

Application for Registration as a Registered Organization - Questions and Answers

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Staff/Organization/Appendix A

1. What is the definition of a “Principal Stakeholder?” Can an individual be an “Owner” without being a “Principal Stakeholder?” Can an individual be a “Principal Stakeholder” without being an “Owner?”

A “principal stakeholder” is a natural person that has an ownership interest in an entity, and that entity has a direct or indirect ownership interest in an applicant for registration as a registered organization. An “owner” is an entity or a natural person with an ownership interest in an applicant. An individual may be a principal stakeholder of an applicant, without being an owner of the applicant, if for example one of the owners identified in the application is a corporation, then the owners of such corporation, if natural persons, would be considered principal stakeholders in the applicant, although not direct owners of the applicant.

2. Appendix A, question 18 requests a variety of information regarding “Offices Held or Ownership Interest in Other Businesses.” In the section describing the business, the application requests that the individual select one of three options “open; closed; or proposed.” Is this simply inquiring whether the business entity currently exists, formally existed, or is proposed to exist in the future?

Yes. Question 18 of the application requests the current operating status of any business identified.

3. Subsection 74(B) of Section H (Legal Disclosures) of the registration application states that if any “owner, partner or member of the applicant is not a natural person,” then the application must include a statement setting forth, among other information, “the identification of all those holding an interest or ownership in the entity and the percentage of interest or ownership held in the entity.” Subsection 74(B) of section H further instructs that “[i]f an interest or ownership interest in the entity is not held by a natural person, the information and documentation requested herein must be provided *going back to the level of ownership by a natural person (Principal Stakeholder)*” (emphasis added). Similar language is included in the instructions to Appendix A, entitled “Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors and Members.” The reference in both sets of instructions, as well as in the corresponding section of the Department’s regulations (10 NYCRR §1004.5(b)(6)), to “principal stakeholder” suggests that this disclosure obligation applies to any individual holding direct ownership in the applicant, regardless of the percentage interest of such ownership, but that for upstream or indirect owners – i.e., any individuals whose ownership is in a parent or other upstream owner, not the applicant itself – the obligation to complete Appendix A applies only to those natural persons whose ownership interest exceeds a threshold percentage. Please clarify whether, for such upstream or indirect owners, submission of Appendix A is required even if their interest

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in the applicant, when calculated on a percentage basis, is below a minimum threshold – for example, ten percent.

The Department will accept affidavits from shareholders with a ten (10) percent or greater ownership interest in the company. Those shareholders of publicly traded companies with less than a ten (10) percent interest in the company do not need to submit Appendix A affidavits as part of the application. This applies for both principal stakeholders of a publicly traded company that have an ownership interest in an applicant and owners/shareholders of an applicant that is a publicly traded company. All others are required to complete Appendix A, regardless of whether they have decision making authority or not.

4. In Appendix A and staffing plan: can we include people in the staffing plan that will only be hired if the application is approved? Should we label this information in the staffing plan?

The staffing plan should include all individuals who will be hired if an applicant is granted registration. The staffing plan should be clearly labeled to differentiate between existing staff and that staff which will be hired if granted a registration. Note that any managers, whether already hired or planned to be hired upon registration of the applicant, who may come into contact with or handle marijuana will be required to complete the fingerprinting process described in Appendix A, question number 5.

To provide fingerprint services for out-of-state employees, applicants must follow one of the following two processes:

- a. *Travel to New York State and be fingerprinted at any one of MorphoTrust’s New York locations.*

OR

- b. *Mail completed fingerprint cards and fees for each of the out-of-state employees to the Department through the following process:*
- 1. An applicant requests fingerprint cards and instructions by emailing the Department at nmp@health.ny.gov with the subject line “Out-of-state Fingerprint Service Request.” Be sure to specify the number of fingerprint cards required and a single contact name and mailing address to which the cards and instructions should be sent.*
 - 2. Once the request is received, the Department will send the fingerprint cards and directions to the address provided by the applicant.*
 - 3. The applicant has each required out-of-state employee complete a fingerprint card as specified in the provided instructions.*

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4. *The applicant mails all completed fingerprint cards to the Department with the appropriate fees. The Department address, payment details, and mailing requirements will be specified in the provided instructions.*
 5. *Upon receipt of the completed cards and appropriate payment, the Department will send the cards and payment to MorphoTrust for processing.*
 6. *MorphoTrust will process the cards and payment and release the results to the Department for review.*
5. What level of specifics are required for the staffing plan? For example, should name, title, function, and job description be included?

The required staffing plan must meet the requirements of § 1004.5(b)(18)(i)-(v). The staffing plan should also include, at a minimum, the following information:

- *All staff positions which will be involved in activities related to cultivation, manufacturing and dispensing of medical marijuana, as well as staff with oversight responsibilities of such activities. With respect to staff with oversight responsibilities, the staffing plan should include, but not be limited to, the name, title, function, education, experience, and job description for each staff position.*
 - *Identification of and education and work histories for all key personnel, including officers, directors, managers and supervisors.*
 - *A staffing timeline.*
 - *Training requirements.*
 - *Method of ongoing evaluation of staff performance.*
 - *Total number of anticipated staff to support the activities of the Registered Organization.*
6. Related to Section I, boxes 85 and 91 of Appendix A, will the Department verify employment?

The Department reserves the right to verify the truth and accuracy of all information provided in the application, including verification of employment. Any material omissions, material errors, misrepresentations, or failure to provide any requested information may result in the denial of an application or other action as allowed by law. The Department may, in its discretion, reject an application if it determines that information contained therein is not true and accurate.

7. If appropriate, should an applicant attach gun permits to Appendix A?

It is not necessary to list or attach gun permits to Appendix A. Appendix A only requires disclosure of professional licenses issued by a governmental or other regulatory entity.

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8. Does the DOH intend to complete background checks prior to award or subsequent to award? Please confirm this is not required to be filed contemporaneous with the filing of this application but rather prior to hire of such managers.

The Department requires background checks for managers who may come into contact with or handle medical marijuana prior to awarding a registration. The background checks must be completed prior to the June 5, 2015 deadline for receipt of applications.

9. Does the Affidavit requirement of Appendix A only apply to those board members, officers, etc., with decision making authority? How does a public company apply for a license deal with Appendix A?

Appendix A must be completed by all board members, officers, managers, owners, partners, principal stakeholders, directors, and members of the applicant. For publicly traded companies, the Department will accept affidavits from shareholders with a ten (10) percent or greater ownership interest in the company. Those shareholders of publicly traded companies with less than a ten (10) percent interest in the company do not need to submit Appendix A affidavits as part of the application. This applies for both principal stakeholders of a publicly traded company that have an ownership interest in an applicant and owners/shareholders of an applicant that is a publicly traded company. All others are required to complete Appendix A, regardless of whether they have decision making authority.

10. Section 18 defines “affiliation” to include serving as an “owner.” Additionally, the first question asks whether the affiant has owned or operated a business. Is the Department requesting information regarding the affiant’s equity stakes in publicly traded companies, including with respect to potentially de minimis equity stakes (i.e., is there a minimum ownership threshold)?

For purposes of completing Appendix A, disclosure of an ownership interest in a publicly traded company is only required if the affiant owns ten (10) percent or more of a company. Ownership interests of less than ten (10) percent in a publicly traded company do not need to be disclosed. If an ownership interest is held in an entity that is not publicly traded it must be disclosed regardless of the percentage owned.

11. May a trust have ownership in the Registered Organization? For example, may a trust be a member of a Limited Liability Company that is a Registered Organization? If so, who must complete Appendix A for the trust – would only the owners of the trust need to complete Appendix A, or would the beneficiaries (including minors) be required to complete Appendix A?

Yes. To the extent New York State law allows a trust to have an ownership interest in a corporate entity, a trust may have an ownership interest in an applicant for registration

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as a registered organization. Under such circumstances, Appendix A must be completed by the settlor(s) or owner(s) of the trust, any beneficiaries of the trust and the trustee.

12. Question 84 of the application asks for copies of organizational and operational documents of the applicant. What are examples of documents the department is looking for other than for instance an organization chart? Is there an example of an operational document?

This documentation should identify the organizational structure of the applicant. Examples can be found in 10 NYCRR § 1004.5(b)(5) and include, as applicable: certificates of incorporation, bylaws, articles of organization, partnership agreements, operating agreements and other applicable documents and agreements, including all amendments thereto.

13. The regulations require senior staff to have at least one year good agricultural practices experience. May this person have received and currently be working outside of New York?

Yes. The regulations do not require experience in good agricultural practices to come from within New York State. Individuals may receive this experience, and be currently working, outside of New York.

14. What is the definition of the word “drugs” in question #6 of Appendix A?

For the purpose of completing Appendix A, the word “drug” (as defined by Public Health Law § 3302) shall refer to any substances recognized as drugs in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in man or animals; or substances (other than food) intended to affect the structure or a function of the body of man or animal. It does not include devices or their components, parts or accessories.

15. Can the contact person and/or the business have physicians as members and owners? Could a health system submit an application in the form of a joint venture between a subsidiary of the health system and at least one third party with medical marijuana experience? Do the provisions in the regulations (primarily those found in section 1004.22 Practitioner Prohibitions) prevent the employed physicians from issuing certifications for medical marijuana in the event that the Joint Venture was selected to be a registered organization? With regard to practitioner prohibitions, what does this mean for nursing home operators?

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Section 1004.22(b) of the regulations states that a practitioner who issues written certifications, and such practitioner's co-worker, employee, spouse, parent, child, or sibling shall not have a "direct or indirect financial interest" in a registered organization or any other entity that may benefit from a certified patient's or designated caregiver's acquisition, purchase or use of approved medical marijuana products, including any formal or informal agreement whereby a registered organization provides compensation if the practitioner issues a written certification for a certified patient or steers a certified patient to a specific dispensing facility. For purposes of this section, a "direct or indirect financial interest" includes:

- A direct or indirect ownership interest in the registered organization or in an entity that has an ownership interest in the registered organization;*
- A direct or indirect investment interest in the registered organization or in an entity that has an investment interest in the registered organization;*
- An employment arrangement involving payment or other consideration that takes into account, directly or indirectly, the revenue of the registered organization or the revenue of any entity that is an owner of the registered organization;*
- Any employment arrangement that includes terms or conditions that would incentivize, or require a practitioner to engage in, activities under the Compassionate Care Act, and*
- Any other possible financial conflicts.*

Applicants must also consider § 1004.22(a)(1)-(4) of the regulations which state that a practitioner that is registered with the department shall not: (1) directly or indirectly accept, solicit, or receive any item of value from a registered organization; (2) offer a discount or any other item of value to a certified patient based on the patient's agreement or decision to use a particular practitioner, registered organization, brand or specific form of approved medical marijuana product produced by a registered organization; (3) examine a qualifying patient for purposes of diagnosing a debilitating medical condition at any location owned or operated by a registered organization, or where medical marijuana products or related products necessary for the approved forms of administration of medical marijuana are acquired, distributed, dispensed, manufactured, sold, or produced; or (4) directly or indirectly benefit from a patient obtaining a written certification. Such prohibition shall not prohibit a practitioner from charging an appropriate fee for the patient visit.

Furthermore, applicants should be mindful of § 1004.21(b) of the regulations, which states that: "No person associated with a registered organization shall enter into any agreement with a registered practitioner or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the dispensing facility at which the certified patient or designated caregiver will purchase approved medical marijuana products."

Independent of the Medical Marijuana regulations, practitioners and registered organization applicants must also comply with New York Public Health Law § 238 et seq (NY's version of the "Stark" law). The Compassionate Care Act (PHL § 3364(11))

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provides that a registered organization shall be deemed a “health care provider” for purposes of PHL § 238. Also, the Department interprets registered organizations dispensing of medical marijuana as “dispensing of drugs” under PHL §238(14). As a result, the prohibition of financial arrangements and referrals under PHL § 238-a is applicable.

16. What documentation will be accepted to verify/prove training and experience for quality control personnel?

Any relevant documents relating to education, certifications, training and relevant professional experience that prove competence to perform the duties of quality control should be provided.

17. Question 74 of the Application asks whether the applicant is “a corporate subsidiary or affiliate of “another corporation.” (emphasis added). However, pursuant to PHL 3364(1), the applicant may not itself be a corporation. What is meant by the use of the term “another corporation”?

An applicant may be a for-profit business entity, including a corporation, or a not-for profit corporation. Application Question 74 requires applicants who are subsidiaries of another corporation or who are affiliated with another corporation to disclose the nature of the relationship.

18. Should the information sought by the “List any affiliations...” request in Section 18 of Appendix A be listed in the boxes provided or is a separate list required?

The information requested in Section 18 of Appendix A should be entered directly into the text boxes provided below the question. If additional space is required, page 6 can be reprinted as needed to provide additional text boxes.

19. Question 6 of Appendix A seeks information regarding the affiant’s management or ownership interest in businesses that manufacture or distribute drugs. To the extent information sought pursuant to Question 18 has already been provided pursuant to Question 6, should the affiant re-disclose such information in its response to Question 18?

Yes. When applicable, the affiant must disclose any position of management or ownership during the preceding ten years in the text boxes provided for both Question 6 and Question 18.

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20. One of the information requests below Section 18 asks for information regarding the “Office Held/Nature of Interest.” What types of responses are sought by the question seeking information about the “Nature of Interest”? Is the Department requesting information about the monetary value of interest or the number of shares or percentage of ownership?

For this question, only a general response about the type of ownership interest held (i.e. majority/minority shareholder, sole proprietor, managing partner, etc.) needs to be provided.

21. The final information request below Section 18 seeks the name, address and phone number of any applicable licensing/regulatory agency. Most business entities are regulated and/or licensed in one manner or another by one or more government agencies. For example, a restaurant is subject to regulation by the local department of health, fire department, buildings department and others. A pharmaceutical company is regulated by the FDA and other federal and/or foreign regulatory agencies. Does the Department seek information about all of the agencies that regulate or license the affiant’s other business, or only such agencies that have a specific type of relationship to these businesses?

Applicants need to list contact information only for regulatory authorities with a direct relationship to the business, where the regulatory authority is responsible for licensing, permitting or otherwise overseeing the specific type of business listed.

22. Application Form, Question #84, are applicants required to identify ownership that is contemplated as part of post license arrangements or only ownership as the company is currently organized?

The applicant must identify those holding an interest or ownership in the applicant as currently organized at the time of submission of the application. However, the following requirements of regulation must be taken into consideration as the applicant contemplates post-registration arrangements:

- *Section 1004.10(b)(5) states that registered organizations shall not change the composition of the entity which is the registered organization, including but not limited to, a change in sole proprietor, partner, director, stockholder, member or membership interest of the registered organization without the prior written approval of the department.*
- *Section 1004.7(c)(1) states that any material change as determined by the department in the information, circumstances or factors listed in section 1004.5 is required as a part of the renewal application process.*

23. Section 1004.5(b)(15) refers to an “affiliate.” Can you please direct me to where I can find a definition of affiliate for this context?

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A corporate affiliate is a person who directly or indirectly owns or controls, is owned or controlled by, or is under common ownership or control with, another person. Solely for purposes of this definition, the term "owns," "is owned" and "ownership" mean ownership of an equity interest, or the equivalent thereof, of ten percent or more, and the term "person" means an individual, partnership, committee, association, corporation or any other organization or group of persons.

24. Can a single person apply for the medical marijuana license? If so, what is the process for getting registered as an organization?

Public Health Law § 3364(1) provides that a registered organization shall be a for-profit business entity or a not-for-profit corporation organized for the purpose of acquiring, possessing, manufacturing, selling, delivering, transporting, distributing or dispensing of marijuana for certified medical use. Therefore, only those types of entities may apply.

