

Application Instructions: Manufacturing Facilities

(Revised March 28, 2018)

Application Due Date

April 19, 2018

4:00 PM CST



Division of Medical Marijuana
600 East Blvd Ave, Dept 301
Bismarck, ND 58505-0200
Phone: 701.328.1311
Email: medmarijuana@nd.gov

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North Dakota Department of Health Division of Medical Marijuana Manufacturing Facilities Application

Overview:

North Dakota Century Code (NDCC) Chapter 19-24.1 authorizes the North Dakota Department of Health (Department) to establish a medical marijuana program to allow for the production, processing, sale, and dispensing of usable marijuana.

The Department is accepting applications from entities interested in obtaining a registration certificate to operate a manufacturing facility. A manufacturing facility is a Department registered entity authorized to produce and process and to sell usable marijuana to a Department registered dispensary. The requirements related to the operation of a manufacturing facility are included in North Dakota Century Code (NDCC) Chapter 19-24.1 and North Dakota Administrative Code (NDAC) Chapter 33-44-01.

Information Management System:

The Department has selected BioTrackTHC as the state's information management system. A manufacturing facility has the authority to select a different inventory control information system for its use. However, a manufacturing facility's inventory control information system must adequately interface with the BioTrackTHC system. If a manufacturing facility's selected inventory control information system does not adequately interface, as determined by the Department, the Department has the authority to require the manufacturing facility to use the BioTrackTHC system.

Number of Registrations and Registration Process:

The Department is accepting registration applications for two manufacturing facilities to be located throughout North Dakota. The Department reserves the right to register less than two manufacturing facilities. If the Department determines additional manufacturing facilities are necessary to increase access to usable marijuana, the Department may register additional manufacturing facilities.

The Department will deposit all nonrefundable application fees at the close of the application period. In accordance with NDCC Section 19-24.1-14, only complete applications are eligible for Department review. The requirements for a complete application are included in NDCC Chapter 19-24.1 and NDAC Chapter 33-44-01.

A review panel will review all complete applications using a 'blind review.' The review panel will not have access to identifiable entity information or individual names. The review panel will select the two manufacturing facility applicants eligible for registration. Applicants notified of their eligibility for registration must comply with the requirements in NDCC Section 19-24.1-15 in order to receive a registration certificate. All Department decisions regarding the selection of manufacturing facility applicants eligible for registration are final.

Any applicant awarded a manufacturing facility registration through the Department shall operate in accordance with the representations made in its application, or as modified upon mutual agreement with the Department.

Timeline:

EVENT	DATE
Open application period begins	March 16, 2018
Deadline for submission of application questions	March 23, 2018
Deadline for Department response to application questions	March 28, 2018
Open application period ends	April 19, 2018
Department will select applicants eligible for registration (estimated)	May 17, 2018

Application Fees:

A nonrefundable application fee of \$5,000 is required with the submission of each application. A check should be made to the North Dakota Department of Health, Medical Marijuana Program.

Application Deadline and Submission:

A complete application and the \$5,000 nonrefundable application fee must be mailed to:

**North Dakota Department of Health
Accounting Division
600 East Blvd Ave, Dept 301
Bismarck, ND 58505-0200**

The Department will date stamp each application upon receipt. Faxed or emailed applications will not be considered. It is the applicant's responsibility to allow sufficient time to address potential delays and ensure the application is submitted on or before the due date. The application must be received by the Department's Division of Accounting by 4:00 p.m. (central standard time) on April 19, 2018. Late applications will not be accepted.

Communication with the Department:

All questions about the application and the application process must be submitted to the Department by email at medmarijuana@nd.gov. Emails should include in the subject line "Manufacturing Facility Application Question." Questions and answers of a substantive nature will be posted on the Division of Medical Marijuana's website <https://www.ndhealth.gov/MM/> to ensure all applicants have access to the same information. All other communication, except for contacting the Division of Accounting as described in the following section "Modifications to Applications," with Department personnel is prohibited.

Modifications to Applications:

If an applicant deems it necessary to modify, add, or delete information in a previously submitted application, the applicant must submit a new, complete application, including a new \$5,000 nonrefundable application fee before the application deadline. The original application and check will be returned to the applicant upon receipt of the revised application; or, upon the applicant's request, shredded by the Department. The Division of Accounting may be contacted at 701.328.2392 to confirm receipt of an application or to request withdrawal of a previously submitted application.

Disqualifications:

The Department may disqualify any applicant who:

- Fails to submit a complete application.
- Fails to pay the application fee prior to the deadline.
- Submits incomplete, false, inaccurate, unresponsive, or misleading information.

The Department's decision to disqualify an applicant is final.

