

Kentucky Board of Pharmacy Advisory Council

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October 10, 2023

9:00AM

Agenda

- I. Call to Order
- II. Minutes
- III. Old Business
 - a. Non-Resident Pharmacist Licensure
- IV. New Business
 - a. White, Clear, Brown Bagging
 - b. Proposed 201 KAR 2:480 Telework for Remote Prescription Processing
- V. Adjournment

KENTUCKY BOARD OF PHARMACY

via Zoom

ADVISORY COUNCIL

October 10, 2023

10:00 a.m.

MINUTES

Members present: Kimberly Crowley, Maragret Sidebottom, John Spencer, Tabithia Fischbeck, Robert Fink, Julie Anderson, Kelly Zaccarelli, Casey Humes. Staff: Executive Director Chris Harlow, General Counsel Eden Davis, Pharmacy and Drug Inspector Paul Daniels, and Executive Assistant Nikki Holiday. Board Member: Vice President Jonathan Van Lahr.

CALL TO ORDER: Chairwoman Kimberly Crowley called the meeting to order at 9:04 a.m.

MINUTES: Julie Anderson motioned to approve the minutes from the September 19, 2023 meeting. Maragret Sidebottom seconded, and the motion passed unanimously.

NON-RESIDENT PHARMACIST LICENSURE: Executive Director Chris Harlow walked through the non-resident licensure transfer process that was originally proposed by the Board using the NABP Verify program. The proposed amendment to 201 KAR 2:030 created a new limited type of non-resident pharmacist licensure. He went on to explain the NABP Verify program and what this type of licensure would entail. The components of this type of licensure were the following: application, application fee, and a background check, as well as the NABP Verify credential. It bypassed all the other license transfer requirements such as exams, exempt from annual continuing education requirement for Kentucky. Then beyond that it was just a renewal application going forward each year.

Bill Cover then explained the NABP Verify program. An applicant must have at least one active license in a U.S. state, and any other licenses whether they are active, inactive, lapsed, etc. cannot have an active sanction against it. The applicant pays the \$50 annual Verify fee to NABP, which covers the ongoing monitoring on a continuous basis. At any time if something changes the state is notified by NABP of whatever has changed. For example, new discipline, change in license status, etc.

The council members had some questions about the reporting of discipline and how the individual Boards can act with the Verify program. If a person is in the NABP Verify program and is sanctioned, then they lose their credentials with the Verify program and Boards are notified. The Boards can then start their administrative process, whatever that looks like, when a non-reside pharmacist no longer holds the Verify credential. Executive Director Harlow walked the council members through our grievance process and how that works now. The Verify credential would give the Board jurisdiction to act and hold the pharmacist accountable.

The fee was never addressed but is certainly something that can be addressed by the Board.

General Counsel Eden Davis then reviewed some data regarding cases involving non-resident pharmacists.

2022 – 32 cases on non-resident pharmacies and PICs

2023 – 62 cases on non-resident pharmacies and PICs

These cases involved everything from medication errors, to compounding issues, to potentially not having a PIC, to shipping into KY with lapsed permits. They really involve a lot of different issues.

The Board does not want to nor intends to create a burden or restrict access for patients, but at the same time we need to do what is best for the citizens of KY and ensure patient safety.

Idaho and Iowa were also brought up as they are doing an abbreviated type of licensure for non-resident pharmacists. Currently this is only required for the PIC in these states.

Bill Cover went over some details of how North Carolina implemented Verify into their non-resident licensure process.

Council member(s) asked if there were things that could be amended in the withdrawn regulation, or if it will be necessary to completely start over. Cost and background checks seem to be the main issues with the stakeholders, and the cost is something that can be addressed. Background checks are required in statute so they must be done.

Chairwoman Kim Crowley asked Dr. Harlow to review the regulations for remote work, shared services, central fill, and common database regulations for the group. Any pharmacies/pharmacists working in these situations are currently required to be licensed. There is clean up that needs to be done on several regulations, but this non-resident licensure topic must be wrapped up before we can move forward with these other regulations.

The question was asked if it was possible to implement only the Verify program for two years as a pilot program and then assess how it has worked. Eden explained that the Verify program must be linked to some type of registration or licensure to create jurisdiction. We also do not have statutory authority to author a temporary regulation. Regulations provide the Board with the flexibility to amend if something is not working or withdraw it completely.

The question was asked if historical discipline was reported to the Verify program. Bill Cover explained that Verify only reports ACTIVE sanctions or discipline, not historical discipline.

General Counsel Eden Davis went through the entire rule making process from beginning to end so the members had an idea of what type of timeline they were looking at after this recommendation to the Board.

The Council decided to move on to the next topic they have been charged with, which is white, clear, and brown bagging, and come back to the non-resident licensure topic at the end of the meeting.

WHITE, CLEAR, BROWN BAGGING: Dr. Harlow gave an overview and definitions of white, clear, and brown bagging to introduce the topic and the issues surrounding it.

White bagging – specialty pharmacy dispenses to provider for administration to the patient; it may or may not need to be further manipulated.

Clear bagging – the provider and the specialty pharmacy are under common ownership.

Brown bagging – medication dispensed to patient who is then responsible for taking it to their provider for administration.

Policy considerations/questions include:

- Is white bagging distribution or dispensing?
- Who is responsible?
- Determining what is distribution vs. dispensing. If it is being further manipulated it is not dispensed. A drug can only be dispensed once.
- Challenge not to create barriers to access.
- A drug can be dispensed to a provider.

ACTION: Tabitha Fischbeck motioned to recommend the following to the Board: NABP verify, background check and application for non-resident licensure at a lower cost to-be-determined. This excludes any additional testing and CE requirement. (The language that is in the regulation 030 that was withdrawn but lowering the cost.) John Spencer seconded the motion.

After discussion, the Council decided to postpone the vote on this motion until the next meeting.

ADJOURNMENT: Robert Fink motioned to adjourn. John Spencer seconded, and the meeting adjourned at 11:53 a.m.

NEXT MEETING: November 14, 2023 at 9:00 a.m.