



COMMONWEALTH of VIRGINIA

Arne W. Owens
Director

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

www.dhp.virginia.gov
PHONE (804) 367- 4400

TO: The Honorable Glenn Youngkin
Governor of Virginia

The Honorable Robert D. Orrock
Chairman, House Committee on Health, Welfare, and Institutions

The Honorable Louise L. Lucas
Chairman, Senate Committee on Education and Health

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

DATE: December 21, 2023

RE: Annual Report Regarding the Operation of Pharmaceutical Processors and
Cannabis Dispensing Facilities

This report is submitted by the Virginia Board of Pharmacy in compliance with Virginia Code § 54.1-3442.7(C), which states:

The Board [of Pharmacy] shall report annually by December 1 to the Chairmen of the House Committee for Health, Welfare and Institutions and the Senate Committee on Education and Health on the operation of pharmaceutical processors and cannabis dispensing facilities issued a permit by the Board.

Should you have questions about this report, please feel free to contact me at (804) 367-4578 or caroline.juran@dhp.virginia.gov.

Enclosure

CC: The Honorable John Littel, Secretary of Health and Human Resources

Preface

This report is submitted in compliance with Virginia Code § 54.1-3442.7(C), which requires:

The Board [of Pharmacy] shall report annually by December 1 to the Chairmen of the House Committee for Health, Welfare and Institutions and the Senate Committee on Education and Health on the operation of pharmaceutical processors and cannabis dispensing facilities issued a permit by the Board.

Contents

I.	Executive Summary	1
II.	Permits of Pharmaceutical Processors and Cannabis Dispensing Facilities	2
III.	Registration of Individuals	3
IV.	Registration and Dispensing of Cannabis Products	3
V.	Licensing Software.....	4
VI.	Transition of Program Oversight.....	5

I. Executive Summary

The Code of Virginia authorizes the Board to issue up to five pharmaceutical processor permits. These permits authorize the holder to establish facilities to cultivate cannabis, produce and dispense cannabis products to patients issued a written certification by a physician, nurse practitioner, or physician assistant for the use of such products for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. As of the date of this report, there are four current active pharmaceutical processor permits. On September 26, 2023, the Board of Pharmacy voted to rescind the 2020 Request for Application (RFA) to award the fifth pharmaceutical processor permit. Because statutory and regulatory oversight of the medical cannabis program will transition from the Board of Pharmacy to the Virginia Cannabis Control Authority (VCCA) as of January 1, 2024, it is anticipated that the VCCA will develop a new RFA for awarding the fifth permit.

The Code also authorizes the Board to award up to five cannabis dispensing facility permits per Health Service Area. A cannabis dispensing facility must be partly owned by the pharmaceutical processor located in the Health Service Area. Currently, there are 18 permitted cannabis dispensing facilities in the Commonwealth. Patients may obtain medical cannabis products from these 18 facilities, in addition to the four pharmaceutical processors.

All pharmaceutical processors are currently cultivating cannabis and submitting applications to the Board to register various formulations of medical cannabis products. Since the inception of the program, the Board has registered 3,629 medical cannabis products. During the past year, pharmaceutical processors continued to have the following available for dispensing: cannabis oil products such as nasal spray, chewables, suppositories, and topical gel; oral oils; inhaled (vaped) products to include oil, wax concentrate, and bubble hash concentrate; whole flower, pre-rolled joints; and ground flower products. Of the products currently dispensed, the vaped inhalation products from oils, wax concentrates, and bubble hash concentrates have the highest THC/THC-A combined concentrations, ranging from 0.25% - 90.80%. Tablet/capsules are available with a THC/THC-A range of 0.26% - 74.20%. Botanical cannabis products have the next highest THC/THC-A combined concentration, ranging from 7.57% - 36.74%.¹

As of July 1, 2022, medical cannabis patients and parents/legal guardians are no longer required to register with the Board of Pharmacy prior to obtaining medical cannabis products but may voluntarily request a registration card pursuant to an enactment clause of Chapter 391 of the 2022 Acts of Assembly. Since July 1, 2022, the Board has seen an 88% reduction in patient registration applications. As of July 1, 2023, practitioners are no longer required to register with the Board of Pharmacy and registered agents are not required to register with the Board if a practitioner has added their name to the patient's written certification for the use of medical cannabis. (See Chs. 760 and 780 of the 2023 Acts of Assembly.) Currently, there are 1,051 registered practitioners.

