

This page provides responses to questions asked about the Notice of Open Applications for Health Service Area 1. The CCA will update this page as it receives new questions.

1. In addition to the 50-page business plan, are applicants allowed to include appendices such as SOPs or other relevant documentation?

If applicants choose to include appendices, the appendices will count towards the 50-page limit.

2. Does the inclusion of titles/deed/or rental documentation to establish ownership count toward the total 50 pages allowed in the business plan?

If an applicant chooses to include titles/deeds/or rental documentation in the business plan, those pages will count toward the 50-page limit.

3. Page 9/15 of the Notice of open applications says we may include facility blueprints, will those blueprints count toward the 50-page total for the business plan?

Blueprints uploaded in the "Facility Blueprint" section do not count toward the 50-page limit. Only documents uploaded in the "Business Plan Documents" section will count toward the 50-page limit. In "Business Plan Documents," information submitted in other parts of the application may be referenced without being submitted redundantly.

4. The NOA does not prescribe font, font size, or page spacing, is this at an applicant's discretion or does the CCA have requirements?

What formatting restrictions should be used within the 50-page limit for the business plan (e.g., margins, text size, font, spacing)?

Are there font/spacing restrictions for the 50-page Business Plan?

Are there any format requirements (font style/size, margins, etc.) for the application materials?

Applicants should use their best judgment when formatting (e.g. font, font size, margins) the business plan and other application materials.

5. Is there a limit on file size for documents that need to be uploaded to the portal? / What's the file size upload limit for submitting the application online?

Files are limited to 1 GB.

6. May the materials on page 4, a-f, be accompanied by any explanatory narrative (e.g., subpart c asks for "information about any previous or current involvement in the medical cannabis industry" – may that be offered via a narrative)?

The online application asks applicants to upload information about current or previous medical cannabis involvement. A narrative might be informative under certain circumstances. Applicants should use their best judgment when providing information responsive to this request.

## 7. What materials can be included under item c on page 4? May there be explanatory attachments?

Applicants should use their best judgment when providing information responsive to this request.

8. What materials can be included under item b on page 4? May there be a narrative explaining how local requirements "will be met prior to issuance of a permit"?

Applicants should use their best judgment when providing information responsive to this request.

# 9. Are the materials on page 4, a-f, the only additional materials that may be appended to the application?

The online application requires applicants to upload materials including:

- Ownership information.
- Criminal history information (if applicable).
- Civil action history information (if applicable).
- License or registration suspension or revocation history (if applicable).
- Documentation establishing that applicant is authorized to conduct business in Virginia and other state and local requirements (including ordinances and building, fire, and zoning requirements) are, or will be, met prior to issuance of the permit.
- Information about ownership entity's involvement in the medical cannabis industry, which shall include, if applicable: (1) current or previous medical cannabis industry involvement including the status of that application, permit or registration; and (2) current or past disciplinary action information regarding the registration, or an associated license.
- A business plan addressing the eight required categories, and all related components, as detailed in the Notice of Open Applications: 1) Proposed Location; 2) Finances; 3)
   Likelihood of Success; 4) Cultivation of cannabis; 5) Manufacture and creation of cannabis products; 6) Dispensing of medical cannabis; 7) Quality control and quality assurance; and 8) Prevention and detection of diversion of medical cannabis.
- Any text or graphic material showing the exterior appearance of the proposed pharmaceutical processor.
- Blueprints of the proposed pharmaceutical processor that clearly identify, at a
  minimum; 1. The square footage of each area of the facility; 2. The safes or vaults for the
  storage of cannabis plants and products; 3. The areas that contain cannabis plants and
  products; and 4. The placement of walls, partitions, counters and all areas of ingress
  and egress.

10. May the business plan have attachments that do not count towards the 50-page limit but that are referenced by the text within the 50-page limit?

Any attachments submitted with the business plan will count towards the 50-page limit.

11. Are there page limits for attachments?

There are no page limits for attachments, except that any attachments submitted with the <u>business plan</u> will count towards the 50-page limit.

12. May we upload letters of support, letters of intent, and/or standard operating procedures under "Business Plan Documents?"

Any supporting documentation uploaded with the business plan will count toward the 50-page limit.

13. May we submit redacted materials subject to the terms of the Freedom of Information Act (FOIA), Virginia Code title 2.2, chapter 37?

All application materials submitted to the CCA are subject to FOIA. If an applicant submits redacted materials, the review panel will be unable to review any information subject to the redactions.

14. Is each section worth 2 points?

Each category in the business plan is worth a maximum of 2 points, for maximum total score of 16 points.

