FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING

Tuesday, May 23, 2023
Commonwealth Conference Center
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER:	A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 9:05AM.
PRESIDING:	Kristopher Ratliff, DPh, Committee Chairman
MEMBERS PRESENT:	Patricia Richards-Spruill, RPh Wendy Nash, PharmD Ling Yuan, PharmD Larry Kocot, JD
MEMBER ABSENT:	Bill Lee, DPh
STAFF PRESENT:	Caroline Juran, RPh, Executive Director Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP Ellen B. Shinaberry, PharmD, Deputy Executive Director Beth O'Halloran, RPh, Deputy Executive Director Ryan Logan, RPh, Deputy Executive Director Annette Kelley, MS, CSAC, Deputy Executive Director Sorayah Haden, Executive Assistant
QUORUM:	With 5 committee members present, a quorum was established.
APPROVAL OF AGENDA:	Agenda was approved as presented.
PUBLIC COMMENT:	No public comment was offered.
UPDATE ON REGULATORY ACTIONS	Ms. Barrett reviewed the chart of regulatory action found on pages 2-4 of the agenda packet.
UPDATE ON TRANSFER OF MEDICAL CANNABIS PROGRAM TO VIRGINIA CANNABIS CONTROL AUTHORITY	Ms. Barrett provided a verbal update for the transfer of the medical cannabis program to the Virginia Cannabis Control Authority (VCCA) which will occur on January 1, 2024. Ms. Kelley and other staff members of the Board are routinely meeting with VCCA staff to ensure a smooth transition. Both agencies are waiting for legal advice from the Office of the Attorney General regarding the handling of the Request for Application for a pharmaceutical processor permit in Health Service Area I. Ms. Barrett indicated the Board will vote to repeal its regulations in December,

effective January 1, 2024. Board staff is working with VCCA staff who will address the required regulatory changes from 2023 legislation and incorporate the proposed regulatory changes from 2022 legislation that remain under administrative review.

AMEND GUIDANCE ON HYDROCARBON SOLVENTS

Becky Hobden, Lab Director, Green Analytics Virginia provided a PowerPoint presentation entitled "Residual Solvents Testing in Cannabis". The slides of the presentation were included on pages 21-29 of the agenda packet. In December 2022, the Board adopted the guidance without butane and propane because the solvents are not explicitly listed in Table 12 of the American Herbal Pharmacopeia Cannabis Inflorescence, 2014. Ms. Hobden highlighted that the Table is pulled from the International Conference on Harmonization (ICH) for the establishment of solvents and limits which is not an exhaustive list. She provided information regarding numerous states that have authorized the use of butane and propane and the associated limits for exposure as a residual solvent in cannabis products. She indicated that tests do exist for assessing residual levels of butane and propane and therefore, would comply with 18VAC110-60-300(G)(6) and 18VAC110-60-281.

MOTION:

The committee voted unanimously to recommend to the full board that it amend Guidance Document 110-45 found on page 6 of the agenda packet by inserting butane and propane as a class 3 solvent with a permissible daily exposure of 50mg/day. (motion by Nash, seconded by Richards-Spruill)

ADOPT GUIDANCE REGARDING CANNABIS ADVERTISING REGULATIONS AS APPLIED TO PACKAGING

Ms. Juran explained that staff will occasionally seek direction from members of the Board when reviewing cannabis product applications for approval. Dr. Nash and Ms. Garvin had recently suggested to staff that input from the Board may be appropriate when considering the approval of cannabis product names and packaging. Ms. Kelley stated that the guidance would assist the industry as well when preparing applications for product approval. The committee reviewed the draft guidance included in the agenda packet regarding cannabis product packaging requirements. Mr. Kocot recommended that product names not be associated with "social media influencers" as well.

MOTION:

The committee voted unanimously to recommend to the full board that it adopt the guidance document entitled "Cannabis Product Packaging Requirements" as presented and amended by inserting "social media characters" into the sentence for which brand names may not be associated. (motion by Yuan, seconded by Kocot)

RECONSIDER AMENDMENT OF 18VAC110-20-555

Ms. Barrett reminded the Committee that the Board adopted a proposed regulatory action in March 2023 resulting from a petition for rulemaking to exempt requirements in 18VAC110-10-555 for pharmacist review of a prescription/order and electronic authorization for accessing a drug when

the automated dispensing device is solely stocked with drugs for stat or emergency use. She and Ms. Juran indicated board counsel recently advised that the proposed regulatory action appears to violate federal requirements and therefore, may be inconsistent with the requirement in 18VAC110-20-555 (13) which requires a pharmacy to comply with a written policy and procedure for complying with federal regulations related to the storage and dispensing of controlled substances. This advice appeared to be based on a 2016 letter from DEA to ASCP and the 2022 DEA Pharmacist's Manual. The Committee expressed a desire to hear more from board counsel and Dr. St. Clair at the upcoming full board meeting before deciding on the matter.

