KANSAS STATE BOARD OF PHARMACY BOARD MEETING MINUTES December 10, 2020

Meeting Location: Due to COVID-19, the meeting was conducted virtually on the WebEx platform.

Members Present: Jonathan Brunswig, PharmD., President; Bill Walden, RPh., Vice President; Terica Gatewood, PharmD., Inv. Member; Tiffany Strohmeyer, PharmD.; Erick Axcell, PharmD.; Andrew Truong, PharmD.; Cheri Pugh, Public Member

Staff Present: Alexandra Blasi, JD, MBA, Executive Secretary; Jim Kinderknecht, R.Ph., Licensed Pharmacy Inspector; Carly Haynes, R.Ph., Licensed Pharmacy Inspector; Shelley Rosebrook, R.Ph., Licensed Pharmacy Inspector; Melissa Martin, Compliance Inspector; Kayla Montgomery, Compliance Inspector; Jennifer Donnelly, MPH, K-TRACS Assistant Director & Sr. Epidemiologist; LaTonyua Rice, PharmD, K-TRACS Pharmacist; Gayle Donaldson, K-TRACS Public Information Officer; Jackie Yingling, Assistant Director; Rachel Gardner, Administrative Assistant; Randy Forbes, JD, General Counsel

Opening

The President called the open meeting to order at 8:39am.

Administrative Proceedings

20-291 Nedra Winfield – pharmacy technician applicant

- Ms. Winfield appeared in person via video conference call.
- The Board's Executive Secretary gave an introduction of Ms. Winfield's appeal of the case.
- Ms. Nedra Winfield provided a brief statement regarding her offense history and application disclosure.
- Dr. Gatewood had several questions for Ms. Winfield relating to her offense history.
- The Board entered into closed session for KAPA deliberations at 9:01am. (Walden/Gatewood)
- The President reconvened the open proceedings at 9:11am.
- A motion was made and seconded for a roll call vote to approve Ms. Winfield's technician license. (Strohmeyer/Truong). President Brunswig – yea; Vice President Walden – yea; Dr. Gatewood – yea; Dr. Strohmeyer – yea; Dr. Truong – yea; Dr. Axcell – yea; Ms. Pugh – yea. Motion passed.

Board Discussion

COVID-19 Updates –

• <u>Guidance</u>: Following the October Board meeting, remote work was extended through February, to be revisited at that month's meeting. The Executive Secretary, Ms. Haynes, and Ms. Rosebrook continue to meet weekly to discuss necessary updates to the guidance. The Board is still receiving questions regarding the Federal PREP Act immunization authority versus the statewide vaccination protocol. KDHE and the State are making a big push to deploy more COVID-19 testing sites. Field hospital info has been included in the Board guidance and inspectors are at the ready - trying to be as responsive as possible to make sure adequate controls are still in place, while allowing pharmacists to serve in volumes/locales that were previously unforeseen. The Board *has* seen an increase in pharmacist immunization certification, but most technicians are still in process.

Legislation 2021 -

The Executive Secretary provided an additional overview of the Pharmacy Act revisions proposed for 2021 legislation. The Executive Secretary explained the legislative process for new Board members, and noted that the Board's staff, attorney, and stakeholders are the main supports in putting together updated language.

- In discussing the ongoing Telepharmacy Pilot Project, Ms. Rosebrook indicated monthly reports are not detailed and provide minimal information. The Board requested the Pilot Project provide a presentation at the February 2021 meeting.
- The Executive Secretary will notify the Insurance Commissioner regarding planned updates to the use of terms "pharmacy, Rx, apothecary, drugstore, etc." for Kansas business not registered as pharmacies.
- After discussion, the Board directed the Executive Secretary to add language to the bill draft allowing technicians to transfer prescriptions and receive orders for continuation of therapy.
- The Board discussed allowing pharmacist prescription adaptation but determined that a notification to the prescriber was a necessary part of the process.

Recess: The Board recessed at 10:55am. **Reconvene:** The Board reconvened at 11:05am

Board Discussion (cont.)

Regulations – Planned updates to Board administrative regulations include:

- Compliance regarding PIC inventory upon PIC change
- All PICs needing to pass the exam with 85%, not just new PICs
- Clarification of responsibility to notify Board of a new PIC
- Codification of 30-day extension for notification of new PIC
- Changing regulatory framework to define PIC responsibilities in one section (KAR 68-1-9)

After brief Board discussion, the Executive Secretary will revisit the new language here which states that if a pharmacist upon termination is not allowed to complete inventory due to concerns of diversion, another pharmacist may be designated to do so within the proper time frame. Concerns were raised as to the instance that the PIC and owner were the same person or upon a death.

FDA Guidance of Splitting Insulin Pen Boxes – Continued Board discussion from previous meetings.

