



Virginia Department of
Health Professions



Commonwealth of Virginia

REQUEST FOR APPLICATIONS (RFA)

Issue Date: September 25, 2020

RFA No. PHR-2020-01

Title: Pharmaceutical Processors-Health Service Area I

Issuing Agency: Department of Health Professions
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Ste. 300
Henrico, VA 23233

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Virginia Board of Pharmacy
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Application Due Date: December 4, 2020 at **2:00 P.M.**

All inquiries for information should be directed to Annette Kelley.

Purpose

The purpose of this Request for Application (RFA) is to solicit applications for a permit to operate a pharmaceutical processor in Health Service Area (HSA) I. As authorized in law, the Virginia Board of Pharmacy (Board) may award conditional approval for no more than one pharmaceutical processor for each of the five health service areas established by the Board of Health. The counties served by HSA I are listed in Attachment 1. A pharmaceutical processor is a facility that is authorized to: cultivate Cannabis plants intended only for the production and dispensing of cannabis oil; produce cannabis oil; and, dispense cannabis oil to patients for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by a practitioner to benefit from such use. With the exception of wholesale distribution to another pharmaceutical processor or cannabis dispensing facility, or delivering dispensed cannabis oil under certain conditions, the cultivation, production, and dispensing will occur on-site at the address of record of the facility.

The application process for the pharmaceutical processor permit in HSA I will occur in three stages: submission of initial application, awarding of conditional approval, and granting of a pharmaceutical processor permit. The review and scoring of the applications will be performed by an ad hoc committee appointed by the Board which will recommend to the Board the awarding of conditional approval or the need to re-issue the RFA should the committee determine there is an insufficient number of qualified applications. Persons interested in being considered for obtaining conditional approval must submit, in accordance with this RFA, the Code of Virginia, and the Regulations Governing Pharmaceutical Processors, an initial application and the non-refundable application fee of \$10,000, as listed in 18VAC110-60-20.

If granted conditional approval, an applicant will have one year from date of notification to complete all requirements for issuance of a permit to include 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, an agent of the Board will perform an inspection of the facility to assess compliance with the granted conditional approval and the relevant laws and regulations. Written corrective action will be submitted to the Board for any deficiencies identified during the inspection and a reinspection will be performed, if necessary. An application for initial permit, along with any required documentation, the initial permit fee of \$60,000 and any reinspection fees, if required, will be submitted to the Board prior to performing the inspection. Once the pharmaceutical processor permit is issued, the facility may obtain Cannabis seeds and begin operation. Barring suspension, revocation, or refusal to grant or renew such permit as outlined in 18VAC110-60-160, the permit will be valid for one year from the date of issuance and may be renewed annually pursuant to Board regulations for continued operation.

Background

The Virginia Board of Pharmacy is one of 13 health regulatory boards within the Department of Health Professions, a state agency that licenses and regulates over 380,000 health care professionals across 62 health professions. The Department is also composed of the Board of Health Professions, the Health Practitioners Monitoring Program, the Healthcare Workforce Data Center, and the Prescription Monitoring Program. The mission of the Department is to ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public. Information on these health regulatory boards and programs may be accessed on the Department's Web site, <http://www.dhp.virginia.gov/>.

Legislation was passed during the 2016 Virginia General Assembly Session and reenacted in 2017 (<http://leg1.state.va.us/cgi-bin/legp504.exe?171+ful+SB1027ER>) which authorized the permitting of pharmaceutical processors. The Virginia Board of Pharmacy subsequently adopted emergency regulations governing pharmaceutical processors, effective August 7, 2017 through February 6, 2019. (18VAC110-60-10 et sec., found at <http://register.dls.virginia.gov/details.aspx?id=6508> This created a regulatory framework for “pharmaceutical processors”, a term that was defined in Code to mean “a facility that (i) has obtained a permit from the Board pursuant to § [54.1-3408.3](#) and (ii) cultivates Cannabis plants intended only for the production of cannabidiol oil or THC-A oil, produces cannabidiol oil or THC-A oil, and dispenses cannabidiol oil or THC-A oil to a registered patient or, if such patient is a minor or an incapacitated adult as defined in § [18.2-369](#), such patient's parent or legal guardian for the treatment of intractable epilepsy.” Additionally, the Code was amended to authorize a “practitioner” to issue a written certification for the use of cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of a patient’s intractable epilepsy. The term “practitioner” was defined in Code to mean “a practitioner of medicine or osteopathy licensed by the Board of Medicine who is a neurologist or who specializes in the treatment of epilepsy.”

