

DRAFT/UNAPPROVED

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

July 26, 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 (left at 3:05pm)  
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 (left at 3:30pm)  
Baylor Rice, community compounding pharmacist  
Jake Bergman, Surterra Holdings, Inc.  
Julia Whiting, MD, concerned parent/physician  
Chuck Morris, concerned family member  
Paul Lyons, MD, child neurologist
- MEMBERS ABSENT:** Svinder Toor, MD, Board of Medicine/child neurologist
- 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 presented for review including presentations by Ms. Juran with reports on action items from the previous meeting of the panel 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 identified areas needing correction. Item #15 with regard to dosing for the patient should read 20-30mg/kg/day and in Item #20 the panel decided to remove the term "agreed" and replace with "discussed" as the general consensus was that the panel did not come to an agreement on the number of patients to which prescribers should be limited.

**MOTION:**

**The Panel voted unanimously to approve the minutes as amended for the Regulation Advisory Panel meeting held on July 1, 2016. (motion by Warriner, second by Whiting)**

**PUBLIC COMMENT:**

Heather Davies, concerned parent and board member of the Unified Prevention Coalition of Fairfax County, spoke regarding concerns over diversion of the medical product by teenagers, the marketing of medical marijuana, and the impact it will have on youth and their perception with regard to its recreational use. Ms. Davies also spoke about her concerns regarding possible links between marijuana use and suicide. Other comments addressed by Ms. Davies included:

- Need for a definition of drug-resistant epilepsy;
- Compared to other state laws, SB701 allows the highest level of THC to be present in cannabidiol oil and THC-A oil;
- Descriptive statistics of target patient population needed to determine allowable facility size, production and inventory;
- Prescribing information should be submitted by applicants, consistent with FDA labeling regulations and approved by the Board of Pharmacy as part of permit;
- The Board of Pharmacy needs to survey Virginia physicians for interest in prescribing oils;
- Contraindications – prescribing to pregnant and lactating women
- Labeling and patient information clearly stating these products are not FDA approved;
- Dosing guidelines, a critical determinant of facility permit conditions;
- Adverse event reporting process needed, similar to FDA MedWatch;
- Documentation of patient response to treatment;
- Physician requirements – should be for neurologists only;
- Mandatory use of patient blood monitoring to determine beneficial dose, deter diversion;
- Photo identification for qualified patients and/or caregivers;
- Permitted administration methods – no vaping;
- Require physician training requirement;
- Emergency room guidelines for managing overdosing, adverse events;
- Consultation and approval of local jurisdictions for facility siting, location-specific conditions and zoning requirements;
- Standardized test protocols, lab accreditation;
- Shelf life, expiration determination;
- Drug-testing of all employees;
- Training standards – employees;
- Worker safety standards – personal protective equipment, indoor air quality;
- Absolutely no advertising;
- Penalties for violation of these regulations.

Marla Watson, legislative chair for the Community Coalitions of Virginia and Central Virginia Marijuana Prevention Task Force Coordinator, provided comment regarding concerns for the regulations to support SB701, emphasizing that use of marijuana remains illegal federally. Ms. Watson provided comment and a handout that explained participants in the marijuana industry should be thoroughly vetted including background checks, free of felony charges, no liens or judgements and have not been barred from any contracting processes. Ms. Watson also expressed concern over the one month supply and the lack of research on the dosage to calculate a one month supply. Ms. Watson commented that practitioners that issue a certification to patients should only do so as a last resort to traditional medications and that physicians should take a course on the use of marijuana oils as this subject is not taught in medical schools traditionally. Ms. Watson also stated that the state should create a board of doctors, health officials, addiction experts and law enforcement officials who are unaffiliated with the marijuana industry that will create the course based on scientific evidence.

Kevin Carroll, president of the Fraternal Order of Police of Virginia, provided comment on the ability to convert THC-A to THC when heated and the concern for where the plants are grown and possible diversion from the facilities. Mr. Carroll stated he has concerns over the security of the product and how it is going to be distributed.

REPORT ON ACTION ITEMS:

Information was shared and discussed regarding action items identified in the minutes from the July 1, 2016 meeting.

- Action Item-Basic Requirements for Temperature and Humidity

Mr. Bergman provided information regarding basic requirement for temperature and humidity. The following information was provided by Mr. Bergman:

	<u>TEMPERATURE</u>	<u>HUMIDITY</u>
“Mother” room	65-75 F	50-60 %
Nursery phase	77-85 F	65-75 %
Vegetation phase	77-85 F	55-65 %
Flower/Harvest phase	77-85 F	55-60 %
Drying/Extraction rooms	< 75 F	55-60 %
  
- Action Item – Whether SB701 allows a pharmaceutical processor to deliver dispensed oil to a patient’s residence

Mr. Rutkowski informed the panel that while SB701 states delivery must be “in person” it does not state where the delivery should take place and therefore a delivery driver could be used to deliver the dispensed oil to the patient’s residence. He indicated delivery could not be performed by a third party.
  
