Pharmaceutical Processors in the Commonwealth of Virginia

The Virginia Board of Pharmacy is tasked with regulating the production and dispensing of Cannabidiol (CBD) and THC-A oil. On November 28, 2018, conditional approval to produce and dispense these oils was finalized for:

- Pharmacann (Health Service Area I)
- Dalitso (Health Service Area II)
- Green Leaf (Health Service Area IV)
- Columbia Care (Health Service Area V)

On December 18, 2018, conditional approval to produce and dispense these oils was finalized for:

- Dharma (Health Service Area III)

Legislative History:

- 2015 legislation provided an affirmative defense for the possession of cannabidiol or THC-A oil pursuant to a valid written certification for patient use of the oils from a physician to alleviate intractable epilepsy, but made no provision for a patient to acquire these substances.
- Legislation passed in 2016 and 2017 authorized five pharmaceutical processors, one in each Health Service Area, to produce and dispense these oils, under a permit issued by the Board of Pharmacy.
- Legislation in 2018 expanded the use of these oils to any diagnosed condition or disease, upon recommendation from any physician, and required that dispensing of these oils be reported to the Prescription Monitoring Program (PMP), and that physicians request information from the PMP prior to issuing written certifications. (PMP link here)

Regulations:

Current Emergency Regulations pertaining to Pharmaceutical Processors - Effective from: 10/1/2018 to 2/6/2019

Frequently Asked Questions:

What are cannabidiol (CBD) and THC-A oils? CBD and THC-A oils are oils that are derived from the Cannabis plant. They are minimally psychoactive and can be used to treat or lessen the symptoms of many disease processes. This is a low-THC oil program.

Why do theses oil require a written certification?
Marijuana remains illegal federally and in Virginia. Because of this, these oils cannot be PRESCRIBED; however, a physician may issue a written certification for the use of the oils.

Must a physician obtain Board of Pharmacy registration prior to or continuing to issue a written certification for a patient to possess CBD oil or THC-A oil?
Yes, before a physician can issue or continue issuing written certifications, he or she must register with the Board of Pharmacy.

Does the law provide for an affirmative defense for possession of CBD oil or THC-A oil?
Yes. 18.2-250.1(C) states, "In any prosecution under this section involving marijuana in the form of cannabidiol oil or THC-A oil as those terms are defined in § 54.1-3408.3, it shall be an affirmative defense that the individual possessed such oil pursuant to a valid written certification issued by a physician in the course of his professional practice pursuant to § 54.1-3408.3 for treatment or to alleviate the symptoms of (i) the individual's diagnosed condition or disease or (ii) if such individual is the parent or legal guardian of a minor or of an incapacitated adult as defined in § 18.2-369, such minor's or incapacitated adult's diagnosed condition or disease. If the individual files the valid written certification with the court at least 10 days prior to trial and causes a copy of such written certification to be delivered to the attorney for the Commonwealth, such written certification shall be prima facie evidence that such oil was possessed pursuant to a valid written certification."

What other conditions must be met to assert the affirmative defense?
In addition to being issued a valid written certification from a Board of Pharmacy-registered physician, the patient *and*, if such patient is a minor or an incapacitated adult as defined in 18.2-369, such patient's parent or guardian, must obtain registration from the Board of Pharmacy. The written certification alone does not satisfy the conditions for asserting an affirmative defense for possessing CBD or THC-A oil.

Who is eligible to possess CBD oil and/or THC-A oil?
Currently, the law restricts the use of either oil to a BOP-registered patient or, if such patient is a minor or an incapacitated adult as defined in 18.2-369, such patient's parent or guardian for the treatment or alleviation of symptoms of any diagnosed condition or disease determined by the physician to benefit from such use.

What is a pharmaceutical processor?
A pharmaceutical processor is a facility that has obtained a permit from the Board of Pharmacy pursuant to § 54.1-3408.3 to cultivate Cannabis plants for the production of CBD oil and/or THC-A oil, and to dispense oils to patients registered by the BOP and who have obtained a written certification from a board-registered physician. It is a "vertical" operation meaning that the plants are grown, oils produced, and oils dispensed all from the same facility. Each facility is responsible for the quality of oils produced.

As set forth in §54.1-3442.6 of the Code of Virginia, the Board may issue or renew in any year a maximum of five pharmaceutical processor permits, one for each health service area established by the Board of Health. The application process for pharmaceutical processor permits has three stages: submission of initial application (deadline June 2018), awarding of conditional approval (Fall 2018), and granting of a pharmaceutical processor permit (likely in 2019, after construction and board inspection of the facility). The quality of the applications will determine which applicant(s) will awarded conditional approval. Up to five pharmaceutical processors are expected to go online in 2019.

What are the selection criteria for a BOP pharmaceutical processing permit?
The selection criteria is contained in pages 5 – 7 of the Request for Application.

Why did the September 4 BOP pharmaceutical processing ad hoc committee close its meeting to the public?
The BOP Ad Hoc Committee on Pharmaceutical Processors convened a closed session meeting September 4, 2018 pursuant to Virginia Code sections 54.1-108 and 2.2-3711(A)(5) to consider and score applications for pharmaceutical processors in compliance with state confidentiality laws.

What is the tentative timeline for permitting pharmaceutical processors?

- September 4, 2018 - In-person, but closed session, meeting of the ad hoc committee of the BOP to discuss scoring of applicants
- September 25, 2018 - BOP reviewed scoring and identified the applicants who were awarded conditional approval. This conditional approval is contingent upon the results of a criminal background check.
- October 5, 2018 - Deadline for fingerprinting and submission of information for criminal background checks
- November 28, 2018 - BOP reviewed results of the criminal background checks and finalized the awarding of pharmaceutical processor conditional approvals for Health Services Areas I, II, IV, and V.
- December 18, 2018 – BOP will finalize the awarding of pharmaceutical processor conditional approval in Health Service Area III.
- It is expected the first pharmaceutical processors will go online in 2019 after construction and board inspection.

When may a patient, parent, or legal guardian apply for BOP registration?
Patients, parents, and legal guardians may apply now to obtain registration from the BOP. A patient, parent, or legal guardian must have a written certification issued to them by a physician prior to applying for registration with the Board of Pharmacy and possessing the oils. Here is the link to the BOP website to "Learn More about Patient, Parent/Guardian Registration."

How can a patient locate a registered physician?
A list of physicians registered with the BOP who can issue a written certification to possess CBD and THC-A oils is now searchable on License Lookup on the BOP website. When searching, select the "occupation" of "Registered Physician for CBD/THC-A oil".

Where can meeting minutes and notices of BOP pharmaceutical processor actions be found?
Resources for BOP meeting dates and meeting minutes can be found on --Virginia Regulatory Townhall and BOP's website -- http://www.dhp.virginia.gov/pharmacy/pharmacy_calendar.htm

Additional information may be found on the Pharmaceutical Processors page of the BOP website. Media requests should be directed to Diane.Powers@dhp.virginia.gov

The Virginia Board of Pharmacy (BOP) is one of the Department of Health Professions (DHP) 13 health regulatory boards which ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public. The BOP regulates the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices.

The BOP licenses or registers over 35,000 individuals (pharmacists, pharmacy technicians, pharmacy interns and dispensing physicians) and permits 3,900 facilities (pharmacies, wholesale distributors,

warehousers, medical equipment suppliers, manufacturers, controlled substances registrants, third-party logistics providers, outsourcing facilities, non-resident pharmacies, non-resident third party logistic providers, non-resident warehousers, non-resident outsourcing facilities, and non-resident wholesale distributors).

# # #