Virginia Medical Cannabis Work Group
As Required by 2020 Acts of Assembly Chapter 711

Meeting One
August 3, 2020
3:00-5:00pm

Virtual Meeting—Register Here:
https://covaconf.webex.com/covaconf/onstage/g.php?MTID=ee16d6873a4d1ef79ae65ae1f043257d2

If people need to call in:
Phone number: 866-692-4530
Event code: 161 517 9780

Agenda

1. Public Meeting/FOIA Overview – TBD *5 min*

2. Introductions – facilitated by Dan Carey, Secretary of Health and Human Resources *10 min*

3. Virginia Medical Cannabis Program Overview – Caroline Juran, Executive Director, Virginia Board of Pharmacy and Annette Kelley, Deputy Executive Director, Virginia Board of Pharmacy *30 min*

4. Work Group Charge and Proposed Work Group Agenda – Catie Finley, Assistant Secretary of Health and Human Resources *10 min*

6. Group Discussion & Finalize Work Plan – All *40 min*

7. Public Comment (2 min per person) *25 min*

8. Adjournment

To pre-register for public comment, please indicate that you would like to speak when registering for the WebEx meeting. The host of the meeting will call on each speaker in the order in which they registered to speak for 2 minutes. After we have gone through each pre-registered commenter and if any time remains, we will also hear from members of the public who may wish to speak but did not pre-register. If you did not pre-register but would like to speak, use the "Raise Hand" function in the WebEx platform; or if you are calling into the meeting from a telephone, press *3.

VIRGINIA FREEDOM OF INFORMATION ACT

An Overview

Notice of Chapter

- Any person elected, reelected, appointed or reappointed to any body not excepted from this chapter shall:
- (i) be furnished by the public body's administrator or legal counsel with a copy of this chapter within two weeks following election, reelection, appointment or reappointment; and
- (ii) read and become familiar with the provisions of this chapter.

Intent of FOIA

- To ensure the people of the Commonwealth access to public records in the custody of a public body.
- Provide free entry to meetings of public bodies wherein the business of the people is being conducted.
- The affairs of government are not intended to be conducted in an atmosphere of secrecy since at all times the public is to be the beneficiary of any action taken at any level of government.

How is the intent expressed?

- By liberally construing the provisions to promote an increased awareness of governmental activities and afford citizens every opportunity to witness the operations of government.

- Exemptions from public access to records or meetings shall be narrowly construed and no record shall be withheld or meeting closed to the public unless specifically made exempt pursuant to this chapter or other specific provision of law.

Two Sides of FOIA

1. Public Records

2. Meetings

Public Records

What are public records?

"*Public records*" means all writings and recordings, however they are stored, and regardless of physical form or characteristics, prepared or owned by, or in the possession of a public body or its officers, employees or agents in the transaction of public business.

Minutes, including draft minutes, and all other records of open meetings, including audio or audio/visual records shall be deemed public records and subject to the provisions of this chapter.

Public Records are Open

- All public records shall be open to inspection and copying by any citizens of the Commonwealth.
- Except as otherwise specifically provided by law.

A Note Regarding Email

- Email relating to public business is accessible just like any other public record.

- Email may be withheld from public disclosure only if a particular exemption applies to the content of the email.

Response to a FOIA Request

- Public body has five days to respond to a FOIA request by producing records or providing a response.
- You may secure another seven work days.
- Failure to respond to a request for records shall be deemed a denial.
- No public body shall be required to create a new record if the record does not already exist.

MEETINGS

All meetings of public bodies shall be open, except as provided by law.

Definition of Public Body

"Public body" means any legislative body, authority, **board**, bureau, commission, district or agency of the Commonwealth or of any political subdivision of the Commonwealth . . . ; and other organizations, corporations or agencies in the Commonwealth supported wholly or principally by public funds.

It shall include any committee, subcommittee, or other entity however designated, of the public body created to perform delegated functions of the public body or to advise the public body. It shall not exclude any such committee, subcommittee or entity because it has private sector or citizen members.

