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The Honorable Robert D. Orrock TO:

Chairman, House Committee on Health, Welfare, and Institutions

The Honorable Louise L. Lucas

Chairman, Senate Committee on Education and Health

FROM:

Annette S. Kelley Asset Kelley
Deputy Executive Director, Virginia Board of Prarmacy

Virginia Department of Health Professions

DATE: February 17, 2023

RE: Annual Report on the Operation of Pharmaceutical Processors

Attached is the annual report of the Board of Pharmacy on the operation of pharmaceutical processors and cannabis dispensing facilities as well as 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, pursuant to subsection C of § 54.1-3442.7 of the Code of Virginia.

Should you have questions about this report, please feel free to contact me at (804) 367-4456 or annette.kelley@dhp.virginia.gov.

## Report on Operation of Pharmaceutical Processors and Medical Cannabis Dispensing Facilities

# Virginia Board of Pharmacy Pursuant to Code of Virginia - § 54.1-3442.7 (C) December 2022

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 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.

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 authorizing the facilities to cultivate cannabis, produce and dispense cannabis products. As of the date of this report, there are four current active permits. All pharmaceutical processors are currently cultivating cannabis and submitting medical cannabis products to the Board for approval. The pharmaceutical processors continue to have cannabis oil products such as nasal spray, chewables, suppositories, topical gel, oral oils and vaped oil, wax concentrate, and bubble hash concentrate inhalations available for dispensing along with whole flower, pre-rolled joints and ground flower products for dispensing. Tetrahydrocannabinol (THC) is the psychoactive component of cannabis. Tetrahydrocannabinol-A (THC-A) can be converted into THC through decarboxylation. 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%-90.37%. Tablet/capsules are available with a THC/THC-A range of 1.87%-74.20%. Botanical cannabis products have the next highest THC/THC-A combined concentration, ranging from 7.57% to 36.74%.

Conditional approval issued to PharmaCann for a fifth pharmaceutical processor permit located in Health Service Area I was rescinded in June 2020. Deadline for a subsequent Request for Application (RFA) to competitively award a permit in this health service area was December 4, 2020. 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 ordered the Board to cease reviewing applications until further order by the Court. In March 2022, the Henrico County Circuit Court ruled in the favor of the Board of Pharmacy. PharmaCann subsequently filed an

appeal with the Virginia Court of Appeals. As a result, the Board must wait for the Court's resolution of PharmaCann's appeal, which remains ongoing at this time.

The Board may also 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 nine permitted cannabis dispensing facilities in the Commonwealth. Patients may obtain medical cannabis products from these nine facilities, in addition to the four pharmaceutical processors.

As of July 1, 2022, medical cannabis patients and parents/legal guardians are no longer required to register with the Board of Pharmacy and may obtain product by presenting a current written certification issued by a registered practitioner recommending use of medical cannabis and an unexpired Government-issued identification card. However, an enactment clause of HB 933 passed during the 2022 General Assembly Session authorizes a patient to voluntarily request a registration card from the Board of Pharmacy. Since July 1, 2022, the Board has seen a reduction of 88% in patient registration applications. As of November 13, 2022, there are 40,335 registered patients, 173 registered parents/legal guardians, 164 registered agents, and 1,119 registered practitioners. Registrations for 2,101 medical cannabis products have also been issued to date.

The Board continues to actively pursue implementation of a new licensing software system to improve efficiencies in both the patient and medical cannabis product registration process. It is anticipated that the system will be active in the first quarter of 2023.

### 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; 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 ordered the Board to cease reviewing applications until further order by the Court. In March 2022, the Henrico County Circuit Court ruled in the Board's favor. PharmaCann submitted an appeal to the Virginia Court of Appeals in April 2022. As a result, the Board must wait for the Court's resolution of PharmaCann's appeal, which remains ongoing at this time. If and when the Board is allowed, 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, 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 three cannabis dispensing facilities located in Sterling, Alexandria and Fairfax, 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 three cannabis dispensing facilities located in Salem, Christiansburg, and Lynchburg, 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 two cannabis dispensing facilities located in Glen Allen and Richmond, 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 one cannabis dispensing facility located in Virginia Beach, Virginia.

#### Permits for Cannabis Dispensing Facilities

Currently, there are nine permitted cannabis dispensing facilities, three each in Health Service Areas II and III, two in Health Service Area IV, and one in Health Service Area V.

### 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 a reduction of 88% in patient registration applications. The total number of patient registrations issued per year through July 2022 are as follows:

- 2018 = 200 +
- 2019 = 1.372
- 2020 = 7,192
- $\bullet$  2021 = 33,396
- 1/22-7/22 = 22.001

The total number of current active registrations as of November 13, 2022 are listed below:

Registered Practitioners	1,119
Registered Patients	40,335
Registered Parents/Guardians	173
Registered Agents	164

#### Dispensing Volume

The following data is derived from dispensing information within the Prescription Monitoring Program:

- Monthly unique patients receiving cannabis products increased almost six (6) times between January 2021 and August 2022 or 3,391 to 20,300, respectively.
- Monthly prescribers of dispensed products more than doubled between January 2021 and August 2022 or 201 to 440, respectively.
- Monthly dispensations increased almost eight (8) times between January 2021 and August 2022 or 18,000 to 139, 000, respectively.
- Thirty-five percent (35%) of dispensations result from written certifications issued by out-of-state prescribers registered with the Board of Pharmacy.
- Between January 2022 and May 2022:
  - o 415,902 dispensations resulted from written certifications issued by 453 practitioners.
  - Monthly dispensations/practitioner
  - O Average number of monthly dispensations per practitioner was 184; Median was 20.
  - $\circ$  Half of the registered practitioners are associated with  $\leq$ 20 dispensations/month.
  - o 66% of dispensations are attributable to 5% of registered practitioners.
    - Each of these 23 practitioners have >1,000 dispensations/month.
    - Nine of the 23 (39%) are out-of-state.

#### Registration of Cannabis Products

Registrations for 2,101 medical cannabis products have been issued. There is currently no restriction on 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 90.37%, 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	0.84-0.95%	0.55%-0.63%
Topical Gel	0.17%-57.87%	0.0%-18.10%
Oral Oils	0.01%-1.28%	0.03-2.82%
Vaped Inhalations from Oils,	0.25%-90.37%	0.00%-48.47%
Wax Concentrates and		
Bubble Hash Concentrates		
Tablet/Capsule	1.87%-74.20%	0.18%-3.80%
Lozenge	0.26%-0.47%	0.26%-0.68%
Botanical cannabis	7.57%-36.74%	0.00%-12.72%