Scoring of Applications:

Only complete applications will be eligible for review and scoring by the Department. The application review panel established by the Department will only review and score all complete applications after the close of the open application period. The review panel will receive a copy of each complete application. All personal and identifying information in an application will be redacted by the Division of Accounting prior to the review panel receiving, reviewing, and scoring the applications.

Each panel member will review and score every complete application. The cumulative total of all the scores assigned to an application by each panel member is the final score. The final score will determine which applicants are eligible for registration. The Department reserves the right to select fewer than two applicants to be eligible for registration.

Scored Elements for Manufacturing Facility Applications:

Category	Points Possible
Suitability of Facility Location	3
Character and Experience	10
Operations and Services Plan	15
Recordkeeping	3
Safety, Security, and Preventing Diversion	8
Affordability	5
Packaging and Labeling	4
Testing of Marijuana and Usable Marijuana	4
Plan for Producing	25
Plan for Processing	15
Types of Usable Marijuana to Transfer to a Dispensary	5
Transportation	3
TOTAL	100

See Appendix A for additional scoring criteria.

Disclaimer:

The number of qualifying patients participating in the Medical Marijuana Program is unknown; therefore, the demand for usable marijuana is unknown. The Department does not provide any assurances regarding the demand for usable marijuana under the program.

How to Apply:

For an application to be complete and eligible for review, the applicant must follow these instructions:

1. Be familiar with NDCC Chapter 19-24.1 and NDAC Chapter 33-44-01 that governs the Medical Marijuana Program, including manufacturing facilities. The state law and administrative rules are available for review on the Division of Medical Marijuana website (<http://www.ndhealth.gov/MM/>). Applicants should use the statutory definitions to assist with completing the application. Applications that do not meet all criteria set forth in NDCC Chapter 19-24.1 and NDAC Chapter 33-44-01 will not be considered for review.

2. Hand written applications will not be accepted. Applicants should complete application forms prior to printing. Application forms will expand to fit all information submitted.
3. Applicants are solely responsible for submitting all required forms and payment.
4. Submit a check payable to the North Dakota Department of Health, Medical Marijuana Program in the amount of \$5,000.
5. Attach a one page cover letter to the application materials.
6. Complete and submit **Form A**, which includes:
 - a. Legal name and physical address of the applicant.
 - b. Certification of proposed location to a pre-existing public or private school.
 - c. Attachments to Form A:
 - (1) Articles of incorporation or articles of organization.
 - (2) Bylaws or operating agreement.
 - (3) Evidence of the applicant's registration with the North Dakota Secretary of State and certificate of good standing.
7. Complete and submit **Form B**, which includes:
 - a. Evidence of approval from local zoning authority.
8. Complete and submit **Form C**, which includes:
 - a. The name, address, and date of birth of each principal officer, board member, member-manager, manager, or governor of the proposed manufacturing facility.
 - b. Consent to a criminal history record check for each principal officer, board member, member-manager, manager, or governor of the proposed manufacturing facility.

If the applicant needs additional space to add more names and accompanying information, please continue on a new Form C.
9. Complete and submit **Form C1**, which includes (**new form added on March 28**):
 - a. The name, address, and date of birth of employees, volunteers, and agents of the proposed manufacturing facility (which includes consultants). If none or unknown, please indicate "None" or similar on Form C1.

- b. Consent to a criminal history record check for each employee, volunteer, and agent of the manufacturing facility.

If the applicant needs additional space to add more names and accompanying information, please continue on a new Form C1.

10. Complete and submit **Form D**, which includes:

- a. A description of each principal officer, board member, member-manager, manager, or governor's relevant experience (including training or professional licensing related to medicine, pharmaceuticals, natural treatments, botany, food science, food safety, production, processing, and experience running a business entity) and other pertinent information.

If the applicant needs additional space to add more descriptions and accompanying information, please continue on a new Form D.

11. Complete and submit **Form D1**, which includes (**new form added on March 28**):

- a. A description of each employee, volunteer, and agent's experience, training, and other pertinent information. If none or unknown, please indicate "None" or similar on Form D1.

If the applicant needs additional space to add more descriptions and accompanying information, please continue on a new Form D1.

12. Complete and submit **Form E**, which includes:

- a. A list of all individuals or business entities having direct or indirect authority over the management or policies of the proposed manufacturing facility.
- b. A list of all individuals or business entities having an ownership interest in the proposed manufacturing facility, whether direct or indirect, and whether the interest is in profits, land, or building, including owners of any business entity that owns all or part of the land or building.
- c. The identity of any creditor holding a security interest in the proposed manufacturing facility premises.
- d. The total amount of capital and source of funds that will be used to open the proposed manufacturing facility.
- e. A description of how the amount of capital included in Form E is sufficient to operate the proposed manufacturing facility.