25. Are local governments eligible as growers and dispensers of marijuana?

Public Health Law § 3360(17) defines a registered organization applicant as “a for-profit entity or not-for-profit corporation.” So long as a local government can meet all of the application requirements, there is nothing that explicitly prohibits a local government from applying for registration as a registered organization.

26. Can an Article 28 facility or a pharmacy be a dispensing facility without also being a manufacturer of medical marijuana products? In general, can an entity apply to be just a dispensing facility without also being a grower/manufacturer?

No. Applicants selected for registration as a registered organization will be responsible for acquiring, possessing, manufacturing, selling, delivering, transporting, distributing and dispensing marijuana for certified medical use.

27. Are dispensing facilities the only organizations allowed to grow medical marijuana or can other organizations such as greenhouses or nurseries also grow medical marijuana?

Section 1004.5 of the regulations states that no person or entity other than a registered organization shall produce, grow or sell medical marijuana. Public Health Law §§ 3364(8) and (9) require registered organizations to manufacture and dispense medical marijuana in an indoor, enclosed, secure facility located in New York State, which may include a greenhouse. Greenhouses or nurseries are not authorized to grow medical marijuana in the Medical Marijuana Program unless granted a registration by the Department as a registered organization.

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Architectural/Appendix B

1. Regarding sections 75 and 76 of the application, what is the difference between “lease” and “rental?” What does the Department mean that the lease or rental is complete? What does the Department mean by “construction”?

These questions request the applicant to specify whether: 1) the facilities are constructed, meaning built and ready for use; 2) the facilities have signed lease agreements, i.e., a contract or agreement for a period of time to utilize a facility; 3) if the facilities have signed rental agreements, i.e., month-to-month rent is paid for a specified or unspecified period of time; or 4) if the facilities have been purchased. For Question 75, if any of these have been fulfilled for the proposed manufacturing facility, then the applicant should select the “YES” box. For Question 76, the “YES” box should only be checked off all of the proposed dispensing facilities have been either constructed, leased, rented, or purchased.

2. Question 75 of the application asks the applicant to state whether the “construction, lease, rental, or purchase of the manufacturing facility [has] been completed.” If an applicant has leased a facility for manufacturing but will need to retro-fit the space, will the applicant be considered to have completed the construction, lease, rental, or purchase of the manufacturing facility?

Applicants should select “YES” if they have completed any of the following steps: construction of the facility, lease of the facility, rental of the facility or purchase of the facility. Where a facility has been leased or purchased but additional construction is required, applicants should still select “YES” for purposes of this question.

3. Questions 75 and 76 of the application asks if “construction... has been completed.” Does construction refer to construction of the building or the interior build out of the facility?

These two questions request applicants to inform the Department whether a proposed facility has been constructed, meaning the physical structure has been built and is ready for use. If a facility needs only to be retro-fitted or for work to be completed to the interior of the facility, then it has been “constructed” for purposes of these two questions.

4. Does the applicant have to disclose a complete budget for the manufacturing facility or Capital Expenditure to get the facility up and running for Appendix B?

Appendix B does not require the submission of a construction budget. However, section 1004.5(b)(17) requires a statement indicating the anticipated source and application of the funds to be used in such purchase, lease, rental or construction if the construction, rental, or purchase of the manufacturing and/or dispensing facilities have not been

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completed. This requirement is included in Section H, number 75 and 76 on the Application for Registration as a Registered Organization

5. Questions 75 and 76 are complex and appear to have been asked, in part, in other sections of the application. Since questions 30, 38, 46, 54, 62 request information about the ownership, leasing or optioning of property, are questions 75-76 meant to obtain information about the status of construction? What specific information will be required regarding the “anticipated source and application of the funds”?

Questions 75 and 76 on the application form are intended to determine the acquisition status of the applicant’s proposed facilities and, where applicable, the anticipated source and application of funding that will ensure the acquisition of these facilities. Although other questions relate to ownership, this information is required in regulation per 10 NYCRR § 1004.10(b)(17) and therefore must be provided. Anticipated source and application of funding may include costs and funding source associated with the purchase of an existing building and the cost of renovations, construction cost of new facility, or costs associated with the leasing or rental of the facility.

6. What are the zoning restrictions for the Dispensing Location?

Zoning restrictions are determined by local law, which provide the parameters and districts outlining land use.

7. Does the dispensing facility have to be a Commercial property? Can it be Residential/Commercial mixed use?

Applicants must determine the occupancy use and classification as per applicable NYS Building Codes and determine applicable land use as per local zoning ordinances. Dispensing facilities may be residential/commercial mixed use if the architectural and engineering designs of the proposed facilities are approved by the local municipality and by the Department.

8. Does the dispensing facility have to be ground floor/Retail? Does it have to be storefront or can it be on another floor such as an office?

Facilities must meet the ICC/ANSI A117.1-2003 Standards, which require all sites, facilities, buildings and the building elements that are accessible to and usable by people with physical disabilities, to meet all applicable accessibility requirements. As part of the criteria for consideration of applications, the Department will evaluate the suitability of proposed dispensing facilities, including but not limited to the suitability of the location and architectural and engineering design of the proposed facilities.

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9. Is there a minimum square foot restriction for each dispensing location?

No. There is no minimum square foot restriction for dispensing facilities. However, applicants should ensure that they have enough space to meet the needs of certified patients and each location must comply with all state and local laws and regulations.

10. Is there a map of zones which will define location diversity for the dispensing facilities or is that up to the applicants to determine?

There are no maps or defined zones to determine the location of dispensing facilities. It is up to applicants to determine the location of each dispensing facility to best suit the applicant's operating plan and to serve certified patients across New York State. Applicants should be mindful that geographic distribution will not be demonstrated if an applicant's proposed dispensing facilities are all concentrated in counties of New York State that are neighboring or in close proximity.

11. If the applicant has posted the \$2,000,000 bond, how do they complete Appendix B, the Architectural Program and complete item #10, seeking construction classification, from Appendix B? Is it reasonable to require that the applicant be in possession of real estate for all 4 locations, manufacturing and growing facilities if they are not sure that they will be chosen? How will having a bond as an alternative to finding locations be scored in comparison to having the locations? How can the operating plans and Standard Operating Procedures be written if the applicant has not secured real estate yet? How can an applicant have a security plan for a building that is not yet owned or leased? Is it sufficient for the applicant just to complete the information for the facilities that are already confirmed?

All applicants, even those who post a bond, must complete Appendix B – Architectural Program, for every proposed manufacturing and dispensing facility. Applicants are not required to be in possession of all real property at the time they submit their application. Applicants must identify, however, the proposed locations/facilities that they intend to use for the activities covered under the registration, if granted, and may submit proposed deeds, leases, and rental agreements or executed option contracts related to the applicant's real property interests. An applicant that posts a bond in lieu of providing executed and proposed deeds, leases, and rental agreements or executed option contracts will not be penalized for doing so, provided all information required by the application is submitted for each of the proposed facilities, but may not score as highly as one that does.

12. If the applicant posts a bond of \$2,000,000, can the requirement for a property-specific security plan, internet access proof and Appendix B – Architectural Program be submitted post-award?

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No. These items must be submitted upon application. A statement from an internet provider that the proposed sites are in serviceable areas for internet will be sufficient proof that a location has internet access. Applicants who post a bond must also identify a security plan and complete Appendix B based upon proposed locations that will be acquired.

13. What level of detail must be provided directly in Appendix B versus what can be shown on drawings? Are applicants permitted to answer a Facility Actual Value field with “Refer to drawings” provided the requested information is contained within drawings included in the application?

The fields regarding the Code Compliance Review information in Appendix B, shall be completed per each number and topic. Applicants must complete the fields with all applicable information as requested. However, information in some fields must also be demonstrated in the architectural and engineering plans to ensure clarity and demonstrate that the required code value is obtained (i.e, Appendix B, Part II- Site Plans requires applicants to identify the location and dimension of certain items on the site plan attached by the applicant). Should any text information not fit into the field, applicants should attach additional sub-sheets, clearly identified and coordinated to each applicable field.

14. Appendix B No. 4 - Hazardous Materials Control Areas - Are applicants to list classification and quantity of each particular material or quantity of each classification of material to be stored within a control area or can we simply state that all hazardous materials will be stored within the allowable exempt quantities for a control area?

No. 4 specifically requires applicants to: “Provide additional information indicating number, size, materials stored, and quantity of each material.” A boilerplate statement of intent to follow applicable laws and regulations governing hazardous materials is not an acceptable response.

15. Appendix B No. 5 - Building Area & Height - All calculations and applicable code sections for increased Building Area & Height are requested. There are allowable increases for automatic sprinklers and street frontage. Is the intent to show all the calculations in the Appendix or can we indicate the final total as an allowed code value with the actual value shown in the last column? If all calculations are to be shown, should that be a separate attachment?

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Yes. All calculations must be shown, including allowable increases of building height and building area. Should any text information not fit into the field, applicants should attach additional sub-sheets, clearly identified and coordinated to each applicable field.

16. For Appendix B No. 22 – Fire Alarm & Detection Systems, it appears that only code sections are being requested rather than information about the proposed design. In this case, the Required Code Value would list the applicable code sections while the Facility Actual Value would list the applicable code sections to which the facility will comply. Please confirm this is what is being requested.

Both the code information of all applicable requirements and the actual systems that will be installed at the facility should be included within each Appendix B submitted per facility.

17. For Appendix B No. 26 - Occupant Load, can applicants just indicate "Refer to Plan" for the required code value/allowed code value and facility's actual value?

The applicant shall, as per NYS BC 1004.1, Table 1004.1.1, clearly identify in Appendix B the function of space, the floor area in square feet per occupant, the design load with any allowed increases. All information may be cross referenced to schematic floor plans.

18. In Appendix B, part 1 “Architectural program and construction timeline,” what do the checked boxes indicate? Would the applicant check the boxes if they have these requirements or if they haven’t yet met these requirements?

Applicants must identify all of the planning requirements necessary for the facility by checking each box that applies to the specific facility, regardless of whether or not the applicant has met the requirements within the box.

19. Should the applicant complete Appendix B for each physical location? For example, if the applicant has 1 manufacturing site and two dispensing sites, would the applicant complete and submit 3 Appendix B forms?

Yes. As stated on the Appendix B form, “A separate ‘Appendix B’ shall be completed for each separate building and/or facility included in the organization’s business plan.”

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20. Do applicants need site maps/ architectural drawings for every single location (manufacturing and dispensing facilities) in Appendix B? Do applicants need Community Board approvals for every location at the time of the application?

A separate "Appendix B" shall be completed for each separate building and/or facility included in the organization's business plan. Schematic architectural and engineering design drawings must be included with each Appendix B. Community approvals are not a requirement of application, but must be included on the construction timeline and should be included by the applicant if they have obtained approvals.

21. Do we need to have all of the approvals listed in Appendix B Part 1 completed and in hand by the time we submit the application?

Appendix B Part I only requires Applicants to identify planning requirements. To the extent approvals have already been completed, they should be reflected in the planning requirements submitted.

22. According to Appendix B, applicants are required to outline the architectural details of each facility. As it is expected that patient adoption will increase over time, is the State requesting the applicants' detail only Phase 1 facilities to meet Year 1 demands, or must details be provided for Year 1 through full build out?

It is unclear by the question received what "Phase 1" pertains to. If applicants have an architectural plan that provides for an initial phase and further build-out of that facility to accommodate additional patient demand, applicants should include such information in the application. However, if an applicant is selected, only the initial phase for the facility will be approved.

23. In Appendix B, can the applicant do the following: attach relevant notes to the code review that are pertinent to pages 4 -13, attach drawings to Appendix B – e.g., 11x17 trifold drawings that would fit into an 8 ½ x 11 format, and submit full size building plans (e.g., 22 x 34)?

Applicants must complete all applicable fields in Appendix B. However, should any text information not fit into the field, applicants should attach additional sub-sheets, clearly identified and coordinated to each applicable field.

Schematic architectural and engineering design drawings, and other design requirements, must be included with the application in order for Appendix B – Architectural Program to be determined by the Department to be complete.

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Drawings submitted should be a minimum of 8½"x11" and a maximum of 24"x 36" size sheets. All drawings should be sized appropriately to scale, such that all information may be clearly identified and verified.

24. With regard to Question 82 of the application, does an executed lease demonstrate "right to use?"

An executed lease agreement that clearly sets forth as a purpose the manufacturing and/or dispensing of medical marijuana and contains the language set forth in 10 NYCRR §1004.5 (b)(9) is sufficient to demonstrate the applicant's right to use the property. Applicants must also ensure they are able to comply with all state and local laws and regulations, including any zoning restrictions, that may be applicable to the property/facility.

25. As part of the Architectural Program (Appendix B), may an applicant include plans and drawings from facilities approved for medical marijuana manufacturing by states other than New York, if those plans and facilities will demonstrate how the proposed facility will appear in New York?

No. The building and architectural program of each facility must be specific to New York in order to comply with all applicable state and local laws and regulations.

26. Will property measurements regarding the 1,000 foot rule (§ 1004.10(b)) be done as the crow flies? Are daycare centers considered "schools" within the meaning of the rule?

Yes. Pursuant to 10 NYCRR § 1004.10(b)(7), the measurements are to be taken in straight lines from the center of the nearest entrance of the premises sought to be used as a dispensing facility to the center of the nearest entrance of such school, church, synagogue or other place of worship. A daycare center is considered a school within the meaning of the rule.

27. Are there any state zoning limitations or expectations for the dispensing sites? Such as retail, commercial, or mixed use?

Zoning requirements are determined by local law, which provide the parameters and districts outlining land use per occupancy classifications. Applicants must determine the occupancy use and classification as per applicable NYS Building Codes and determine applicable land use as per the local zoning requirements.

28. Are there any zoning limitations for the processing facility? Such as agricultural, industrial, or commercial?

Application for Registration as a Registered Organization - Questions and Answers

Zoning requirements are determined by local law, which provide the parameters and districts outlining land use per occupancy classifications. The applicant must determine the occupancy use and classification as per applicable NYS Building Codes and determine applicable land use as per the Local Zoning requirements.

29. With regard to § 1004.16(a)(1), the regulations provide that signage of a dispensary shall only be in black and white. If a registered organization operates a dispensary located in a municipality with zoning ordinances that require the use of different colors, is the registered organization mandated to comply with the state's regulatory requirement?

Yes. Applicants must comply with the NYS Department of Health Regulations, including 10 NYCRR § 1004.16(a)(1).

30. What kind of identification is the applicant required to supply in answering Question 80 (Attachment A)? Does the Department want a list of addresses?

Identification includes, but is not limited to, building or property names, addresses, descriptions, photographs, and maps.

31. Regarding Appendix B, for architectural graphics, what is the required format for sheet size, black and white or color copies, and title blocks?

Drawings submitted should be a minimum of 8½"x11" and a maximum of 24"x 36" size sheets. All drawings should be sized appropriately to scale, such that all information may be clearly identified and verified. Black and white or color copies are acceptable for submission. All submitted graphics must be clearly labeled to show the facility to which it pertains.

32. Regarding Appendix B, are applicants required to submit signed and sealed documents for each facility or will a code compliance statement prepared and signed by a certified professional be sufficient?

A code compliance statement alone is not sufficient. The application does not require signed and sealed documents for each facility but rather, as per 10 NYCRR § 1004.5(b)(11)(ii) requires the submission of schematic architectural and engineering design drawings and single-line sketches to appropriate scale to show code compliance.

33. Regarding Appendix B, can applicants submit a code summary attachment referencing the building and site plans (instead of in the plans)?

Application for Registration as a Registered Organization - Questions and Answers

Applicants may not submit a code summary attachment in lieu of completing Appendix B. A separate "Appendix B" shall be completed for each separate building and/or facility included in the organization's business plan, with all fields completed. In addition to Appendix B, applicants must submit schematic architectural and engineering plans as required by 10 NYCRR § 1004.5(b)(11). The applicant may attach additional documentation that is clearly labeled to supplement Appendix B.

