

(FINAL/APPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING**

November 21, 2019
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:10 AM.

PRESIDING: Kristopher Ratliff, Committee Chairman

MEMBERS PRESENT: Glen Bolyard, Jr.
Patricia Richards-Spruill
Cheryl Nelson(Arrived 9:17am)
Rebecca Thornbury
Cynthia Warriner

STAFF PRESENT: Caroline D. Juran, Executive Director
Ellen B. Shinaberry, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director (Exited 12:45pm)
Beth O'Halloran, Deputy Executive Director
Annette Kelley, Deputy Executive Director (Exited 1:15pm)
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General
Kiara Christian, Executive Assistant

QUORUM: With six members of the Committee present, a quorum was established.

APPROVAL OF AGENDA: The agenda was approved as presented.

MOTION: **Motion by Warriner, seconded by Thornbury**

PUBLIC COMMENT: Katie Hellebush, Executive Director of the Virginia Medical Cannabis Coalition, shared comment regarding inhalation devices. She offered VMCC's desire to ensure patient safety related to the use of inhalation devices, and asked that the board not restrict the sales of inhalation devices as this takes away a critical option for patients for whom other forms of administration would not work as well.

Aaron Lopez, Dalitso LLC, offered comment that echoed comment provided from Virginia Medical Cannabis Coalition.

Farzana Kennedy provided comment regarding the priority of patient safety.

Hunter Jamerson, Esq., speaking as Regulatory Council for Greenleaf,

offered support of the previous comments made regarding inhalation devices and the priority of patient safety. Mr. Jamerson also added that Maryland did not ban all vaped products, but only those vape products containing Vitamin E acetate.

Natalie Nguyen, Legislative Committee Chair for Virginia Society of Health-System Pharmacists (VSHP) stated a general support for Carousel and RFID technology.

Jenn Michelle Pedini, Development Director for the National Organization for the Reform of Marijuana Laws (NORML), shared concerns of patients obtaining illicit, unregulated vaping products if the board chooses to not allow the sale of vaping products.

Update on Regulatory/Policy
Actions

Ms. Yeatts reviewed the Chart of Regulatory Actions found in the agenda packet.

Recommendation on Adoption of
Guidance for Sample Size for
Pharmaceutical Processors

Regulation 18VAC110-60-300 stated the sample size should be a statistically valid sample size determined by the board.

• **MOTION:**

The committee voted unanimously to recommend to the full board to adopt a draft guidance document for sample size for pharmaceutical processors as presented. (motion by Warriner, second by Thornbury)

Discussion on Prohibiting CBD
and THC-A Oil Vaping
Formulations

There was discussion among the committee of a possible recommendation to the full board regarding what action, if any, should be taken to address concerns with CBD or THC-A formulations intended to be vaped, and the timeframe in which any regulatory action could take place. Ms. Warriner shared concerns of listing banned ingredients and questioned if banned products should be generalized as those that include "illicit substances" or "hydrophobic oils". Ms. Yeatts added that this topic may be an issue that will eventually need to be addressed statewide by the Commissioner of Health.

MOTION:

The committee voted 5:1 to recommend to the full board that it promulgate an emergency regulation to prohibit CBD or THC-A formulations intended to be vaped or inhaled from containing Vitamin E acetate and to recommend to the Health Commissioner that he also consider taking a more immediate action to prohibit these products from containing vitamin E acetate. (motion by Nelson, second by Bolyard; opposed by Warriner)

Discussion of Topics not included in the Periodic Regulatory Review

The committee had some discussion regarding comments previously received that could not be acted on during the periodic regulatory review period. The committee decided to table the discussion until after the General Assembly session to see if legislation is passed that would increase educational standards for pharmacy technicians.

Recommendation on Adoption of Regulations for Use of Medication Carousels and RFID technology Currently used in Innovative Pilot Programs

The committee reviewed draft amendments of 18VAC110-20-425 and 18VAC110-20-460 that would incorporate allowances for medication carousels with robotic systems and for use of RFID technology in provision of floor stock.

Mr. Johnson provided the committee with two handouts titled Medication Carousel and Radio Frequency Identification (RFID), and provided the committee an overview of each of the technologies.

Ms. Nelson shared concern of not scanning each unit prior to patient administration, and asked that the language be amended in 18VAC110-20-425 (C) (2) to require scanning, under certain circumstances, before administering medication to patients.

