(FINAL/APPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING

April 24, 2018
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER:	The meeting was called to order at 9:15am
PRESIDING:	Michael I. Elliott, Committee Chairman
MEMBERS PRESENT:	Rafael Saenz Rebecca Thornbury Ryan K. Logan Cynthia Warriner
STAFF PRESENT:	Caroline D. Juran, Executive Director J. Samuel Johnson, Jr., Deputy Executive Director Beth O'Halloran, Deputy Executive Director Ellen Shinaberry, Deputy Executive Director Elaine J. Yeatts, Senior Policy Analyst James Rutkowski, Board Counsel, Office of the Attorney General
APPROVAL OF AGENDA:	Agenda presented for review included a regulatory update, consideration for adoption of revised emergency regulations for pharmaceutical processors, further consideration for petition for rulemaking regarding delivery of dispensed prescriptions, a review of legislation relating to delivery of schedule VI prescription devices and a periodic review of guidance documents.
MOTION:	**The Committee voted unanimously to approve the agenda as presented for the Regulation Committee meeting (motion by Warriner, second by Logan)**
PUBLIC COMMENT:	No public comment was offered to the Board.
AGENDA ITEMS:	
Regulatory Update:	Ms. Yeatts provided a brief overview of the regulatory actions that are pending for the Board of Pharmacy. The only recent change was the proposed action to increase fees has moved to the Office of the Attorney General for review.

Adoption of Revised Emergency Regulations for Pharmaceutical Processors of Cannabidiol Oil and THC-A Oil

Ms. Yeatts provided information regarding the 2018 General Assembly bills on this subject. Some of the legislative changes were as follows: expands the conditions for obtaining a written certification from intractable epilepsy to any diagnosed condition or disease, expands allowance for issuing a written certification to any physician registered by the Board of Pharmacy, changes the days' supply that may be dispensed from 30 to 90 days, requires the reporting of CBD oil and THC-A oil dispensing to the PMP, requires the practitioner to query the PMP prior to issuing a certification, requires the Board of Pharmacy to create a process for registering the products, and requires applicants for pharmaceutical processor permits to complete an criminal background check. The bills included an emergency clause. Staff advised that the Board should amend the emergency regulations based on the legislative amendments.

In addition to the agenda packet, a one-page handout with revisions of 18VAC110-60-310(A and B) was provided for their consideration. Staff provided a page-by-page walk through of the changes required in the emergency regulations. The committee discussed several points such as the possibility of requiring identification upon delivery of the dispensed drug and the number of plants required for a 90-day supply.

ACTION ITEM:

Prior to the board considering amendments to 18VAC110-60-240(A)(1), board staff will research the number of plants required to provide a 90-day supply of cannabidiol oil or THC-A oil to a patient.

MOTION:

The Committee voted unanimously to recommend to the full board that it revise the emergency regulations as indicated below or as otherwise presented, with the exception of 18VAC110-60-240(A)(1) that will be discussed at the June board meeting:

- **18 VAC 110-60-110(B)(3) change "owner or owners" to "applicant"**
- **18 VAC 110-60-285(B) strike "marijuana"**
- **18 VAC 110-60-310(A)(3), at the end of the sentence insert "and shall maintain a record in accordance with policy and procedures of the processor".**
- **18 VAC 110-60-310(C)(5) change from "20 oz" to "60 oz"**
- **18 VAC 110-60-310(G) change "intractable epilepsy" to "any diagnosed condition or disease". (motion by Saenz, second by Warriner)**

Further Consideration of Petition for Rulemaking from Lavino Regarding Delivery of Dispensed Prescriptions – 18 VAC 110-20-

The committee reviewed the petition from Joseph Lavino and the comments received from the petition. This petition was discussed at the December, 2017 full board meeting where the board voted to have the Regulation Committee further review and provide a decision on issuing a

275

NOIRA.

MOTION:

The committee voted 3 to 2 to recommend to the Board to issue a NOIRA regarding the petition for rulemaking for the delivery of dispensed prescriptions. (motion by Saenz, second by Logan; opposed – Warriner and Thornbury)

Review of Legislation Relating to the Delivery of Schedule VI Devices

Ms. Juran provided background information on the HB878 and SB413 passed during the 2018 General Assembly session that allows a permitted manufacturer, wholesale distributor, warehouse or nonresident warehouse, third-party logistics provider or nonresident third-party logistics provider or registered nonresident manufacturer or nonresident wholesale distributor to deliver a Schedule VI prescription device directly to an ultimate user or consumer. The bill directs the Board of Pharmacy to promulgate regulations within 280 days. The draft regulations for this law will be available for the full board's consideration at the June meeting.

ACTION ITEM:

Board staff to provide draft regulations related to HB878 and SB413 to the board for its consideration at the June 2018 full board meeting.

Periodic Review of Guidance Documents

The committee reviewed eight guidance documents that have not been revised in over seven years to determine if the board should keep, amend or repeal the guidance.

ACTION ITEM:

Board members to send Ms. Juran possible amendments to Guidance Document 110-16 prior to June board meeting.

MOTION:

The committee voted unanimously to recommend to the full board re-adoption of Guidance Documents 110-10, 110-11, 110-19, 110-22, 110-24, and 110-25. (motion by Warriner, second by Thornbury)

ADJOURN:

Next meeting TBD.

With all business concluded, the meeting adjourned at 11:50A.M.

Michael I. Elliott, Chairman

Caroline D. Juran, Executive Director

6/21/18
DATE

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