34. Under which attachment can a Registered Organization applicant include future plans for additional dispensing facility locations?

Applicants must complete Appendix B – Architectural Program for each proposed dispensing facility. Appendix B requires the applicant to identify planning requirements for each facility, including any future plans, along with a construction timeline. Applicants who wish to become a registered organization may have up to four dispensaries, geographically dispersed. To the extent the potential applicant's question was with regard to future plans for additional dispensing facilities beyond the four proposed facilities identified in the application, such information is irrelevant to the current application and should not be submitted to the Department.

35. Can the Department please confirm whether Appendix B requires a floor plan illustrating the scope and organization of program at each site, supported by code analysis sufficient to address the points of the Appendix B?

A separate Appendix B must be completed for each separate building and facility included in the applicant's business plan. A floor plan illustrating the scope and organization of program at each site supported by code analysis sufficient to address the points of Appendix B must be submitted.

Application for Registration as a Registered Organization - Questions and Answers

Facility Locations

1. Can the applicant propose or list more than one potential manufacturing facility with the understanding that only one manufacturing facility will be permitted?

The Department will not accept alternate proposals for manufacturing sites as they may affect other aspects of an applicant's operating plan.

2. Is a Registered Organization permitted to have more than one manufacturing facility and is there a limit in the number of manufacturing facilities? If more than one manufacturing facility for a registered organization is permitted, does the Department have guidance on how the facilities' respective uses can be split? May one registered organization cultivate (or perform another single manufacturing activity) at more than one location?

An applicant may have more than one proposed manufacturing facility. The directions in Section C of the application form state that the additional fields 32 through 39 are provided for "applicants who are proposing to use more than one manufacturing facility (responsible for cultivation, harvesting, extraction or other processing, packaging and labeling)." Applicants must provide complete information on all proposed manufacturing facilities as described in Section C of the Application for Registration as a Registered Organization. All manufacturing, including cultivation, harvesting, extraction or other processing, packaging and labeling must take place at the manufacturing facility. Applicants will not be registered for the sole purpose of manufacturing, as a registered organization will also be required to transport, distribute and dispense marijuana for certified medical use. Specialization of functions between or among manufacturing facilities of the same Registered Organization is not permitted.

3. Will the Department allow for more than four (4) dispensing facilities to be proposed (with the understanding that only four dispensing facilities will be permitted) in the event that the final site is precluded by local opposition, the Department determines that the locations need to be more dispersed around the State, or to allow the State to decide which facilities they prefer? Will the locations of the dispensing facilities be final or is the state contemplating site locations can be changed?

The Department will not accept alternate proposals for dispensing facility sites. Applicants have a continuing duty to report to the Department any changes in facts or circumstances reflected in the application or any newly-discovered or occurring facts or circumstances which are required to be included in the application. If a dispensing facility site becomes unavailable, it is a change in circumstance that must be reported. If a location becomes unavailable after registration has been granted, Public Health Law § 3365(3)(e) provides that a registered organization may amend its registration to allow it to relocate within the state. The Department will consider whether to grant or deny such amendments at such time.

Application for Registration as a Registered Organization - Questions and Answers

4. If the applicant identifies particular sites but does not yet have final land use/zoning approval for said sites, will that be looked at less favorably by the DOH?

One of the criteria for consideration the Department must consider is whether an applicant is ready, willing, and able to properly conduct the activities set forth in 10 NYCRR Part 1004. Therefore, while final land use and zoning approvals are not required for application, those applicants who have secured final land use and zoning approval for their sites will score more favorably.

5. 10 NYCRR § 1004.10(b)(1) provides that the manufacturing facility cannot be the same “location” as a dispensing facility. Is there a minimum required distance between the proposed manufacturing facility and a dispensing facility? Would this prohibit a dispensing facility from being located at the same mailing address as a manufacturing facility, if physical separation segregated the dispensary from the growing and manufacturing space?

There is no minimum required distance between the manufacturing facility and dispensing facility. Zoning requirements are determined by local law, which provide the parameters and districts outlining land use per occupancy classifications. Applicants must determine the occupancy use and classification as per applicable NYS Building Codes and determine applicable land use in accordance with local zoning requirements. If no zoning laws govern, applicants should sufficiently separate manufacturing and dispensing facilities to ensure the security of their manufacturing facilities.

6. Does the 1,000 foot distance rule apply in all directions, *i.e.*, is it a radius around the location, or can it include vertical distance (e.g., if a dispensing facility is located 1,000 feet above ground and there is no school or other defined location between the dispensing facility and the ground, would that meet the definition)?

Pursuant to 10 NYCRR § 1004.10(b)(7), the measurements in this paragraph of this subdivision are to be taken in straight lines from the center of the nearest entrance of the premises sought to be used as a dispensing facility to the center of the nearest entrance of such school, church, synagogue or other place of worship. To the extent a dispensing facility is located above or below a school, church, synagogue, or other place of worship, it would not meet the requirements of this section of regulation because vertical distance is not included.

7. Will the Department consider waiving or seeking a waiver of the school distance rule in New York City and other densely occupied urban areas, due to the difficulty in satisfying the requirement in such areas?

Application for Registration as a Registered Organization - Questions and Answers

No. A dispensing facility may not be located on the same street or avenue and within one thousand feet of a building occupied exclusively as a school, church, synagogue or other place of worship. Accordingly, the restriction only applies if both conditions are met. This will allow dispensing facilities to be located in both urban and rural areas.

8. The application does not appear to require a dispensing facility structure that is completely stand-alone. Would underutilized space within an existing pharmacy that is completely walled-off with separate ingress and egress be permissible as long as all required security measures could be achieved?

May the proposed manufacturing facility co-locate with another activity? For instance, may the applicant use a greenhouse where another attached greenhouse is used to cultivate produce, or conduct extraction activities in a secured portion of a building where other unrelated lab activities are occurring, provided all security and sanitation requirements are met?

With regard to 10 NYCRR §1004.5(b), may a dispensing facility be located in a subleased space? Specifically, may a dispensing facility share building space with other entities, recognizing that they will have to comply with the other requirements in the regulations (i.e. security)?

10 NYCRR § 1004.10(b)(1) states that no registered organization shall “dispense approved medical marihuana products from the same location where the marihuana is grown or manufactured.” Neither the regulations nor the statute prohibit an applicant’s proposed facilities from using underutilized space or from being co-located with other facilities, so as long as all requirements of 10 NYCRR Part 1004 are met without compromising any of the security requirements.

9. The DOH allows for an application to be amended to allow the registered organization to relocate within the state or to add or delete permitted registered organization activities or facilities. Does the relocation apply to the manufacturing and dispensing facility locations?

Yes. Public Health Law § 3365(3)(e) and 10 NYCRR § 1004.6(e) allow a registered organization to apply to the Department to amend its registration to allow the registered organization to relocate within the state or to add or delete permitted activities or facilities. These sections apply to both manufacturing and dispensing facilities of registered organizations. However, these sections do not apply to applicants for registration. 10 NYCRR 1004.5(c) allows an application for registration to be amended while the application is pending before the Commissioner, if approved by the Commissioner upon good cause shown.

Application for Registration as a Registered Organization - Questions and Answers

10. Given the security issues and operational oversight requirements associated with manufacturing, healthcare delivery and transportation issues, would the DOH give consideration to granting the initial five licenses on a geographic basis, if, and only if, adequate coverage is ensured throughout the state when all licensors activities are considered as a whole? Please clarify the rationale for the geographic distribution requirement and the optimal pattern of geographic distribution. For example, is it sufficient to have one of four dispensaries not “neighboring or in close proximity?”

In considering an application for registration, the Commissioner will take into consideration whether the number of registered organizations in an area will be adequate or excessive to reasonably serve an area, including whether there is sufficient geographic distribution across the state. The Department seeks to ensure practitioner and patient options with respect to medical marijuana products, and ensure access to medical marijuana to certified patients across the state. Therefore, to be geographically distributed, the proposed dispensing facilities of an applicant must be located in multiple counties across New York State to best serve certified patients in the Medical Marijuana Program state-wide. Applicants will be scored based on their ability to demonstrate geographic distribution statewide. Geographic distribution will not be demonstrated by applicants whose proposed dispensing facilities are all concentrated in counties of New York State that are neighboring or in close proximity.

11. The application states that dispensing facilities must be geographically distributed across multiple counties and the geographic distribution will not be demonstrated if facilities are concentrated in neighboring counties or in close proximity. Will that be based on distance or a combination of distance and population density? Or will the DOH determine proximity based on the regions in which the facilities would be located?

Applicants will be scored based on the number of dispensing facilities proposed in non-neighboring counties.

12. If the DOH determines that sufficient geographic diversity has not been achieved in the submissions of the highest ranking applicants, will the DOH seek to work with said applicants to achieve geographic diversity by providing guidance as to desired locations and permitting alternate proposed locations to address same? Can an applicant request direction from DOH regarding the location of dispensaries by submitting an application identifying only the cultivation/production site, posting a \$2 Million bond, and requesting that DOH designate counties/cities requiring dispensary locations?

The Department will not designate counties or cities requiring a dispensing facility. Geographic distribution is but one factor of the application that is scored. Applicants will be scored based on the number of dispensing facilities proposed in non-neighboring counties. Applicants who do not propose dispensing facility locations, or who propose all of their dispensing facilities to be co-located within the same county, will not have demonstrated geographic distribution and will be notified in writing pursuant to §

Application for Registration as a Registered Organization - Questions and Answers

1004.6(d) that the Commissioner is not satisfied that the applicant should be issued a registration.

13. Does the geographic distribution mentioned also refer to placement of the manufacturing facility? Is this placement to be judged only by distance, or are the criteria linked to population areas? If only by distance in between dispensing facilities, has the State considered the security challenges raised by extended transport of product?

The geographic distribution mentioned in Criterion 8 refers only to dispensing facilities, not to a manufacturing facility. Applicants that plan to only serve a particular region will limit practitioner and patient options and could create shortages if a regionalized registered organization were to encounter problems with supply (i.e. due to crop infestation or increased demand). Therefore, to be geographically distributed, the proposed dispensing facilities of an applicant must be located in multiple counties across New York State to best serve certified patients in the Medical Marijuana Program state-wide. Geographic distribution will not be demonstrated by the applicant if the proposed dispensing facilities of the applicant are all concentrated in counties of New York State that are neighboring or in close proximity.

14. How will the Department decide on where dispensaries will be located? How will the Department resolve overlaps in locations from qualifying Registered Organization applicants? Could the Department provide additional clarification on the definition of “close proximity”? For example, are there specific requirements for distance between facilities, time and mileage, etc.?

As part of the Registered Organization application, applicants are asked to submit proposed dispensing facility sites. The instructions provide that, to be geographically distributed, the proposed dispensing facilities of an applicant must be located in multiple counties across New York State to best serve certified patients in the Medical Marijuana Program state-wide. Geographic distribution will not be demonstrated by the applicant if the proposed dispensing facilities of the applicant are all concentrated in counties of New York State that are neighboring or in close proximity. To ensure geographic distribution, applicants that demonstrate four dispensing facilities geographically distributed across the state will score more favorably during the Department’s review of applications. The Department will also take into consideration whether the number of registered organizations in an area will be adequate or excessive to reasonably serve such area, including whether there is sufficient geographic distribution across the state. Close proximity is simply a relative term. There are no specific requirements for the distances or travel times between facilities. The greater the number of counties between each proposed facility, the better an applicant demonstrates geographic distribution and the more favorably it will score for that particular criterion. Applicants that demonstrate four dispensing facilities geographically distributed across the state will score more favorably during the Department’s review of applications.

Application for Registration as a Registered Organization - Questions and Answers

15. Section 1004.10(b)(7) states that a dispensing facility may not be located on the same street or avenue and within one thousand feet of a building occupied exclusively as a school, church, synagogue or other place of worship. Could the Department please specify what qualifies as a school or provide a definition of a school?

The term "school" includes any public, private or parochial child caring center, day nursery, day care agency, nursery school, kindergarten, elementary, intermediate or secondary school.

16. Will the public have an opportunity to object to a facility and its proposed location?

Applicants will need to comply with all applicable State and local laws and regulations, including zoning and planning requirements, which may include any public hearings, to build or renovate a facility for a manufacturing or dispensing facility of a Registered Organization. The Department will not conduct a separate process for the public to object to the proposed locations of manufacturing and dispensing facilities.

17. What are the real estate guidelines? What city/counties are allowing these? What is needed for each grow site and dispensing facility site?

Applicants will need to identify locations for the proposed manufacturing and dispensing activities, and ensure that it is able to comply with all applicable local laws. Applicants will need to determine any zoning restrictions for the cities and counties in which they propose manufacturing and dispensing facilities. No real estate guidelines have been issued; however, the regulations prohibit a dispensing facility from being located on the same street or avenue and within one thousand feet of a building occupied exclusively as a school, church, synagogue or other place of worship. [10 NYCRR § 1004.10(b)(7)].

Application for Registration as a Registered Organization - Questions and Answers

Bond

1. If the applicant is able to identify the information required in Questions 80 and 82 of the application for the manufacturing site and at least one dispensing facility, is a \$2 million bond still required if the information is not yet available for the remaining proposed dispensing facilities?

Section 1004.5(b)(9) of the regulations requires a registered organization applicant to show the possession or right to use of land, buildings, and equipment to carry on the registered organization's activities, or in the alternative to post a bond of not less than \$2,000,000. Applicants must identify all the proposed locations/facilities, including dispensing facilities that they intend to utilize for the activities covered under the registration. If an applicant does not have possession or right to use land, buildings and equipment to carry on all anticipated registered organization activities for each of the proposed dispensing facilities at the time of application, an applicant must post a bond of not less than \$2,000,000.

2. Will the State consider a \$2 million irrevocable line of credit as meeting the bond requirement?

May an applicant who does not at the time of the submission of the application have executed deeds, leases, rental agreements, or executed options contracts showing that the applicant has the right to use sufficient land, buildings, premises, and equipment satisfy the bond requirement by posting a letter of credit in the amount of \$2,000,000? If so, does Department of Health have any requirements that the letter of credit must satisfy?

Regarding Section I, required attachments number 82, as an alternative proof of ability to execute on required real estate transactions, can this application requirement be in the form of a cash deposit in an escrow account? If so, is there a requirement as to who the escrow agent must be?

Public Health Law § 3365 (1)(a)(ii)(B) requires an applicant to show possession or right to use sufficient land, buildings and other premises specified in the application to properly carry out the activities proposed, or in the alternative, to post a bond of not less than two million dollars. A cash deposit in an escrow account, or a letter of credit will not be accepted to meet this statutory requirement.

3. Does one \$2,000,000 bond cover both the manufacturing facility and the four dispensing facilities or is it per facility at \$2,000,000 each?

One bond covers the manufacturing facility and the dispensing facilities.

Application for Registration as a Registered Organization - Questions and Answers

4. If an applicant chooses to post a \$2 million bond as an alternative to describing specific locations for manufacturing and dispensing facilities in the application, what details is the Department still expecting related to proposed locations, real property, site control, etc. in the application? We assume more detail is preferable, but at what point would changes in proposed/planned details trigger the need to resubmit or amend the application due to a material change when site control is actually secured?

