

DRAFT/UNAPPROVED

**VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATORY ADVISORY PANEL MEETING REGARDING CANNABIDIOL
OIL AND THC-A OIL**

August 30, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

- CALL TO ORDER:** The meeting was called to order at 10:10 am
- PRESIDING:** Ryan K. Logan, Chairman
- MEMBERS PRESENT:** Cynthia Warriner, Board of Pharmacy
Jody H. Allen, Board of Pharmacy
Senator David W. Marsden
William L. Harp, MD, Board of Medicine
Alexander Pytlarz, Virginia Pharmacists Association
Ed McCann, former owner of cannabis facility
Regina Whitsett, Substance Abuse Free Environment, Inc.
Beth Collins, Americans for Safe Access
Baylor Rice, community compounding pharmacist
Julia Whiting, MD, concerned parent/physician
Chuck Morris, concerned family member
Paul Lyons, MD, child neurologist
Svinder Toor, MD, Board of Medicine/child neurologist
- MEMBERS ABSENT:** Jake Bergman, Surterra Holdings, Inc.
- STAFF PRESENT:** Caroline D. Juran, Executive Director
J. Samuel Johnson, Deputy Executive Director
David E. Brown, DHP Director
Elaine J. Yeatts, Senior Policy Analyst
Jim Rutkowski, Assistant Attorney General
Beth O'Halloran, Individual Licensing Manager
- APPROVAL OF AGENDA:** Agenda from the previous meeting of the panel presented for review by Ms. Juran and a review of the proposed language for draft regulations prepared by Board of Pharmacy staff.
- APPROVAL OF MINUTES:** A review of the draft minutes from the previous meeting of the panel was presented by Ms. Juran.
- MOTION:** **The panel voted unanimously to approve the minutes for the Regulation Advisory Panel meeting held on July 26, 2016 as presented (motion by Rice, second by Warriner)**

PUBLIC COMMENT:

Col. Thierry Dupuis, chief of police for Chesterfield County, addressed the concerns for safety in the community in regards to dispensing, security and the fiscal impacts of this product. Col. Dupuis pointed out that there was no law enforcement representation on the panel and felt that this was an oversight. He also addressed his concern regarding the fiscal impacts on localities and offered to assist in setting up standards for security for the pharmaceutical processors. Col. Dupuis urged the panel to keep in mind that a large locality such as Chesterfield County may have the resources available for this type of facility but other smaller localities may not have those resources.

Tim Jones, Chief of Police, City of Roanoke, addressed the concerns that this is the first in the lead of federal legalization of marijuana. Mr. Jones urges the stringent oversight of the use of medical marijuana.

Colleen French, Board member with the Roanoke Prevention Alliance, provided comment over the concerns with a lack of definition of intractable epilepsy, the broad allowance for the practitioners allowed to obtain a certification and the allowance of the practitioner using professional judgement on the evaluation of the patient authorized to receive the oils. Ms. French stated that instructions on the administration should be provided to the patient at the time of prescribing. Ms. French stated that she believes there should be a prohibition on the location of the processor so as not to allow close proximity to children. She also stated that the use of marijuana in middle school students is more than the use of alcohol.

Dr. Mary Crozier, substance abuse prevention provider and college professor, suggested that the legislation would have been better to wait until the FDA completed their research on CBD to avoid a “ready, aim, fire” approach. Dr. Crozier stated this product would be safe to dispense through a pharmacy and that money should be allocated towards education for the providers and patients.

Nancy Hans, Chair of the Community Coalitions of Virginia, suggested a “smart” approach to marijuana. Ms. Hans stated that all fully legalized states opened the door with medical marijuana and feels that this legislation will have direct effect on our workforce and community.

Lennice Wirth, an advocate for drug law reform, voiced concerns over too much regulation inhibiting patient access to needed and helpful medication. Ms. Wirth does not agree with regular bloodwork required of patients on TCH-A or CBD oils.

Mary Lynn Mathre, registered nurse and certified addiction specialist and founder of Patients Out Of Time, stated that CBD oil is not at risk for children attempting to gain for abuse. Ms. Mathre also spoke regarding concerns for mandatory blood testing of patients, the prohibition of vaping, the need for a shelf life of the oils and the need for an educational course for physicians.

- Review proposed language for draft regulations prepared by staff

Prior to the discussion of the draft regulations, Jim Rutkowski, assistant attorney general, provided the legal background on the prohibition on delivery. Based on the narrow allowance in law and the definition of a pharmaceutical processor, which is a facility, and the wording in the legislation that states “in person” refers to dispensing from the building, therefore prohibiting delivery of the product. Mr. Rutkowski had initially opined that delivery of the oils was allowed in the law.

Ms. Yeatts provided the background on the decision to require a pharmacist on premises at all times the location is open and there are other personnel in the facility. The “personal supervision” as written in law refers to “in person” so it cannot be delegated or subcontracted out. Since the law only provides for a single facility that both cultivates and dispenses, the pharmacist must be on premises to personally supervise the activities of all processes in the facility.

The panel then began to review the remaining draft regulations on pages 33-59 of the agenda packet, and offered comments and suggestions to the language. Comments/suggestions offered for consideration included:

- On page 35, add the word “administration”, incorporate #7 within #5 and remove the word “reasonably”.
- On page 35, guidelines should be established for physicians to provide #4, #5, #6 and #7.
- Strike the “conditional approval” on page 40, #2 as this would limit facilities in small localities.
- Increase 180 days to 1 year to commence business.
- Page 36, letter C, to be edited to say “self” instead of “practitioner” to make sentence easier to read.
- Suggestion to change 14 day requirement to report death of a registered patient to 15 days consistent with Department of Health notification.
- Suggestion to add requirement for training courses in requirements for a practitioner
- Suggestion to add lab reports to the allowable posting on websites for processor, page 48
- Add the words “petroleum based” to the prohibition of organic solvents as these are the toxic solvents.
- Page 40 letter A, strike #2 about maintenance of low THC concentration plants.
- Add a quarterly inspection fee
- During application process, the plans should adequately address security and screening
- Page 40, letter B, #2, to strike the last half of the sentence and instead add “daycare, recreation area and parks to be more specific about the requirements for restrictions on location.
- Maintain records for 3 years
- In laboratory testing section, B, suggestion to edit wording to more clearly state the sample shall be from each batch.
- Add the word “properly” in front of dispose on page 56, letter E

- Page 58, letter G, strike debilitating medical condition and replace with intractable epilepsy
- Page 58, letter H, add “in consultation with the practitioner” after THC-A oil to a registered patient

ADJOURN:

With all business concluded, the meeting adjourned at approximately 4:00 pm.

Ryan K. Logan, Chairman

Caroline D. Juran, Executive Director

DATE

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