Board Delegation of Authority Guidance Document -

A motion was made to ratify the Board Delegation of Authority guidance document. (Truong/Axcell) Motion passed.

2021 Officer Elections –

A motion was made and seconded to elect the following slate: President – Mr. Brunswig, Vice President and Alt Investigative Member – Mr. Walden, Investigative Member – Ms. Gatewood. (Strohmeyer/Truong) Motion passed.

Other Discussion Items – The Board has received a request for clarification from Walgreens and others as to the responsibility of pharmacists to council upon a refill. Tracie Bowman of Walgreens, and Nichole Cover of their Pharmacy Affairs Team, attended the meeting to discuss whether there is a need to counsel a patient for a prescription that is a continuation of therapy but not a refill (not the same prescription number). Ms. Haynes noted that this is currently required in the language of K.A.R. 68-2-20, which needs to be updated to recognize the continuation of therapy. The Executive Secretary noted that the Board is currently working on updates to this regulation and such changes will be included.

Reports

Attorney Report – Mr. Forbes noted that a question had been raised regarding a non-resident pharmacy's responsibility to maintain an adequate inspection within the 18 months prior to registration. Mr. Forbes determined that K.A.R. 68-7-12a refers both to type or quality of inspection/inspector conducted *and* the outcome of inspection. Mr. Forbes will clarify this language as he responds to the registrant.

Approvals

Stipulation & Consent Agreements -

- Motions were made and seconded to approve Stipulation & Consent Agreements as presented for cases 19-529 (Strohmeyer/Truong), 20-255 (Truong/Axcell), and 20-259 (Gatewood/Strohmeyer). Motions passed.
- A motion was made and seconded to reject the Stipulation & Consent Agreement for case 20-223 upon the recommendation from the Executive Secretary and the Board's attorney. (Gatewood/Walden) Motion passed.

Reports (cont.)

Board Member Reports – None.

Director Report -

- Budget The Executive Secretary presented to the Joint Budget Committee regarding the funding plan for K-TRACS. The Joint Committee commended the Board and stakeholders for crafting a viable plan. The Board submitted a budget appeal to the Division of Budget include the new 2020 Harold Rogers BJA Grant funding for FY2022 and FY2023. The Governor's budget will be released after the State of the State in the second week of January 2021.
- FDA MOU With the MOU finalized and released, the Board has one year to determine whether it will sign the MOU. A committee is already in place to review provisions and the Board's response on signing. Two concerns include that NABP is pushing to be the collections site for all the information, and that we don't know if reporting will be automated or require extra staff.
- DEA National PDMP RFP The DEA wants to establish a national prescription drug monitoring process, which would not be a protection tool, nor a doctor-shopper tool; just a tool for legal and disciplinary actions at the federal level. The Executive Secretary will continue to bring information to the Board as she learns more on the subject.

The Executive Secretary reminded the Board of meeting dates for 2021.

Approvals (cont.)

New Licensees & Registrants -

A motion was made and seconded to approve new Licensees & Registrants since October 20, 2020. (Walden/Strohmeyer) Motion passed.

Executive Session

A motion was made and seconded at 12:13pm to enter into executive session per K.S.A. 75-4319(b)(1) to discuss matters of non-elected personnel, and to include the Board's attorney until 12:31 and then to add the Board's Executive Secretary, and to return to the open meeting at 1:00pm. (Walden/Truong) Motion passed.

Executive Session: The President closed the meeting for the executive session at 12:13pm. **Reconvene:** The President called the open meeting back to order at 1:00pm.

Public Comment

- Kristin Villa with KU School of Pharmacy commented that Amazon has created a new pharmacy, through which transfer requests are being sent via fax and not straight from prescribers, causing concern that a bad actor(s) could take and use this information. In response, the Executive Secretary noted that the regulations are clear in this case, and that the Board investigates every complaint. She recommended that complaints be submitted with as much specific information as possible (ie., patient name, prescription number, etc.) rather than simply general pharmacy chain information, to allow staff to conduct a thorough investigation.
- Tyler with O'Brien Pharmacy expressed concern that the FDA MOU will greatly limit the business
 practice of many Kansas pharmacies shipping in- and out-of-state, and questioned whether the
 Board would be signing it, who would have input regarding that decision, and when an update on
 such might be received. The Executive Secretary responded that a working group has been formed
 with the Board's attorney, Board member, and staff to make the signing decision; that such decision
 will require stakeholder input; and that the Board's webpage on proposed regulations, etc. would
 include solicitations for public comment.

The Executive Secretary noted that the next Board meeting will be held on Friday, February 19th, 2021, and is anticipated to be virtual.

Adjourn: The President adjourned the meeting at 1:10pm.