Details of each facility's proposed location must be provided. They include identifying the address, city, and county of each location. Regardless of whether an applicant submits proof of a \$2,000,000 bond, pursuant Section 1004.5(b)(2) of the regulations, all applicants must provide "identification of all real property, buildings and facilities that will be used in manufacturing, as defined in Section 1004.11 of this part, and dispensing of the medical marijuana products." The regulations state that if an applicant posts a bond in lieu of providing documentation of sufficient land, buildings and equipment, and the applicant is selected to be granted a registration, the applicant will be required to submit applicable executed deeds, leases and rental agreements prior to issuance of the registration to the applicant. If the proposed or planned details concerning one or all of the applicant's facilities changes, the applicant must notify the Department as this would be a change in fact or circumstance pertaining to information which is required to be included in the application. Section 1004.5(c) of the regulations states that an application under this section may be amended while the matter is pending before the commissioner, if approved by the commissioner upon good cause shown.

5. Will the Department accept any of the following as an acceptable showing that the applicant has the right to possess and use the premises as set forth in § 1004.5(b)(9), or would the applicant be required to post a bond of not less than \$2 million:
- A lease or a purchase and sale agreement with contingencies (e.g. for financing or award of a medical marijuana license);
 - A fully executed Letter of Intent to lease real property between applicant and a third-party, contingent only upon applicant's award of a Medical Marijuana License;
 - A fully executed real property lease between applicant and a third-party, the terms of which become effective upon applicant's award of a Medical Marijuana License;
 - A fully executed real property lease, the terms of which include applicant-lessee's right to terminate the lease if it is not awarded a Medical Marijuana License, as an acceptable showing that the applicant has the right to possess and use the premises as set forth in § 1004.5(b)(9);
 - A fully executed purchase and sale agreement on real property, contingent only upon applicant's award of a Medical Marijuana License; or
 - The applicant has entered into a long-term lease with a contract vendee of real estate, subject to the applicant's right to terminate if a license is not awarded, and the purchase and sale contract is contingent only upon the contract vendee's entering into such long-term lease.

Application for Registration as a Registered Organization - Questions and Answers

Pursuant to § 1004.5(b)(9), an applicant who does not post a bond of \$2,000,000, must submit copies of all applicable executed and proposed deeds, leases, and rental agreements or executed option contracts related to the organization's real property interests, that shows that the applicant possesses or has the right to use sufficient land, buildings, and other premises as specified in the application and equipment to properly carry on the activities for which registration is sought. The applicant may submit executed deeds, leases, and rental agreements or executed option contracts that are contingent only on the applicant obtaining registration as a registered organization or allow the applicant to terminate the deed, lease, rental agreement or option contract if the applicant is not granted registration.

6. Can the Department clarify when a bond that is posted by an applicant will be released? If, before any registered organization status is awarded, an applicant that has posted a bond presents the necessary documentation regarding possession or control of land to the Department, will the bond be released at that time? Must the bond continue until the end of the application evaluation process, and then be released once all of the registered organizations have been approved (assuming that the applicant can show possession or control of land at that time) or disapproved? Will the bond be released if an applicant withdraws from the application process before any registered organization status has been awarded? Is it possible that the Department may approve an applicant subject to satisfying the condition relating to obtaining the necessary real estate (at which time the bond would then be released)?

If an applicant obtains a bond in lieu of demonstrating that it possesses or has the right to possess sufficient land, buildings and other premises necessary to carry on the intended activities, the bond must continue until the applicant's submission of the applicable executed deeds, leases, and rental agreements are received and reviewed by the Department. For applicants who are not selected for registration as a registered organization, or who withdraw from the application process before registrations are awarded, the bond will be released in full. 10 NYCRR 1004.5(b)(9) provides that if an applicant who posts a bond in lieu of providing the requested documentation is selected for registration, the applicant's submission of the applicable executed deeds, leases and rental agreements shall be required before the registration may be issued.

7. Will Registered Organization applicants be expected to have lease options on dispensary locations or can the bond money simply be provided?

Section 1004.5(b)(9) requires applicants to provide all applicable executed and proposed deeds, leases, and rental agreements or executed option contracts related to the organization's real property interests, that show that the applicant possesses or has the right to use sufficient land, buildings and other premises as specified in the application, to properly carry on the activities for which the registration is sought, or in the alternative, the applicant may post a bond of at least \$2,000,000. If an applicant who posts a bond is selected as a Registered Organization, the applicant must submit proof of

Application for Registration as a Registered Organization - Questions and Answers

executed deeds, leases and rental agreements, as applicable, prior to the issuance of a registration. These requirements must be met for both manufacturing and dispensing facilities.

8. The application to become a Registered Organization requires the applicant to provide executed and proposed deeds, leases and rental agreements, or, in the absence of these documents, proof of a bond of not less than \$2 million. Can the Department provide the name of the required bond or the form number? Can the Department please provide the following information on the bond requirements: name of the required bond or form number, Type of Bond, Obligee Name, Obligee Address, Bond Requirement and Specifications of Bond? Is a special bonding form required? If so, please provide instructions on how to obtain the form.

No particular form is required by the Department. Applicants who wish to post a bond in lieu of providing documentation of sufficient land, buildings and equipment should contact an entity that issues bonds for more information on the requirements to obtain a bond. The Obligee, in this case should be the New York State Department of Health as the provider of the registration. The Obligee Address should be listed as follows:

*Carol Sherman
Director, Bureau of Accounts Management
Corning Tower Room 2701
Albany, NY 12237-0016*

9. What constitutes proof that the bond has been posted?

Either the bond itself, or a copy of the bond are acceptable proof of its posting.

Application for Registration as a Registered Organization - Questions and Answers

Equipment

1. What level of description is required for the equipment to be used at each of the phases identified (manufacturing, processing, transportation, distributing, sale and dispensing activities)? For example, should applicants provide the name of the manufacturer, supplier, color, style, and specifications? Should the equipment be broadly described by each process step? For example, is it sufficient to generally describe the method of transportation or must a specific vehicle and VIN be identified?

At a minimum, applicants should include the name of the equipment, a description of the equipment, the purpose of the equipment, and any special considerations regarding the equipment (for example, its specific implications on the ventilation of a facility). Applicants should use their judgement to determine the sufficient level of detail for the equipment identified to demonstrate compliance with 10 NYCRR Part 1004. For example, the specifications of a vehicle used to transport medical marijuana products would help to determine compliance with the requirements of 10 NYCRR § 1004.13.

2. What is considered equipment and at what cost? How is cost defined (e.g., capital, operating or cost/dose)?

Pursuant to section 1004.5(b)(3) of the regulations, applicants should identify all equipment that will be used to carry out the manufacturing, processing, transportation, distribution, sale and dispensing activities described in the application and operating plan. Applicants should list any equipment that will be used directly in the activities described above. Applicants should provide as much detail as possible. The cost of the equipment does not have to be identified in the application.

3. Related to Section I of the application, number 81, Attachment B -What is the level of detail required beyond the major pieces of equipment (e.g., supercritical extractor) -- should equipment such as cloning scissors, plant stakes, containers and scales be listed as well?

Pursuant to section 1004.5(b)(3) of the regulations, applicants should identify all equipment that will be used to carry out the manufacturing, processing, transportation, distribution, sale and dispensing activities described in the application and operating plan. Applicants should list any equipment that will be used directly in the activities described above. Applicants should provide as much detail as possible.

4. In response to Section I of the application, number 83, Attachment D, Section 10 (Recordkeeping) – Is a description of hardware, data storage, etc. required? Which recordkeeping functions should be described?

Application for Registration as a Registered Organization - Questions and Answers

Section 1004.5(b)(4)(vii) requires applicants to provide detailed descriptions of plans, procedures and systems adopted and maintained for tracking, record keeping, record retention and surveillance systems, relating to all medical marijuana at every stage including cultivating, possessing of marijuana, and manufacturing, delivery, transporting, distributing, sale and dispensing by the proposed registered organization. Recordkeeping functions related to marijuana at each stage described in 1004.5(b)(4)(vii) must be described in the application. The systems that will be utilized for these functions, including hardware, data storage, and other equipment identified by the applicant, must be detailed in the application. Applicants should provide as much detail as possible.

5. With regard to listing equipment, is this requirement limited to equipment already on the property that the applicant would use or does it also include additional equipment (e.g., a CO2 extractor) that the business might lease to support operations?

The application should include both equipment already on the property that the applicant plans to use as well as any additional equipment that the applicant does not currently own or lease, but requires to carry out the manufacturing, processing, transportation, distribution, sale, and dispensing activities.

6. Will an applicant be able to amend the equipment list for processing cannabis after sending in the application? Section I, Attachments A and B lays out the equipment for the entire operation - transport, dispensing, processing, etc. Can an applicant amend both attachments in the future?

Attachment A and Attachment B are required to be submitted upon application. Pursuant to 10 NYCRR § 1004.5(c) of the regulations, “An application under this section may be amended while the matter is pending before the Commissioner, if approved by the Commissioner upon good cause shown.”

Application for Registration as a Registered Organization - Questions and Answers

Manufacturing

1. In the “Instructions for Application for Registration as a Registered Organization,” the Department notes that among the criteria used in considering applications, DOH will consider the applicant’s “ability to manufacture approved medical marijuana products, each with a consistent cannabinoid profile . . . and each able to pass the required quality control testing as further described in 10 NYCRR § 1004.11.” That regulation provides, among other things, that “[e]ach brand shall have a maximum of 10 mg total THC per dose.” Will this limitation also apply to vaporized-pen cartridges, or may a single cartridge include more than one dose, provided that each dose was limited to the 10 mg?

The limitation of 10 mg total THC per dose will apply to each dose that is delivered from vaporized-pen cartridges. As a drug delivery system, the vaporized-pen cartridge may hold more than one dose.

2. 10 NYCRR § 1004.11(c)(6) requires that, for each brand offered, the registered organization shall only utilize a distinct approved name that shall not be “coined or fanciful”, may not include any “street”, slang, etc., and shall not reference any specific condition. There is a need to assign such nomenclature in certain parts of the operating plan. Is it likely that the nomenclature will be modified at a later time with Department guidance and / or may the nomenclature be affected by standardization requirements from the medical marijuana seed to sale tracking system?

Would the following naming practices be acceptable under this provision:

- (a) Descriptive of composition, e.g. 1 to 1 Blend
- (b) Descriptive of color or taste, e.g. Strawberry or Purple
- (c) Descriptive generally, e.g. Evening Blend
- (d) Proprietary name similar to pharmaceutical brand names, e.g. Flonase, Wellbutrin, Lipitor
- (e) Names associated through a distinctive prefix or suffix, e.g. Apo-XXX, Apo-YYY, Apo-ZZZ.

Is the registered organization allowed to make reference to genetics, Indica, Sativa, etc., or are they only allowed to reference brands based on THC/CBD values?

Names must comply with 10 NYCRR § 1004.11(c)(6) for the brands offered by a registered organization. After the registered organizations are selected, the Department will work with each registered organization to approve brand names. There is not a requirement to have proposed names for each brand offered at the time of application. However, applicants may propose names or use a place holder designation in the application where necessary to assign such nomenclature in the operating plan. The Department will consider any standardization requirements of the Seed to Sale tracking system as it relates to field length only.

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3. Will the Department consider medicated gum, a sublingual means of drug administration, an approved medical marijuana product?

10 NYCRR § 1004.11(g) lists the approved forms and routes of administration. Liquid or oil preparations are included for sublingual administration. A medicated gum is not a currently an approved form of medical marijuana.

4. With respect to the meaning of the words “form” and “brand”, as defined in 10 NYCRR § 1004.11, and as it applies to an operating plan to be provided in the Application to become a Registered Organization, will Registered Organizations initially be restricted to the three forms listed in 10 NYCRR Section 1004.11(g)? What will be the process for seeking to provide marijuana in a different form?

Registered organizations may only produce medical marijuana in the forms provided for in 10 NYCRR § 1004.11(g). While smoking is expressly prohibited, the Commissioner is authorized to approve additional forms in the future, and the Department will issue guidance on the process for interested stakeholders to submit information on this issue.

5. With respect to the five different brands that each RO will be allowed to produce and dispense, may there be any variation of composition within each brand, particularly with respect to changes in the terpene profile within each brand? In short, may each brand have a variety of sub-brands, based on changes to elements such as the brand’s terpene profile?

A registered organization may not produce a variety of sub-brands within each brand. Each brand must have a consistent cannabinoid profile.

6. What will the process be for seeking to expand the initial number of five brands?

The regulations provide that each registered organization may initially produce up to five brands of medical marijuana, and thereafter, additional brands may be approved by the Department. The Department will provide guidance on the process for obtaining approval to produce additional brands in the future.

7. In review of the "edible" portion of the program, it states that a dose can be no more than 10mg per piece. Is it acceptable to sell a 20 piece product that contains 20mg each with a 10mg serving?

No. 10 NYCRR § 1004.11(g)(5) of the regulations states that approved medical marijuana products may not be incorporated into edible food products by the Registered Organization, unless approved by the Commissioner. Edibles are not a currently approved form. In accordance with 10 NYCRR § 1004.6, the Department will consider

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whether the applicant, if selected, is ready, willing and able to properly carry on the activities set forth in 10 NYCRR Part 1004. This includes the ability to manufacture only those forms currently approved by 10 NYCRR § 1004.11(g).

8. It is our understanding that a "brand" as defined in the regulations is a delivery system and not a strain. If that is accurate is the sale of CO2 cartridges and vape pen applications an allowable brand?

10 NYCRR § 1004.11(a)(2) defines a "brand" as a "medical marijuana extraction product that has a homogenous and uniform cannabinoid concentration and product quality, produced according to an approved and stable processing protocol." It does not include the form nor the delivery system. Allowable forms and routes of administration, including metered liquid or oil preparations for vaporization, are detailed in 10 NYCRR § 1004.11(g). The form of medical marijuana refers to the final preparation of an approved medical marijuana brand. The CO2 cartridges and vape pen provide one delivery system for administration of the brand that is produced in its final form. The brand, in its final form, should not be limited to the use of a single delivery device.

9. Please expand upon the definition of "brand", as found in Section 1004.11(a)(2) of the Medical Marijuana Program Regulations.

A "brand" is an approved medical marijuana product with a homogenous and uniform cannabinoid concentration and product quality. Brands may be manufactured in the forms set forth in 10 NYCRR § 1004.11(g) of the regulations. Upon approval from the Department, a brand may be made up of one or more strains if the brand is reproducible and the total THC and CBD concentration for that brand is within 95-105% of the specified milligrams per dose for that brand. The brand must adhere to the composition and concentration of inactive ingredients as defined for the brand and determined by laboratory testing by an approved independent laboratory.

10. Where in the application do we identify our five brands?

An applicant's brands should be identified in Attachment D – Operating Plan, in Section 1 – Manufacturing.

11. The regulation specifies maximum mg dosage of THC -- is there any associated restriction on the maximum dosage of CBD? Or of any other cannabinoid content?

No. The regulations do not specify a maximum dosage of CBD or of any other cannabinoid.

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12. Regarding the definition of “approved medical marijuana product,” if the brand has the same cannabinoid profile, across all forms within the brand, does this mean that the active and inactive ingredients have to be the same across the various forms in a brand? Or are the cannabinoids the same, within the brand, and the other ingredients can vary depending on the form?

10 NYCRR § 1004.11(a)(2) of the regulations defines “Brand” as follows: a defined medical marijuana extraction product that has a homogenous and uniform cannabinoid concentration and product quality, produced according to an approved and stable processing protocol. The specified brand shall have a total THC and total CBD concentration that is within 95 – 105% of that specified in milligrams per dose for that brand and shall have the same composition and concentration of inactive ingredients as that defined for the brand. In order to offer the same brand in multiple forms, there can be no variation in the items defined above, including inactive ingredients, without Department approval.

13. Does the limitation on "brands" to five limit the number of marijuana strains that can be grown?

No, the regulations do not limit the number of strains that may be grown.