¹ Tetrahydrocannabinol (THC) is the psychoactive component of cannabis. Tetrahydrocannabinol-A can be converted into THC through decarboxylation.

The Board implemented a new licensing software system to improve efficiencies in both the patient and medical cannabis product registration process in September 2023. The system allows the practitioner to issue an electronic written certification in lieu of the paper format provided by the Board and provide the patient with a digital card that validates the possession of the written certification. The system also streamlines the registration process for patients should they voluntarily choose to obtain registration.

II. Permits of Pharmaceutical Processors and Cannabis Dispensing Facilities

Currently, there are 4 permitted pharmaceutical processors and 18 permitted cannabis dispensing facilities in the Commonwealth from which patients may obtain medical cannabis products. A cannabis dispensing facility must be partly owned by the pharmaceutical processor located in the health service area.

PharmaCann Virginia, LLC (Health Service Area I): On June 16, 2020, the 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, 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 Board received 26 applications during the RFA period. PharmaCann appealed the Board's decision and, on January 14, 2021, the Henrico County Circuit Court enjoined the Board from reviewing applications until further order by the Court. In March 2022, the Henrico County Circuit Court ruled in the Board's favor. PharmaCann, however, submitted an appeal to the Virginia Court of Appeals in April 2022. In April 2023, the Virginia Court of Appeals affirmed the Board's Order to rescind the conditional permit approval. In September 2023, the Board of Pharmacy voted to terminate the RFA and refund the application fees to the 26 applicants due to the impending transfer of the medical cannabis program to the VCCA. The Board cannot effectively and fairly review applications prior to the transfer of the program. Such a review requires seating an ad hoc committee, revising the scoring rubric, and providing the applicants with 90 days to submit updated applications that would address any changes to the original application and regulatory and statutory changes made since the original RFA was posted. Among the concerns, the Board of Pharmacy determined it could not complete the review of the revised applications to award conditional approval prior to the transition of the medical cannabis program to the VCCA on January 1, 2024. It is anticipated that the VCCA will issue a new RFA for Health Service Area I after transition of statutory and regulatory oversight.

Dalitso, LLC (Health Service Area II, Manassas): Dalitso received a pharmaceutical processor permit on August 18, 2020. Dalitso submitted initial medical cannabis products for approval in July 2021. Dalitso has received a permit for five cannabis dispensing facilities located in Sterling, Alexandria, Fairfax, Arlington and Woodbridge, VA.

Dharma Pharmaceuticals, LLC (Health Service Area III, Abingdon): Dharma received a pharmaceutical processor permit on January 14, 2020, and submitted initial medical cannabis product registration applications to the Board in October 2020. Dharma has received a permit for five cannabis dispensing facilities located in Salem, Christiansburg, Lynchburg, Danville and Bristol, VA.

Green Leaf Medical of Virginia, Inc. (Health Service Area IV, Richmond): Green Leaf received a pharmaceutical processor permit on May 12, 2020. Green Leaf submitted initial medical cannabis products for approval to the Board in November 2020. Green Leaf has received a permit for three cannabis dispensing facilities located in Glen Allen, Richmond and Colonial Heights, VA.

Columbia Care Eastern Virginia, LLC (Health Services Area V, Portsmouth): Columbia Care received a pharmaceutical processor permit on April 6, 2020, and submitted initial medical cannabis products for approval in June 2021. Columbia Care has received a permit for five cannabis dispensing facilities located in Virginia Beach, Williamsburg, Hampton, Norfolk and Suffolk, Virginia.

III. Registration of Individuals

Registration of practitioners, patients, and parents/legal guardians began in July 2018, and registration of registered agents began in December 2019. As of July 1, 2022, patients and parents/guardians are no longer required to obtain registration from the Board but may voluntarily request registration. Since July 1, 2022, the Board has seen an 88% reduction in patient registration applications. The total number of patient registrations issued per year through September 2023 is as follows:

- 2018 = 193
- 2019 = 1,372
- 2020 = 7,192
- 2021 = 33,396
- 2022 = 24,117
- January 2023 – September 2023 = 1,751

The total number of current active registrations as of October 29, 2023 is illustrated below:

Registered Patients	6,719
Registered Patients/Guardians	34
Registered Agents	98

IV. Registration and Dispensing of Cannabis Products

Since the inception of the program, the Board has issued registrations for 3,629 medical cannabis products. The law does not currently restrict the maximum allowable THC concentration per product. The THC/THC-A concentration of vaped inhalations from oils, wax concentrates and bubble hash concentrates range up to 90.80%, 74.20% for tablets/capsules, and 36.74% for

botanical cannabis. Concentrations of THC/THC-A and cannabidiol/cannabidiol-A (CBD/CBDA) in the approved products are listed in the table below.

