KANSAS STATE BOARD OF PHARMACY BOARD MEETING MINUTES

December 2, 2019

Meeting Location: Board of Healing Arts Conference Room 800 SW Jackson, Lower Level Topeka, KS 66612

Monday, December 2, 2019

Members Present: John Worden, PharmD., President; Jonathan Brunswig, PharmD., Vice-President; Bill Walden, R.Ph., Investigative Member; Terica Gatewood, PharmD; Tiffany Strohmeyer, 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 Jones, Compliance Inspector; Jackie Yingling, Assistant Director; Reyne Kenton, K-TRACS Program Manager; Jennifer Donnelly, Assistant K-TRACS Director; Linda Blasi, LMSW, Public Service Administrator; Rachel Gardner, Administrative Assistant; Randy Forbes, JD, General Counsel; Loren Snell, JD, Administrative Law Judge.

ADMINISTRATIVE HEARINGS:

Case 18-793 Logan Abbott

- The Board was represented by Mr. Forbes.
- Logan Abbott appeared in person with counsel, Diane Belquist.
- Motion was made and approved to enter into a closed hearing to review protected health information, and including the Board's attorney, the Executive Secretary, the Compliance staff, KsPRN staff, and Mr. Abbott, his counsel, and family members. (Walden/Brunswig)
- Board Exhibits 1-17 and 19 were admitted.
- Respondent Exhibits A-N were admitted.
- Mr. Snell swore in Ms. Carly Haynes, inspector for the Board, who provided testimony.
- Board Exhibit 21 was admitted.
- Mr. Snell swore in Ms. Kelly Rockers, KsPRN Coordinator, who provided testimony.
- Ms. Belguist made objection to Exhibit 18 as to relevance and foundation.
- Ms. Belquist made objection to Exhibit 20 as to relevance, but Mr. Snell maintained its weight and admitted the evidence.

Recess: The Board recessed at 9:50am.

Reconvene: The Board reconvened the closed session at 9:57am.

- Ms. Stephanie Roberts, President of Change Your Life Enterprises, Inc., was called via phone to provide testimony. Mr. Snell stated on the record that his discretion to allow this call would not stand as any sort of precedent to allow individuals in the future to present their witness via phone. Mr. Snell swore in Ms. Roberts, who provided testimony.
- Mr. Snell recalled Ms. Rockers to finish her testimony.
- Ms. Belquist argued that Exhibit 20 was not relevant to Ms. Rockers' role in the case; Mr. Forbes objected; Mr. Snell admitted the evidence but cautioned the Board to assign it proper weight.
- Mr. Snell swore in Mr. Ralph Holbrook, CIPP Chair, who provided testimony.

Recess: The Board recessed at 10:59am.

Reconvene: The Board reconvened the closed session at 11:13am.

- Mr. Snell swore in Mr. Abbott, who provided testimony.
- Mr. Snell swore in Mr. Joe Heidrick, Assistant Dean, KU School of Pharmacy, who provided testimony.
- At 12:29pm, the Board entered into closed session for KAPA deliberations.
- Dr. Worden reconvened the hearing at 1:03pm.
- Motion was made and seconded that Mr. Abbott violated the Consent Order and that the Order
 of Suspension would be upheld by the Board for a period of one year beginning December 2,
 2019 and ending upon completion of one year of full compliance with the KsPRN program.
 (Gatewood/Brunswig) Mr. Walden abstained. Motion carries.

Case 19-427A Maniga Haney

- Ms. Haney did not appear for her scheduled hearing.
- Motion was made to issue an Order of Default, allowing Ms. Haney seven days to appeal before the Summary Order of the Board would become a Final Order. (Brunswig/Strohmeyer) Motion carries.

Call to Order:

The President called the open meeting to order at 1:10pm.

PUBLIC COMMENT:

None

BOARD DISCUSSION:

2020 Election of Officers

The terms for Dr. Worden and Mr. Lonergan will expire in April and they are not eligible for reappointment.

- Motion was made and seconded to nominate Dr. Brunswig as President. (Walden/Worden)
 Motion carries.
- Motion was made and seconded to nominate Mr. Walden as Vice President. (Brunswig/Gatewood) Motion carries.
- Motion was made and seconded to nominate Dr. Gatewood as the Investigative Member and Mr. Walden as the Alternate Investigative Member. (Worden/Strohmeyer) Motion carries.

Board Delegation of Authority

Motion was made and seconded to re-approve the Board's Delegation of Authority Guidance Document. (Walden/Gatewood) Motion carries.

The Board discussed adding a second meeting day to the February 2020 Board meeting to allow room for all agenda items, and will look at legislative break(s) in March. The Board discussed the future opportunity for Board members to conduct mock hearings in a pharmacy classroom setting, as it would be beneficial for school of pharmacy students to observe hearings and deliberations.

ADMINISTRATIVE HEARINGS (cont.):

Case 19-503 Mercedes Lozano- Ruiz

- The Board was represented by Mr. Forbes.
- Mercedes Lozano-Ruiz appeared in person without counsel.
- As no objections were made, Exhibits 1-3 were admitted as evidence.

