



VIRGINIA
**Cannabis
Control
Authority**

Notice of Open Applications

Pharmaceutical Processor – Health Service Area One

Issue Date: February 28, 2024

NOA No. CCA-2024-1

Due Date:

April 30, 2024

5:00 P.M

Direct all inquiries to:

applications@cca.virginia.gov

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I. Purpose

The purpose of this Notice of Open Applications (“Notice”) is to solicit applications for a permit to operate a pharmaceutical processor in Health Service Area (HSA) 1, which covers the Shenandoah Valley and localities in Virginia such as Charlottesville, Fredericksburg, Spotsylvania, and Stafford.¹ The Cannabis Control Authority (CCA) may award a permit for no more than one pharmaceutical processor in HSA 1.

A pharmaceutical processor is a vertically integrated facility authorized, on-site at the address of record of the facility, to cultivate cannabis plants, produce cannabis products, and dispense cannabis to qualified patients. Virginia Code section 4.1-1600 defines a pharmaceutical processor as:

a facility that (i) has obtained a permit from the Board pursuant to § 4.1-1602 and (ii) cultivates Cannabis plants intended only for the production of cannabis oil, botanical cannabis, and usable cannabis, produces cannabis products, and dispenses cannabis products to a patient pursuant to a written certification, his registered agent, or, if such patient is a minor or a vulnerable adult as defined in § 18.2-369, such patient's parent or legal guardian.

Persons interested in being awarded a pharmaceutical processor permit in HSA 1 must apply online and submit the non-refundable application fee of \$18,000. The application process for the pharmaceutical processor permit in HSA I will occur in four stages:

1. Submission of applications,
2. Review of applications,
3. Award of conditional approval, and
4. Grant of a pharmaceutical processor permit.

Section III of the Notice discusses the application requirements in more detail. The Board may disqualify any applicant:

1. Who submits an incomplete, false, inaccurate, or misleading application;
2. Who fails to submit an application by the published deadline;
3. Who fails to pay all applicable fees;
4. Who fails to comply with all requirements for a pharmaceutical processor; or,
5. For whom there is evidence of a criminal conviction that would disqualify the applicant under 3VAC10-30-110.

No person who has been convicted of a felony under the Code of Virginia or another jurisdiction within the last five years shall have a 5.0% or greater ownership, be employed by, or act as an

¹ Attachment 1 contains a full list of the localities served by HSA 1.

agent of a pharmaceutical processor. Criminal history background checks are required before the Board can grant conditional approval.

The applicant granted conditional approval will have one year to complete all requirements for issuance of a permit. The fee for the initial permit is \$165,000. Once the pharmaceutical processor permit is issued, the facility may begin operation. Barring suspension, revocation, or refusal to grant or renew such permit as outlined in 3VAC10-80-10, the permit will be valid for one year from the date of issuance and may be renewed annually for continued operations pursuant to Board regulations, including the payment of an annual renewal fee.

II. Background

Legislation passed during the 2016 General Assembly Session, and reenacted in 2017, authorized the Board of Pharmacy to issue five pharmaceutical processor permits, one in each HSA established by the Board of Health.

The Board of Pharmacy issued a request for applications in 2018 and awarded five conditional approvals, requiring the pharmaceutical processors to become operational within one year. In 2019, the Board of Pharmacy issued pharmaceutical processor permits in four of the HSAs. The conditional approval awarded in HSA 1 was rescinded in 2020, and the Board of Pharmacy issued a second request for applications, pending the outcome of litigation over the rescission of the conditional approval. Litigation regarding the rescinded conditional approval concluded in May 2023. The Board of Pharmacy rescinded the pending request for applications in September 2023.

Effective January 1, 2024, regulatory oversight of the medical cannabis program transferred from the Board of Pharmacy to the CCA. As an independent, apolitical subdivision of the Commonwealth, the CCA promotes public safety, advances public health, and protects communities in Virginia through effective medical cannabis oversight and balanced and inclusive cannabis regulation, policy, and education.

III. Application Process

A. Anticipated Timeline for Conditional Approval

| | |
|--------------------------------|--|
| February 28, 2024 | Issue Notice of Open Applications |
| April 30, 2024, at 5:00 pm EDT | Applications Due |
| June 26, 2024 | Board reviews scoring and lottery results to determine which applicant will be awarded conditional approval |
| July 8, 2024 | Deadline for fingerprinting and submission of information for criminal history background checks |
| August 14, 2024 | Finalize the awarding of conditional approval upon review of criminal history background checks or select alternate applicant for conditional approval |

B. Stages

Stage 1: Submission of Applications

Application Requirements and Procedures

To be considered for selection, an applicant must submit a complete Application for a pharmaceutical processor permit for HSA 1 with required documentation and non-refundable application fee of \$18,000 no later than April 30, 2024, at 5:00 p.m. EDT.