14. The ‘Message from the Commissioner’ section of the Department of Health website states the following, “Correctly, and in keeping with New York's longstanding commitment to eliminate all smoking, we chose to ban the smoking of marijuana and instead limit its delivery to alternative methods including vaporization, oils, pills, and other consumables.” Is there a list that details the “other consumables” mentioned on this page?

Yes. Section 1004.11(g) of the regulations sets forth the approved forms and routes of administration for medical marijuana. Approved forms and routes of administration include liquid or oil preparations for metered oromucosal or sublingual administration or administration per tube, metered liquid or oil preparations for vaporization, capsules for oral administration or any other form and route of administration approved by the Commissioner. Smoking is not an approved route of administration. In addition, approved medical marijuana products may not be incorporated into edible food products by the registered organization, unless approved by the Commissioner. The regulations may be accessed from the Medical Marijuana Program web page using the following link: https://www.health.ny.gov/regulations/medical_marijuana/.

15. Does the Department have any additional documentation on the approved excipient and additive list that is alluded to in the final regulations?

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No. Each registered organization may have different manufacturing processes outlined in their operating plans, therefore a single Department-approved list may not be appropriate for every registered organization. The Department will work with each registered organization to create a list of ingredients approved for use by the registered organization in its manufacturing process. A registered organization need only obtain prior approval of an additive one time prior to approval of the brand.

16. Based on the definitions in 10 NYCRR Section 1004.11, it appears that, unless specific permission for a variation is received from the Commissioner, a registered organization may produce a maximum of 15 forms of medical marijuana, as follows: 5 brands, with each brand allowed to be produced in the 3 forms defined in 1004.11(g). Variations within each brand, e.g., inclusion of additional ingredients, etc., is expressly forbidden unless prior approval from the Department is received. Is it possible to confirm this understanding?

Section 1004.11(a)(2) of the regulations defines “Brand” as follows: a defined medical marijuana extraction product that has a homogenous and uniform cannabinoid concentration and product quality, produced according to an approved and stable processing protocol. The specified brand shall have a total THC and total CBD concentration that is within 95 – 105% of that specified in milligrams per dose for that brand and shall have the same composition and concentration of inactive ingredients as that defined for the brand. In order to offer the same brand in multiple forms, there can be no variation in the items defined above without department approval. So long as the forms produced by a registered organization have the same composition and concentration of inactive ingredients as the defined brand, the registered organization can produce each brand in any of the three allowable forms.

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Laboratory Requirements

1. Subsection 83 of Section I (Required Attachments) of the registration application requires the applicant to submit “Quality Assurance Plans” in Section 7 of “Attachment D-- Operating Plan,” consistent with § 1004.5(b)(4)(iv). Among these requirements, the applicant must detail plans for quality assurance of products that involve submission of medical marijuana samples to off-site DEA-licensed laboratories (pursuant to 10 NYCRR §1004.14 “Laboratory testing requirements for medical marihuana”). Please clarify whether the registered organization or the off-site laboratory is responsible for arranging for the transportation of these samples.

It is the registered organization’s responsibility to arrange for the transportation of these samples to and from the laboratory.

2. Section 55-2.155 of the regulations states that each Registered Organization must use an independent laboratory to perform testing of medical cannabis. Will there be qualified “independent laboratories” established in New York State prior to the effective date of operation of the registered organizations or for the registered organizations to include in their processing plans? Is the Department certain that NYS-licensed laboratories will be able to provide this service, given that they must also be federally licensed by the DEA and the conflict this may create relative to federal marijuana laws? If it comes to pass that the DEA will not allow such analysis in laboratories that it licenses in NYS, will the Department license non-DEA-licensed laboratories, such as exist in other states, in time for the January 1, 2016 implementation?

Initial quality assurance testing of medical marijuana products will be performed by the Department’s Wadsworth Center. The Department will issue permits to laboratories, through the Wadsworth Center Environment Laboratory Approval Program, for ongoing medical marijuana testing. The Department will not be issuing certificates of approval to non-DEA registered laboratories. The Wadsworth Center will perform this testing until there are laboratories who meet these requirements.

3. Has the State defined uniformed costs for testing, as this is critical to defining product costs by the Registered Organization?

No. It is not within the Department’s authority to establish private laboratory testing costs.

4. Regarding plant brands/strains, should the Registered Organization provide its own existing state certified lab test results to the New York State prior to selecting the brands to prove the CBD and THC content?

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As part of the application, an applicant may provide existing state-certified laboratory test results from another state to demonstrate the applicant's ability to manufacture medical marijuana products with a consistent content of CBD and THC. Final brand approval by the Department for the registered organization's brands will be determined based on review of appropriate validation studies.

5. With respect to 10 NYCRR § 1004.11, and the development of an operating plan as required in the application, please clarify the meaning of the word “reported” in 10 NYCRR § 1004.11(c)(2), i.e., to whom does each listed cannabinoid substance in the product, as well as any other cannabinoid substance with a concentration of greater than 0.1% need to be reported, and do each of these substances need to be included in the product labeling as defined at 10 NYCRR § 1004.11(k)? Furthermore, does the exact milligram and/or percentage concentration of each cannabinoid requiring disclosure need to be listed on the product label?

Registered organizations will be required to report the results of the cannabinoid profile testing to the Department. Independent laboratories located in New York State, registered by the DEA and issued a certificate of approval through the Wadsworth Center Environmental Laboratory Approval Program, that perform the cannabinoid profile testing will complete such testing and report the results to the registered organization. The registered organization will be required to report those results to the Department. The Wadsworth Center will perform this testing until there are laboratories approved by the Department that may perform the testing. Results of cannabinoid profile testing performed by the Wadsworth Center do not have to be reported to the Department as the Department will have the results. As laboratories are approved, the Department will provide additional information concerning the method by which results should be reported. The requirements pertaining to the label to be applied at the manufacturing facility are set forth in 10 NYCRR § 1004.11(k)(1) through (9). The single dose total THC and total CBD content for the product set forth in milligrams (mg) must be included on both the product and dispensing labels.

6. With respect to 10 NYCRR § 1004.11, and the development of an operating plan as required in the registered organization application, 10 NYCRR Part 1004 requires that registered organizations show stability 60 days after opening, but refers only to sublingual extracts in oil. Is there a process in place for approving these stabilized formulae?

10 NYCRR § 1004.11(m) requires registered organizations to demonstrate the stability of each approved medical marijuana product produced by testing performed over time at an approved laboratory in accordance with 10 NYCRR § 1004.14. The regulations do not limit this stability testing to sublingual extracts in oil. The Wadsworth Center will perform this testing until there are approved laboratories that may perform testing. As laboratories are approved, the Department will provide additional information concerning the method by which results should be reported. The single dose THC and

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CBD content for the product set forth in milligrams (mg) must be included on the product and dispensing label. The total THC and total CBD concentration at 60 days must still meet the brand definition. The Wadsworth Center will provide the process for submission of stability studies to registered organizations.

7. With respect to the Application, Attachment D: 10 NYCRR § 1004.14(g) states that the commissioner shall make a list of acceptable limits of required analytes. Will this list be based on acceptance specifications set out in US Pharmacopoeia or equivalent international pharmacopoeia listed in Schedule B of the US Pharmacopeia (including the European Pharmacopoeia)? If not, how will the determination be made and when will that list be available?

Acceptable limits of tested analytes will be determined based on an analysis of all relevant sources of information including Pharmacopeia and will be posted on the Department's Medical Marijuana Program website.

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Operating Plan

1. The registration application requires the applicant to submit a “Standard Operating Procedure” as Section 6 of “Attachment D--Operating Plan,” consistent with § 1004.5(b)(4)(iii). One of the provisions of § 1004.5(b)(4)(iii) requires that “procedures shall include use of good agricultural practices (GAPs) and must conform to all applicable laws and rules of New York State.” Please clarify whether the term “good agricultural practices” refers to a specific document or program that the Department expects registered organizations to implement.

The Department does not expect applicants to implement a specific document or program regarding good agricultural practices.

2. In section 83 of the application, can the Department offer guidance on what is meant by a “detailed description” to determine minimum standards for submission of the standard operating procedure manual or the quality assurance plan?

The Department cannot specify standards for a universal operating plan that will fit the needs of each and every applicant due to differences in organizational structure, manufacturing, and other variances among organizations. Applicants should use their best judgement to determine a level of detail sufficient to provide the information requested. Applications will be evaluated based upon the completeness and quality of their responses to questions, and demonstration of an operating plan that complies with NYCRR 10 Part 1004.

3. Can the Department describe the types and kinds of information and documents that an applicant must submit to demonstrate that the applicant has the financial capacity to accomplish its business and operating plans as it pertains to Section I, field 83 (“Attachment D”) and generally?

The applicant must attach its most recent financial statement prepared in accordance with generally accepted accounting principles (GAAP) applied on a consistent basis and certified by an independent certified public accountant in accordance with the requirements of 10 NYCRR § 1004.5(b)(16). Applications will be evaluated based upon their ability to respond completely to questions and provide quality responses that demonstrate an operating plan that complies with NYCRR 10 Part 1004.

4. With respect to 10 NYCRR § 1004.11(b) and the development of an operating plan as required in the registered organization application, may a registered organization use both CO₂ **and** ethanol to produce their products? The referenced section uses the word “or” but is not clear on whether both may be used in combination.

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10 NYCRR § 1004.11(b) allows a registered organization to use either CO2 extraction or ethanol extraction to produce its product. Both methods may be used in combination.

5. With respect to 10 NYCRR § 1004.11(e)(3) and the development of an operating plan as required in the registered organization application, is there a list of pesticides approved for use in greenhouse growing?

No. A registered organization must identify the pesticides, fungicides and herbicides it wishes to use, if any, and obtain approval prior to use.

6. With respect to Section 83, Attachment D of the application, will requirements for odor control/filtration be required as part of the applicant's operating plan, and if so, what are the applicable requirements?

Applicants providing information concerning odor control/ filtration shall include this information in Appendix B and Attachment B, as applicable, not in Attachment D. Appendix B: Architectural Program requires an applicant to provide information concerning energy sources and engineering systems, which includes ventilation requirements. Question 81 of the application also requires applicants to identify equipment in Attachment B. Any special requirements of the equipment as they relate to implications for ventilation and odor control should be defined in this Attachment.

7. Can the Department provide guidance on what is considered a "material change" to the operating plan? What changes would require Department review and approval?

10 NYCRR § 1004.10(b)(6) requires a registered organization to obtain prior written approval of the Department for modifications or revisions to its operating plan, including policies and procedures related to cultivation, processing, manufacturing, distributing or dispensing policies or procedures. Additional guidance will be provided to registered organizations concerning changes to operating plans.

8. Are applicants expected to submit a separate operating plan for each dispensing facility location for question #83 from the application form or should the operating plan serve as a template for all sites with specific variations noted for each of the locations? For example, security plans for each location may have variances based on facility size and location. Should these differences be referenced in the single document or should 5 separate plans be submitted?

Separate operating plans should not be submitted for each dispensing site. Any site-specific variations should be noted within the operating plan.

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9. Section 1004.5(b)(4)(iii) of the regulations state, “The procedures shall include use of good agricultural practices (GAPs) and must conform to all applicable laws and rules of New York State.” Is a list of applicable laws and rules available or are there specific guidelines to be used in developing standard operating procedures for the Medical Marijuana Program?

No. It is at the discretion of applicants to determine the contents of their standard operating procedure manual and to ensure that the procedures conform to all applicable laws and rules of New York State.

10. Should an applicant address inventory controls given that the Department will mandate an inventory system which cannot be assessed at this stage?

Yes. Although a specific seed to sale software solution will be provided by the Department for registered organizations to track growing, manufacturing, distributing, and dispensing; applicants should address inventory controls, including policies and procedures related thereto, in their operating plan.

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Dispensing

1. Has the Department addressed potential licensure concerns (e.g. DEA licenses) that would impact the on-staff licensed pharmacists that registered organizations are required to have at each dispensary location?

This was addressed in the assessment of public comment, which is posted to the Department's Medical Marijuana Program website, for the recently adopted regulations.

2. Often in pharmacies, pharmacy degree interns (who have passed the Pharmacy Technician Certification Board exam) are allowed to play a role fulfilling prescriptions. Will the State allow for a similar role with the medical cannabis dispensaries?

The regulations do not prohibit a registered organization from hiring pharmacy technicians or pharmacy interns, with pharmacy experience, from working in a registered organization's dispensing facility. However, this does not substitute for the regulatory requirement that each dispensing facility have a New York State licensed pharmacist on-site to directly supervise the activity within the facility. As a point of clarification, there is no license for a certified pharmacy technician in New York State.

3. There is no mention in the regulations of accessibility of non-English speaking patients. Will the Department of Health require the Registered Organization to conform to New York's Limited English Proficiency standards for pharmacies in terms of providing interpreter and translation service for qualifying patients? This stems from 8 NYCRR 63.11.

The requirement to provide oral interpretation services and translation services in accordance with 8 NYCRR 63.11 applies to pharmacies and requirements for prescription drugs. The requirements in 8 NYCRR 63.11 are inapplicable to the Medical Marijuana Program as registered organizations are not pharmacies, and medical marijuana is not a prescription drug.

4. What is the monthly maximum quantity of medical marijuana that can be dispensed to a certified patient?

The maximum is defined in days supply, and as a result the quantity may vary. Each dose cannot have more than 10 mg of THC. Pursuant to PHL § 3364(5)(b), when dispensing medical marijuana to a certified patient or designated caregiver, the registered organization shall not dispense an amount greater than a thirty day supply to a certified patient unless the certified patient has exhausted all but a seven day supply provided pursuant to a previously issued certification.

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5. Will the pharmacist in a dispensing location be allowed to dispense a written supply as directed by physicians? Can the pharmacist fill out the bulk manufacturer vial, as they would for a regular prescription, or does the manufacturer have to give sealed pre-determined day supply medications?

The regulatory requirement that each dispensing facility have a New York State licensed pharmacist on-site is to directly supervise the activity within the facility. The pharmacist will not be dispensing the medication pursuant to a written supply as directed by physicians. Instead, to dispense medical marijuana to a certified patient, a dispenser must use the registry identification card issued to the certified patient. The registry identification card is required to plainly state any recommendation or limitation by the practitioner as to the form or forms of medical marijuana or dosage for the certified patient. The product that is supplied by the manufacturing facility will be in unit-dose packaging. The amount of unit-dose packaging will depend upon the quantity recommended by the practitioner and included on the registry identification card.

6. If a certified patient who has a designated caregiver picks up the prescription “recommendation,” without the designated caregiver present, does the caregiver have to be named on the “prescription line”, on the dispensed medication?

The medical marijuana dispensed is not pursuant to a prescription. It is dispensed pursuant to the registry identification card issued by the Department to a certified patient. The registry identification card issued to the certified patient is required to plainly state any recommendation or limitation by the practitioner as to the form or forms of medical marijuana or dosage for the certified patient. The designated caregiver need not be named on the dispensing label if the certified patient is picking up the medication.

7. Does the “recommendation” from the physician have an expiration date, i.e., for CII-CV is it 30 days?

The registry identification card is required to plainly state any recommendation or limitation, including expiration of certification, by the practitioner as to the form or forms of medical marijuana or dosage for the certified patient. Expiration of certification is defined in 10 NYCRR § 1004.2(b) as follows:

(1) The certification shall state the date upon which the certification shall expire, which shall be no longer than one year after the date it was issued, unless the patient is terminally ill.

(2) If the practitioner issues a certification to a patient who is terminally ill, the certification shall not expire until the patient’s death or the practitioner revokes the certification.

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(3) If the practitioner issues a certification to a patient who is not a resident of New York but is receiving care and treatment in this state, the certification shall be valid for a period of time which is no longer than the applicant is reasonably anticipated to be residing in New York State for the purposes of care and treatment, but in no event shall it be valid for more than one year after the date it was issued.

