rules and possible changes.

Dr. Sheard asked if the self-inspections would be submitted to the Division or maintained on site of each pharmacy.

Dr. Gunning suggested maintaining the inspections onsite as there isn't value in submitting the form to the Division.

Mr. Furlong agreed with Dr. Gunning to maintain reports on site, as submission to the Division would be an undue burden to DOPL staff as a result of the number of pharmacies in the state.

Dr. Dunford made a suggestion to add an attestation of completing a self-inspection on both the PIC change form and renewal form. Dr. Dunford suggested discussing self-inspections and virtual inspections in the August meeting.

Mr. Furlong suggested including a self-inspection for new pharmacies to assist in time-lines for opening new locations which would be followed up by an investigator within a year.

ADVISORY COMPOUNDING EDUCATION COMMITTEE (Audio Part 5 0:03)

Dr. Higley stated there will be some clarifying information added and a letter will be composed to be sent to all pharmacies by email about the committee and some FAQs concerning compounding questions.

Dr. Higley stated the topic of essential copy was a question that has been asked and the committee will draft some language for clarification. Mr. Higley stated USP 800 is finalized; however, it is not in effect due to appeals. Mr. Higley stated for USP 797 and 795 are not finalized and nothing will be adopted until those are finalized.

Dr. Dunford stated the next USP open forum discussion is on September 15th and there is a section on the Pharmacy webpage concerning the advisory committee meetings.

TEMPORARY POLICY ON PRESCRIPTION DRUG MARKETING ACT REQUIREMENTS FOR DISTRIBUTION OF DRUG SAMPLES DURING COVID-19 PUBLIC HEALTH EMERGENCY (Audio Part 5 0:10)

Ms. Falkenrath stated this policy would allow manufactures to ship prescription samples directly to the patient.

Dr. Dunford stated one key point in this policy is allowing the sample to be mailed directly to patient's home, this causes a concern due to lack of labeling. Dr. Dunford asked if there is anything in the rule which would address this policy.

Ms. Posey introduced herself and addressed the concern of labeling stating there would be an expectation that the virtual visit includes explanation of labeling requirements, administration instructions, and other pertinent information concerning the shipping of medication samples. Ms. Posey stated a signature will be required at the time of delivery.

Dr. Dunford stated concerns of patient knowledge and memory of the administration of medication after a time-lapse from the time of the virtual appointment to the time of medication delivery.

Ms. Posey stated there has been discussion which would require a letter be included with the delivery which would include administration instruction, which would not change the labeling. Ms. Posey stated the FDA has allowed this process on a temporary basis and they require following all request and receipt requirements; including storage requirements.

Dr. Sheard asked if the presentation of this policy is to inform the Board or if Board approval is required.

Ms. Posey stated each state must approve the plan to allow the policy to go into effect in their state.

Mr. Garfield referenced Utah statute 58-17b-610; which address rules for samples.

Dr. Gunning suggested tabling the remainder of the discussion for the August meeting as it is a more involved than previously imagined.

Dr. Dunford requested information on how the system will work specifically the concerns of instructions and labeling.

Ms. Posey stated they do have a workflow drafted that may need some adjustments due to several state's input. Ms. Posey stated she will contact Ms. Falkenrath with the workflow information and an appointment for the August meeting.

VETERINARY DRUG REFERENCE (Audio Part 5 0:34)

Ms. Falkenrath stated she was contacted requesting adding a veterinary drug reference for farm animals in the rule under operating standards. Ms. Falkenrath stated the cost of the change to each pharmacy. Ms. Falkenrath stated subsection K covers the option of maintaining the veterinary drug reference if the pharmacy requires this reference.

Dr. Sheard stated there is a limited amount of pharmacies that would utilize a specific veterinary reference.

Dr. Dunford stated the current rule doesn't specify that the reference must be human drug references specifically.

ALLERGY BUTLER (Audio Part 5 0:38 and Audio Part 6)

Ms. Falkenrath stated Mr. Loomis from Allergy Butler is present for this discussion.

Mr. Loomis stated the Physician Board had concerns about the collaborative practice agreement as provided. Mr. Loomis requested the Pharmacy Board provide a statement or motion that the collaborative agreement is within the scope of a pharmacist.

