Kentucky Board of Pharmacy Advisory Council

Kentucky Board of Pharmacy via teleconference at

https://us02web.zoom.us/j/89560958377?pwd=T2NKZElyRy80cGdrUGs0d2ttSFNyZz09

Meeting ID: 895 6095 8377 Passcode: 9pwFeL

Dial by your location +1 646 558 8656 US (New York) +1 312 626 6799 US (Chicago)

Meeting ID: 895 6095 8377 Passcode: 358267

April 28, 2021 9:00 a.m.

Agenda

- I. Call to Order
- II. Approval of Minutes from April 15, 2021
- III. Discussion items:
 - A. Compliance with House Bill 219

"House Bill 219 was recently signed into law, effective 90 days from the end of the legislative session. This legislation will eliminate the syringe/needle log for OTC sales of syringes and needles. Chris Harlow moved to charge the Advisory Council to amend current regulations or draft a new regulation for clarification of recordkeeping/remote order entry due to House Bill 219. Jody Forgy seconded, and the motion passed unanimously."

IV. Adjournment

KENTUCKY BOARD OF PHARMACY via teleconference using Zoom ADVISORY COUNCIL April 28, 2021

9:00 a.m.

MINUTES

Chairperson Matt Martin called the meeting to order at 9:02 a.m. Members present: Tony Tagavi; Chris Clifton; Jason Poe; Wes Rowe and Laurel Smith. Absent: Tyler Bright; Donna Drury and Cindy Cummings. Staff: Eden Davis, General Counsel and Darla Sayre, Executive Staff Advisor.

Guests included: Shelly Nance; Danny Bentley; Steve Sheldon; Ben Mudd and Nichole Cover.

Chris Clifton moved to accept the minutes of the April 15, 2021 meeting. Jason Poe seconded, and the motion passed unanimously.

Compliance with House Bill 219 Chairperson Martin introduced Representative Steve Sheldon to provide background on House Bill 219. House Bill 219 was introduced to provide easier access to syringes to the public. During the course of deliberation, remote order entry and verification by closed door pharmacies were added to the bill. This language was a specific need for two larger companies in Jefferson County to reduce the economic impact when the emergency order allowing for this practice is lifted. Pharmacies open to the public were excluded to allow for feedback and to determine the impact.

Nancy Galvagni and Bud Warman, Kentucky Hospital Association stated that the passage of this bill could prohibit the current practice of hospital pharmacies regarding remote order entry and verification by a pharmacist after hours and on weekends. If this is not allowed, it will detrimental to hospitals and require additional staffing. Mr. Warman noted that the Joint Commission on Accreditation of Healthcare Organizations requires a pharmacist review all medications dispensed in the hospital and specifically inquires about processes utilized after hours. Mr. Warman stated that this practice has been utilized by small, rural hospitals across the state for nearly twenty years. Without utilizing remote verification by a licensed pharmacist, it could present patient-safety issues. Mr. Warman mentioned that the average rural hospital performs 45-50 remote orders per hour during afterhours.

Chris Killmeier, AmerisourceBergen raised concerns over the 100-mile radius restriction, and stated that the way HB219 reads, it could lead to Amerisource Bergen not being able to utilize their current model and possibly relocating their Kentucky operation elsewhere. This would impact their ability to provide access to specialty drugs for their patient assistance program.

Ben Mudd, Kentucky Pharmacist Association expressed concerns that this legislation was initiated for a select few without regards to the impact on the pharmaceutical profession. We are now faced with cleaning up the issues created. Was this remote order entry and verification not allowed prior to this legislation? What allowed hospitals to do this previously? From a legal perspective, do we have the option of "not following" a statute?

Representative Sheldon responded that hospital pharmacies were not intended to be impacted by the passage of House Bill 219. The Bill was intended to benefit all closed-door pharmacies. The Kentucky Board of Pharmacy was the entity responsible for the 100-mile radius limitation. The legislature is open to amendments on this bill. Representative Bentley inquired as to why the interested parties had not contacted them regarding these concerns. Both Representative Bentley and Representative Sheldon welcome discussion during the legislative process.

