KANSAS STATE BOARD OF PHARMACY BOARD MEETING MINUTES

April 27, 2023

Meeting Location:

1020 S. Kansas Ave. Topeka, KS 66612

Members Present: Terica Gatewood, PharmD., President; Erick Axcell, PharmD., Vice President; Tiffany Strohmeyer, PharmD., Inv. Member; Bill Walden, R.Ph.; Lucinda Noches-Talbert, 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; Jason Syring, R.Ph., Licensed Pharmacy Inspector; Christy Seufert, Licensed Pharmacy Inspector; Gayle Donaldson, K-TRACS Assistant Director; LaTonyua Rice, PharmD, K-TRACS Pharmacist; Jackie Yingling, Assistant Director; Linda Blasi, LMSW, Public Service Administrator; Ashley Smith, Public Service Administrator II; Jeanine Brizendine, R.Ph., Sr. Administrative Assistant; Marilyn Nicol, Administrative Specialist; Tammy Brown, Administrative Assistant; Bradford DeYoung, Attorney; Beth Greene, K-TRACS; Ninette Schnacker, K-TRACS; Amy Bloom, K-TRACS/Compliance; Brenda Head, JD, General Counsel

OPEN MEETING

At 8:32 am, the President called the open meeting to order.

APPROVALS

Stipulation and Consent Agreements

• A motion was made and seconded to approve the three Stipulation and Consent Agreements, 22-065, 22-328, and 23-038 (Walden/Noches-Talbert). All in favor. Motion carries.

A motion was made and seconded to approve the February 23, 2023 meeting minutes, DEA exempt product list August 2022, guidance documents for Facility Renewals without Inspections and Non-Resident Inspection Types, and the new licensees and registrants since February 15, 2023. (Strohmeyer/Truong) Motions carry.

REPORTS

Licensing-

 The results for the 2022 Pharmacy Technician Continuing Education Audit were: 1,935 technicians were compliant, and 144 technicians were noncompliant. 103 technicians responded to the audit and 41 technicians did not respond and were revoked for failure to respond.

PUBLIC HEARING ON ADMINISTRATVIE RULES AND REGULATIONS

The Board President commenced the Public Hearing at 9:00am.

The Board President announced that the Attorney General had rescinded its approval of K.A.R. 68-23-1 through 68-23-6 pending additional review and instructed the Board to postpone the public hearing on these proposed regulations.

The Board President then explained the rules for the public hearing, including requiring participants in attendance sign-in or be recorded online, that public comment would be limited to five minutes per person per regulation packet for review, that the Board had received written comments prior to the meeting and had reviewed such comments, and that individuals wishing to address the Board for public comment should state their name and any organization with which they were affiliated. A hearing before the Joint Committee on Administrative Rules and Regulations was held on Friday, March 3, 2023, and the Board President read their comments: "The Committee commends the agency for proactively updating its rules and regulations and using consistent language in those rules and regulations. It also commends the agency representative for concisely and precisely explaining the various topics presented in these proposed rules and regulations and providing additional information as requested."

The Board President opened the hearing on the following regulations and briefly explained each: K.A.R. 68-1-1b, 68-1-2a, 68-1-9, 68-2-20, 68-7-8, 68-7-11, 68-7-12, 68-7-15, 68-7-16, and 68-7-19. The Board received written comments from Walgreens and CVS. The Board President opened the hearing for public comment.

• Grace Sesi, Executive Director of Regulatory Affairs with CVS commented on their support for the regulations and a request for minor edits on K.A.R. 68-7-8.

The Board President concluded the hearing on K.A.R. 68-1-1b, 68-1-2a, 68-1-9, 68-2-20, 68-7-8, 68-7-11, 68-7-12, 68-7-15, 68-7-16, and 68-7-19. A motion was made and seconded to approve the regulations (Truong/Strohmeyer). The Executive Secretary called the roll for a vote on the motion. By unanimous vote, the regulations were approved for adoption.