During the 2018 General Assembly Session, several bills were passed that amended the laws associated with pharmaceutical processors:

<http://leg1.state.va.us/cgi-bin/legp504.exe?181+ful+HB1251ER> (2018 Va. Acts of Assembly ch. 246)

<http://leg1.state.va.us/cgi-bin/legp504.exe?181+ful+SB330ER> (2018 Va. Acts of Assembly ch. 567)

<http://leg1.state.va.us/cgi-bin/legp504.exe?181+ful+SB726ER> (2018 Va. Acts of Assembly ch. 809)

Such amendments included expanding the use of cannabidiol oil and THC-A oil to any diagnosed condition or disease determined by the practitioner to benefit from such use, authorizing any practitioner of medicine or osteopathy licensed by the Virginia Board of Medicine (and registered by the Virginia Board of Pharmacy) to issue written certifications, and further elaborating on allowances and requirements for pharmaceutical processors.

Legislation passed during the 2019 General Assembly Session allowed for physician assistants licensed with the Board of Medicine and nurse practitioners jointly licensed by the Board of Medicine and the Board of Nursing to issue a written certification; the ability for a patient, or the patient’s parent or legal guardian to choose a board-registered individual to act as a registered agent to receive cannabis oil on behalf of the patient; and the option for a pharmaceutical processor to wholesale distribute cannabis oil products to another pharmaceutical processor.

<https://lis.virginia.gov/cgi-bin/legp604.exe?191+ful+SB1557ER+pdf>

<https://lis.virginia.gov/cgi-bin/legp604.exe?191+ful+SB1719ER+pdf>

During the 2020 General Assembly Session, several bills were passed that impact the pharmaceutical processors. Of significance: the definitions of “cannabidiol oil” and “THC-A oil” were replaced with a new definition, “cannabis oil”; practitioners may employ the use of telemedicine consistent with federal requirements for the prescribing of Schedule II through V controlled substances; an individual who temporarily resides in Virginia that has been issued a valid written certification and is registered with the Board may access cannabis oil products; and, the Board may permit up to five cannabis dispensing facilities in each HSA. The dispensing facilities must be owned in part by the pharmaceutical processor permitted in that HSA. Note: The application process for a cannabis dispensing facility permit is independent of this RFA for obtaining a pharmaceutical processor permit. Consideration of a cannabis dispensing facility permit application is contingent upon emergency regulations becoming effective and at least one owner maintaining a current active pharmaceutical processor permit in the same HSA.

<https://lis.virginia.gov/cgi-bin/legp604.exe?201+ful+SB976ER2+pdf>

Anticipated Timeline

September 25, 2020	Issue RFA
December 4, 2020, 2:00p.m.	Applications due
December 11, 2020	Applications and submitted documentation to ad hoc committee
February 5, 2021	In-person meeting of ad hoc committee to discuss scoring of applicants

February 17, 2021	Board reviews scoring and identifies which Applicants will be awarded conditional approval
February 26, 2021	Deadline for fingerprinting and submission of information for criminal background checks
March 30, 2021	Board reviews results of criminal background check and finalizes the awarding of the conditional approvals

Application Submission and Instructions

In order to be considered for selection, an Applicant must submit a complete Application for a Pharmaceutical Processor Permit for HSA 1 (Attachment 2) with required documentation and application fee in accordance with this RFA no later than December 4, 2020 at 2:00p.m. EST. **Note: Applications submitted without the required fee or information or in a manner that is significantly inconsistent with the RFA will be deemed incomplete and will not be considered for selection, nor will applications received after the submission due date.**

Application Submission: The application and all required attachments must be provided as follows:

1. Twelve (12) hard copies (printed), one marked Original, for a total of twelve (12) copies; and twelve (12) soft copies (CD or thumb drive) with a searchable PDF copy of the complete submission labeled with the RFA number and name and address of the pharmaceutical processor as indicated on the application.
2. All copies of applications and documentation must be mailed or hand-delivered to the address below. Mail sent using the United States Postal Service, including those requesting a certified mail receipt, is received in approximately one week. Mail sent using private mail carriers, e.g., UPS and FedEx, is more efficient as it arrives directly to the Board’s address. It is strongly recommended that Applicants track delivery to ensure timely receipt of their mailing.