Definition of Meeting

A “meeting” includes work sessions, when sitting physically, or through telephonic or video equipment . . . as a body or entity, or as an informal assemblage of –

(i) as many as three members, or

(ii) a quorum, if less than three, of the constituent membership, wherever held, with or without minutes being taken, whether or not votes are cast, of any public body.

Not a Meeting

- The gathering of employees of a public body or gathering or attendance of two or more members of a public body at any place where the purpose of such gathering is not the discussion or transaction of any public business, **and**

- Such gathering or attendance was not called or prearranged with any purpose of discussing or transacting any business of the public body.

Meeting Notice Requirements

- Every public body shall give notice of the date, time, and location of its meetings by placing the notice:
- On its official website.
- In a prominent public location.
- At the office of the clerk or chief administrator of the public body.
- A central, publicly available electronic calendar maintained by the Commonwealth, which is required by all state public bodies subject to the provisions of this chapter.

Meetings are Open

- All meetings of public bodies shall be open except as provided by law.
- No meeting shall be conducted through telephonic, video, electronic or other communication means where the members are not *physically assembled* to discuss or transact public business except as provided by law.
- However, there are ways to do an electronic meeting that involve a quorum of members physically.
- The General Assembly changed the protocols for public meetings to address the risk of COVID-19. Many of the same notice requirements still apply.

Meeting Required

- The transaction of public business, other than by votes at a meeting, is prohibited unless otherwise provided by law.

- However, one may separately contact the membership, or any part thereof, for the purpose of ascertaining a member's position with respect to the transaction of public business, provided the contact does not constitute a meeting.

Email Exchange Becomes a Meeting

An improper closed meeting occurs where the emails involve some sort of back-and-forth exchange of the three required members; the messages generate group conversations or responses with multiple recipients.

RECAP

- 1) A public body can not transact public business without meeting.
- 2) A public body can not conduct an electronic meeting to discuss public business (except if you follow certain requirements).
- 3) Members can be "separately" contacted to ascertain the member's position so long as communication does not become a meeting. Communication can not have feature of simultaneity with quorum or three members.

Best Practices

- Remember that what you put in writing is a public record subject to FOIA.
- Think first. If unsure, reach out and ask questions.
- Use a separate account for your public business.
- Pick up the phone.
- If in writing, send emails to staff for distribution.

FOIA Violation

- If the petitioner substantially prevails on the merits of a case:
- The petitioner is entitled to recover reasonable costs including reasonable fees for expert witnesses and attorneys from the public body.
- If the court finds that a violation was willfully and knowingly made, the court shall impose upon such officer, employee, or member in his individual capacity . . . a civil penalty of not less than $ 500 nor more than $ 2,000. . . For a second or subsequent violation, such civil penalty shall be not less than $ 2,000 nor more than $ 5,000.

FOIA Resources

Virginia Freedom of Information Advisory Council

http://foiacouncil.dls.virginia.gov/foiacouncil.htm

Introductions of Work Group Members

- Dr. Daniel Carey, Secretary of Health and Human Resources
- Catie Finley, Assistant Secretary of Health and Human Resources
- Dr. David Brown, Director of Health Professions
- Caroline Juran, Executive Director of the Board of Pharmacy
- Delegate Glenn Davis, Member of the House of Delegates
- Senator David Marsden, Member of the Senate
- Ngiste Abebe, Director of Public Policy, Columbia Care
- Jack Page, Chief Operating Officer, Dharma Pharmaceuticals
- Sara Payne, Senior Corporate Counsel Jushi, parent company, Dalitso, dba Beyond/Hello
- Joy Strand, Vice President, Green Leaf of Virginia
- Lisa and Hayley Smith, patient representatives
- Jenn Michelle Pedini, Executive Director of Virginia NORML
- Dr. Sam Caughron, Charlottesville Wellness Center Family Practice
- Dr. Preston Grice, University of Virginia