Ralph Bouvette, American Pharmacy Services Corporation stated he had no additional issues or concerns to bring. Mr. Bouvette did state that House Bill 219 was a compromised bill, but that the changes it made must be followed once it becomes effective.

Nichole Cover, Walgreens stated that this bill could impact permitting of non-resident pharmacies outside the 100-mile radius required. Ms. Cover stated that Walgreens is using remote support to assist pharmacies in thirty-six states.

Shelly Nance, Kroger said that currently 50% of Kroger's order entry and verification is performed remotely. Kroger has over one hundred pharmacists that do remote order entry and verification from their Cincinnati location. All pharmacists are licensed in Kentucky and Kroger Health Connect (KHC) does possess a non-resident permit. Kroger has been doing this since 2014 and it has assisted store locations to stay open with COVID-19. This has proved beneficial during the pandemic and allows for greater use of pharmacists for vaccine clinics.

Kelley Abell and Mike Biagi, the Rotunda Group introduced Van Anderson, attorney for McKesson and Deirdre Boling-Lewis, attorney for Chewy. Mr. Anderson stated that McKesson would be in favor of lifting the 100-mile radius restriction. Mr. Anderson stated that the NABP model act supports remote work and electronic supervision and that Ohio and North Carolina have even broader allowances. Ms. Boling-Lewis agreed and stated that Chewy would also be in favor.

Eden Davis, General Counsel provided the Counsel with a breakdown of the current emergency orders in effect. She also provided a list of possible statutes and regulations that the Board may have utilized previously to not allow remote order entry or verification. Ms. Davis stated that the allowance of remote order entry by hospitals is not specified in statute or regulation. Rather, despite not being captured in statute or regulation, per the inspection supervisor, this practice has been allowed by the Board for patient safety. Chairperson Martin stated he could not locate any reference within the law.

Chris Clifton said that the actual dispensing of medication is the only act that requires a pharmacist be physically present in the permitted pharmacy. Ms. Davis recommended that the current definitions in KRS 315.010 be updated to reflect modern practice and technology.

Anthony Tagavi stated that in his opinion House Bill 219 changes nothing that is currently allowed and has no effect on current practices. Mr. Tagavi believes that under existing law, nothing prohibits remote order entry or verification. Mr. Anderson stated that various interpretations of law that are not written down can cause confusion and should be codified in statute or regulation for clarity. He suggested a new regulation clarifying that order entry can be done under general supervision which includes electronic means.

General Counsel posed questions to the Advisory Council to determine if remote order entry was in fact prohibited under current law. The Council agreed that remote order entry is part of the practice of pharmacy and therefore must be supervised. The Council all agreed that remote order entry is not "dispensing." The council agreed that remote order entry is subject to general supervision rather than immediate per 201 KAR

2:045. The council accessed the definition of "supervision" in KRS 315.010(27) and stated that this is "general supervision," but that they read "presence of a pharmacist on the premises" to include "electronic presence." General Counsel made note that the definition of supervision does not mention the location of the technician and would therefore not prohibit a technician from being remote.

After further discussion, the following recommendations were made:

- Anthony Tagavi moved to recommend to the Board that general supervision includes supervision by electronic means. Chris Clifton seconded, and the motion passed unanimously.
- Chris Clifton moved to recommend to the Board that "remote order entry" requires general supervision. Jason Poe seconded, and the motion passed unanimously.
- Chris Clifton moved to recommend to the Board that the definitions in KRS 315.010 be reviewed and updated to reflect modern practice and technology. Laurel Smith seconded, and the motion passed unanimously.
- Anthony Tagavi moved to recommend to the Board that after view of House Bill 219 the current body
 of law does not prohibit remote order entry or verification; therefore, House Bill 219 has no
 implication on current practices. Chris Clifton seconded, and the motion passed unanimously.

The next meeting will be held via teleconference on June 8, 2021 at 9:00 a.m.

On motion by Chris Clifton, seconded by Wes Rowe and passed unanimously, Chairperson Martin adjourned the meeting at 11:24 p.m.