Applicants shall submit all requested materials, including a business plan and the following information and documentation:

- a. The name and address of the applicant and the applicant's owners;
- b. Documents sufficient to establish that the applicant is authorized to conduct business in Virginia and that all applicable state and local building, fire, and zoning requirements and local ordinances are met or will be met prior to issuance of a permit;
- c. Information about any previous or current involvement in the medical cannabis industry;
- d. Whether the applicant has ever applied for a permit or registration related to medical cannabis in any state, and if so, the status of that application, permit, or registration, to include any disciplinary action taken by any state on the permit, the registration, or an associated license;
- e. Text and graphic materials showing the exterior appearance of the proposed pharmaceutical processor; and
- f. A blueprint of the proposed pharmaceutical processor that shall show and identify (i) the square footage of each area of the facility; (ii) the location of all safes or vaults used to store the cannabis plants and products; (iii) the location of all areas that may contain

cannabis plants or cannabis products; (iv) the placement of walls, partitions, and counters; and (v) all areas of ingress and egress.

The application and all required attachments must be submitted electronically. Applicants can access the online application here: <https://www.cca.virginia.gov/NOA-HSA1>.²

The application will not be considered complete until the CCA receives the non-refundable application fee. The application fee must be submitted in the form of a check made payable to “Treasurer of Virginia” and submitted to the Cannabis Control Authority at P.O. Box 6411, Richmond, VA 23230, along with a payment coversheet.³ **If the application fee is not received by the application deadline, the applicant will be disqualified.** If a check is not honored or not paid in full by the applicable bank or other entity (including stop payments and disputes), the payment will be treated as a dishonored payment and subject to a Handling Fee (3VAC10-20-30). The applicant will be disqualified unless the CCA receives full payment by the deadline established by CCA staff.

The Board may disqualify any applicant:

1. Who submits an incomplete, false, inaccurate, or misleading application;
2. Who fails to submit an application by the published deadline;
3. Who fails to pay all applicable fees;
4. Who fails to comply with all requirements for a pharmaceutical processor; or,
5. For whom there is evidence of a criminal conviction that would disqualify the applicant under 3VAC10-30-110.

The CCA will not consider any applications received after the submission due date. Applications submitted without the required non-refundable fee, with incomplete information, or in a manner that is significantly inconsistent with the Notice will be deemed incomplete and will not be considered for selection.

The Board reserves the right to amend the Notice prior to the application submission deadline. Such amended Notice will be published in the same manner as the original Notice. The Board may cancel the Notice prior to awarding a pharmaceutical processor permit.

² Prospective applicants can ask for additional technical assistance with using the online application by contacting applications@cca.virginia.gov.

³ Attachment 2 is a copy of the required payment coversheet. Applicants who choose to use a carrier other than the United States Postal Service for delivery of their application fee can direct their payments to Virginia Cannabis Control Authority, 2220 Dabney Road #6411, Richmond, VA 23230.

Freedom of Information Act Notice

Applicants should be aware that all materials associated with this Notice are subject to the terms of the Freedom of Information Act (FOIA), Virginia Code title 2.2, chapter 37.

Stage 2: Review and Scoring of Applications

The review committee will score the applications based on the business plans submitted and make recommendations to the Board regarding the award of conditional approval or the need to re-issue the Notice. Each applicant’s business plan shall detail the applicant’s plan to become operational within one year of receiving conditional approval and shall, at a minimum, address the eight categories in the table below. The business plan may incorporate by reference other documentation submitted with the application, such as ownership details, evidence of regulatory history, and facility blueprints. **The applicant’s business plan shall not exceed 50 pages.**

Business Plan Requirements

| Category | Components |
|--------------------------|--|
| 1. Proposed location | <ul style="list-style-type: none"> a. Facility’s proposed location is within HSA I and documentation substantiates the location is not within 1,000 feet of a school or daycare; and b. Description of the facility’s proposed location addressing the location’s accessibility to patients, compatibility with other commercial and residential structures in the immediate neighborhood, any evidence of support from the immediate neighborhood or locality, and ability to safely dispose of unwanted product. |
| 2. Finances | <ul style="list-style-type: none"> a. Current financial position (indicating all assets, liabilities, income, and net worth) or expected funding source demonstrating the financial capacity of the applicant to build and operate a facility to cultivate, produce, and dispense cannabis and remain a long-term, stable, and sustained source of cannabis for patients. This may include any evidence of financial soundness, including any evidence of an escrow account, letter of credit, loan commitment agreement, or performance surety bond; and b. Anticipated startup costs and anticipated revenue for the first year of initial operations. |
| 3. Likelihood of success | <ul style="list-style-type: none"> a. Preparedness for running a successful business in a highly regulated environment; b. Anticipated timeline for beginning cultivation activities and dispensing cannabis and cannabis products wholesaled from currently operating pharmaceutical processors; and c. Future plans, including proposed locations, if known, for opening and operating additional cannabis dispensing facilities in HSA 1. |

