

Kentucky Board of Pharmacy Advisory Council

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**February 13, 2024
9:00 AM**

Agenda

- I. Call to Order
- II. Minutes
- III. 201 KAR 2:470, Central Fill and Shared Pharmacy Services
- IV. 201 KAR 2:210, Patient Records, Drug Regimen Review, Patient Counseling, and Final Product Verification
- V. Adjournment

KENTUCKY BOARD OF PHARMACY

via Zoom

ADVISORY COUNCIL

February 13, 2024

9:00 a.m.

MINUTES

Members present: Kimberly Crowley, Meg Sidebottom, John Spencer, Robert Fink, Julie Anderson, Kelly Zaccarelli, Casey Humes, Jamie Biliter, and Tabithia Fischbeck. Staff present: Executive Director Chris Harlow, General Counsel Eden Davis, and Executive Assistant Nikki Holiday.

CALL TO ORDER: Chairwoman Kimberly Crowley called the meeting to order at 9:03 a.m.

MINUTES: There were two changes that were requested to the minutes. Under the Central Fill/Shared Services notes, a line was requested to be removed that stated this only applies to non-dispensing pharmacies. This line was removed. Meg Sidebottom's name was spelled incorrectly. That correction was also made.

Action: Robert Fink motioned to approve the minutes with the changes stated above. John Spencer seconded, and the motion passed unanimously.

201 KAR 2:470, CENTRAL FILL AND SHARED PHARMACY SERVICES: The Council continued their discussion on Central Fill and Shared Pharmacy Services, specifically the labelling component. They discussed what would be important to the patient on the label without adding so much information that it could become confusing for them. As well as how small the font would need to be to provide all of the information for multiple pharmacies. Examples from other states were provided to the Council and discussed. Another option that was discussed was putting all of this additional information in the paperwork attached to the bag/prescription, so it is available to the patient, but not taking up all of the room on the actual label. The issue comes back to the fact that there is limited real estate on the label, so providing all the information for both the central fill is difficult.

Executive Director Harlow then provided some background information about the statutory language and what it requires in regard to labeling. (201 KAR 2:230) This new regulation will replace our current rule, but the current regulation states that the name and address of the pharmacy that prepared the prescription as well as the name and address of the pharmacy that is dispensing the prescription. As far as the phone number is concerned, it is not required in the current version of 201 KAR 2:230, but in the non-resident pharmacy regulation the phone number is required. So, the challenge here is the statutory language the non-resident statute. Some other states are using some type of code, or identifier that informs the patient that the prescription was filled at a different location than where the patient is being picked up.

However, if the central fill is shipping/dispensing the prescription directly to the patient, then the phone number would be an important piece of information for that patient. In this situation, all the requirements of a mail order pharmacy would need to meet the requirements of the mail order statutory language.

The Council continued discussions about labeling requirements. They reviewed the report of other states' rules that was provided in the meeting materials.

Julie Anderson volunteered to provide the group with a sample label. The Council then moved on to the review of 201 KAR 2:210.

See the updated draft of 201 KAR 2:210 attached, including notes by General Counsel.

Action: No action was taken on this agenda item.

201 KAR 2:210, Patient Records, Drug Regimen Review, Patient Counseling, and Final Product Verification: Eden Davis brought up this draft regulation and reviewed where the group left off last time at the Definitions section. This included discussion about automated filling systems, electronic verification, electronic verification systems, final product verification, supervision of technicians (registered and certified), patient records and retention, and quality testing/checking.

Kim requested that anyone who has any information on automated systems to send that information to Nikki for inclusion in the next meeting materials.

See the updated draft of 201 KAR 2:210 attached, including notes from General Counsel.

ADJOURNMENT: Casey Humes motioned to adjourn the meeting. Robert Fink seconded, and the meeting adjourned at 11:57 a.m.

NEXT MEETING: March 12, 2024 at 9:00 a.m.