8. Must the pharmacist be employed by the dispensing facility?

The pharmacist must be employed by the registered organization. Contractors may not be used to fulfill this requirement.

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Security

1. Specific to the security plan and employment of security staff, there are advantages with areas such as recruitment, retention, training and expertise through a comprehensive security service contract that is well integrated to the registered organization's requirements. Would the Department entertain this approach as an option to staff employment for discussion if included as an option in the application? May a registered organization use an experienced security vendor to provide on-site staffing which is overseen by employees of the registered organization to design, implement and oversee security protocols?

The regulations do not allow for contractors as an option to staff employment for services in relation to any activities that must be carried on by the registered organization (acquiring, possessing, manufacturing, selling, delivering, transporting, distributing, or dispensing marihuana for certified medical use).

2. In response to Form DOH-5138 #83 Operating Plan (Attachment D) and # 89 Security Plan (Attachment H), what is the distinction between the *Security and Control* description required in the Operating Plan (Section 5) and the *Security Plan* required in Attachment H? Does the Department expect the security plan to be included in both the operating plan Attachment D (question 83) and as a response to question 89, Attachment H? Please clarify the differences, if any, between the types of security and control information sought in each attachment.

Question 83 refers to the required component of the applicant's operating plan which must be labeled Attachment D-Section 5 and must specifically address operational policies and procedures related to security and control measures that will be in place to prevent diversion, abuse, and other illegal or unauthorized conduct relating to medical marijuana. Question 89 refers to the applicant's full security plan proposal which must be labeled Attachment H and must demonstrate compliance with the requirements set forth in 10 NYCRR § 1004.13.

3. 10 NYCRR § 1004.13(j) sets out a requirement for medical marihuana products to be stored in a department approved safe or vault. Is there a set of minimum standards for such a safe or vault, and if so, when/how will such standards be made available?

At a minimum, applicants manufacturing facilities should have a safe or vault that meets the requirements of 10 NYCRR § 80.13, which includes minimum security standards for non-practitioner handling of Schedule I and II controlled substances.

4. 10 NYCRR 1004.13(i) requires all marihuana that is not part of a finished product to be stored in a "secured location" accessible only by restricted personnel. What qualifies as a

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secured location – for instance, would a dedicated room with a lock and controlled access be sufficient?

A secured location would be a separate, locked room with controlled access. Marijuana that is not part of a finished product may also be stored in the safe or vault required by 10 NYCRR § 1004.13(j).

5. With respect to the Application, Attachment H: 10 NYCRR 1004.13(a)(1) requires a perimeter alarm. Does this refer to the perimeter of the facility (i.e., the building) or the perimeter of the property (i.e., a fence), and if the latter, is a fence required?

A perimeter alarm utilizing commercial grade equipment is required for the outside perimeter of all facilities operated by a registered organization, not for the real property boundaries. A perimeter fence for the entire real property boundary is not required by regulation.

6. With respect to the Application, Attachment H: 10 NYCRR 1004.13(a)(4) requires “twenty-four hour recordings;” must the cameras record continuously, or may they be programmed to record on motion activation?

To comply with regulation, all required video cameras must record continuously to provide the Department with twenty-four hour recordings upon request.

7. With respect to the Application, Attachment H: 10 NYCRR 1004.13(c) requires a back-up alarm provided by a company other than the company supplying the primary system. Must the primary and/or back-up alarm systems be monitored by a third-party monitoring station, and if so, can they be monitored by the same company, or can one or both of the alarm systems be monitored by internal security staff of the registered organization?

The regulations do not allow for contractors as an option to staff employment for services in relation to any activities that must be carried on by the registered organization (acquiring, possessing, manufacturing, selling, delivering, transporting, distributing, or dispensing marijuana for certified medical use).

8. Will off-duty active law enforcement officers be permitted to be employed as security by a registered organization?

Yes.

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Financial

1. What is meant by “certified” financial statement in Section 90 of the application? If the applicant is a new for-profit entity without any operating history, is it acceptable to submit a pro-forma balance sheet with projections upon commencement of operation? If so, what level of accountant review is required?

All applicants need to submit a financial statement prepared in accordance with generally accepted accounting principles (GAAP) and certified by an independent certified public accountant to be considered for registration as a registered organization. There is no substitute for the information that is required by regulation in § 1004.5(b)(16).

2. Please confirm that you are requesting a CPA report stating that the financial statement compilation was performed in accordance with Statements on Standards for Accounting and Review Services.

No. The CPA report must indicate that the financial statement was prepared in accordance with Generally Accepted Accounting Principles (GAAP).

3. Is the financial statement referenced in Section 90 of the application the same financial statement referenced in 10 NYCRR 1004.5(10)? If not, what is the difference between the two statements?

Pursuant to 10 NYCRR § 1004.5(10), Field 87 requires the applicant to provide “a financial statement setting forth all elements and details of any business transactions connected with the application, including but not limited to all agreements and contracts for consultation and/or arranging for the assistance in preparing the application.” This section pertains only to the transactions connected with the preparation of the application. On the other hand, Field 90 requires the applicant to provide “the most recent financial statement of the applicant prepared in accordance with generally accepted accounting principles (GAAP) applied on a consistent basis and certified by an independent certified public accountant, including a balance sheet as of the end of the applicant's last fiscal year and income statements for the past two fiscal years, or such shorter period of time as the applicant has been in operation,” pursuant to 10 NYCRR § 1004.5(16). This section applies more broadly and includes all financial information concerning the applicant, including financial information outside of the preparation of the application.

4. Will the state accept a statement from a CPA stating that, “the CPA certifies the financial statements are prepared in accordance with GAAP applied on a consistent basis?”

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Yes. The Department will accept documentation from an independent CPA which certifies the financial statement was reviewed and GAAP was applied on a consistent basis.

5. With respect to the Application, Attachment I: does “most recent financial statement” refer to most recent annual audited financial statements, or most recent interim financial statements?

This refers to the most recent financial statement, which could be an annual or interim statement depending upon the date of completion, and must also include a balance sheet as of the end of the applicant’s last fiscal year and income statements for the past two fiscal years, or such shorter period of time as the applicant has been in operation.

6. Is there any operational budgetary requirement? For example, as part of financials, does the Department expect to see money in the bank for the first two years of operation and does New York expect this from the GAAP (question 90, et al)?

The Department expects that the applicant’s financial standing will support the real property, equipment and operational needs (including staffing) the applicant proposes.

7. Is New York State going to provide access to a state banking facility or are there any federal guarantees of access to traditional banking facilities? Given restrictions in federal law, what specific banking or depository relationships does the Department expect a registered organization to have in place?

It is not within the Department’s authority to provide access to a state banking facility or to provide any federal guarantees of access to traditional banking facilities.

8. Is the state giving consideration and or requirements to applicants with established fully disclosed marijuana banking relationships?

The Department will give consideration to all applicants that meet the criteria for “Acceptance of Applications” provided for on pages 2-3 of the application instructions. The regulations do not include any requirements related to banking relationships.

9. When can the Applicant expect to receive the refunded registration fee if the license is not granted? Will the refund be in the form of a check payable to an account of the applicant’s choosing or will the Department wire transfer the amount per instructions provided by the applicant? Will DOH be withholding any portion of the \$200,000 for unsuccessful applicants or returning it to the applicants in full? If withholding, for what purpose(s) will the funds be withheld?

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The registration fee of \$200,000 shall be returned in full to the applicant if the applicant is not granted a registration. The Department will issue a bank check to the contact provided in the application within Section B: Primary Contact of the application. Any registration fee refunds will be made after the selected applicants are notified, unless an application is identified as not meeting the minimum criteria for consideration provided under "Acceptance of Application" within the instructions of the application. Registration fee refunds will be made to these applicants after this determination.

10. Will the costs incurred by DOH for processing applicant applications be taken from the \$10,000 non-refundable application or, if an applicant is successful, from the \$200,000 registration fee?

The \$10,000 non-refundable application fee represents the Department's processing costs.

11. Once registered organizations have been selected, will the costs incurred by the Department for conducting background investigations on the organizations be taken from the \$10,000 non-refundable application fee or the \$200,000 registration fee?

The fee for the background check for managers who may come into contact with or handle marijuana is the responsibility of the individual undergoing the background check and is not included in the \$10,000 non-refundable application fee or the \$200,000 registration fee.

12. Could the Department clarify what is required in Section 1004.5(b)(16)? Specifically, it appears that this section is only applicable for the applicant (the entity applying for the initial registration as a Registered Organization). In the case of a partnership/LLC, are personal financial statements of the partners/members also required or suggested? Will the requirement be effected if an entity is in a start-up stage and does not have a significant balance sheet or income and expense activity?

Section 1004.5(b)(16) requires the most recent financial statement of the applicant prepared in accordance with generally accepted accounting principles (GAAP) applied on a consistent basis and certified by an independent certified public accountant. Applicants must also provide a balance sheet as of the end of the applicant's last fiscal year and income statements for the past two fiscal years. To the extent an entity has been in operation for less than two fiscal years, balance sheets and income statements for such shorter period of time must be provided. In the case of a partnership or LLC, the most recent financial statement of the partnership or LLC itself, not that of its partners or members, must be submitted.

Application for Registration as a Registered Organization - Questions and Answers

13. Is the \$200,000 registration fee payment required up front, in full via bank accounts, or may it be paid in installments? Can the fees be delayed and paid at a later date? Is there a possibility of putting up assets as collateral for the registration fee?

The registration fee must be made by certified check payable to the “New York State Department of Health.” The \$200,000 registration fee, along with the \$10,000 application fee, must be paid in full at the time the application is submitted. These fees cannot be paid in installments and must be submitted by the deadline for Department receipt of applications (June 5, 2015). Any application received that does not include the \$10,000 application fee as well as the \$200,000 registration fee will be considered incomplete and will not be reviewed by the Department.

14. Can the Department provide an estimate or a figure required for investing in the program?

No. Each applicant will incur distinct costs depending on the size and location of its proposed facilities, as well as its specific operating plans.

Application for Registration as a Registered Organization - Questions and Answers

Pricing/Advertising/Marketing

1. 10 NYCRR § 1004.15 defines “price” as “the cost to manufacture, market and distribute approved medical marijuana products plus a reasonable profit”. With respect to “cost”, please confirm that cost will be determined on an SG&A basis, i.e., cost includes all indirect costs. With respect to “reasonable profit”, can you provide an approximate margin range that the department would consider reasonable? Finally, can you provide information on when the department will perform this cost analysis, e.g. shortly after licensing (based on projected costs) or just prior to distribution (based on actual costs)? Regarding Section 1004.15, how does the NYSDOH define a reasonable profit? Does reasonable profit include cost of financing?

Registered Organizations, not applicants, must submit the proposed prices of approved medical marijuana products to the Department for approval with documentation to support them. Documentation shall include all costs the Registered Organization considered to arrive at its proposed price. In doing so, the Registered Organization may submit documentation related to indirect costs for consideration by the Department. The Department will provide additional guidance concerning price proposals and approvals.

2. 10 NYCRR §1004.15(c)(4) states that “the department may approve the proposed price, refuse approval of a proposed price, or modify or reduce the proposed price.” Is there a process by which a registered organization can appeal a determination by the department relative to the department’s determinations on pricing?

While there is no formal appeal process set forth in regulation to appeal the Department’s determination on pricing, pursuant to 10 NYCRR § 1004.15(f), a “registered organization may request that the price be modified based upon a material change in the registered organization’s costs.” In addition, 10 NYCRR §1004.15 (g) provides a registered organization the opportunity to immediately notify the department of any cost or pricing data submitted that it determines was inaccurate, incomplete or noncurrent as of the date of the department’s approval of the price. The Department will provide additional guidance concerning price proposals and approval of price at a later date.

3. What would be the rationale for the denial or modification of pricing by a registered organization? Would the Department like to see different pricing for different geographic areas in New York State?

10 NYCRR § 1004.15(c)(3) states, “the department may consider whether the costs represent inefficient and uneconomical practices; are not costs appropriately attributable to the price; and/or are costs unsupported by sufficient documentation or information to justify their inclusion in the proposed price.” Price is defined as the cost to manufacture, market and distribute approved medical marijuana products plus a reasonable profit. The Department recognizes that costs can vary depending on the geographic area in

Application for Registration as a Registered Organization - Questions and Answers

which a facility may be located. Proposed pricing for different geographic areas in New York State may be submitted by a registered organization.

4. The regulations are specific to advertising of medical marijuana by a registered organization. How does the Department anticipate regulating 3rd party advertising of medical marijuana in New York?

The department intends that the marketing requirements apply to agents of the registered organization acting on the registered organization's behalf.

5. Where in the application would an applicant include a plan on subsidizing the cost for patients? Where would the applicant include a business plan?

Applicants may provide details on any plans to subsidize patient costs, if they choose to do so, as well as the details of a business plan, in Attachment D – Operating Plan.

6. Regarding 10 NYCRR § 1004.16(h)(6), what is the forum for determination of “substantial evidence”? What constitutes a “Statement of efficacy” -- can we say “has been reported to be useful for X conditions?” Can we use patient testimonials? Can we make general claims about potential symptomatic uses, rather than specific statements of medical effect?

Substantial evidence, as set forth in the regulation, means peer-reviewed medical literature. Anecdotal evidence, including patient testimonials or general claims does not constitute substantial evidence or substantial clinical data and will not be accepted. All advertisements must be submitted to the Department for approval.

Application for Registration as a Registered Organization - Questions and Answers

Compliance

1. Question 94, Attachment M requires that the applicant has attached, "a statement and/or documentation showing that the applicant is able to comply with all applicable state and local laws and regulations...which it intends to engage under the registration..."
 - Because the entire application requires attestation and signature from the a chief executive officer duly authorized by the board or a similar form of granting authority, can for example, Attachment M consist of a statement from the chief executive officer that attests to the content of § 1004.5(b)(8)?
 - Please clarify whether the required “documentation” consists solely of affidavits supporting these “statements” or whether additional forms of documentation are contemplated. If the latter, please provide examples of such documents.
 - Is the State requesting the applicant to specifically state the actions, and other measures that are necessary to achieve these requirements?
 - Does “applicable state and local laws and regulations” for purposes of the application include only the regulations adopted by the New York Department of Health pursuant to the Compassionate Care Act?
 - Is the State considering specific applicable state or local laws, rules, or regulations in Attachment M? For instance, does the state anticipate particular application of environmental, zoning, finance, and/or tax law?

An applicant may attach an affidavit or statement, which must be signed by the individual identified in “Section J: Attestation and Signature” of the application. Applicants are required to comply with, and acknowledge the ability to comply with, all applicable laws and regulations, not just the Compassionate Care Act and 10 NYCRR Part 1004. This would include local laws that may be applicable. The Department does not require the applicant to specifically state the measures necessary to achieve these requirements as this should be demonstrated by the applicant within the submitted operating policies and procedures that demonstrate compliance with state and local laws and regulations.

2. To meet the term "proof" required for item number 92, Proof of Internet Connectivity for Attachment K, would a statement from either the contractor responsible for the manufacturing and dispensary facilities, or from the CEO as to confirmation from the identified local Internet service provider suffice?

Item number 92 from Section I requires that the applicant submit proof from the local internet service provider(s) that all of the applicant’s manufacturing and dispensing facilities are located in an area with internet connectivity. A statement from a contractor or the CEO may not be substituted or act as a replacement for proof from a local internet service provider.

3. The registration application and program materials on the Department’s website use the terminology “medical marijuana,” whereas the Compassionate Care Act and Part 1004

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regulations refer to “medical marihuana.” Please clarify which spelling applicants should use in preparing their application materials.

Applicants may use either spelling on the application, but should remain consistent throughout the application.