| | |
|--|--|
| 4. Cultivation of cannabis | <ul style="list-style-type: none"> a. Agricultural techniques required to cultivate cannabis, familiarity with good agricultural practices, and any relevant certifications or degrees; b. Strain variety and plant genetics; c. Odor mitigation practices; d. Best practices for water usage and wastewater disposal; and e. Pest control and disease management practices. |
| 5. Manufacture and creation of cannabis products | <ul style="list-style-type: none"> a. Procedures to produce cannabis products that are safe, unadulterated, and compliant with all legal requirements, and that satisfy quality assurance testing; b. Compliance with all product registration requirements; c. Using appropriate extraction methods and sourcing of extraction equipment and associated solvents, or intended methods and equipment for non-solvent extraction; d. A list of product formulations or products proposed to be manufactured with estimated cannabinoid profiles, if known, including products that (i) contain cannabidiol (CBD) as their primary cannabinoid and (ii) have low levels of or no tetrahydrocannabinol (THC); and e. Sourcing of all non-cannabis ingredients used in the manufacture and creation of cannabis products, including methods to verify or ensure the safety and integrity of those ingredients and their potential to be or contain allergens. |
| 6. Dispensing of medical cannabis | <ul style="list-style-type: none"> a. Pharmaceutical practices and any relevant certifications or degrees; b. Prescription monitoring programs; c. Counseling patients to ensure appropriate dosing; d. Educating patients and others on the medical use of cannabis, how to safely secure cannabis, and how to properly dispose of unwanted cannabis; e. Prevention of medical cannabis use by persons not authorized to possess medical cannabis or for recreational purposes; f. Packaging and labeling of cannabis that does not encourage the use of medical cannabis for recreational purposes; g. Management of dispensing errors; h. Proposed dispensing hours; and i. Information related to any compassionate need program the applicant intends to offer. |

| | |
|--|---|
| 7. Quality control and quality assurance | <ul style="list-style-type: none"> a. Analytical chemistry and testing of cannabis; b. Sampling procedures; c. Compliance with contaminant testing requirements; d. Recall plans; and e. Implementation and compliance with a quality assurance program. |
| 8. Prevention and detection of diversion of medical cannabis | <ul style="list-style-type: none"> a. Security and surveillance plans for the facility; b. Inventory control and tracking software or systems for the cultivation, production, and dispensing of medical cannabis; c. Onsite and offsite recordkeeping; d. Employee training; and e. Waste disposal plans. |

Scoring

The review committee will score the business plan based on the applicant’s response addressing each of the categories above. The members of the review committee will score each of the categories based on the following scoring table:

| Assessment | Points |
|--|---------------|
| Unsatisfactory – Minimum expectations for category not met; failure to address all required components; significant weaknesses and lack of detail and/or clarity; little or no confidence in the response or applicant’s ability to fulfill category components. | 0 |
| Satisfactory – Minimum expectations for category met and all required components addressed; no significant weaknesses exist, and response is clear and detailed; confidence in the response and applicant’s ability to fulfill category components; offers no significant benefits beyond the minimum expectations. | 1 |
| Exceptional – Response offers significant benefits beyond the minimum expectations; answer presents innovative and/or best-in-class solutions; high confidence in the applicant’s ability to fulfill claims. | 2 |

After reviewing and scoring the applications, the review committee will average each applicant’s total score from the committee members using customary rounding. The maximum score an applicant can receive is 16 points. An applicant that receives fewer than 1 point in any individual category or fewer than 8 points total will be deemed to have submitted a non-competitive application and, therefore, will be disqualified from further consideration. If no applicant submits a competitive application, the review committee will recommend that the Board reissue the Notice.

Stage 3: Awarding of Conditional Approval

If more than one applicant receives at least 8 points, the review committee will prepare a ranked list of applicants according to the average scores. The committee will recommend to the Board the issuance of conditional approval to the applicant with the highest ranked score and may recommend an otherwise qualifying alternate applicant for consideration, should the highest scored applicant choose to withdraw, otherwise not accept the conditional approval, or be deemed disqualified based on the criminal history check. In the event multiple applicants have the highest ranked score, the Board may use a lottery, or other similar method, to select the applicant that will receive conditional approval. The Board will notify applicants of denial or conditional approval. The decision of the Board not to grant conditional approval to an applicant will be final.