- Action Item – Maximum number of plants a pharmaceutical processor should be allowed to possess at any given time

Mr. Bergman stated that the number of plants depends on the dosing for the patient and how many plants are needed to treat that patient. Each plant will yield between 12-15grams of oil. It takes generally 4 months to grow a plant. If the maximum dose is 15 grams per month that would equal approximately 1 plant per month per patient. To address concerns

with the viability of plants, it was suggested that a 20% buffer for the cloning stage and a 5% buffer for the cultivating cycle should be considered, along with idea that patient may immediately not respond well to dispensed product and may need subsequent dispensing. Thus, Mr. Bergman recommended processors be allowed to possess 4-5 plants per patient at any given time. Additionally, time for testing the oil prior to dispensing should be considered. It was, also, suggested by a panel member that an amendment of the bill to limit the square footage for the growing area per patient rather than the number of plants may be a better approach. Ms. Juran stated that the National Alliance for Model State Drug Laws (NAMSDL) reports that states addressing the private production of low THC/cannabidiol (Virginia, Missouri, Texas, and Florida) do not generally address a number of plants that may be possessed, with the exception of Florida which appears to indicate the producer be capable of large-scale production. States with broader medical marijuana allowances do tend to address the number of plants a producer may possess.

- Action Item – to what standards should production of oils be held  
Ms. Juran reported that per NAMSDL, states do not generally appear to reference a particular standard, e.g., USP, FDA cGMPs, but rather have identified individual requirements in regulation for cultivation and testing.
- Action Item – what constitutes a 30-day supply and how should the board interpret the requirement to define this element  
Ms. Juran stated that NAMSDL reports that there are a few states that limit the actual dose of oil. Georgia limits a person to 20 fluid ounces of low THC oil, Iowa limits a person to 32 fluid ounces of oil, and Missouri restricts persons to 20 fluid ounces of hemp extract. It was discussed that the amount of active ingredient should be taken into consideration to ensure the amount of necessary carrier oil doesn't negatively impact the amount permissible to be dispensed. Ms. Collins stated that patients typically need fewer milligrams of THC-A oil for treatment than cannabidiol oil. Mr. Rutkowski simply advised that the board must have a reasonable explanation for the limit it sets.
- Action Item – number of patients that a practitioner may issue a written certification and how should the board interpret the requirement to define this element  
Ms. Juran stated that NAMSDL reports that the other states limited to low THC/cannabidiol oil do not address this issue. Since the end of January 2015, when Iowa's law went into force, roughly 100 applications for cannabidiol registry cards have been received. Mr. Rice clarified that his suggestion of 600 patients during the last meeting was referencing allowances for medical concierge, but should not be the maximum number of patients a practitioner may issue a written certification.
- Action Item-how DHP could structure the registration process  
Ms. Juran indicated she will be meeting with other DHP staff members later this week to discuss this issue and hopes to have more information to share at the next panel meeting.

- Review proposed language for draft regulations prepared by staff

The panel began a review of the draft regulations, pages 8 through 28 of the agenda packet, and offered comments and suggestions to the language. Comments/suggestions offered for consideration included:

- Add definition for intractable epilepsy; no single definition, tends to be based on a practitioner's clinical decision;
- Define what constitutes residency; staff to locate existing definitions in law; should address military transfers, and persons relocating who need continued cannabidiol therapy;
- Strike any reference to compounding;
- Proposed fees appear too low;
- Require in-person visits with practitioner for one year then may use telemedicine based on practitioner's professional judgement;
- Clarify record retention requirements;
- Require blood draws; unnecessary and overly burdensome for patients;
- Require training for practitioners;
- Background check for registration process for patient, parent, guardian should determine if convicted for possession as well;
- Review FDA standards for allowing compassionate use when convictions are present;
- When considering issuance of registration add great weight for consideration of the best interest of the child;
- Patient, parent, guardian should exercise reasonable precautions to prevent theft, loss, access by unauthorized persons;
- Don't require to carry written certification or registration, unless it's a wallet card;
- Application process for pharmaceutical processors should involve 3 phases, e.g., initial review of paperwork, initial approval to proceed with plan, and inspection
- Should not allow for monopolies;
- Consider a performance surety bond;
- Requirement for applicant to report actions taken in other states;
- Location restrictions should default to local zoning requirements;
- Impact of local ordinances preventing agriculture and retail on same lot; Right to Farm;
- Production process should allow for non-pharmacists and non-pharmacy technicians, e.g., chemists;
- Change required registration timeframe for eligible pharmacy technicians to two years, consider recognizing experience in other states;
- PIC should be required to perform criminal background checks on employees performing non-dispensing functions, decision to perform drug testing should be left to pharmacist-in-charge;
- Consideration for whether a pharmacist must be present at all times when in operation and if key and alarm code should be restricted to pharmacist(s);
- Consider restricting non-pharmacists to cultivation area based on design model with increased security, e.g., surveillance cameras, and requirement for drug testing;

- Add requirement to notify public if closing;
- Require processors to post pricing of oil on Internet website;
- If employed agent allowed to deliver oil need mechanism for verifying identify of patient, parent, guardian, as applicable;
- Surveillance videos should be required both inside and outside facility;
- Combine sections of regulation, as appropriate, for ease of reading.

ADJOURN:

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

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Ryan K. Logan, Chairman

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Caroline D. Juran, Executive Director

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