If the applicant needs additional space to add more names and accompanying information, please continue on an additional new Form E.

13. Complete and submit **Form F**, which includes:

- a. A copy of a complete Operations Manual which demonstrates compliance with NDCC Chapter 19-24.1. Applicants must remove all references to business/entity names, personnel names, and other similar identifying information from the Operations Manual. Use of the term "Business" or similar verbiage may be used in place of the business/entity name. Use of titles may be used in place of personnel names.
- b. Potential staffing of the proposed manufacturing facility.
- c. Description of training curriculum for manufacturing facility agents.
- d. Description of the plans to ensure an adequate supply of usable marijuana for registered qualifying patients and registered designated caregivers.
- e. Description of procedures to ensure accurate recordkeeping.
- f. Description of the enclosed, locked facility to be used in the production and processing of marijuana, including steps to be taken to ensure the production and processing is not visible from the street or other public areas.
- g. Description of proposed security and safety measures and procedures for safety measures, security measures, and prevention of diversion and theft.
- h. An example of the design and security features of usable marijuana containers and a description of packaging and labeling procedures (may attach a picture of proposed containers).
- i. Description of procedures for transportation of usable marijuana.
- j. Description of how the proposed manufacturing facility will make products available on an affordable basis to registered qualifying patients with limited financial resources.

14. Complete and submit **Form G**, which includes:

- a. Description of producing plans.
- b. Description of processing plans.

15. Complete and submit **Form H**, which includes the Attestation Form.

NOTE: If you have difficulty accessing the PDF application form, please verify you have a current version of Adobe Reader installed on your computer. We also strongly recommend the use of the Internet Explorer 11 as your browser. The Microsoft Edge browser is not supported at this time. We do have browser instructions for Chrome and Firefox at <https://www.nd.gov/eforms/>. You may also right-click the form link and choose Save Link As to save, complete and send the form on your desktop.

Appendix A Scoring Criteria

Suitability of Facility Location	
Point Value	Explanation
0	Not addressed or response of no value
1	Fair. Limited applicability
2	Good. Some applicability
3	Excellent. Total applicability

Character and Experience	
Point Value	Explanation
0	Not addressed or response of no value
1-2	Fair. Limited applicability
3-5	Good. Some applicability
6-8	Very Good. Substantial applicability
9-10	Excellent. Total applicability

Operations and Services Plan	
Point Value	Explanation
0	Not addressed or response of no value
1-3	Fair. Limited applicability
4-7	Good. Some applicability
8-11	Very Good. Substantial applicability
12-15	Excellent. Total applicability

Recordkeeping	
Point Value	Explanation
0	Not addressed or response of no value
1	Fair. Limited applicability
2	Good. Some applicability
3	Excellent. Total applicability

Safety, Security, and Preventing Diversion	
Point Value	Explanation
0	Not addressed or response of no value
1-2	Fair. Limited applicability
3-4	Good. Some applicability
5-6	Very Good. Substantial applicability
7-8	Excellent. Total applicability

Appendix A Scoring Criteria

Affordability	
Point Value	Explanation
0	Not addressed or response of no value
1-2	Fair. Limited applicability
3	Good. Some applicability
4-5	Excellent. Total applicability

Packaging and labeling	
Point Value	Explanation
0	Not addressed or response of no value
1	Fair. Limited applicability
2	Good. Some applicability
3	Very Good. Substantial applicability
4	Excellent. Total applicability

Testing of Marijuana and Usable Marijuana	
Point Value	Explanation
0	Not addressed or response of no value
1	Fair. Limited applicability
2	Good. Some applicability
3	Very Good. Substantial applicability
4	Excellent. Total applicability

Plan for Producing	
Point Value	Explanation
0	Not addressed or response of no value
1-6	Fair. Limited applicability
7-12	Good. Some applicability
13-19	Very Good. Substantial applicability
20-25	Excellent. Total applicability

Plan for Processing	
Point Value	Explanation
0	Not addressed or response of no value
1-3	Fair. Limited applicability
4-7	Good. Some applicability
8-11	Very Good. Substantial applicability
12-15	Excellent. Total applicability

Appendix A Scoring Criteria

Types of Usable Marijuana to Transfer to a Dispensary	
Point Value	Explanation
0	Not addressed or response of no value
1-2	Fair. Limited applicability
3	Good. Some applicability
4-5	Excellent. Total applicability

Transportation	
Point Value	Explanation
0	Not addressed or response of no value
1	Fair. Limited applicability
2	Good. Some applicability
3	Excellent. Total applicability