Virginia Department of Health Professions

Virginia Board of Pharmacy

Medical Cannabis Workgroup

August 3, 2020

Caroline D. Juran, RPh
Executive Director, Board of Pharmacy

Virginia Department of Health Professions

Department of Health Profession

- Mission: To ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public.
- 13 health regulatory boards, Board of Health Professions, Prescription Monitoring Program, Health Practitioners' Monitoring program, Healthcare Workforce Data Center
- Regulates healthcare practitioners over 60 professions

Virginia Department of Health Professions

Department of Health Profession

- Non-General Fund agency
- Must cover expenses through licensing fees
- Monetary penalties must be transferred to State Literary Fund within DOE

Virginia Department of Health Professions

Board Members

Kristopher S. Ratliff, *Chairman*

Cheryl H. Nelson, *Vice Chairman*

Glenn Bolyard

Melvin L. Boone, Sr., *Citizen*

James L. Jenkins, Jr., *Citizen*

Ryan K. Logan

William Lee

Patricia Richards-Spruill

Rebecca Thornbury

Cynthia Warriner

Virginia Department of Health Professions

Pharmaceutical Processor Laws

2015

- Authorized physician to issue written certification providing affirmative defense for possessing CBD oil and THC-A oil

2016

- Directed BOP to oversee CBD oil and THC-A oil production and dispensing by up to 5 pharmaceutical processors for treatment of intractable epilepsy

Virginia Department of Health Professions

Pharmaceutical Processor Laws

2017

- Reenacted legislation, as required by 2016 bill.
- August 2017: Emergency regulations became effective; establish health, safety and security requirements for processors

2018

- Expanded program to allow physician to issue certification for the use of CBD oil or THC-A oil for the treatment of any diagnosed condition or disease

Virginia Department of Health Professions

Pharmaceutical Processor Laws

2019

- Expanded authority to physician assistants and nurse practitioners to issue written certifications
- Created authority for BOP to register a “registered agent” who may be designated by a patient to receive CBD or THC-A oil on his/her behalf
- Allows processors to wholesale distribute oil products between processors

Virginia Department of Health Professions

Pharmaceutical Processor Laws

2020

- Removes affirmative defense
- Replaces “cannabidiol” and “THC-A oil” terms with “cannabis oil”; removes 5% THC cap, but retains THC cap/dose
- Authorizes use of telemedicine consistent with federal requirements for Rx drugs
- Allows persons temporarily residing in Virginia to obtain patient registration
- Authorizes up to 5 cannabis dispensing facility permits per HSA

§54.1-3408.3

- "Cannabis oil" means:
  - any formulation of processed Cannabis plant extract, which may include oil from industrial hemp extract acquired by processer, or a dilution of the resin of the Cannabis plant
  - that contains at least 5 mg of CBD or THC-A and
  - no more than 10 mg of delta-9-tetrahydrocannabinol per dose.

§54.1-3408.3

- "Cannabis oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law, unless it has been acquired and formulated with cannabis plant extract by a pharmaceutical processor.

Pharmaceutical Processor

- Facility permitted by Board of Pharmacy
- Vertical operation:
  - Indoor cultivation of Cannabis plants;
  - Production of cannabis oil;
  - Dispensing of oils by pharmacist to registered patients

Pharmaceutical Processor, cont.

- Operates under supervision of a pharmacist.
- Board quarterly inspections required.
- Oils independently laboratory tested prior to dispensing.
- Lab results available upon request to patients, parents/guardians, practitioners.
- Products must be registered by BOP

Pharmaceutical Processors

- HSA I = vacant
- HSA II = Dalitso LLC, Manassas
- HSA III = Dharma Pharmaceuticals, Bristol
- HSA IV = Green Leaf Medical of Virginia LLC, Richmond
- HSA V = Columbia Care Eastern Virginia LLC, Portsmouth

Lab Testing of Oil Products

- Microbiological: microorganisms
- Mycotoxin: fungus, mold
- Heavy metal: Arsenic, Cadmium, Lead
- Pesticide chemical residue: no chemicals/petroleum based solvents
- Residual solvent test: organic volatile chemicals
- Active ingredient analysis (CBD, CBDA, THC, THC-A)
- Expiration date based on stability test

Availability of Oil Products

- Approximately 3-6 months to cultivate and produce oils
- Processor anticipates availability of oils in August
- Patients may access any of the pharmaceutical processor sites

Practitioner Requirements

Virginia Department of Health Professions

Practitioner Requirements 18VAC110-60-30

- Conduct an assessment and evaluation of the patient to develop a treatment plan; obtain patient's medical history, prescription history, current medical condition
- Diagnose the patient;
- Be of the opinion that the potential benefits of cannabidiol oil or THC-A oil would likely outweigh the health risks of such use to the qualifying patient;

Practitioner Requirements, cont.