15. What decimal place will scores be rounded to? (Example: .1, .01, .001, .0001?)

Will there by decimals when scoring the applications? For example, if 2 = Minimum Standards, and 3 = Best in Class, is there a 2.5 that could be awarded?

Scores will be rounded to the nearest whole number using conventional rounding. The maximum score for any single category is 2. And the maximum total score is 16.

16. Are the following except from The Virginia Freedom of Information Act (FOIA), Title 2.2, Chapter 37? Trade Secret Financials; Trade Secret Security Plans; Trade Secret Procedures; Trade Secret Operational Plans; Trade Secret Formulations

No. There is no FOIA exception that would enable the CCA to withhold disclosure of these trade secrets if submitted as part of an application.

17. Although the RFA provides that the entire submission is subject to FOIA, the Uniform Trade Secrets Act would protect these items from disclosure due to the sensitivity and damaging nature of the public disclosure. If these items are protected, would the CCA like a redacted version and an unredacted version of the Applicant's submission?

Under FOIA, the CCA has an obligation to disclose public records upon request, unless an exception applies. Applications for a permit issued by the CCA are public records, and there are no exceptions under current law allowing the CCA to withhold any specific information

included in an application, including information the applicant considers to be trade secrets. It is an applicant's prerogative to take reasonable efforts to maintain secrecy of trade secrets; however, the review panel can only consider information submitted with the application when scoring the applicant's business plan.

### 18. What are the performance bond requirements?

There are no set performance bond requirements. If an applicant submits evidence of a performance bond, the review panel will evaluate the details provided by the applicant when scoring the "Finances" category of the business plan.

### 19. Is this for adult use, or is this for medical cannabis?

The Notice of Open Applications is for prospective pharmaceutical processors who wish to be considered for a permit to cultivate, manufacture, and dispense only medical cannabis and medical cannabis products to patients with a valid written certification.

## 20. So only 1 will be awarded to each municipality listed in attachment 1 correct? And this is including like adult use dispensaries?

Only one pharmaceutical processor permit will be issued in Health Service Area 1. A permit will **not** be issued in each locality listed in Attachment 1 of the Notice. The Notice is unrelated to adult-use dispensaries, which are not authorized under current law.

# 21. With the 50-page limit for the Business Plan, plus references that can be made from the Business Plan, is there a limit on how many pages can be referenced?

Applicants can reference other materials submitted as part of the application (e.g., ownership structure, blueprints, licensing history). These materials will not count toward the 50-page limit. However, any other materials included in the business plan will count toward the 50-page limit.

# 22. Are there references to be titled as Appendices, or Addendums, or Exhibits? Does the VCCA have a preference?

Applicants should use their best judgment when titling materials. The CCA does not have a preference.

# 23. How should reference materials be made available to the VCCA? Is there a format preference?

Only materials submitted with the application will be considered by the review panel. All materials should be submitted as part of the business plan unless specifically requested in another section of the application.

## 24. When scoring the application, will the VCCA only be scoring the Business Plan, or the references as well?

The review panel will score the business plan, and the scoring will consider any materials referenced in the business plan and submitted as part of the application requirements.

# 25. If each Category is scored separately, how does the VCCA feel about redundant information? Our team wants to focus on ownership & leadership, which does not have its own category, but rather can be referenced in multiple categories, would we want to bring this up multiple times?

Applicants should use their best judgment regarding redundant information. Each member of the review panel will review the applications and business plans of all applicants in their entirety.

### 26. Are there new rules released to accompany the RFP?

The requirements for the Notice of Open Applications are outlined in the Notice. Current CCA regulations can be found here: https://law.lis.virginia.gov/admincode/title3/agency10/.

# 27. Will questions submitted to the VCCA be published for public review on the website under FAQs (or similar heading)?

Questions submitted to the CCA will be published for public review on the CCA website. A link to Frequently Asked questions will be available on this page: https://www.cca.virginia.gov/NOA-HSA1.

### 28. Is there a file type requirement for the application (PDF, Word, etc)?

Applicants can upload the following types of files: pdf, doc, docx, xls, xlsx, csv, txt, rtf. Applicants should use their best judgment when selecting what type of file to upload.

## 29. Is a standard check acceptable for payment or does it need to be cashier's check/money order?

A standard check is acceptable. 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.

# 30. May we pay our application fee in advance of application submission to ensure timely payment?

Applicants may submit their application fee in advance; however, be aware application fees are non-refundable.

#### 31. Do reference materials have to be digitally linked within the business plan?

Applicants can reference other materials submitted with the application without digitally linking them with the business plan. Any materials submitted with the business plan will count toward the 50-page limit.

# 32. Is there an option to save an application and come back and finish it later (it doesn't look like it on the portal)?