Department of Health Professions
 Board of Pharmacy
 Perimeter Center
 9960 Mayland Drive, Suite 300
 Henrico, VA 23233

Important information for hand-delivering application materials:

In response to COVID-19 social distancing precautions, the Department of Health Professions’ public reception area is currently not accommodating walk-in services. If you wish to hand deliver your application materials prior to December 4, 2020, please

contact Annette Kelley at: cbd@dhp.virginia.gov to coordinate staff availability for delivery. Board of Pharmacy staff will be on-site on December 4, 2020 from 8:15 am until 2:00 pm for receipt of application materials.

In order to be considered for selection, Applicants must submit a complete response to this RFA.

In the event state business operations are suspended (office is closed) on the date set for receipt of applications, applications will be due at the same time on the next regular business day.

3. All packages must be sealed. The following information must be included in the return address and identified as follows:

From: _____
Name of Applicant **RFA Number: PHR-2020-01**
Health Service Area I

Street or Box Number

City, State, Zip Code

Pursuant to §54.1-3442.6 of the Code of Virginia, the number of permits that the Board of Pharmacy may issue or renew in any year is limited to one for each health service area established by the Board of Health. There are five health service areas in the Commonwealth. This RFA is for HSA I only. A permit has already been awarded to a facility in each of the other HSAs. Incomplete applications will not be considered. In the event the Board determines that there are no qualified applicants to award conditional approval for a pharmaceutical processor permit in HSA I, the Board may republish, in accordance with 18VAC110-60-100, a notice of open applications for pharmaceutical processor permits.

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 18VAC110-60-110(D).

The Board, and the ad hoc committee acting on its behalf, reserves the right to waive minor irregularities or to request clarifications, modifications, or amendments to an application, provided such application substantially complies with the RFA. The board also reserves the right to amend the notice of open applications prior to the deadline for submitting an application. Such amended notice will be published in the same manner as the original notice of open applications. The Board may cancel a notice of open applications prior to an award of a pharmaceutical processor permit.

Evaluation Criteria

The evaluation of applications will involve the scoring of each application by the ad hoc committee of the Board. While a maximum of 275 points is possible, proposals must achieve a minimum score of 160 points to be awarded conditional approval for a pharmaceutical processor permit. If an insufficient number of applications obtain a score of at least 160 to award a conditional approval in HSA I, the ad hoc committee may request modifications from those applicants whose scores are closest to 160 so as to render the applications acceptable. Alternatively, if the ad hoc committee determines that sufficient modifications cannot be made to render the applications in HSA I acceptable, the ad hoc committee may recommend to the Board that it re-issue the RFA.

In conducting its evaluation of each of the criteria listed below, the Board, and the ad hoc committee acting on its behalf, may conduct interviews, contact references, contact state or local officials in any other state(s) where the applicant, applicant's backers or others associated with the applicant have engaged, or sought to be engaged in, similar activities and visit the location of the proposed facility or other related businesses associated with the applicant or applicant's backers or key personnel.

The number of points after each component listed below is the maximum number of points that may be awarded for each of the corresponding components of the RFA. For each component, the applicant's score will be based on the totality of the response to the corresponding component. The description listed within each component is not intended to be an exhaustive list of all relevant factors, but rather is intended to provide guidance as to the focus of the Board's analysis.

- Financial Position (25 points):** An analysis will be performed of the submitted information detailing the applicant's financial position, indicating all assets, liabilities, income and net worth, to demonstrate the financial capacity of the applicant to build and operate a facility to cultivate Cannabis plants intended only for the production and dispensing of cannabis oil. This will include an evaluation of financial soundness, funding sources, any evidence of an escrow account, letter of credit, or performance surety bond, and a determination of the applicant's ability to remain a long-term, stable, and sustained source of cannabis oil for patients.

- Location within the Health Service Area (25 points):** An analysis will be performed of the submitted description of the facility's proposed location within HSA I as established by the Board of Health, which cannot be within 1,000 feet of a school or daycare. This will include an evaluation of the 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.

- **Security Plans (25 points):** An analysis will be performed of the submitted plans detailing the proposed security to maintain adequate control against the diversion, theft, or loss of the Cannabis plants and the cannabis oil. This will include an analysis of any proposed training opportunities for employees and processes to be implemented to protect against diversion, theft, or loss. Additionally, the analysis will include how the pharmaceutical processor will comply with security requirements pursuant set forth in 18VAC110-60-240 through 18VAC110-60-270 and the requirement for an electronic tracking system pursuant to 18VAC110-60-130 and as defined in 18VAC110-60-10.