Dr. Dunford stated concerns of the plan not clearly stating how the patient would be referred to the pharmacist. Dr. Dunford stated an additional concern of lacking a standard procedure to return to the referring physician for care. Dr. Dunford also stated this plan is different as it seems the pharmacist is administering the test and interpreting them rather than a diagnosis and then a treatment.

Mr. Loomis stated the pharmacist wouldn't be able to perform the allergy test unless a referral and order was received from a physician of the patient's choice.

Mr. Hale stated the diagnosis part is a big concern for the Physician Board and the agreement is with a physician outside of Utah.

Mr. Loomis stated the two items removed from the original plan are administering medications and diagnosing.

Mr. Marx stated one concern from the Physician Board was if this is within the standard of care of the practice of pharmacy and the use of a computer program to decide what allergy treatment to provide. Mr. Marx stated another concern was who would provide standard of care and safe-guards as discussed.

Dr. Dunford stated this is not standard practice for pharmacists and may recommend having it reviewed by an allergist. Dr. Dunford recommended the pharmacy hold a Class A license.

Mr. Brinton stated the Physician Board was skeptical of the plan due to the collaborative physician being located in another state and is not an allergist. Mr. Brinton stated the Physician Board was also concerned with patient safety. Mr. Brinton stated these types of shots are typically administered in a physician's office and the patient must wait in that office for some time prior to being discharged for safety reasons.

Mr. Marx stated an allergist on the Physician Board did express concerns of the safety of administering those treatments in a residence. Mr. Marx stated there have been incidents of patients requiring immediate attention.

Dr. Dunford stated concern of the collaborative physician being an anesthesiologist in another state. Dr. Dunford stated there should be a way for the administrator of the agreement to be available for any need for the patient care.

Dr. Dunford stated the supervision, administration, and approval rights are within the Physician Board's. Dr. Dunford stated the Pharmacy Board has concerns about the presented collaborative plan.

Dr. Gunning made a motion to take a break.

Mr. Ligori seconded the motion.

The Board motion passed unanimously.

The meeting closed at 12:43 pm.

The meeting opened at 1:03 pm.

NEWSLETTER (Audio Part 9 0:11)

Dr. Dunford asked what the deadline for the next newsletter is.

Ms. Falkenrath stated the next newsletter is in November and the deadline is Oct 1st

Dr. Dunford asked Ms. Hawks about the article concerning the controlled substance database.

Ms. Hawks stated she will continue working with Mr. Larsen and will try to include some visuals aids as well.

Dr. Dunford asked if we know who receives the newsletters.

Ms. Falkenrath stated the newsletter is sent out to anyone that has signed up to receive it.

Dr. Dunford stated the importance of getting the information to pharmacy technicians as it is important to understand the penalties in connection with misuse of the database.

BREAK

APPOINTMENTS:

COMPLIANCE REPORT – SICILY HILL (Audio Part 7)

Ms. Hill reviewed the compliance report as provided.

SPENCE'S NORTH PHARMACY, PROBATION REVIEW (Audio Part 8 0:18 & Audio Part 9)

Dr. Dunford asked when Ms. Hales took over as the pharmacist in charge.

Ms. Hales reviewed her background and stated she took over as PIC in July.

Mr. Hale asked if Ms. Hales has read the stipulation for Spence's pharmacy.

Mr. Comp stated Ms. Hales has read a summary of the stipulation however has not read the full stipulation.

Mr. Hale reviewed the compliance of the pharmacy as of the start of probation.

Ms. Hales stated she has a check-list of the findings and the pharmacy has made updates.

Mr. Hale asked if the pharmacy is ready to start doing sterile compounding.

Mr. Comp stated they are not prepared to do sterile compounding at this time. Mr. Comp stated they were prepared to attend some training opportunities that were cancelled due to health concerns. Mr. Comp stated they are seeking online training options.

Dr. Dunford recommended Ms. Hales read the full stipulation as the pharmacist in charge.

Mr. Hale made a motion to set a follow-up appointment for July 2021.

Dr. Hawks seconded the motion.

The Board motion pass unanimously.

Dr. Dunford stated the supervisor report may be submitted to the Division; however, it is not a requirement of the stipulation.