This function has been enabled on the application.

33. Are all references from the Business Plan intended to be uploaded into the Business Plan Document section and then Facility Exterior and Facility Blueprint documents also to be uploaded in those sections or how are the supporting/reference documents supposed to be uploaded? Are redundancies a problem?

Applicants can reference materials that are uploaded in response to directives in other sections of the application without having to upload them again in the business plan document section.

34. Who will be grading the RFP? Will it be graded by a review committee? Will it be graded by a 3rd party, such as KPMG?

Applications submitted in response to the Notice will be scored by an internal review panel made up of Board members and CCA staff.

35. Can the CCA explain the minimum capital requirements and assets needed to be held or if there is a minimum.

There are no minimum capital or asset requirements. The review panel will consider each applicant's estimated expenses, sources of capital, other assets, and expected revenues.

36. Is the state willing to grant any capital to qualified applicants to fund the building of a GMP vertically integrated operation?

The CCA does not have the authority or funding to make grants to qualified applicants.

37. Regarding the distance measuring from the designated facilities, i.e., schools & daycares, where does the measuring start from (i.e.) is it facility door to facility door, boundary line to boundary line, etc.?

The distance requirements are computed by measuring a straight line from the nearest legal parcel line of the land used for the school or daycare to the nearest edge of the building or structure in which the pharmaceutical processor is proposed to be located.

What is included in the terms "school" and "daycare" as dictated by the distancing requirements. Does "school" include any institutions higher than high school such as community colleges, colleges and/or universities? Does "school" include preschool? Also, what is considered a "daycare" since I did not see it defined in the regulations?

The term "school" does not include institutions of higher education, but it does include preschools. The term "daycare" includes "child day center" and "family day home" as those are defined in Virginia Code § 22.1-289.02.

38. Is there any way to allow applicants to submit unredacted & redacted (very limited redacted) versions, provided redactions of banking information, personnel locations and certain security information to ensure that appropriate information is are kept confidential?

Any information submitted to the CCA may be subject to disclosure under FOIA. Applicants should use their discretion when submitting redacted materials.

39. The application requires the applicant to describe the applicant's ability to legally conduct business at the chosen site, the proposed location, and the applicant's timeline for operations. Is it possible to receive full credit for these items in the event that the applicant proposes to use a site that another applicant also proposes to use, assuming that both applicants' right to use the property (whether through purchase or lease) would be contingent on award of a license, such that no more than one applicant would ultimately have the right to use the property?

Assuming all other requirements are met, an applicant will be considered as meeting the minimum requirements if the applicant's right to use and possession of the proposed property is contingent upon receiving conditional approval for the pharmaceutical processor permit in HSA 1.

- **40. Applicants are required to submit a 50-page Business Plan, which "..**¡shall?at.a. minimum?address.the.eight.categories.in.the.table.below¡**..**", including:
  - Category 5(d): A list of product formulations or products
  - Category 7(d): Recall plans
  - Category 7(e): Implementation and compliance with a quality assurance program
  - Category 8(a): Security and surveillance plans for the facility
  - Category 8(e): Waste disposal plans

Our security and recall plans are greater than 50 pages. Per the FAQs, such plans count toward our 50-page limit. How can we submit an application that meets "minimum. expectations" when the 50-page limit prevents the submission of such material?

Applicants must address the categories listed above and can meet that requirement by summarizing or providing other descriptions of existing or future plans the applicant will rely on to satisfy the components of each category. Applicants do not need to submit copies of each of the plans specified. However, any plans submitted will count toward the 50-page limit.

41. Does "ownership entity full legal name" refer to an entity with ownership in the pharmaceutical processor, or is it asking for the legal name of the actual Applicant and proposed operator? for example. Company A is applying for the pharmaceutical processing permit and is a subsidiary of Company B. Company B owns 5% or more in Company A and therefore is an owner of Company A. Would "ownership entity legal name" be Company A (the applicant) or Company B (the owner and parent company)?

Ownership entity legal name refers to the legal name of the applicant. In the proposed example, it would be Company A.

42. Should individual entity owners include only material owners or are all individual owners, even with ownership under 5%, also required to be disclosed?

Applicants are required to disclose only material owners. If no owner has 5% or greater ownership, a material owner means an owner who also serves in the executive leadership of the company.

43. Would entities that have ownership in the applicant (such as a parent company) be listed as an "individual" owner or is there another place to designate Entities with ownership in the Applicant?

Entities with material ownership in the Applicant should be listed in the individual owner section.