- Explain proper administration, potential risks and benefits, prior to issuing the written certification;
- Be available or ensure that another practitioner is available to provide follow-up care and treatment to determine efficacy of CBD oil or THC-A oil for treating the diagnosed condition or disease;
- Access to the Virginia Prescription Monitoring Program;

Practitioner Requirements, cont.

- Practitioner shall not delegate responsibility of diagnosing a patient or determining whether a patient should be issued a certification.
- Cannot issue more than 600 certifications at any given time. Can petition Boards of Pharmacy & Medicine for increase.

Practitioner Prohibitions

Virginia Department of Health Professions

Prohibited Practices of Practitioner, 18VAC110-60-40

- Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia;
- Offer a discount or any other thing of value to a qualifying patient, parent or guardian based on the patient's agreement or decision to use a particular pharmaceutical processor or cannabidiol oil or THC-A oil product;

Virginia Department of Health Professions

Prohibited Practices of Practitioner, 18VAC110-60-40

- Examine a qualifying patient for purposes of diagnosing the condition or disease at a location where cannabis oil is dispensed or produced;
- A practitioner, and such practitioner's co-worker, employee, spouse, parent or child, shall not have a direct or indirect financial interest in a pharmaceutical processor or any other entity that may benefit from a qualifying patient's acquisition, purchase or use of cannabis oil

Virginia Department of Health Professions

Prohibited Practices of Practitioner, 18VAC110-60-40

- A practitioner shall not issue a certification for himself or for family members, employees or co-workers
- A practitioner shall not provide product samples containing cannabis oil other than those approved by the United States Food and Drug Administration.

Board Registrations

Virginia Department of Health Professions

Registrations

- Online applications
- Patient & Practitioner = $50 initial and annual fee
- Parent/Legal Guardian = $25 initial and annual fee
- Registered Agent = $25 initial and annual fee

Virginia Department of Health Professions

Registrations as of 7/24/2020

- Registered Practitioners: 423
- Registered Patients: 3814
- Registered Parents/Guardians: 50
- Registered Agents: 6

Virginia Department of Health Professions

Contact Information

Department of Health Professions
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233
(804) 367-4456