- **Authorization to Conduct Business (20 points):** An analysis will be performed of the submitted documents sufficient to establish that the applicant is authorized to conduct business in Virginia in good standing, such as through the State Corporation Commission, 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 the permit. This will include the review of any proof of the Applicant's right to occupy the proposed premises.

- **Industry Involvement and Disciplinary Action (25 points):** An analysis will be performed of the information submitted regarding previous or current applications for permits, licenses, or registrations related to the cultivation, production, or dispensing of cannabis oil in any state and the status of that application, permit, license, or registration. This will include the review of any disciplinary action taken by any state or federal entity on the permit, license, or registration.

- **Agriculture, Production, and Dispensing Expertise (50 points):** An analysis will be performed of the information submitted that describes the collective expertise of the applicant and employees in: agricultural techniques required to cultivate Cannabis for the production of cannabis oil; production techniques for accurately producing unadulterated cannabis oil that satisfies concentrations defined by law and quality assurance testing; and dispensing techniques for safely dispensing cannabis oil to patients, to include counseling patients to ensure appropriate dosing. Consideration will be given to any education obtained and any proposed training opportunities for staff to safely cultivate, and accurately produce and dispense unadulterated cannabis oil.

- **Marketing Plans (20 points):** An analysis will be performed of the submitted marketing plan based on its ability to effectively educate patients and others on the medical use of cannabis oils, how to safely secure the oil, and how to properly dispose of unwanted oil. The analysis will include the care that is taken to not promote the use of marijuana or the

cannabis oil for recreational purposes or by persons not authorized to possess and administer cannabis oil.

- **Facility Exterior and Blueprint (25 points):** An analysis will be performed of the submitted text or graphic material showing the exterior appearance of the proposed pharmaceutical processor. The analysis will include a review of the blueprint of the proposed pharmaceutical processor which shows and identifies square footage of each area of the facility, to include the location of all safes or vaults used to store the Cannabis plants and oil and the location of all areas that may contain Cannabis plants, cannabis oil, showing the placement of walls, partitions, counters and all areas of ingress and egress. The information submitted should also support the Applicant's ability to comply with 18VAC110-60-250. Consideration will be given to any systems that will be used to reduce or prevent off-site odors.

- **Product and Site Safety (20 points):** An analysis will be performed of the list of cannabis oil products anticipated to be produced and dispensed at the proposed location. It will include an evaluation of the robustness of the Applicant's submitted plan to cultivate Cannabis and produce cannabis oil products that are safe, unadulterated, comply with the legal definitions for cannabis oil, and satisfy quality assurance testing. The analysis will also review the Applicant's submitted plan to produce a safe work environment for its employees.

- **Expected Hours of Operation (15 points):** An analysis will be performed of the Applicant's proposed hours of operation which will be at least 35 hours per week for eligible persons to purchase oil, except as otherwise authorized by the Board.

- **Additional Points (25 points):** An evaluation will be performed of each plan listed below and its ability to meet the objectives of the category.
 - Compassionate need plan, e.g., discounted pricing for qualifying patients (5 points)
 - Delivery service plan that mitigates risk of diversion, theft, or loss (15 points)
 - Research plan (5 points)

Maximum Total of Eligible Points = 275

Awarding of Conditional Approval

After completing the review and scoring, the ad hoc committee will rank each application according to its score. The committee will recommend to the Board the issuance of conditional approval to the Applicant in HSA I with the highest ranked score and may recommend an otherwise qualifying alternate Applicant for consideration, should the top Applicant choose to withdraw or

otherwise not accept the conditional approval upon awarding, provided: the recommended Applicant's or alternate Applicant's total scores exceed the minimum established score and no reasons exist to deny issuance of conditional approval. Selection will be made of applicants deemed to be fully qualified and best suited among those submitting applications based on the evaluation criteria and results of the criminal background check. The Board will grant conditional approval to the Applicant that, in its opinion, has made the best application. 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 Background Check:

The Applicant who is notified of the Board's willingness to grant it conditional approval must, as a condition of the awarding, 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. The cost of fingerprinting and the criminal history record search must be paid by the applicant. The Central Criminal Records Exchange will forward the results of the criminal history background check to the Board or its designee, which will be a governmental entity. An analysis will be performed of the results of the criminal history record information, to include a review of any identified irregularities or falsified information submitted on the application.