Criminal History Background Check

The Board cannot finalize conditional approval until it has conducted a criminal history background check on the material owners of the selected applicant. Material owners are those that hold a 5% or greater interest in the applicant. Material owners of the applicant selected for conditional approval must submit to fingerprinting and provide personal descriptive information to be forwarded along with their fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding the applicant's material owners by the deadline established in the timeline in this Notice. The applicant must pay the cost of fingerprinting and the criminal history record search. The Central Criminal Records Exchange will forward the results of the criminal history background check to the Board or its designee. An analysis will be performed of the results of the criminal history record information, including a review of any identified irregularities or falsified information submitted on the application.

Stage 4: Granting of a Pharmaceutical Processor Permit

If granted conditional approval, an applicant will have one year from date of notification to complete all requirements for issuance of a permit, including the construction or remodeling of a facility, installation of equipment and security, local zoning approval, and employment of a pharmacist-in-charge and other personnel necessary for operation.

Upon completion of all requirements, the applicant will submit an application for an initial permit, along with any required documentation and the application fee of \$165,000. The Board will not issue a pharmaceutical processor permit until an agent of the Board performs an inspection of the facility to confirm compliance with the granted conditional approval and all relevant laws and regulations.

Once the pharmaceutical processor permit is issued, the facility may begin operation, including obtaining cannabis seeds and receiving cannabis and cannabis products through wholesale distribution from other pharmaceutical processors in Virginia. Barring suspension, revocation, or refusal to grant or renew such permit as outlined in 3VAC10-80-20, the permit will be valid for one year from the date of issuance and may be renewed annually for continued operation pursuant to Board regulations.

Attachment 1 – HSA 1 Localities

| HEALTH SERVICE AREA | COUNTY EQUIVALENT | CITY COUNTY |
|------------------------------------|------------------------------|------------------------|
| I | Augusta | County |
| I | Bath | County |
| I | Buena Vista | (city) |
| I | Harrisonburg | (city) |
| I | Highland | County |
| I | Lexington | (city) |
| I | Rockbridge | County |
| I | Rockingham | County |
| I | Staunton | (city) |
| I | Waynesboro | (city) |
| I | Clarke | County |
| I | Frederick | County |
| I | Page | County |
| I | Shenandoah | County |
| I | Warren | County |
| I | Winchester | (city) |
| I | Culpeper | County |
| I | Fauquier | County |
| I | Madison | County |
| I | Orange | County |
| I | Rappahannock | County |
| I | Albemarle | County |
| I | Charlottesville | (city) |
| I | Fluvanna | County |
| I | Greene | County |
| I | Louisa | County |
| I | Nelson | County |
| I | Caroline | County |
| I | Fredericksburg | (city) |
| I | King George | County |
| I | Spotsylvania | County |
| I | Stafford | County |



Attachment 2 – Payment Coversheet

licensing@cca.virginia.gov
www.cca.virginia.gov

PAYMENT COVERSHEET

General Information

This form must accompany any payments made to the Virginia Cannabis Control Authority.

For product registrations, one payment coversheet and check may be submitted for up to 10 products.

For each other payment type, complete a separate payment coversheet and check.

Make check payable to “Treasurer of Virginia” and submit to the Virginia Cannabis Control Authority at P.O. Box 6411, Richmond, VA 23230. **Application fees are not refundable.**

Payer Information

| | |
|-----------------------|--------------------------------|
| Payment Submitted By: | Area Code and Telephone Number |
| Email Address | Health Service Area |
| Facility Name | |

Select Type of Payment (Include requested information under “Additional Information”)

- Product registration. List total # of products included: _____. (List NDC #'s, separated by commas)
- Initial application for permit
 - Pharmaceutical processor (NOA #, Trade Name)
 - Cannabis dispensing facility (Facility Address)
 - Cannabis cultivation facility (Facility Address)
- Annual permit renewal
 - Pharmaceutical processor (Permit #)
 - Cannabis dispensing facility: (Permit #)
 - Cannabis cultivation facility: (Permit #)
- Other (List fee type and include relevant information)

| | | |
|--|--------------|-------------------|
| Total Payment Amount | | |
| Additional Information | | |
| Signature of PIC, Responsible Party, or Authorized Agent | Name Printed | Date (MM/DD/YYYY) |