



Overview

Pursuant to Public Health Law (PHL) § 3365(9), the Commissioner of the New York State Department of Health ("Department") shall register up to five applicants as registered organizations to manufacture and dispense approved medical marijuana products in New York State. In accordance with PHL § 3365(9), the Department will register five applicants as registered organizations, and is accepting applications from April 27, 2015 through and including May 29, 2015 for this purpose.

Each applicant must submit two fees with its application: a non-refundable application fee in the amount of \$10,000, and a registration fee in the amount of \$200,000. The fees are payable together or separately by certified check to the "New York State Department of Health."

The \$200,000 registration fee will be refunded to the applicant only if the applicant is not issued a registration.

Registrations issued by the Department shall be valid for a period of two (2) years. The Department will evaluate all completed applications received on or before the deadline in accordance with the criteria set forth in PHL § 3365(3) and Title 10 of the New York Code of Rules and Regulations (NYCRR) § 1004.6.

Application Timeline

Table with 2 columns: Event, Date. Rows include Application Window Opens (04/27/2015), Deadline for Submission of Application Questions (05/05/2015 4:00 PM ET), Deadline for Department Response to Application Questions (05/14/2015), Deadline for Department Receipt of Applications (05/29/2015), Registrations Issued (Estimated Timeframe) (Approximately July 2015).

Important Notices

- 1. The Department shall only review completed applications received by the above Deadline for Department Receipt of Applications and for which the application and registration fees have been submitted. Any cost incurred by the applicant in connection with the application, including but not limited to obtaining or creating the information, documents, materials and certifications required by the application, shall not be a charge upon the Department.
2. All notices from the Department to an applicant regarding an application that has been submitted will be sent to the email address that the applicant provides on the registration application Form DOH-5138. Applicants must immediately notify the Department of any change of address by email only at mmp@health.ny.gov with the subject line "Registered Organization Address Change."



3. The applicant shall be under a continuing duty to report to the Department any change in facts or circumstances stated in the application or any newly-discovered or occurring fact or circumstance which is required to be included in the application.
4. The applicant shall verify the truth and accuracy of the information and documentation submitted in its application. Any material omissions, material errors, misrepresentations, or failure to provide any requested information may result in the denial of the application or other action as may be allowed by law. The Department may, in its discretion, reject an application if it determines that information contained therein is not true and accurate.
5. An applicant that is issued a registration to operate as a registered organization shall be subject to and operate in accordance with Title V-A of Article 33 of the PHL and 10 NYCRR Part 1004 and all other applicable state and local laws and regulations.

Questions and Answers

All questions about the application or application process must be submitted to the Department by May 5, 2015. Questions must be submitted **by email only** at mmp@health.ny.gov with the subject line "Registered Organization Application Question" and include the reference to the application section and field number, where applicable. Applicants should identify and bring any questions to the Department's attention as soon as possible. The Department reserves the right to contact applicants for clarification and/or additional information concerning their questions. The Department will evaluate questions as they are received up until the deadline for submission of questions. Responses to all questions will be posted to the Department's web page (https://www.health.ny.gov/regulations/medical_marijuana/) by May 14, 2015. No questions will be accepted by telephone or means other than through the email address noted above.

Acceptance of Applications

The Department will not accept for consideration any application which is not complete by May 29, 2015 4:00 PM ET. An application is not complete unless the following have been received by the Department:

1. The certified check(s) made out to the "New York State Department of Health" totaling \$210,000, consisting of the \$10,000 application fee (non-refundable) and the \$200,000 registration fee (refundable if the Department does not select the applicant as a Registered Organization); and
2. The registration application Form DOH-5138, together with all attachments, appendices and supporting documentation, including:
 - a. Attachments "A" through "M" as required by Section I;



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- b. The applicant's chief executive officer duly authorized by the board of a corporate applicant, or a general partner or owner of a proprietary applicant, has signed the application and the signature is notarized;
 - c. Appendix A – Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members (Form DOH-5145); and
 - d. Appendix B – Architectural Program (Form DOH-5146).

Criteria for Consideration of Applications

The Department shall review all information and documentation submitted by the applicant, and consider the criteria set forth in PHL § 3365 and 10 NYCRR § 1004.6, in making its determination. The applicant's submissions should demonstrate how it will meet said criteria, including but not limited to:

- 1. the ability to manufacture approved medical marijuana products, each with a consistent cannabinoid profile (the concentration of total tetrahydrocannabinol (THC) and total cannabidiol (CBD) will define the brand), and each able to pass the required quality control testing as further described in 10 NYCRR § 1004.11;
- 2. the ability to produce sufficient quantities of approved medical marijuana products, as further described in 10 NYCRR § 1004.11, as necessary to meet the needs of certified patients;
- 3. the ability to maintain effective control against diversion of marijuana and medical marijuana products as further described in 10 NYCRR § 1004.13;
- 4. the ability to comply with all applicable state and local laws and regulations;
- 5. that, if selected, the applicant is ready, willing, and able to properly carry on the activities set forth in 10 NYCRR Part 1004;
- 6. possession of, or the right to use, sufficient real property, buildings, and equipment to properly carry on the activity described in its operating plan, or in the alternative, the applicant has posted a bond in the amount of \$2,000,000;
- 7. that it is in the public interest that such registration be granted to the applicant;
- 8. that the applicant's four proposed dispensing facilities are geographically distributed. 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.