4. The regulations call for operations to begin within 6 months of issuance of Registration. Does “begin operations” require that facility construction is completed within six months, one or more dispensing facilities are able to sell finished product, plants are being grown or does it mean something broader such as a demonstration of satisfactory progress? Please specify what is meant by “begin operations”. Can the Department clarify what “begins operations” means for this purpose?

A registered organization will be expected to provide a finished product that can be dispensed to patients commencing January 2016. The Department plans to closely monitor the progress of a registered organization’s operations upon issuance of a registration and recognizes that there may be some factors that are beyond the registered organization’s control.

5. The regulations contemplate that the registered organization has the flexibility to use an affiliate or a subsidiary corporate entity and contemplate that a parent may be financially or contractually responsible for obligations of the subsidiary registered organization. (§ 1004.5 (b)(15)). Is delegation of responsibilities among affiliate/parent/subsidiary companies permissible? For example, can a parent own all real property used by the subsidiary registered organization for manufacturing and dispensing? May a registered organization delegate core functions to a wholly-owned subsidiary as long as the registered applicant entity maintains ultimate responsibility?

No. Although the regulations contemplate that applicants may be a corporate subsidiary or affiliate of another corporation, the regulations do not contemplate registered organizations having their own corporate subsidiaries. The current regulations do not allow registered organizations to contract out services in relation to any activities that must be carried on by the registered organization (acquiring, possessing, manufacturing, selling, delivering, transporting, distributing, or dispensing marihuana for certified medical use).

6. Criteria #2 in the Application under “Criteria for Consideration of Applications” stipulates that each Registered Organization must produce “sufficient quantities” of medical marijuana products (10 NYCRR § 1004.6). Can the State please define the term “sufficient?”

Applicants for registration as a registered organization must demonstrate an ability to manufacture enough medical marihuana to meet the anticipated needs of certified

Application for Registration as a Registered Organization - Questions and Answers

patients in New York State and must also demonstrate an ability to ensure availability of each brand offered for at least one year. The Department cannot provide projected patient volumes at this time.

7. 10 NYCRR § 1004.11(c)(7) states that each registered organization shall ensure the availability of at least a one year supply of any offered brand unless otherwise allowed by the department. Must a registered organization stockpile supply in advance of distributing products, or must a registered organization simply ensure that its projected production will be sufficient to supply its patients? If the latter, how should a registered organization determine anticipated patient requirements (what assumptions should be made regarding patient counts, consumption amounts, etc.)? Moreover, will this requirement be in place at the outset, or will an allowance be made during an initial period of operations?

The requirement that registered organizations ensure availability of at least a one year supply for each brand offered requires the registered organizations to demonstrate, through their standard operating procedures, that they are able to ensure availability of each of their brands for at least one year. The regulations do not require physical availability of a one-year supply of product.

8. Will there be any regulations on the number of plants that each registered organization can have within their production facility at a time? If so, how many for each phase of growth?

No. The regulations do not detail any limitations on the number of plants allowed for each Registered Organization during any specific timeframes or any growth phases nor does the Department have any immediate plans to include such a regulation.

9. 10 NYCRR § 1004.8 provides that registrations are non-transferable. Under what conditions may an applicant make changes to the ownership structure? Under what conditions may a registered organization make changes to the ownership structure? For instance, would it be permissible for corporation A, which owns all of the shares of a registered organization (corporation B), to conduct an arms-length sale of a controlling number of the shares of corporation B to unaffiliated corporation C? What if corporation C is an affiliated or sister corporation?

10 NYCRR § 1004.10(b)(5)-(6) state as follows:

(b) Registered organizations shall not:

(5) change the composition of the entity which is the registered organization, including but not limited to, a change in sole proprietor, partner, director, stockholder, member or membership interest of the

Application for Registration as a Registered Organization - Questions and Answers

registered organization without the prior written approval of the department; or

(6) materially modify or revise its operating plan, including its policies and procedures related to cultivation, processing, manufacturing, distributing or dispensing policies or procedures, without prior written approval of the department.

The Department recognizes that, as with all other entities, registered organizations may desire to change their ownership structures. Changes to the ownership structure of a registered organization, by definition, fundamentally alter its composition and capabilities, with ultimate ramifications for patient care. Therefore, any changes in ownership structure require the express written approval of the Department as a necessary condition precedent.

10. 10 NYCRR § 1004.10(a)(7) requires methods of disposal, and 10 NYCRR § 1004.11(l)(1) requires methods of destruction, that are in accordance with the registered organization's approved operating plan. Does the Department currently have an approved or preferred method of disposal/destruction, or general principles for disposal/destruction? What is the preferred method of destruction for lots not meeting the minimum standards, by the State of New York? Is a license holder allowed to destroy marijuana products using an onsite incinerator?

Applicants are required to submit policies and procedures concerning disposal of marijuana and manufactured medical marijuana products. Proper disposal renders a product unrecoverable beyond reclamation. Disposal procedures should incorporate the use of a witness to the disposal. The regulations do not prohibit registered organizations from using an onsite incinerator to destroy marijuana products.

11. Does the DOH have specific guidelines for the management of waste, including soil, water, and plant bio-mass?

Registered organizations must comply with all applicable state and local laws and regulations. This includes any requirements of the Department of Environmental Conservation, the Department of Agriculture and Markets, and any other regulatory authority in New York State concerning soil and water waste. Applicants are required to submit policies and procedures concerning disposal of marijuana and manufactured medical marijuana products.

12. Will the approval of a delivery service be considered routine or extraordinary? Under what circumstances will the Department grant such approval?

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Approval of delivery services will depend upon an assessment by the Department of the need for delivery services to appropriately service certified patients.

13. Can the dispensaries deliver directly to certified patients at health care facilities?

If a registered organization receives prior written approval for a delivery service, the delivery must be made to a certified patient or designated caregiver, as they are the only ones able to lawfully possess medical marijuana. When seeking Department approval for a delivery service, registered organizations will need to describe the details of such delivery and include any specific requirements related to delivery to a certified patient who is located in a health care facility. The delivery approval process will be separate from the application for registration as a registered organization process.

14. Once operational, will each organization be required to start each plant from seed, or will they be allowed to clip clones from a mother plant as long as each new growth is tracked with an appropriate RFID tag?

The regulations do not limit the origin of the first plants. Registered organizations can determine how to start each plant, so long as growth is tracked through the seed to sale software solution provided by the Department.

15. Must the applicant be a New York State registered entity? Please confirm there are no other residency requirements.

The regulations do not specify any residency requirements for entities who wish to apply to become Registered Organizations.

16. The instructions state that material omissions, errors, and misrepresentations, or the failure to provide requested information, may result in denial of the application or “other action” as may be allowed by law. Please clarify what “other action” may be taken. Is denial of the application or “other action” against the Applicant possible even for inadvertent or mistaken, but nonetheless material, omissions and errors?

The Department reserves the right to any and all remedies available to it, including civil and criminal legal action. Denial of an application is possible even for any material omission, error or misrepresentation, of for the failure to provide requested information.

17. Prior to the deadline for applications to be submitted, will the Department be issuing guidance concerning the pre-authorization process or factors to be considered in authorizing or denying access to visitors to a facility of a Registered Organization?

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No. The Department will not issue guidance related to visitor processes prior to the deadline for applications.

Application for Registration as a Registered Organization - Questions and Answers

Timeline

1. To assist with registered organization planning and schedule for implementation, when will the Department expect to be able to share information concerning the medical marijuana seed to sale tracking system, the process and schedule for practitioner registration, and the process and schedule for patient certification and registration?

The seed to sale tracking system contract has been conditionally awarded to a vendor contingent upon approval by the Office for the State Comptroller. The award will be announced in the New York State Contract Reporter. The Department is actively working on the implementation of the Medical Marijuana Program and will post additional information concerning practitioner education and the patient certification and registration process to the Department's Medical Marijuana Program website as soon as it becomes available. The Department will communicate updates with registered organizations throughout the implementation process.

2. If the applicant posts a bond of \$2,000,000 in lieu of providing the real estate documentation requested in the application, what is the timeframe required (after an award) to submit all executed deeds, leases and rental agreements for the various properties? What is the timeframe required (after an award) to submit proof that all local land use/zoning approvals are finalized for the various properties? What is the timeframe required (after an award) to submit Appendix B – Architectural Program for the various properties?

*Registrations are expected to be issued approximately July of 2015. Pursuant to 10 NYCRR § 1004.5(b)(9), "if the applicant posts a bond in lieu of providing the documentation requested herein, the applicant's submission of the applicable executed deeds, leases and rental agreements shall be required **prior to** the issuance of a registration to the applicant, if selected." As stated on Appendix B (DOH 5146), a separate "Appendix B" must be completed for each separate building and/or facility included in the organization's business plan at the time of application. All applicable Appendix B forms are required to be attached with the Applicant's application.*

3. The application is due June 5, 2015. If after submittal, additional information emerges regarding building permits, state of facilities, or other information, is the Registered Organization allowed to submit those updates to the State after the June 5, 2015 submittal?

Per the application instructions, applicants are under a continuing duty to report to the Department any changes in facts or circumstances stated in the application or any newly-discovered or occurring facts or circumstances which are required to be included in the application.

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4. Assuming that questions of a technical nature with respect to completing the RO Application will arise subsequent to the deadline for submission of questions regarding the application, how may a prospective Registered Organization address such questions to the Department?

All questions concerning the application or application process were due to the Department by May 5, 2015 at 4:00 PM ET. The Department will only evaluate questions that were received by the deadline to maintain a fair process for all applicants.

5. Under the regulations, if the commissioner is not satisfied that the applicant should be issued a registration, he or she shall notify the applicant in writing of those factors upon which further evidence is required. To clarify, if there are questions related to the submission of the application, the DOH will notify the applicant and allow them up to 30 days to submit additional material to the commissioner or demand a hearing, or both during the application process?

The Department may seek clarification from the applicant during the application evaluation process by issuing a letter to the individual listed in the application as the primary contact, which will provide a date by which information is required. After the Department has completed its final evaluation of applications, all applicants will be issued a letter providing them with the determination of the Commissioner, to which they will have thirty (30) days to respond.

6. In consideration of the recent enactment of the Compassionate Care Act and promulgation of accompanying regulations, as well as the upcoming submission deadline and length of time that it takes for municipal zoning boards to properly consider applications, what guidance can the Department provide concerning the necessary approvals or information needed to be included in an applicant's application at time of submission?

The proposed regulations were posted to the Department's Medical Marijuana Program website on December 18, 2014, for public comment. There were no substantive changes to the proposed regulations, which were filed for adoption on March 31, 2015. Prospective applicants could have reviewed the regulatory requirements, begun researching prospective manufacturing and dispensing sites, and started to obtain any zoning board approvals that may be necessary for such sites. Appendix B – Architectural Program, requires applicants to provide a timeline for such approvals. If an applicant anticipates zoning board approvals to be required for the manufacturing and/or dispensing facility sites, the anticipated date of completion should be included in the timeline.

7. The DOH is to establish a process and educational course for practitioners approved by the Commissioner on the use of medical marijuana. Can you please provide a timetable

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as to when this course will be offered to practitioners, who will be offering the course, and will the DOH keep a listing practitioners who have taken the course to be available to the public?

Additional information concerning the course and any timelines associated with the course, which must be approved by the Department, will be shared in the future on the Department's Medical Marijuana Program website. This information will not be provided prior to the deadline for submission of applications to become a registered organization. As a part of the practitioner registration process, the Department will document course completion by practitioners. The Department will review all FOIL requests as required by Public Officers Law, Article 6, and respond accordingly.

8. Does the DOH anticipate registering all 5 applicants at the same time or could the DOH give out less than 5 and others later?

The Department anticipates registering five (5) applicants simultaneously, provided that there are five (5) applicants who meet the application requirements.

9. If a registration is surrendered to the department upon failure to operate within six months of the issuance of a registration, will the Department open up the process to additional applicants?

Yes. If a registered organization's registration is surrendered, the Department will open a new application window for the acceptance of applications.

10. If the registered organization has fulfilled its commitments, but the regulatory process has created a situation by which product cannot be offered in a 6 month window, will the Department provide an extension based on circumstances out of their control?

10 NYCRR § 1004.9(a) requires that registered organizations begin operations, to the satisfaction of the Department, within six (6) months of issuance of registration. If a registered organization has fulfilled its commitments but cannot offer product to patients within the six (6) month window because of circumstances out of the registered organization's control, then the Department has the discretion to provide an extension.

11. The DOH allows for up to 5 registered organizations in the first 2 years with an extension. Does the DOH anticipate a process to allow for additional registered organizations after that time frame?

Public Health Law § 3365 authorizes the Commissioner to register additional Registered Organizations and dispensing facilities. Any additional registrations would occur pursuant to a separate application window.

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FOIL

1. Related to FOIL on page 6 of the application, will people or entities submitting questions be publicly disclosed? Will the identity of all proposed shareholders, investors and lenders involved with the applicant be subject to public disclosure during the application process?

The Department will disclose records in response to Freedom of Information Law requests as required by Public Officers Law article 6. If you believe that information you submit to the Department should be excepted from disclosure in accordance with Public Officers Law § 89(5), as “trade secrets” or “critical infrastructure information,” you should request such an exception in accordance with that provision as set forth on page 6 of the Instructions for Application for Registration as a Registered Organization.

2. The discussion of FOIL in the application instructions is limited to “trade secrets: and “critical infrastructure information,” but Public Officers Law 87 contains other exceptions as well. How are these additional exceptions to be identified in the application? What protections does NY State provide to keep the information we share private so that it is not disclosed to other agencies or organizations?

The Department will disclose records in response to Freedom of Information Law requests as required by Public Officers Law article 6. If you believe that information you submit to the Department should be excepted from disclosure in accordance with Public Officers Law § 89(5), as “trade secrets” or “critical infrastructure information,” you should request such an exception in accordance with that provision as set forth on page 6 of the Instructions for Application for Registration as a Registered Organization.

3. Will all applications be available to the public online? If so will applicants be allowed to submit a redacted version of their application asserting FOIL privileges for the redacted portion?

The Department may provide non-confidential information concerning the application process online. In addition, the Department will disclose records in response to Freedom of Information Law requests as required by Public Officers Law article 6. If you believe that information you submit to the Department should be excepted from disclosure in accordance with Public Officers Law § 89(5), as “trade secrets” or “critical infrastructure information,” you should request such an exception in accordance with that provision as set forth on page 6 of the Instructions for Application for Registration as a Registered Organization.

4. Can an application be submitted anonymously, so that the public cannot see the individual owners of the applicant? (Nevada permitted this.)

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Applications must contain the information necessary to complete Appendix A: Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members; applications, therefore, may not be submitted anonymously. If you believe that information you submit to the Department should be excepted from disclosure in accordance with Public Officers Law § 89(5), as “trade secrets” or “critical infrastructure information,” you should request such an exception in accordance with that provision as set forth on page 6 of the Instructions for Application for Registration as a Registered Organization.

5. Which portion(s) of Appendix A and applicant affidavits can be redacted to protect individuals and private entities from the disclosure of confidential information? To what extent will the Department comply with a request to redact personal and financial information provided? Will the financial information set forth in the applications be impounded to protect applicants and individuals from identify theft/bank fraud?

The Department will disclose records in response to Freedom of Information Law requests as required by Public Officers Law, Article 6. If you believe that information you submit to the Department should be excepted from disclosure in accordance with Public Officers Law § 89(5), as “trade secrets” or “critical infrastructure information,” you should request such an exception in accordance with that provision as set forth on page 6 of the Instructions for Application for Registration as a Registered Organization.