cbd@dhp.virginia.gov – CBD, pharmaceutical processor – related questions

pharmbd@dhp.virginia.gov - General board questions

Virginia Department of Health Professions

Virginia Board of Pharmacy

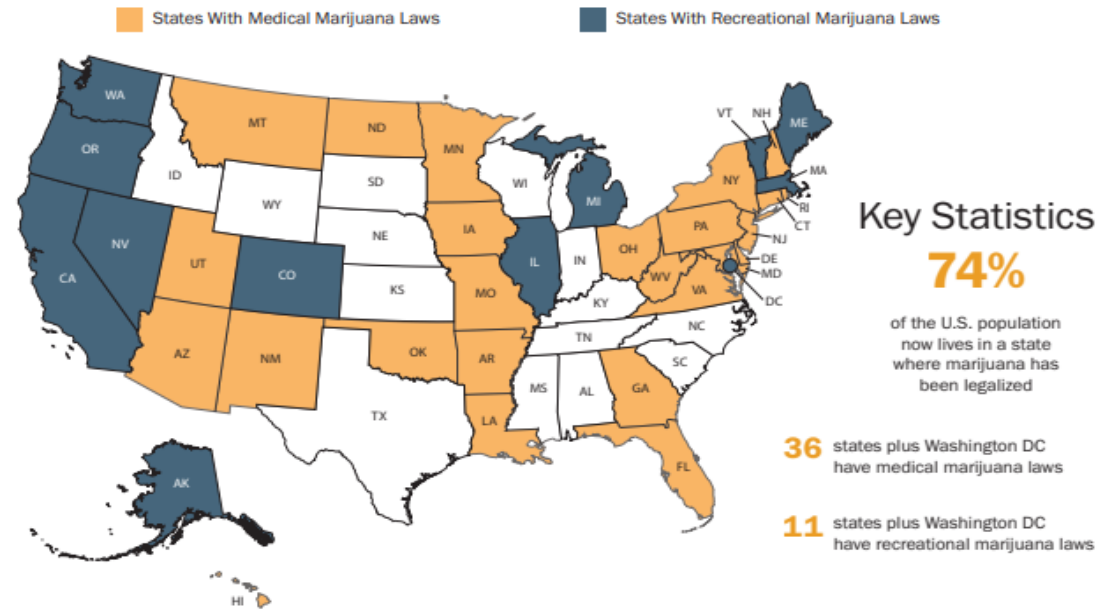
Medical Cannabis Workgroup

August 3, 2020

Annette S. Kelley, M.S.; C.S.A.C.

Deputy Executive Director, Board of Pharmacy

Medical/Recreational by State



Source: 2020 Marijuana Business Factbook, U.S. Census Bureau

Program Design

- Only 9 states have a true vertical program; majority have a combination of cultivators, processors and dispensers that may operate independent of each other
- Most states maintain regulatory oversight of their medical marijuana program within a health services related state agency. 14 states have an identified “Commission” or “Department” to focus on the program.

Program Design

- Extreme variability across states
  - Alternative Treatment Centers
  - Compassion centers
  - For profit and not for profit
  - Cultivator, processor, dispenser separated and some with a combination of these
  - States with 100s of dispensaries and states with only a handful

Fees

- Varies greatly across states
- Initial, License, Renewal
  - 29 states charge a fee for all three categories
- Difficult to compare total fee amount per state as states vary in fees charged
  - $0-$200,000

State Tax Requirements

- 26 states charge a tax for medical marijuana
  - CO-2.9%; WA-37% excise tax
- All recreational marijuana states charge tax except Vermont
  - ME-10%; WA-37% + 9.6% at point of sale
- No tax on medical marijuana:
  - CT, DE, FL, MD, MA, MN, NH, OR, UT, VT, VA

Formulations/Restrictions

- Flower: FL, HI, NJ, ND, CT (baked goods), OH (plant material), UT (unprocessed flower in a blister pack)
- No flower: LA, GA, NY, VA, WV

Formulations/Restrictions

- Edibles not allowed:
  - CT (allow baked goods), GA, HI, IL (limited), IA, NY, ND, NJ (allow for minors), PA, UT, WV
- Vape products not allowed:
  - GA, LA
- Tinctures not allowed:
  - NJ
- Products cannot be attractive to children:
  - AK, AZ, CO, CT, FL, LA, MA, HI, OH, UT, VA, WA, WV

Patient Services

- Patient Registry
  - Required in all but 4 states
    - Voluntary in CA, ME, WA; No registry in LA
- Practitioner Statement/Certification
  - Required in all states
- Caregivers
  - All states allow

Patient Services

- Qualifying conditions
  - 3 states have no restrictions for use of medical marijuana (DC, OK, VA)
  - 14 states have a list and a “physician discretion” clause
  - 20 states have a specific list of conditions/ diseases
- Patient registration fees
  - All states except ME & LA
  - MT-$5; MN & OR-$200

Registered Patients as % of State Population

% of Population	State(s)
7.51	OK
4.0-4.9	ME, NM
3.0-3.9	MT, AZ
2.0-2.9	MI, PA, HI
1.0-1.9	AR, RI, MD, FL, CO, DE, CT, MA
.50-.99	IL, DC, NJ, OH, VT, MO, NH, NY, OR, WA
.03-.49	NV, ND, MN, IA, GA, LA, UT, VA