Attachment 1

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-Pharmaceutical Processor Application



APPLICATION FOR A PHARMACEUTICAL PROCESSOR PERMIT

Check Appropriate Box(es):

<input type="checkbox"/> Initial Application	\$10,000.00	<input type="checkbox"/> Initial Permit ²	\$60,000.00
<input type="checkbox"/> Change of Ownership Requiring Criminal Background ⁷	\$250.00	<input type="checkbox"/> Change of Location ⁴	\$1,000.00
<input type="checkbox"/> Change of Ownership Not Requiring Criminal Background ⁷	\$100.00	<input type="checkbox"/> Remodel, Expansion, Acquisition ⁵	\$1,000.00
<input type="checkbox"/> Change of Name	\$100.00	<input type="checkbox"/> Re-Inspection ⁶	\$1,000.00
<input type="checkbox"/> Change of Pharmacist-In-Charge ¹	\$100.00	<input type="checkbox"/> Change in Hours of Operation ³	No fee

Application fees are not refundable. Applications are valid for one year from the date of receipt. The required fees must accompany the application. Make check payable to "Treasurer of Virginia".

Applicant—Please provide the information requested below. (Print or Type) Use full name not initials.

Name of Pharmaceutical Processor		Area Code and Telephone Number	
Street Address		Area Code and Fax Number	
City	State	Zip Code	Designated Health Service Area
If a current pharmaceutical processor permit is held, indicate the permit number 02		Area Code and Telephone Number (currently working number)	
(Print) Name of the Pharmacist-In-Charge (PIC) (if change of PIC, list incoming) ^{1,2}		License Number of the PIC ^{1,2} 0202-	
Effective Date of Change (if change of PIC, date assuming role as PIC) ¹	Email Address of PIC ^{1,2}		
Hours of Operation ^{1, 2, 3}	Anticipated Opening Date ²		
Name of Owner Applicant	Telephone Number of Owner Applicant		
Email Address of Owner Applicant	Expected Completion Date of Remodel or Expansion or Date for Change of Location ^{4,5}	Requested Inspection Date ^{2,4,5,6}	
FOR OFFICE USE ONLY:			
Date processed:			
Assigned Inspection Date:	Check No:	Receipt No:	Application No:
Permit Number 02	Date Inspected:	Reviewed By:	Date Reviewed:
			Date Issued:
			Date Scanned to MLO:

OWNERSHIP TYPE —			
check one:	Corporation <input type="checkbox"/>	Partnership <input type="checkbox"/>	Individual <input type="checkbox"/>
Other <input type="checkbox"/>			
Name of ownership entity if different from name of application:			
Street Address:			Phone No.
City:	State:	Zip Code:	
State(s) of incorporation:			

List all other trade or business names used by this facility	
Name: _____	Name: _____
Name: _____	Name: _____

LIST OF OWNERS/OFFICERS, RESIDENCE ADDRESSES, AND PERCENTAGE OF SHARES OWNED FOR EACH OWNER OR LIST IS ATTACHED <input type="checkbox"/>	
Name: _____	Title: _____
Residence Address: _____	
Name: _____	Title: _____
Residence Address: _____	

⁷Any owner with 5% or greater share of the total ownership must submit to a criminal history record search and submit the applicable application fee. Instructions will be provided for how to complete the record search once this application is received and processed.

Please respond to all of the following questions:

1. Have you, any owner, employee, or agent of this business entity ever been convicted of, pled *nolo contendere* to, or currently have charges pending for 1) any felony, 2) any misdemeanor involving moral turpitude, or 3) violation of any federal or state law relating to controlled substances? If yes, provide name of owner, employee, or agent, name of jurisdiction and date of charges or convictions, explain, and attach copies of any official documents such as warrants and court orders showing the nature and disposition of such charges or convictions. Yes No
2. Have you, any owner, employee, or agent of this business ever had any civil action under any federal or state statute or regulation or local ordinance relating to the applicant's, licensee's, permit holder's or registrant's profession, or involving drugs, medical devices or fraudulent practices, including, but not limited to, fraudulent billing practices? If yes, provide name of owner, employee, or agent, name of jurisdiction and date of charges or convictions, explain, and attach copies of any official documents such as warrants and court orders showing the nature and disposition of such charges or convictions. Yes No
3. Has any owner, employee, or agent of this business had a license or registration suspended or revoked or denied issuance of such license or registration? If yes, provide name of employee or agent, name of jurisdiction, date of action, and attach copies of any official documents related to the issue. Yes No
4. Does a practitioner of medicine or osteopathy licensed by the Board of Medicine, a physician assistant licensed by the Board of Medicine or a nurse practitioner jointly licensed by the Board of Medicine and the Board of Nursing, and who issues written certifications, or such practitioner's co-worker, employee, spouse, parent or child, have a direct or indirect financial interest in this business? Yes No

NOTE:

Qualifying applicants will be informed of the need to submit to fingerprinting and providing 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.