Application for Registration as a Registered Organization - Questions and Answers

Labor Peace Agreement

1. Question 86, Labor Peace Agreement, Attachment F. The application refers to "...attached documentation that the applicant has entered into a labor peace agreement...." We interpret "entered into" to mean an agreement executed by the parties. Is this understanding correct? Please provide clarification if the term "entered into" means other forms of documentation such as a finished unsigned labor peace agreement accompanied by a memorandum of understanding or letter of intent signed by the parties or other documentation alternatives.

The labor peace agreement must be signed in order to demonstrate that the applicant has entered into this agreement.

2. Is the applicant required to have a signed labor peace agreement with all potential labor organizations or simply require to have a signed labor peace agreement with one labor organization which intends to organize some portion of the employees? If the applicant is to have a signed labor peace agreement with all labor organizations, must it execute the same labor peace agreement for all or may it enter into different labor peace agreements for different unions?

Public Health Law § 3365(a)(iii) requires an applicant to submit documentation that it has entered into a labor peace agreement with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees. The applicant may choose to enter into an agreement with one or more labor organizations, provided that the agreements are executed and the agreements collectively cover all of the applicant's employees.

3. Does section 86 of the application give an applicant the right to propose terms or to decline unreasonable terms in labor peace agreements?

Section 86 requires that the applicant submit documentation that the applicant has entered into a labor peace agreement. Public Health Law § 3360 (14) defines a labor peace agreement as an agreement between an entity and a labor organization that, at a minimum, protects the state's proprietary interests by prohibiting labor organizations and members from engaging in picketing, work stoppages, boycotts, and any other economic interference with the registered organization's business. An entity is free to negotiate the terms of the labor peace agreement and must ensure that the minimum requirements set forth in statute are met.

4. The Public Health Law requires applicants who wish to become a registered organization to enter into labor peace agreements with a labor organization. Does the Department have any model forms, examples or other guidance on a satisfactory labor peace agreement?

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No. Public Health Law § 3360(14), defines a “labor peace agreement” as “an agreement between an entity and a labor organization that, at a minimum, protects the state’s proprietary interests by prohibiting labor organizations and members from engaging in picketing, work stoppages, boycotts, and any other economic interference with the registered organization’s business.” Applicants must ensure that they submit a labor peace agreement that meets these minimum requirements.

5. What happens if no unions want to participate in the cannabis industry?

Public Health Law § 3365(1)(a)(iii) requires that an applicant demonstrate that it has entered into a labor peace agreement with a bona-fide labor organization. The statute further makes clear that maintenance of a labor peace agreement shall be an ongoing material condition of certification. Applicants will need to identify appropriate labor organizations to negotiate with in order to meet the requirements of statute and regulation.

Application for Registration as a Registered Organization - Questions and Answers

Consulting

1. Is it acceptable for an individual to have consulting agreements with more than one Registered Organization applicant?

The regulations do not prohibit consultants from entering agreements with more than one applicant for registration as a registered organization. However, it is the consultant's responsibility to disclose potential conflicts of interest to the applicants they may represent. Likewise, applicants should exercise due diligence to ensure that any consultants they select are free of potential conflicts.

2. With respect to the Application, Attachment G: would contracts with public relations agencies or government relations firms be captured under this information request?

Yes. 10 NYCRR § 1004.5(b)(10) requires the applicant to attach a financial statement setting forth all elements and details of any business transactions connected with the application, including but not limited to all agreements and contracts for consultation and/or arranging for the assistance in preparing the application. This requirement encompasses contracts and agreements with any public or governmental firms or agencies.

3. Please confirm that applicants are required to provide a statement summarizing all business transactions connected with the application (including any agreements thereto), but are not required to provide the agreements themselves.

Correct. 10 NYCRR § 1004.5(b)(10) requires applicants to attach only a financial statement, not the actual agreements.

4. What other documents other than the Consulting/Services Agreement is needed for third party vendors?

If the question is referencing number 87 from Section I of the application, the applicant must attach a financial statement setting forth all elements and details of any business transactions connected with the application, including but not limited to all agreements and contracts for consultation and/or arranging for the assistance in preparing the application pursuant to 10 NYCRR § 1004.5(b)(10). The financial statement is the document that is required.

5. The application requests information from companies that will consult with the applicant (question 87). May such entities be out-of-state or must such consulting companies all be located within New York? If the applicant also owns the consulting companies and there

Application for Registration as a Registered Organization - Questions and Answers

are no formal contracts, will work orders be sufficient to meet the requirements of the Department?

The regulations do not limit the residency of consultants. The regulations require that a financial statement setting forth all elements and details of any business transactions connected with the application be included, in Attachment G. If an applicant owned the consulting company used to complete the application and there were no formal contracts, such work orders would be sufficient proof.

6. Are there consulting firms that can assist in the application process for obtaining registration as a Registered Organization?

Applicants are free to utilize the services of consulting firms, if they so choose, to assist them in preparing applications for registration to become a Registered Organization. The Department does not endorse or recommend any particular consulting firm. Please note, pursuant to 10 NYCRR 1004.5(b)(10), an applicant must submit a financial statement setting forth all elements and details of any business transactions connected with the application, including agreements and contracts for consultation and/or arranging for assistance in preparing the application.

Application for Registration as a Registered Organization - Questions and Answers

Application Evaluations/Scoring

1. Please identify the person or persons who will be reviewing applications.

A team of employees of the New York State Department of Health will review all accepted applications.

2. Please describe the application review process, specifically including whether applications will be “scored” and the method of scoring the Department will use. Will the Department share its weighting system with applicants or provide additional guidance as to how the Department’s reviewers will be scoring responses in the application, particularly with respect to parts of the application that call for a narrative response?

Applications will be evaluated by a team of Department employees using a combination of pass/fail criteria, based upon an applicant’s ability to meet all requirements of the application defined in 10 NYCRR §1004.5, as well as using scored criteria with weights. Narrative responses should be detailed with sufficient information to demonstrate the applicant’s ability to meet the regulatory requirements of 10 NYCRR Part 1004 and to comply with all applicable state and local laws and regulations. Narratives will be evaluated based upon the quality of response and demonstrated abilities, and scored accordingly. The weighting system will not be shared prior to the scoring of applications.

3. Will registered organizations in good standing be given preference to renew their registrations, or will new applicants also be considered at the close of the initial registration term?

Registered organizations will have the opportunity to renew their registrations prior to the Department’s acceptance of new applications.

4. Page 3 of 6 (Instructions), Criterion 7: What specifically is meant by, “it is in the public interest that such registration be granted to the applicant?” How is an applicant to demonstrate that it is in the “public interest” that the registration be granted? Are there specific criteria that the State will be considering in making such a judgment, or specific criteria that applicants should be addressing? If so, what are they?

The Department will consider the application as a whole when making the determination that it is in the public interest that the registration be granted to a particular applicant.

5. Where in the application can we put Letters of support from patient advocacy groups, elected officials or character references? Do letters of support need to be site or

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applicant-specific? Should letters of support be sent directly to DOH or be incorporated into the application?

Letters of support may be included with Attachment M if they provide evidence of an applicant's ability to comply with all applicable state and local laws and regulations relating to the activities in which it intends to engage under the registration. Character references or other such letters of personal recommendation may be included with Appendix A. Letters of support must be specific to the applicant.

6. If a Registered Organization applicant would like to include a display of public interest in the application (included in Criteria for Consideration of Application, question 7 page 3 of instructions) and/or letters of support from town officials, county officials, sheriffs or patient advocacy groups where or how should these be included in the application?

All supporting documentation should be labeled to correspond to the section of the application to which it pertains. For example, if such documentation is used to show that the applicant will comply with applicable state and local laws, then such documentation should be labeled and submitted with Attachment M. If such documentation demonstrates consists of approvals the applicant has secured, it should be attached with Appendix B – Architectural Program. General letters of support will not be reviewed.

7. Are there weights associated with the scoring of each section of the application?

Yes, the Department will be using a weighted scoring methodology.

8. When reviewing zoning approval can an applicant include a letter of support from a town official, a county official and/or sheriff?

Yes, applicants may submit letters of support and any additional supporting documentation. All supporting documentation should be labeled with the section of the application to which it pertains.

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Miscellaneous

1. Is it acceptable for one individual to have an interest in more than one Registered Organization applicant? If there is a joint application made and one of the joint applicants takes a “non-lead” status in said joint application (e.g., an acute care hospital), can that “non-lead” joint applicant participate in more than one application as a “non-lead” joint applicant (i.e., with a different joint applicant)?

An individual can have an interest in more than one applicant. However, particular circumstances could present issues that would require review. The Department will not accept joint applications (i.e., applications submitted by co-applicants). Public Health Law § 3364(1) provides that a registered organization shall be a for-profit business entity or a not-for-profit corporation organized for the purpose of acquiring, possessing, manufacturing, selling, delivering, transporting, distributing or dispensing of marijuana for certified medical use.

2. Can an applicant submit a print application in binders (one original application with nine copies) with dividers for the various sections?

Yes. In accordance with the application submission instructions, applicants must submit all attachments associated with the Application to Become a Registered Organization, all of which must be single sided and securely bound. A binder with dividers will be acceptable. An electronic copy (CD or USB flash drive) of the application and all attachments is also required.

3. Regarding the application instructions, can an applicant use color in the application? Are there formatting requirements related to fonts, margins, etc.? Can exhibits like site plans and SOP flow charts be presented in horizontal layout for enhanced readability?

Applicants should ensure that all documentation is clearly and easily legible. There are no specific formatting requirements related to color, fonts, margins or layout orientation.

4. Are applicants allowed to submit more than one application? If so, are applicants allowed to reuse sites on multiple applications?

No.

5. Must the primary contact person be a proposed owner/member/director/officer of the Registered Organization, or may it be someone else, such as an employee of or consultant to the Registered Organization?

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Applicants may select whomever they wish to be their primary contact, so long as such person is knowledgeable about the application and will be responsive to Department.

6. May applicants submit supplemental information not specifically requested, in order to ensure that the Department has sufficient information to enable proper evaluation according to the Criteria for Consideration of Applications? For instance, can an applicant submit information about its clinical research partnerships, or information showing that they are “ready, willing, and able to properly carry on the activities set forth in 10 NYCRR Part 1004?” May applicants add supplemental materials to its application and label it as ‘Appendix C’?

Applicants may add documentation as necessary as long as items are clearly labeled and legible and pertain to a specific application requirement outlined in 10 NYCRR §1004.5.

7. What other documents are needed other than the Management Services Agreement as to that Management entity?

It is unclear what this question is asking or referring to. If the question is referencing number 87 from Section I of the application, the applicant must attach a financial statement setting forth all elements and details of any business transactions connected with the application, including but not limited to all agreements and contracts for consultation and/or arranging for the assistance in preparing the application pursuant to 10 NYCRR § 1004.5(b)(10). The financial statement is the document that is required.

8. Section 1004.1 of the regulations refers to “practitioners;” however, the referenced section requires licensure as a physician. Can the Department confirm that all other practitioners (including CNP and PA) are ineligible to certify patients for use of medical cannabis?

Only licensed physicians in good standing and practicing medicine in New York State, as defined in article one hundred thirty one of the Education Law, may be eligible to certify patients for the medical use of marijuana. Certified Nurse Practitioners and Physician Assistants are not eligible to certify patients.

9. Will qualified physicians be regulating dosages for each patient, or will each certified patient be deciding that for himself or herself?

Registered practitioners will make dosing recommendations for certified patients.

10. What medical guidelines will be used to support practitioner diagnoses of neuropathies and the associated symptom of severe or chronic pain?

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Certifying practitioners, not employees of registered organizations, must appropriately support their diagnoses.

11. Are there any requirements for a business name that will be tied to the growing operation and the license if/when acquired? For example, when starting a medical practice, one has to register the business with the Department of Health and the business name has to abide by the Department's naming regulations. Are there similar requirements in the Medical Marijuana Program?

There are no specific requirements for the business name of the growing operation and the registration. Applicants should be aware, however, of other laws that may apply, such as New York Business Corporation Law § 301 and New York Limited Liability Company Law § 204.

12. Is the Registered Organization application process subject to the rules governing procurement lobbying? If so, when does the restrictive period begin?

No. The Registered Organization application process is not a governmental procurement, as the applicants selected will be issued a registration and not a contract. According to the Application Timeline provided in the Instructions for Application for Registration as a Registered Organization (DOH-5150), all questions were to be submitted by 4:00 p.m. on May 5, 2015. The Department will not answer questions submitted after that time about the application or application process.

13. Will the Department mandate a specific seed to sale tracking/inventory program for all Registered Organizations or should each Registered Organization specify an inventory tracking program within their application?

The Department posted an RFP (Request for Proposals) for a seed to sale software vendor. The RFP is located on the Department's Grants/Funding Opportunities web page, available at: <http://www.health.ny.gov/funding/rfp/15978/index.htm>. All Registered Organizations will be required to use the seed to sale software that is awarded through this RFP process.

14. Are there estimates available from the Department of Health related to the number of individuals who would qualify for the Medical Marijuana Program given the current list of debilitating medical conditions?

No. The Department is not presently offering an estimate of how many individuals would qualify for the Medical Marijuana Program given the list of conditions covered. The current list of serious medical conditions and clinically associated or complicating

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conditions are not the only factors in determining who may qualify for the Medical Marijuana Program. Other factors, such as whether a physician determines that the patient is likely to receive therapeutic or palliative benefit from the use of medical marijuana, or whether a patient wishes to participate in the Medical Marijuana Program, affect estimates of the number of individuals who may qualify for the Medical Marijuana Program.

15. Can the Department provide the full list of growers or producers of medical marijuana in New York State?

The Application to Become a Registered Organization was released on April 27, 2015, with the deadline for receipt of applications on June 5, 2015. Registered Organizations are for-profit business entities or not-for-profit corporations organized for the purpose of acquiring, possessing, manufacturing, selling, delivering, transporting, distributing, or dispensing marijuana for certified medical use. The Department will announce which applicants have been granted registration to become Registered Organizations in approximately July, 2015.

16. How does the Department plan on addressing access issues for those patients who do not have access to public transportation especially in rural areas?

The Department will carefully monitor patient access following implementation of the program, including whether delivery of medical marijuana is necessary to accommodate patient needs. In addition, Public Health Law § 3362 allows certified patients to have up to two designated caregivers to possess, acquire, deliver, transfer, transport, or administer medical marijuana produced in accordance with the State's Medical Marijuana Program.

17. Are there page limits for any of the sections of the Application for Registration as a Registered Organization?

No. Applicants are encouraged to provide the level of detail necessary to fully respond to each requirement.

18. Because the Application to Become a Registered Organization does not appear to be a request for proposals or involve a government procurement, does that mean that the State Finance Law would not apply to the application process? Are there any rules regarding the selection process, generally, perhaps similar to those covering state franchises authorized by the Racing, Pari-Mutuel Wagering, and Breeding Law? What rules are in place governing an applicant's acts (communications, especially) during the application process?

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The Registered Organization application process is not considered a governmental procurement as the applicants selected will be issued registrations, not contracts. The regulations for the medical marijuana program define the application requirements and the criteria for consideration of applications. The application instructions provided for a question and answer process whereby interested parties were able to submit questions through email only concerning the application and application process. Questions were accepted until May 5, 2015.

19. Once an application is submitted to the Department of Health by the June 5, 2015 deadline, and assuming that the application is NOT selected as one of the five initial registered organizations, will the application continue to be considered by the Department in the event the Commissioner expands the number of registered organizations, or will an additional application be required in the event that the Commissioner expands the number of registered organizations? In the event the Commissioner expands the number of registered organizations, will there be an additional application period (after the June 5, 2015 deadline) during which new applications will be accepted and considered by the Department?

Should the Commissioner decide at a subsequent time to expand the number of registered organizations, any applications submitted pursuant to this initial application window that were not selected would need to be resubmitted along with a new application fee in order to be considered for registration.