The Board President opened the hearing on the following regulations and briefly explained each: K.A.R. 68-7-20a, 68-20-1, 68-20-16, 68-20-18, 68-20-18a, 68-20-19, 68-20-20, 68-20-21 (revocation), and 68-20-22. The Board received no written comments on these regulations. The Board President opened the hearing for public comment.

• No public comment.

The Board President concluded the hearing on K.A.R. 68-7-20a, 68-20-1, 68-20-16, 68-20-18, 68-20-18a, 68-20-19, 68-20-20, 68-20-21 (revocation), and 68-20-22. A motion was made and seconded to approve the regulations and revoke K.A.R. 68-20-21 (Strohmeyer/Axcell). The Executive Secretary called the roll for a vote on the motion. By unanimous vote, the regulations were approved for adoption and K.A.R. 68-20-21 was approved for revocation.

The Board President opened the hearing on the following regulations and briefly explained each: K.A.R. 68-21-1, 68-21-3 (revocation), 68-21-4, and 68-21-5. The Board received no written comments on these regulations. The Board President opened the hearing for public comment.

No public comment.

The Board President concluded the hearing on K.A.R. 68-21-1, 68-21-2, 68-21-3 (revocation), 68-21-4, and 68-21-5. A motion was made and seconded to approve the regulations and revoke K.A.R. 68-21-3 (Strohmeyer/Noches-Talbert). The Executive Secretary called the roll for a vote on the motion. By unanimous vote, the regulations were approved for adoption and K.A.R. 68-21-3 was approved for revocation.

The Board President opened the hearing on K.A.R. 68-7-20a and briefly explained the regulation. The Board received written comments from the Kansas Employers for Affordable Healthcare, Pharmaceutical Care Management Association (PCMA), Walgreens, the University of Kansas Health System, the Kansas Council of Health System Pharmacy, the Kansas Hospital Association, Ascension Via Christi, AdventHealth Shawnee Mission, Salina Regional Health Center, Smith County Memorial Hospital & Family Practice, and Express Scripts. The Board President opened the hearing for public comment.

- Jonathan Buxton, Senior Director with PCMA, commented that the regulation is discriminatory because it treats pharmacies owned by hospitals differently than pharmacies not owned by those hospitals and there will be an economic impact of higher prescription costs for the patients of Kansas.
- Alex Sommer, Prime Therapeutics, commented on the regulation and that the legislature should have authority over this topic, not the Board. The Board President and Mr. Walden asked questions and requested additional information regarding the increase in the number of specialty drugs and number of patients receiving specialty drugs.
- Kandice Sanoiie, Cigna/Express Scripts, reiterated written comments from John Sisto. She suggested to the Board that it limit the rule to require the conditions listed in section (g) as well as a requirement that the initiating pharmacy receives consent from the patient to deliver the prescription to the alternative site.
- Tara Mays, Kanas Hospital Association, reiterated written comments from Karen Braman. KHA supports the regulation and putting structure in place to support quality and patient safety.
 Kansas hospitals continue to share stories of health insurer white bagging practices that have resulted in patient harm.

The Board President concluded the hearing on K.A.R. 68-7-20a. The Executive Secretary discussed the proviso in HB 2184 which was vetoed by the Governor.

A motion was made and seconded to postpone discussion or consideration of proposed K.A.R. 68-7-20a regulation until the legislature concludes any consideration of the Governor's veto (Truong/Walden). All in favor. Motion carries.

Recess: The President called a recess at 9:43 am

Reconvene: The President called the open meeting back to order at 10:00 am.

BOARD DISCUSSION

Covid-19 Update/Emergency Update

The remote work regulation has moved to the Attorney General's office for review. A motion
was made and seconded to extend the Board's current remote work allowances through
December 31, 2023 (Walden/Truong). All in favor. Motion carries.

Draft Regulations

- CQI
 - The Executive Secretary discussed the draft of K.A.R. 68-19-1, amended by staff based on past Board discussion.
 - The Board requested the following changes to the draft:

- The PIC's responsibility to communicate with (versus talk to) staff involved in an incident
- Change the word "distribute"
- PIC be able to delegate initial review of an incident report to the PIC's designee
- The Board discussed the value of a CQI meeting and the opportunity for that to occur at the PIC's discretion and still meet the requirements of the regulation.
- Staff will develop sample route cause analysis and corrective action plan documents.
- USP <795>, <797>, and certain provisions of <800>
 - The Board agreed to seek adoption of USP through the rulemaking process in place of Article 13 of the Board's current regulations.