- Mr. Snell swore in Ms. Lozano-Ruiz, who provided testimony.
- Ms. Lozano-Ruiz offered Exhibit A, proof of passage of the pharmacy technician certification exam, which was admitted as evidence.
- Motion was made and seconded to renew Ms. Lozano-Ruiz's pharmacy technician license.
 (Brunswig/Strohmeyer) Motion carries.

REPORTS:

Myers Pilot Project

Adam Chesler, Čardinal Health, presented on the terms, history, statistics, and economic developments surrounding telepharmacy in the United States. Doug Baggett, owner of the Myers Family Pharmacy and home to the pilot project, offered statistics regarding worker efficiencies, customer conveniences, and community revenues gained through the pilot. Mr. Chesler gave pros, cons, and solutions from this pilot, then spoke about legislative changes, encouraging telepharmacy as an opportunity. Mr. Chesler suggested next steps should be to continue the pilot, pursue statutory changes with the legislature, and concurrently draft telepharmacy regulations. Inspector Rosebrook noted key concerns but agreed that Mr. Baggett, as the new owner, had improved the pharmacy. The following stipulations were discussed: publicly posting lunch times during which the pharmacy is closed; adding a lockbox for the pharmacy's key; continuation of self-reporting and inspections; Mr. Baggett's input when looking to adopt regulations. Motion was then made and seconded to extend the pilot project for 24 months with all proposed stipulations. (Gatewood/Strohmeyer) Dr. Brunswig opposed. Motion carries. Discussion was then briefly had regarding statutory language as a necessary first step to legislative change, and the Board's responsibility to draft said language.

Recess: The Board recessed at 2:26pm.

Reconvene: The Board reconvened at 2:33pm.

Compounding Task Force

Ms. Joanna Robinson, Inpatient Operations Manager for the University of Kansas Health System, reported that the Compounding Task Force, having used a spreadsheet to compare language and differences between the Kansas and USP compounding regulations, would submit for the February meeting drafts of their proposed updates to these regulations. Dr. Worden noted that USP <797> must be updated for consistency in practice, and expects that approval for USP <795> will move quickly. Approvals will ideally balance feedback from the Task Force, the Board, stakeholders, and others. Specific time stamp and next steps will depend on what the Board hears back from USP about the appeals, which could send this back to the drawing board.

BOARD DISCUSSION (cont):

Regulations for Consideration for Adoption

The special meeting in October covered DSCSA, CQI, and K-TRACS data, among other things. At a recent meeting of the Joint Committee on Administrative Rules and Regulations, a member expressed dissatisfaction with the fact that technicians require only a high school education. The Executive Director clarified that the Board requires certification prior to the first renewal, that pharmacy technicians represent an entry level profession that can be grown into a career, that pay is commensurate with the degree of training, that training occurs on the job at the responsibility of the PIC, and that technicians require direct supervision from a licensed pharmacist.

The Joint Committee pushed back on K.A.R. 68-2-10 regarding the economic impact statement, though the Board had indicated a zero dollar impact. Following concerns as to whether the Board's fee fund had money to cover any impact, K.A.R. 68-2-10 was revised to allow closing pharmacies to make Board notification via email, mail, text, or phone, several of which come at no cost. In addition, notification may be made to the household instead of individuals, to decrease costs of individual notifications. Motion was made and seconded to adopt the revised K.A.R. 68-2-10 by roll call vote. (Gatewood/Brunswig) Mr. Lonergan was absent; all others voted "yes."

The DSCSA will add third-party logistics providers, which do not ever take ownership. Therefore, the requirement to tell the Board if it is coming and going between those licensed with us had to be stricken. No revision to the economic impact statement was needed, and all rulemaking requirements were met. Motion was made and seconded to adopt K.A.R. 68-14-2, 68-14-4, 68-14-5, 68-14-7, 68-14-7a, & 68-14-7b, and to revoke K.A.R. 68-14-1 & 68-14-3 by roll call vote. (Brunswig/Gatewood) Mr. Lonergan was absent; all others voted "yes."

A special Board meeting will be held January 3, 2020 at 9:00am for the public hearing on K.A.R. 68-2-5 and 68-5-16 regarding the technician ratio and notification of resignation by pharmacists-incharge.

2020 LEGISLATION:

Pharmacy Practice Act Update

Due to issues with the NABP law portal, a legislative draft has not yet been completed, but will be the top priority following this meeting. The draft will then be circulated for Board feedback to the Executive Director and ironed out with the help of the President and Vice President.

Epinephrine Kits in Schools

K.S.A. 65-1680: The school nurse association provided a draft which includes no school registration. The inspectors provided adjustments to definitions. A statewide protocol similar to naloxone or Kentucky's epinephrine protocol was proposed. The Board needs to voice specific roadblocks (ie, requiring it to be more patient-history specific) or move forward with the legislation provided.

K-TRACS (PDMP Act) Update

Draft legislation is out to the Advisory Committee and stakeholder group for review. The Executive Director provided a briefing of the changes outlined in the draft.

Proposed 2020 Meeting Dates

The Executive Director provided information about 2020 meeting dates, including February TBA, June 4, September 3, and December 10.