9. the moral character and competence of board members, officers, managers, owners, partners, principal stakeholders, directors, and members of the applicant's organization;
10. the applicant's proposed operating plan and suitability of the proposed manufacturing and dispensing facilities, including but not limited to the suitability of the location and the architectural and engineering design of the proposed facilities; and
11. the applicant has entered into a labor peace agreement, as defined in PHL § 3360(14), with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees.

Note: In demonstrating how such criteria are met, the information and submissions made as part of the application must contain specifics to show compliance with the applicable requirements of Title V-A of Article 33 of the PHL and 10 NYCRR Part 1004.

The Department reserves the right to interview any applicant, and/or any individuals identified in an application, to ensure the accuracy and completeness of an application, and to use the information obtained from any such interview in considering the application pursuant to the statutory and regulatory criteria

The applicant shall allow reasonable access to the Department and/or its authorized representatives for the purpose of conducting an on-site survey or inspection of the applicant's proposed manufacturing and/or dispensing facilities. An entity selected as a registered organization is subject to ongoing audits by the Department, which may include unannounced site visits. The registered organization shall provide reasonable access to the Department of its facilities, books, records, personnel, etc.

Clarification Process

The Department reserves the right to contact any applicant after the submission of its application for the purpose of clarifying any item submitted in its application or to request additional information to ensure mutual understanding. This contact may include written questions, interviews, site visits, or requests for corrective pages in the application. Responses must be submitted to the Department within the time specified in the request. As applicable, clarifications will be treated as addenda to an application. Failure to comply with a request for additional information may result in rejection of the application as noncompliant. Nothing herein shall be deemed to extend the deadline for Department Receipt of completed applications.



Application Submission Instructions

1. Complete Form DOH-5138 and include all necessary relevant documents for each item requested in the application. All attachments provided by the applicant must be clearly labeled as to which section the information corresponds so that it is clear to the Department that all requested information is provided.
2. Complete Appendix A: Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members Form DOH-5145. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity. For example, if one of the owners identified in the application is a corporation, Appendix A must be completed by each of the corporation's board members, officers, owners, partners, principal stakeholders, directors, and members. If an interest or ownership in the entity is not held by a natural person, Appendix A must be completed going back to the level of ownership by a natural person (principal stakeholders).
3. Complete Appendix B: Architectural Program Form DOH-5146.
4. Submit the following items to the address below by the application deadline (the Department will only review completed applications received by the application deadline):
 - a. one original and nine copies of the completed application FORM DOH-5138, Appendix A Form DOH-5145, Appendix B Form DOH-5146, and all attachments required by the application, all of which must be single-sided and securely bound;
 - b. a CD, DVD, or USB flash drive containing an electronic version of your completed application, Appendix A, Appendix B, and all attachments in a searchable PDF file; and
 - c. certified checks payable to the "New York State Department of Health" in the amounts of \$10,000 for the non-refundable application fee and \$200,000 for the conditionally refundable registration fee; or a certified check payable to the "New York State Department of Health" in the amount of \$210,000 for both fees.

ADDRESS: **New York State Department of Health**
 Bureau of Narcotic Enforcement
 Medical Marijuana Program
 150 Broadway
 Albany, NY 12204

Applicants who wish to hand deliver their applications must notify the Department by email at mmp@health.ny.gov a minimum of twenty-four (24) hours in advance of the anticipated delivery date to make delivery arrangements and include "Registered Organization Application Delivery Request" in the subject line.



Freedom of Information Law

Disclosure of information contained in submitted applications is subject to the laws of the State of New York, including the Freedom of Information Law (FOIL) contained in Article 6 of the Public Officers Law. **Information constituting trade secrets or critical infrastructure information for purposes of FOIL should be clearly marked and identified as such by the applicant upon submission. Each page containing such information should contain a footer notifying the Department that the material on the page is requested to be exempt from disclosure under FOIL pursuant to one of the exceptions referred to above. Applicants should not merely state generally that the application is proprietary in nature and, therefore, not subject to release to third parties. Determinations as to whether the materials or information may be withheld from disclosure will be made in accordance with Public Officers Law § 87.**