A 14-day notice is required for scheduling an opening or change of location inspection. Cannabis seeds and Cannabis products may not be stocked prior to the initial inspection and approval. An inspector will call prior to the requested date to confirm readiness for inspection or the applicant or PIC may call the Enforcement Division at 804-367-4691 to verify the inspection date with the inspector.

Signature of Owner Applicant

Date

Signature of PIC (required except for initial application if PIC not known)

Date

Information Required for Initial Application

To be considered for issuance of a conditional approval, the following information must be submitted, in accordance with the current Request for Application (RFA), along with the application form and initial application fee. Refer to the *Evaluation Criteria* found within the RFA for how the submitted information will be evaluated.

- Financial Position:** Detailed information regarding the applicant's financial position, indicating all assets, liabilities, income and net worth to demonstrate the financial capacity of the applicant to build and operate a facility to cultivate Cannabis plants intended only for the production and dispensing of cannabis oil. This may include evidence of an escrow account, letter of credit, or performance surety bond.
- Location within the Health Service Area:** Description of the facility's proposed location within the health service area as established by the Board of Health.
- Security Plans:** Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of the Cannabis plants and the cannabis oil.
- Authorization to Conduct Business:** Documents sufficient to establish that the applicant is authorized to conduct business in Virginia in good standing, such as through the State Corporation Commission, 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 the permit.
- Industry Involvement and Disciplinary Action:** Information about current or previous involvement in the medical cannabis oil industry. Information about previous applications for permits or registration related to medical cannabis oil in any state and if so, the status of that application, permit, registration including any disciplinary action taken by any state on the permit, registration, or an associated license.
- Agriculture, Production, and Dispensing Expertise:** Information regarding expertise in agriculture and other production techniques required to produce cannabis oil and to safely dispense such products.
- Marketing Plans:** Information regarding the business and marketing plans related to the operation of the pharmaceutical processor or the sale of cannabis oil.
- Facility Exterior and Blueprint:** Any text or graphic material showing the exterior appearance of the proposed pharmaceutical processor. Include a blueprint of the proposed pharmaceutical processor which shall show and identify square footage of each area of the facility, to include the location of all safes or vaults used to store the Cannabis plants and oils and the location of all areas that may contain Cannabis plants, cannabis oil, showing the placement of walls, partitions, counters and all areas of ingress and egress.
- Product and Site Safety:** Plan to safely cultivate Cannabis and produce cannabis oil that is safe, unadulterated, comply with the legal definitions for cannabis oil, and satisfy quality assurance testing. Plan to produce a safe work environment for employees.
- Expected Hours of Operation:** A facility shall be open a minimum of 35 hours a week for eligible persons to purchase oil, except as otherwise authorized by the Board.
- Compassionate Need Plan:** Documents related to any compassionate need program, e.g., discounted pricing for qualifying patients the pharmaceutical processor intends to offer.
- Delivery Service Plan:** A plan detailing any delivery service the pharmaceutical processor intends to offer that mitigates any risk of diversion, theft, or loss.
- Research Plan:** A plan detailing any research the pharmaceutical processor intends to perform or in which it may participate.

Information Required for Initial Permit

In addition to satisfactory inspection of the facility conducted by the Board or its agent, an applicant that has received conditional approval shall complete the following steps and provide the required information prior to issuance of an initial permit:

- Application:** Submission of an Application for a Pharmaceutical Processor Permit. Check the box indicating “Initial Permit”, designate the pharmacist-in-charge (PIC), indicate the requested inspection date, and submit the required fee for “Initial Permit”.
- Criminal Background Checks:** Evidence of criminal background checks of all employees or agents of the processor to ensure compliance with §54.1-3442.6 of the Code.
- Electronic Tracking System:** Evidence of utilization of an electronic tracking system.
- Attestation:** Submission of an attestation indicating full compliance with all state and local laws and ordinances for the operation of a pharmaceutical processor.