2023 Legislative Session

- SB 66
 - Introduced as HB 2388. Agencies provide a paper and electronic license to providers. If
 the agency provides a printable, electronic version, that satisfies the "paper"
 requirements. The Department of Administration will implement a central system and
 track all statuses of provider licenses and registrations in the state of Kansas.
 Implementation will be in 2025. The Board of Pharmacy and licensees will not incur the
 cost of the licensing system.
- SB 131
 - Aaron Dunkel, Executive Director of KPhA spoke regarding SB 131. Relating to pharmacy;
 authorizing pharmacy technicians to administer certain vaccines.

NABP Annual Meeting Resolutions

The Board reviewed the proposed resolutions and there were no items for discussion.

REPORTS cont.

Attorney-

None.

Board Members-

- Dr. Axcell reported on the Collaborative Drug Therapy Management. The Influenza and Strep protocols have been approved. The committee is currently working on UTI.
- NABP committee on constitution bylaws will be released at their annual meeting.
- Dr. Axcell and the Executive Director spoke to the KU School of Pharmacy P3 class about the Board in March.

Compliance-

- The Director of Compliance reported on prescribers who retire or die and how long the prescription is valid. The guidance has not been updated since 2010. The Board encourages pharmacist professional discretion. Staff will craft an updated newsletter article based on the Board's discussion.
- Patient contracted deliveries are considered dispensed at the counter and cannot be restocked. Pharmacy contracted deliveries may be restocked and re-dispensed.
- An increase in drug diversion has been seen in ekits for LTC facilities. The compliance team
 mentioned possibly limiting drugs and quantities in ekits. Board staff will review to see what
 other states do for guidance.

 The compliance team went to KSU VetMed and TUKHS Southlake. They inspected drug compounding and reviewed policies and procedures.

Director-

- The Executive Secretary reported on 2023 action items that are currently being completed by Board staff.
- The Board pays an annual membership fee of \$250 to NABP for numerous resources that include PMPi, examinations, eLTP, clearinghouse, and inspections.
- Technician CE audit summary orders went out within one week of completion of the audit.
- The Board member and staff retreat will be July 26th, 2023. This is an open meeting but there will be no virtual meeting.
- Assistant Director of K-TRACS, Gayle Donaldson, has been voted as the Chair for the Rx Check Hub Governance Board.

Recess: The President called a recess at 11:47 am.

Reconvene: The President called the open meeting back to order at 1:00 pm.

PUBLIC COMMENT

None.

PRESENTATION

Greg Teale, Pharm D. and Mark Steinbeck, R.Ph. with Saint Luke's presented on Hospital in Your Home. Saint Luke's is requesting the Board allow a hospital to dispense to the HIYH patient's residence mimicking the process they have established in three Missouri based hospitals.

The Board supports the program. A motion was made and seconded to endorse the Saint Luke's hospital in your home program (Truong/Strohmeyer). All in favor. Abstained (Walden) Motion carries. The program will need to appear before the Board in 18 months.

BOARD DISCUSSION

A motion was made and seconded to convene a Special Board Meeting (virtual) on May 17th at 3:00 pm for the Board to discuss and further consider adoption of proposed K.A.R. 68-7-20a (Truong/Walden). All in favor. Motion carries.

EXECUTIVE SESSION

A motion was made and seconded at 2:02 pm to enter into executive session to discuss personnel matters of non-elected personnel per K.S.A. 75-4319, to include the Board's attorney and Executive Secretary, and to be reopened to the public at 2:45 pm (Strohmeyer/Axcell). All in favor. Motion carries.

Adjourn: A motion to adjourn was made and seconded at 2:46 pm. (Strohmeyer/Truong) All in favor. Motion carries.