



Virginia Department of
Health Professions



Commonwealth of Virginia

REQUEST FOR APPLICATIONS (RFA)

Issue Date: April 16, 2018

RFA No. PHR-2018-01

Title: Pharmaceutical Processors

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

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Application Due Date: **June 8, 2018 at 2:00 P.M.**

All inquiries for information should be directed to Caroline D. Juran.

Purpose

The purpose of this Request for Application (RFA) is to solicit applications for a permit to operate a pharmaceutical processor. As required by law, the Virginia Board of Pharmacy (Board) will award conditional approval for no more than one pharmaceutical processor for each health service area established by the Board of Health. There are five (5) defined health service areas. (Attachment 1) A pharmaceutical processor is a facility that is authorized to: cultivate Cannabis plants intended only for the production and dispensing of cannabidiol (CBD) oil or THC-A oil; produce cannabidiol oil or THC-A oil; and, dispense cannabidiol oil or THC-A 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 delivering dispensed oils under certain conditions, the cultivation, production, and dispensing will occur on-site at the address of record of the facility.

The application process for pharmaceutical processor permits 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 issuance of the pharmaceutical processor permit. 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 350,000 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.

Anticipated Timeline

April 16, 2018	Issue RFA
June 8, 2018, 2:00p.m.	Applications due
June 25, 2018	Applications and submitted documentation to ad hoc committee
July 30-31, 2018	In-person meeting of ad hoc committee to discuss scoring of applicants
August 14, 2018	Board reviews scoring and identifies which Applicants will be awarded conditional approval
August 24, 2018	Deadline for fingerprinting and submission of information for criminal background checks
September 25, 2018	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 (Attachment 2) with required documentation and application fee in accordance with this RFA no later than June 8, 2018 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, name and address of the pharmaceutical processor as indicated on the application, and the health service area in which the proposed entity would be located.
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

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 each health service area, 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 one or more health service area acceptable, the ad hoc committee may recommend to the Board that it re-issue the RFA or proceed with the RFA and issue conditional approval for the health service area(s) for which there is an otherwise qualified applicant.

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 cannabidiol oil and THC-A 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 CBD and THC-A oils 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 the health service area 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 cannabidiol oil or THC-A 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 cannabidiol oil or THC-A 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 CBD and THC-A oil; production techniques for accurately producing unadulterated CBD and THC-A oil that satisfies concentrations defined by law and quality assurance testing; and dispensing techniques for safely dispensing CBD oil and

THC-A 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 CBD and THC-A 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 CBD and THC-A oils, how to safely secure the oils, and how to properly dispose of unwanted oils. The analysis will include the care that is taken to not promote the use of marijuana or the oils for recreational purposes or by persons not authorized to possess and administer CBD and THC-A oils.

- **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 oils and the location of all areas that may contain Cannabis plants, CBD or THC-A 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 oils 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 oils that are safe, unadulterated, comply with the legal definitions for cannabidiol oil and THC-A 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):** A 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 an Applicant in each health service area 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(s) which, in its opinion, have 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:

Those Applicants who are notified of the Board's willingness to grant them 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
II	Alexandria	(city)
II	Arlington	County
II	Fairfax	(city)
II	Fairfax	County
II	Falls Church	(city)
II	Loudoun	County
II	Manassas	(city)
II	Manassas Park	(city)

II	Prince William	County
III	Lee	County
III	Norton	(city)
III	Scott	County
III	Wise	County
III	Buchanan	County
III	Dickenson	County
III	Russell	County
III	Tazewell	County
III	Bland	County
III	Bristol	(city)
III	Carroll	County
III	Galax	(city)
III	Grayson	County
III	Smyth	County
III	Washington	County
III	Wythe	County
III	Floyd	County
III	Giles	County
III	Montgomery	County
III	Pulaski	County
III	Radford	(city)
III	Alleghany	County
III	Botetourt	County
III	Clifton Forge	(city)
III	Covington	(city)
III	Craig	County
III	Roanoke	(city)
III	Roanoke	County
III	Salem	(city)
III	Amherst	County
III	Appomattox	County
III	Bedford	(city)
III	Bedford	County
III	Campbell	County
III	Lynchburg	(city)
III	Danville	(city)
III	Franklin	County
III	Henry	County
III	Martinsville	(city)
III	Patrick	County
III	Pittsylvania	County
IV	Brunswick	County
IV	Halifax	County
IV	Mecklenburg	County
IV	Amelia	County

IV	Buckingham	County
IV	Charlotte	County
IV	Cumberland	County
IV	Lunenburg	County
IV	Nottoway	County
IV	Prince Edward	County
IV	Charles City	County
IV	Chesterfield	County
IV	Goochland	County
IV	Hanover	County
IV	Henrico	County
IV	New Kent	County
IV	Powhatan	County
IV	Richmond	(city)
IV	Colonial Heights	(city)
IV	Dinwiddie	County
IV	Emporia	(city)
IV	Greensville	County
IV	Hopewell	(city)
IV	Petersburg	(city)
IV	Prince George	County
IV	Surry	County
IV	Sussex	County
V	Lancaster	County
V	Northumberland	County
V	Richmond	County
V	Westmoreland	County
V	Essex	County
V	Gloucester	County
V	King And Queen	County
V	King William	County
V	Mathews	County
V	Middlesex	County
V	Chesapeake	(city)
V	Franklin	(city)
V	Isle Of Wight	County
V	Norfolk	(city)
V	Portsmouth	(city)
V	Southampton	County
V	Suffolk	(city)
V	Virginia Beach	(city)
V	Hampton	(city)
V	James City	County
V	Newport News	(city)
V	Poquoson	(city)

V **Williamsburg** (city)
V **York** County
V **Accomack** County
V **Northampton** County



COMMONWEALTH OF VIRGINIA

Board of Pharmacy

9960 Mayland Drive, Suite 300
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(804) 367-4456 (Tel)
 (804) 527-4472 (Fax)
pharmbd@dhp.virginia.gov (email)

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	\$1,000.00	<input type="checkbox"/> Change of Location ⁴	\$1,000.00
<input type="checkbox"/> Change of Name	\$100.00	<input type="checkbox"/> Remodel, Expansion, Acquisition ⁵	\$1,000.00
<input type="checkbox"/> Change of Pharmacist-In-Charge ¹	\$100.00	<input type="checkbox"/> Re-Inspection ⁶	\$1,000.00
<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: _____
Name: _____	Name: _____	Name: _____	Name: _____

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

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 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:

In accordance with the RFA, 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 drugs may not be stocked prior to 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 cannabidiol oil and THC-A 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 cannabidiol oil or THC-A 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 cannabidiol oil or THC-A oil industry. Information about previous applications for permits or registration related to medical cannabidiol oil or THC-A 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 cannabidiol oil or THC-A 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 cannabidiol oil or THC-A 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, cannabidiol oil, or THC-A 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 oils that are safe, unadulterated, comply with the legal definitions for cannabidiol oil and THC-A 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.