44. If the applicant has an entity owner, must disclosure trace back to an individual, or what is the threshold for disclosure of ownership required? For example: XYZ, Inc., applicant is a subsidiary of XXYYZZ, Inc. with 5% or more ownership. XXYYZZ Inc. has individual who own 5% or more. Does disclosure stop with XXYYZZ, inc. or trace back to XXYYZZ, inc.'s owners as well.

Applicants should disclosure the material owners of any entities with at least a 5% ownership interest in the applicant.

45. The title box of the ownership information requested is marked as required. Does this title mean an individual's title in the business, like CEO, Cultivator, etc? If they do not hold a position in the business, would the title just be "owner"?

Title means the individual's role in the business. If an owner does not have a titled role within the business, the owner's title can be listed as "owner."

46. Does the pharmaceutical processor trade name mean the common name of the facility (separate from the legal name on articles of organization) for example could XYZ, Inc. put XYZ for trade name? Or can applicant only put a trade name if the entity holds a fictitious business name registration?

A trade name can mean the common name of the facility, including the name the business will use when advertising to patients.

47. In response to the question regarding whether an owner, employee, or agent of the applicant had a business license or registration suspended or revoked or been denied issuance of such a license, is the CCA seeking disclosure of any and all license applications that did not result in the award of a license? For example, should an application submitted in response to a competitive process such as the 2020 RFA issued by the Board of Pharmacy be disclosed in response to this inquiry?

Yes, applicants should disclose any license application that did not result in the award of a license. Under 3VAC10-30-120 (formerly, 18VAC110-60-120), "[f]ollowing review, the board shall notify applicants of denial or conditional approval." Unsuccessful applicants who applied to the Board of Pharmacy in response to a request for applications are considered to have been denied issuance of a license.

48. The VCCA has stated that schools do not include "institutions of higher education", but do include preschools. Is there any actual definition of the word "school" that we can go off of? For example, as we look for properties, both production and retail, there are

many establishments in our target areas that claim to be "\_\_\_\_\_ School", without any information as to the status of such schools. To expand:

- a. Is this for all schools, or only accredited schools?
- b. Does this include home schools?
- c. Is there a Department of Education list we can go to for the Commonwealth of Virginia to get a map of all such schools in the area?
- d. Do after school programs count as well?
- e. Do schools of fine or performance arts, such dance schools, karate schools, music schools, etc. count?
- f. Do church schools count? Do Sunday schools count?

As defined in Virginia Code § 22.1-271.2, the term "school" includes "(i) any public school from kindergarten through grade 12 operated under the authority of any locality within the Commonwealth, (ii) any private or religious school that offers instruction at any level or grade from kindergarten through grade twelve, and (iii) any private or religious nursery school or preschool, or any private or religious child-care center required to be licensed by the Commonwealth." The term "school" does not include home schools, recreational or artistic facilities, unless the facilities otherwise meet the definition of school.

49. The VCCA has stated that "daycare" includes "child day center" and "family day home" - are they any other terms that can be included in the term "daycare"? We have found the code referenced in the FAQ at the hyperlink below, which seems to focus on "Early Childhood Care". There are other terms referenced in this code as well, such as "Child day program". Do we include all other terms found in the Code?

As stated previously, the CCA considers daycare to include "child day center" and "family day home" as those terms are defined in Virginia Code § 22.1-289.02.

- 50. On the Department of Social Services search tool, there multiple terms to select to find child care facilities. The terms listed are "Child Day Center, Family Day Home, Short Term Child Day Center, Religious Exempt Child Day Center, Voluntary Registered Day Homes, Certified Pre School, Center Based, Home Based." Can we assume that by selecting all such terms, this would provide a list of the child care centers for the 1,000 ft rule in HSA I?
  - a. https://www.childcare.virginia.gov/families/finding-child-care
  - b. https://www.dss.virginia.gov/facility/search/cc.cgi

An applicant can use the search tool at <a href="https://www.dss.virginia.gov/facility/search/cc.cgi">https://www.dss.virginia.gov/facility/search/cc.cgi</a> to find a list of facilities that are subject to the 1,000 foot distance requirement by selecting the terms corresponding with Licensed and Regulated Unlicensed facilities.

51. Looking at the Anticipated Timeline for Conditional Approval, there are two key dates that emerge: June 26th for scoring / lottery results, and August 14th for finalizing conditional approval. Does this mean that applicants have one year from June 26th, or August 14th, to commence their facility upon successful conditional approval?

The anticipated timeline in the Notice of Open Applications provides prospective applicants with estimated dates in the application process. The applicant who receives conditional

approval will receive notice of the effective date of the conditional approval. The applicant will have one year from that effective date to complete all requirements for issuance of a pharmaceutical processor permit.