Flavoring as Compounding

To address an individual inquiry seeking the Board's opinion on flavoring as compounding, the Board will issue a statement that it does *not* consider flavoring to fall under current compounding regulation. However, the statement will note that current regulation *does* preclude flavoring from causing any alteration to dosage concentration, and that the Board's opinion does not override that of the FDA.

Kansas Board of Healing Arts Physician Dispensing Conversation

Following the resignation of the Executive Director of the Kansas Board of Healing Arts, Tucker Poling, General Counsel, has been appointed Interim Executive Director. Regarding the delegation of authority for physician dispensing, Mr. Poling offered the opinion that physician companies *can* own drugs, so long as there is a valid patient-physician relationship through a company lawfully practicing medicine and/or surgery. Still, Mr. Poling stressed that the Board's surrounding regulations are out of date and, if updated, might allow for specific cases to be addressed thru joint KBOP-KSBHA investigations. The Executive Secretary proposed that KBOP request KSBHA work to update their regulations, allowing a KBOP Board or staff member to participate in these revisions to maintain consistency. Several concerns were raised around corporate drug ownership, including current DEA restriction to such registration.

Recess: The Board recessed at 3:33pm.

Reconvene: The Board reconvened at 3:46pm.

Rx Name

Regarding the Insurance Department's original concern about non-licensed businesses using "Rx" or "pharmacy" in their name: The Executive Director reported that the Board's list of licensed pharmacies had been cross-matched with the Attorney General's list of businesses in question, and the results were about 50/50. These results will go to the Board's General Counsel for further research by his office. Only about 15 entities would be in violation, several of which are large Fortune 500 companies. The Executive Director will relay relevant updates to Justin McFarland of the AG's office.

REPORTS (cont.):

District 6-7-8 Meeting Report

Jim Kinderknecht represented the Board staff, while Dr. Gatewood went on behalf of the Board members. Their reports noted the following meeting highlights: Canada's economic success since the 2007 decision to allow pharmacists to prescribe; Idaho's allowance of technicians to administer vaccines, which most District 7 states are bound to follow; problems with hiring technicians as the number one complaint across states; a lengthy discussion over the Idaho license compact, which has done away with the MPJE; USP 800 as a subject of confusion, with no states moving to adopt.

Dr. Strohmeyer will attend the Comprehensive Regulatory Training provided by FARB in January.

Committee Reports

The Tripartite committee met for review and has yet to set 2020 dates. There are some concerns which are under attorney-client privilege.

The Collaborative Practice Committee's state-wide immunization protocol has been approved, any pharmacist can download and sign, but they still have to meet all the requirements. Membership of this committee needs to be refreshed, but they have not met within the last year.

The K-TRACS Advisory Committee will meet next Friday. Changes implemented over the past year to the meeting format, objectives, etc. are working well.

DIRECTOR REPORT

2019 Annual Review postponed to first 2020 Board meeting.

Staffing Updates

Following a staff member's resignation, the Senior Administrative Assistant position has been posted, and will stay open for a time. The Board has a strong candidate, but Jackie has developed an assessment to evaluate an individual's ability to do the job's rudimentary duties which may qualify a second candidate.

Harold Rogers Grant

We're working to connect at least one-way with the interstate PDMP data-sharing hub called "Rx Check" and have addressed our concerns in the MOU. If we receive budget approval, we'll be hiring a data auditor, a data reviewer, and a public information officer for 22 months beginning in January.

The Executive Secretary announced her appointment by the Governor to the Information Technology Executive Council of Kansas, which oversees state IT policies. The Board's OITS migration is set to take place before year-end.

The state conducted an HR survey of all cabinet employees and found that the top complaints were lack of appreciation from leadership and under-compensation. This will help lay the groundwork for next year's budgeting with regards to employee compensation.

APPROVALS:

Stipulation & Consent Orders

A motion was made and seconded to approve the Stipulation & Consent Agreements as presented for cases 18-442B, 19-086, 19-094, and 19-413. (Gatewood/Brunswig) Motion carries.

Other Action Items

A motion was made and seconded to approve the minutes from the September 2019 Board meeting, all new licensees and registrants, and the appointments of Drs. Templeton and Estep to the K-TRACS Advisory Committee as nominated by the Kansas Board of Healing Arts. (Walden/Gatewood) Motion carries.

A motion was made and seconded at 4:42pm 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 and Executive Secretary. (Brunswig/Walden) Motion carries.

Reconvene: Dr. Worden reopened the meeting at 4:52pm.

The Executive Secretary announced that the Board had approved one 8-hour day of administrative leave for Board staff, to be taken between December 15, 2019, and January 3, 2019 to commend them for their work during the 2019 calendar year.

A motion was made and seconded at 4:55pm to enter into executive session for the purpose of consulting with the Board's attorney on matters that would be deemed privileged under the attorney-client relationship per K.S.A. 75-4319(b)(2), to include the Board's attorney and Executive Secretary. (Pugh/Walden) Motion carries.

Reconvene: Dr. Worden reopened the meeting at 4:57pm. **Adjourn:** Dr. Worden adjourned the meeting at 4:57pm.