Product Type	Combined THC/THC-A Range	Combined CBD/CBDA Range
Nasal Spray	3.46%	0.0%
Chewable/Edible	0.13% - 5.80%	0.00% - 6.90%
Suppository	0.68 - 0.95%	0.44% - 0.63%
Topical Gel/Lotion	0.12% - 57.87%	0.0% - 18.10%
Oral Oils	0.01% - 64.29%	0.00 - 21.02%
Vaped Inhalations from Oils, Wax Concentrates and Bubble Hash Concentrates	0.25% - 90.80%	0.00% - 57.42%
Tablet/Capsule	0.26% - 74.20%	0.12% - 4.05%
Lozenge	0.26% - 0.47%	0.26% - 0.68%
Botanical cannabis	7.57% - 36.74%	0.00% - 12.72%

Regarding the volume of dispensed medical cannabis products, the following data is derived from dispensing information within the Prescription Monitoring Program:

- Monthly unique patients receiving cannabis products increased over 13 times between January 2021 and September 2023, or 3,389 to 45,434, respectively.
- Monthly dispensations increased over 17 times between January 2021 and September 2023, or 18,000 to 308,380, respectively.
- Between January 2023 and September 2023, 2,447,862 dispensations resulted from written certifications issued by 930 practitioners.
- The average number of monthly dispensations per practitioner was 292; the median was 23.
- Half of the practitioners are associated with ≤ 23 dispensations per month (average).
- 76% of dispensations are attributable to top 5% of practitioners, which amounts to 46 practitioners.
 - Each of these 46 practitioners are associated with $>1,000$ dispensations per month (average).
- 37% of dispensations are attributable to the top 1% of practitioners.
 - Each of these nine practitioners have $> 8,000$ dispensation/month (average).
 - Three of the nine (33%) are out of state.

V. Licensing Software

In September 2023, the Board implemented new licensing software to improve efficiencies in both the patient and medical cannabis product registration processes. Prior to use of this system, the Board relied on licensing software designed to license healthcare practitioners and pharmacies which created limitations and required the inefficient submission of paper documents outside of the electronic platform. The new system also allows the practitioner to issue an electronic written certification in lieu of the paper format provided by the Board and provides the patient with a digital card that validates the possession of the written certification. This negates the need for the patient to carry the paper written certification form to the dispensing facility and while in possession of the medical cannabis product. Additionally, it will mitigate risk of fraudulently issued written certifications. During the implementation phase of the software, the Board directed practitioners to enroll in the platform by January 1, 2024, to begin issuing electronic written certifications. Enrollment in the software simply verifies their license to practice, authorizing the issuance of written certifications. Currently, there are 778 practitioners enrolled in the platform, which includes practitioners currently registered with the Board. The Board's intention is to retire the paper format of the written certification as of January 1, 2024 and rely solely on the electronic format. Practitioners will continue to have the ability to print the written certification for any patient with difficulty accessing an electronic format. Because the program will transition to the VCCA as of January 1, 2024, it will be the responsibility of the VCCA to enforce this transitional plan or determine the best course of action. The new system also streamlines the registration process for patients should they voluntarily choose to obtain registration.

VI. Transition of Program Oversight

Statutory and regulatory oversight of the medical cannabis program will transition from the Board of Pharmacy to the VCCA as of January 1, 2024. Staff from the Board of Pharmacy and the VCCA have been meeting approximately every other week since April 2023 to address this transition. At the December 2023 full board meeting, the Board of Pharmacy will vote to rescind regulations and guidance documents associated with the medical cannabis program effective January 1, 2024. Similarly, the VCCA will take action to enact its regulations, which will include the necessary regulatory amendments based on legislation passed by the 2023 General Assembly Session.