MOTION:

The committee voted unanimously to defer the reconsideration of amendment of 18VAC110-20-555 to the full board meeting in June. (motion by Richards-Spruill, seconded by Yuan)

DISCUSSION OF NUMBER AND LOCATION OF PHARMACY PERMITS IN RECENT YEARS

The committee reviewed an excerpt from the 2022 DHP Biennial Report in the agenda packet regarding the number of current active pharmacy permits between 2012 and 2022. A geo-map of current active pharmacy permits was provided as a supporting handout. On June 30, 2012, there were 1,754 pharmacies in Virginia. As of June 30, 2016, the number of pharmacy permits grew by 100. Between June 30, 2016 and June 30, 2022, the number of pharmacy permits in Virginia declined by 86 for a total of 1,768 pharmacies in Virginia. Staff noted that the population census increased by 8.5% between April 1, 2010 and July 1, 2022. Ms. Juran reminded the Committee that the Board issues only one type of pharmacy permit and therefore, it's difficult to know how many different types of pharmacies exist in Virginia. Dr. Nash and Dr. Ratliff inquired if staff could request pharmacies to self-identify its practice setting upon renewal. The Committee indicated they would possibly like to share this information with other agencies or entities in the future, if helpful, to ensure patient access.

ACTION ITEM:

Staff will research with the IT Department the Board's ability to have pharmacies self-identify its practice setting during the renewal process and for this information to auto-populate in the licensing database.

LEGISLATIVE PROPOSALS:

- Pharmacy technicians accepting refill authorizations or Schedule III-VI prescriptions and clarification of quantity/refills for Schedule VI

The committee reviewed draft legislative proposals for the 2024 General Assembly session.

prescriptions.
- Requiring federal criminal background check for resident and nonresident wholesale distributors and third-party logistics providers
- Clarifying compounding of essentially copies of commercially available drug product.

MOTION:

The committee voted unanimously to recommend to the full board that it adopt the three legislative proposals as presented. (motion by Nash, seconded by Richards-Spruill)

AMEND GUIDANCE DOCUMENTS 110-36 AND 110-9 REGARDING USP REVISIONS

The committee reviewed draft amendments to Guidance Documents 110-36 and 110-9 based on revisions to Chapters <795> and <797> of the United States Pharmacopeia effective November 2023.

MOTION

The committee voted unanimously to recommend to the full board that it amend Guidance Document 110-36 as presented. (motion by Kocot, seconded by Yuan)

The Board further discussed the proposed question and answer #3 within Guidance Document 110-36 and confirmed that all compounding personnel working in multiple pharmacies, to include pharmacy interns on rotations, should pass a media-fill test at each pharmacy prior to performing sterile compounding. Staff informed the Committee that USP has confirmed that this is not a requirement of USP and therefore, the originally proposed "must" in the agenda packet should be changed to read "should".

The Committee voted unanimously to recommend to the full Board that it adopt Guidance Document 110-36 as presented and amended by changing the proposed answer to question #3 to read, "Yes, all compounding personnel working in multiple pharmacies, to include pharmacy interns on rotations, should pass a media-fill test at each pharmacy prior to performing sterile compounding." (motion by Kocot, seconded by Richards-Spruill)

During the discussion of draft amendments to Guidance Document 110-9, Dr. Yuan recommended a new deficiency for those with oversight of compounding personnel, but who do not compound.

The committee voted unanimously to recommend to the full Board that it amend Guidance Document 110-9 as presented and amended by inserting a new deficiency 26b to read, "No documentation of initial and at least every 12 months media-fill testing or gloved fingertip testing for persons who have direct oversight of compounding personnel, but do not compound.", citing 54.1-3410.2 with a suggested monetary penalty of $500. (motion by Yuan, seconded by Richards-Spruill)

DISCUSSION OF MONETARY PENALTIES IN GUIDANCE DOCUMENT 110-9 AS COMPARED TO OTHER STATES

The committee discussed the current monetary penalties associated with the deficiencies within Guidance Document 110-9. Discussion focused on those deficiencies related to theft and loss of drugs. In addition to the information from DC, TN, and PA provided in the agenda packet, Ms. Juran reported that IL imposes a non-disciplinary fee of up to $3,000 for any identified violation. Specifically, it imposes $200 for the first violation, $300 for the second violation, $500 for the third violation, and greater than 3 violations is subject to further discipline.

ACTION ITEM

The Committee requested staff to identify how often Deficiencies #13, 14, 15, and 16 within Guidance Document 110-9 have been cited or repeatedly cited for quarters ending in June 2023 and September 2023 and report back during the next Regulation Committee meeting in November 2023.

DISCUSSION OF ACCEPTANCE OF OUTSOURCING FACILITY INSPECTIONS PERFORMED BY OTHER STATES

The committee discussed the acceptance of outsourcing facility inspections performed by Florida and California to assess cGMP compliance when the outsourcing facility does not have a current FDA inspection report to provide for initial application or renewal pursuant to 54.1-3434.05 and 54.1-3434.5. It was noted that an inspection report resulting from an FDA inspection must be considered by the Board and that an inspection performed by another entity would not preclude this requirement.

MOTION:

The committee voted unanimously to recommend to the full board that it accept an inspection report indicating compliance with current Good Manufacturing Practices performed by the California Board of Pharmacy or Florida Department of Health for licensure purposes of outsourcing facilities when the FDA has not performed an inspection within the required timeframe for a current inspection report pursuant to 54.1-3434.05 and 54.1-3434.5 of the Code of Virginia. (motion by Nash, seconded by Yuan)

ADJOURN: With all business concluded, the meeting adjourned at 1:52PM.

Caroline D. Juran, RPh,
Executive Director

6/16/23
DATE