MOTION:

The committee voted unanimously to recommend to the Board to amend language in 18VAC110-20-425 (C)(2) to require scanning of each unit prior to patient administration and issue a NOIRA regarding allowance for medication carousels with robotic systems. (Motion by Nelson, Seconded by Warriner)

The committee had some discussion regarding the use of RFID technology and requested that staff amend the drafted language to clarify the terms “floor stock” and “use of kit”.

MOTION:

The committee voted unanimously to request staff amend language as discussed and recommend to the Board to issue a NOIRA regarding use of RFID technology in provision of floor stock. (Motion by Nelson, Seconded by Richards-Spruill)

Consideration of Requirements for Maintenance of Records regarding Immunizations

The committee discussed issues related to maintenance of immunization records or reporting to VIIS. There was a handout provided to the committee providing a visual sample of a VIIS Immunization Record.

Mr. Ratliff commented on the benefits of using the Virginia Immunization Information System, such as prevention of vaccine administration duplication. Ms. Yeatts suggested that the Board discuss mandatory reporting using VIIS with VDH, as the Board would need vaccine

reporting from other providers who may administer vaccines for use of VIIS to be effective.

Develop and Recommend
Adoption of Guidance for What
Constitutes a “New” Prescription
Requiring an Offer to Counsel

The committee discussed whether guidance was necessary on this subject.

MOTION:

The committee unanimously agreed to recommend to the full board that no further guidance be provided to define what constitutes a “new” prescription requiring an offer to counsel. (motion by Warriner, second by Bolyard)

Recommendation of Adoption of
Guidance to Clarify if
Collaborative Practice
Agreement is Required for Each
Patient

During a Joint Commission on Health Care study, it was reported to the researcher that confusion exists regarding whether a collaborative practice agreement is required for each patient to participate. The researcher inquired if the board would consider adopting guidance on this subject to clarify the Board’s position.

MOTION:

The committee voted unanimously to recommend to the full board that it adopt the guidance document as presented. (motion by Thornbury, second by Richards-Spruill)

Recommend Amending
Guidance Document 110-15
Delegation of Authority for
Disciplinary Matters

Ms. Juran shared with the committee that staff identified two actions that could be delegated to staff to expedite the handling of certain matters such as:

- The offering of a pre-hearing consent order for the voluntary surrender of a license or registration for reasons not related to disciplinary action.
- Authorizing the executive director to issue an advisory letter to the person who was the subject of a complaint pursuant to §54.1-2400.2(G), when it is determined that the proceeding will not be instituted.

Ms. Juran further added that staff receives approximately 1-2 calls each year from pharmacists requesting to voluntarily surrender their license.

MOTION:

The committee voted unanimously to recommend to the board to adopt Guidance Document 110-15 as presented. (motion by Warriner, second by Nelson)

Recommended Readoption of
Guidance Documents 110-18 and
110-23

It was recommended by staff that the board consider readoption of guidance documents 110-18 Interpretation of "administer" to include preparation for administration, and guidance document 110-23 Practitioner of the Healing Arts Selling Controlled Substances Inspection Deficiency Monetary Penalty Guide as presented with no amendments. Staff explained that all guidance documents require review and action by the board every 4 years.

MOTION:

The committee voted unanimously to recommend to the full board the adoption of guidance documents 110-18 and 110-23 as presented. (Motion by Warriner, Seconded by Nelson)

Recommend Readoption of
Guidance Documents 110-27 and
110-34

The committee was provided with handouts of the amended draft of Guidance Document 110-27 PIC Responsibilities, and the amended draft of Guidance document 110-34 Manufacturer, and Wholesale Distributor Licensure Guidance.

Staff recommended amended language as found on pages 2, 3, and 4 of the Guidance Document 110-27 handout.

Ms. Juran recommended a change to the suggested amendment in Guidance Document 110-34 as shown below:

"An individual that "brokers" the sale of prescription drugs (takes title of the drug and transfers ownership but does not physically possess or distribute drugs), must be licensed as a wholesale distributor ~~or registered as a nonresident wholesale distributor.~~"

MOTION:

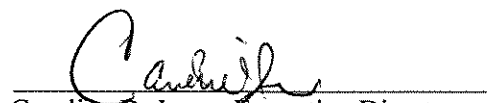
The committee voted unanimously to recommend the full board to adopt guidance 110-27 as presented and guidance document 110-34 as presented and amended. (Motion by Warriner, Seconded by Thornbury)

ADJOURN:

With all business concluded, the meeting adjourned at approximately 1:56 pm.



Kristopher Ratliff, Chairman



Caroline D. Juran, Executive Director

12/9/2019

DATE

12/9/19

DATE