

**Report on Operation of Pharmaceutical Processors and Cannabis Dispensing
Facilities**

Virginia Department of Health Professions

Pursuant to Code of Virginia - § 54.1-3442.7 (C)

December 2020



COMMONWEALTH of VIRGINIA

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MEMORANDUM

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FROM: Caroline D. Juran, RPh 
Executive Director, Virginia Board of Pharmacy
Department of Health Professions

DATE: 11/24/2020

RE: Report on Operation of Pharmaceutical Processors and Cannabis Dispensing Facilities

This report is provided to you pursuant to Code of Virginia - §54.1-3442.7(C). Please feel free to contact me at (804) 367-4578 or caroline.juran@dhp.virginia.gov should you have any questions.

Report on Operation of Pharmaceutical Processors and Cannabis Dispensing Facilities

Virginia Board of Pharmacy

Pursuant to Code of Virginia - § 54.1-3442.7 (C)

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Subsection C of § 54.1-3442.7 of the Code of Virginia specifies that:

C. The Board shall report annually by December 1 to the Chairmen of the House Committee for Courts of Justice and the Senate Committee on the Judiciary on the operation of pharmaceutical processors and cannabis dispensing facilities issued a permit by the Board, including the number of practitioners, patients, registered agents, and parents or legal guardians of patients who have registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3.

In accordance with the statutory provision, the Board of Pharmacy reports the following information:

Executive Summary

The Code of Virginia authorizes the Board to issue up to five pharmaceutical processor permits. As of the date of this report, four permits have been issued. The processors spent much of the year completing facility construction, obtaining board permits, and beginning indoor cultivation of cannabis. Cannabis oil first became available to registered patients in October 2020 from Dharma Pharmaceuticals, LLC located in Bristol, VA (Health Service Area III). A second pharmaceutical processor, Green Leaf Medical of Virginia, Inc. located in Richmond, VA (Health Service Area IV) anticipates dispensing cannabis oil products to patients beginning prior to November 30, 2020. During the 2020 General Assembly Session, the restriction of 5% maximum tetrahydrocannabinol (THC) concentration was stricken in Code. A requirement for no more than 10mg of THC per dose remains in Code, but the term “dose” is not defined. Cannabis oil products are currently available in various formulations with varying concentrations of cannabidiol (CBD), cannabidiolic acid (CBDA), THC, and other cannabinoids. Examples of cannabis oil product formulations available include: oral oil, vaped oil, wax concentrate, bubble hash concentrate inhalation, nasal spray, chewable, suppository, and topical gel. The range of combined THC/THC-A and CBD/CBDA concentrations in currently available products is referenced in the table below.

Product Formulation	Combined THC/THC-A Range	Combined CBD/CBDA Range
Oral Oils	0.32% to 1.02%	0.21-1.10%
Vaped Inhalations from Oils, Wax Concentrates and Bubble Hash Concentrates	34.8% to 82%	0.08%-4.43%

Nasal Spray	3.46%	0.0%
Chewable	0.52%-0.55%	0.33%-0.34%
Suppository	0.84%	0.58%
Topical Gel	0.25%	0.0%

Conditional approval for a fifth pharmaceutical processor permit located in Health Service Area I was rescinded by the Board in June 2020. The deadline for the Request for Application to competitively award a pharmaceutical processor permit in this health service area is December 4, 2020. The Code now authorizes the Board to also award up to five cannabis dispensing facility permits per health service area in 2021, contingent upon the Governor’s approval of the Board’s proposed emergency regulations. Since May 2020, the Board has received an increasing number of applications for patient registrations each week. As of November 16, 2020, there are 6,921 registered patients, 72 registered patients/legal guardians, 12 registered agents, and 567 registered practitioners.

Permits for Pharmaceutical Processors

PharmaCann Virginia, LLC (Health Service Area I): On June 16, 2020, a quorum of the Virginia Board of Pharmacy (Board) denied PharmaCann’s request for an extension of time to comply with the Board’s Order of December 21, 2018 granting PharmaCann conditional approval for a pharmaceutical processor permit. The Board also rescinded PharmaCann’s conditional approval of its application for a pharmaceutical processor permit in Health Service Area I and denied the application of PharmaCann for a pharmaceutical processor permit in Health Service Area I. On September 25, 2020, the Board posted a Request for Application (RFA) for a Pharmaceutical Processor for Health Service Area I. The RFA application deadline is December 4, 2020. The applications will be reviewed by an ad hoc committee appointed by the Chairman in consultation with the executive director, as delegated by the Board.

Dalitso, LLC (Health Service Area II): Dalitso received a pharmaceutical processor permit on August 18, 2020. Dalitso is currently cultivating cannabis plants and anticipates dispensing its own board-registered cannabis oil products in the first quarter of 2021, with the dispensing of registered products obtained via wholesale distribution from other pharmaceutical processors in advance of that target.

Dharma Pharmaceuticals, LLC (Health Service Area III): Dharma received a pharmaceutical processor permit on January 14, 2020. Dharma submitted initial cannabis oil product registration applications to the Board in October, 2020 and currently has had 15 products approved. Dharma began dispensing cannabis oil to the public on October 17, 2020.

Green Leaf Medical of Virginia, Inc. (Health Service Area IV): Green Leaf received a pharmaceutical processor permit on May 12, 2020. Green Leaf submitted initial cannabis oil products to the Board in November, 2020 and currently has two products approved and seven additional products pending submission for approval. Green Leaf plans to begin dispensing cannabis oil products before the end of November.

Columbia Care Eastern Virginia. LLC (Health Services Area V): Columbia Care received a pharmaceutical processor permit on April 6, 2020, is currently cultivating cannabis plants and anticipates having cannabis oil products available for dispensing in the first quarter of 2021.

Permits for Cannabis Dispensing Facilities

At the September 9, 2020 full board meeting, the Board of Pharmacy adopted proposed emergency regulations that included requirements for cannabis dispensing facilities. It is anticipated that those proposed regulations will be approved and implemented in January 2021. At that time, applications for cannabis dispensing facilities will be accepted.

Registration of Individuals

Registration of practitioners, patients, and parents/legal guardians began in July, 2018 and registration of registered agents began in December, 2019.

Registered Practitioners	567
Registered Patients	6,921
Registered Parents/Guardians	72
Registered agents	12

Number of Written Certifications

The Board does not currently know the exact number of active written certifications issued as practitioners are not required to report that information. Once all processors are dispensing product this information may be more readily obtained through the Prescription Monitoring Program. However, because a patient may not obtain board registration without having been issued a written certification, the number of issued written certifications is at least 6,921. A practitioner shall not issue certifications for cannabis oil to more than 600 patients at any given time. However, the practitioner may petition the Board of Pharmacy and Board of Medicine for an increased number of patients for whom certifications may be issued, upon submission of evidence that the limitation represents potential patient harm. A written certification is valid for up to 12 months and is required for issuance and annual renewal of the patient’s board registration. The total number of written certifications issued by practitioners since 2017 is referenced below:

Number of Practitioners	Number of Written Certificates Issued Since 2017
549	0-99
9	100-199
5	200-299
2	300-399
0	400-499
1	500-599