ALI GHAZVINI, PROBATION REVIEW (Audio Part 7 0:08 & Audio Part 8)

Dr. Dunford asked Mr. Ghazvini for a review of events that resulted in a stipulation.

Mr. Ghazvini reviewed the events that lead to a probationary stipulation.

Dr. Dunford asked about the changes Mr. Ghazvini has implemented.

Mr. Ghazvini stated he now works for Wineagar's and has been mentored by the PIC Dominique Thurose. Mr. Ghazvini stated he has become more diligent with documenting, witnessing counts and discrepancies.

Dr. Dunford stated the two possible concerns with the original stipulation were for record keeping or diverting medication for personal use.

Mr. Ghazvini stated only certain people have access to the pharmacy and each employee has an individual code when logging into systems. Mr. Ghazvini stated more people had access to the pharmacy at his former place of employment.

Dr. Dunford stated it was never determined where the missing medications went. Dr. Dunford asked what Mr. Ghazvini's role is at his current pharmacy.

Mr. Ghazvini stated he is an hourly employee and the PIC is not a full-time employee.

Mr. Ligorini asked if Mr. Ghazvini plans on opening his own pharmacy when he is released from probation.

Mr. Ghazvini stated he is not considering opening a pharmacy at this time and intends to remain at the Wineagar's pharmacy. Mr. Ghazvini stated he is maintaining his continuing education and keeping more informed with changes within the profession.

Dr. Dunford suggested receiving information from the Mr. Thurose, the PIC prior to approving early termination.

Mr. Ligori made a motion requesting Mr. Ghazvini return for the August meeting with recommendations from Mr. Thurose.

Dr. Sheard seconded the motion.

The Board motion passed unanimously.

Dr. Dunford requested the last inspection form be included for Mr. Ghazvini's appointment.

MEDS FOR VETS (Audio Part 8 0:07)

The following individuals met with the Board for Meds for Vets interview:

Jan Erickson, Owner

Bill Stilling

Amanda Hansen, Compounding Manager

Chris Cox

Michelle Woods, Licensing Coordinator

Mr. Stilling stated as of the last meeting a full inspection was completed by two individuals with positive outcomes. Mr. Stilling stated the domino effect has continued with action taken in other states due to the Utah stipulation.

Dr. Dunford asked for a review of the completed inspection by Mr. Cox.

Mr. Cox stated he was able to complete an onsite inspection and all concerning items have been addressed and corrected. Mr. Cox states tracking and detail items have been addressed as well.

Dr. Dunford asked if the compounding processes are up to standard and safe for the pets which they are filling for.

Mr. Cox stated he is confident with the staff, the setting and procedures completed at the location.

Mr. Ligori made a motion recommending early termination of probation.

Ms. Hawks seconded the motion.

The Board motion passed unanimously.

SAM FLEGAL (Audio Part 9 0:22)

Dr. Gunning made a motion approving Kaitlyn Brown as supervisor for Mr. Flegal.

Mr. Hale seconded the motion.

The Board motion passed unanimous.

AHMED GHANEM (Audio Part 9 0:03)

Dr. Dunford asked about Mr. Ghanem's employment status.

Mr. Ghanem stated he was working in the Millcreek pharmacy at the time of the stipulation; however, he is currently unemployed. Mr. Ghanem stated he is seeking employment in the pharmacy profession.

Dr. Dunford stated there were several concerns with record keeping and reporting to the CSD at the Millcreek pharmacy. Dr. Dunford asked what Mr. Ghanem is doing to maintain the license.

Mr. Ghanem stated he is maintaining continuing education.

Ms. Hill stated Mr. Ghanem’s stipulation didn’t include a tolling provision and the required continuing education has been completed. Ms. Hill stated supervisor reports are submitted by noting he is not currently working in the field.

Dr. Gunning made a motion to set a follow-up appointment with Mr. Ghanem in January 2021.

Mr. Hale second the motion.

The Board motion passed unanimous.

NEXT SCHEDULED MEETING: Tuesday, August 25, 2020

ADJOURN: Meeting adjourned at 2:48 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.

Date Approved

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

Date Approved

(ss) _____
Jennifer Falkenrath, Bureau Manager DOPL