NORTH DAKOTA DEPARTMENT OF HEALTH
RESPONSE TO QUESTIONS RECEIVED
MANUFACTURING FACILITIES APPLICATION

The "Timeline" section of the "Application Instructions: Manufacturing Facilities" included a deadline for submission of application questions. Based on questions received, the Department of Health **has made a change to the application instructions and added two forms to the application**. The application now includes Form C1 and Form D1 and the instructions include information regarding the two new forms (Pages 6 and 7). Applicants are to submit a complete application following the instructions included in the "How to Apply" section of the "Application Instructions: Manufacturing Facilities" document. Responses to questions submitted by the deadline are as follows.

1. Question: Can we use organic oil-based treatments- such as neem oil, rosemary oil, garlic oil, etc.?

   Response: The application is for entities interested in obtaining a registration certificate to be a manufacturing facility under the Medical Marijuana Program. Please refer to North Dakota Century Code (NDCC) Section 19-24.1-13 for the activities of a manufacturing facility. Please see definitions for terms such as usable marijuana and medical marijuana product in NDCC Section 19-24.1-01.

2. Question: Can your Company/Business purchase plant material or oil from the other licensed manufacturing facility in the event of crop failure or other business interruption? It appears the regulations only define sales to a dispensary. Does that preclude the manufacturing facilities to sell to each other?

   Response: A manufacturing facility is not authorized to sell marijuana or usable marijuana (as the terms are defined in NDCC Chapter 19-24.1-01) to another manufacturing facility. A manufacturing facility is only authorized to sell usable marijuana to a dispensary registered by the Department of Health.

3. Question: Can the Department clarify the maximum mg THC per unit for a tincture product?

   Response: No maximum THC amounts for tinctures dispensed under the program are included in state law or administrative rules.

4. Question: The testing regs reference testing concentrates prior to shipment to a dispensary. I didn't think you were allowed to sell a concentrate by itself in North Dakota. Can we clarify this restriction? What forms and potencies are allowed for concentrates?

   Response: Concentrates are a form of usable marijuana under the Medical Marijuana Program and can be dispensed by a registered dispensary. Please see definitions for terms such as usable marijuana, medical marijuana product, cannabinoid edible product, and cannabinoid concentrate in NDCC Section 19-24.1-01. State law does not identify potency information related to concentrates.

5. Question: Once a manufacturing certificate is granted:
    - How will the department allow applicant to acquire its initial genetics? Must it start from seeds, or can applicant acquire genetics for its important first strains on its own, taking advantage of years of R&D from other locations? If the answer is seeds, how is it to acquire them in a manner that is any different from the alternative above?

    Response: There are no state laws or administrative rules related to this area.

6. Question: In order to accurately predict initial production schedules during applicant's facility buildout:
    - When can applicant begin growing plants? Does live camera feed and card security need to be functional and accessible by the department before the growing of mother plants for cloning can begin?

    Response: The manufacturing facility physical location may not have marijuana in the facility until a registration certificate has been issued. The requirements related to surveillance and security for a manufacturing facility are to be complied with when a registration certificate is issued.

7. Question: Can we assume that we will be paid promptly by check after delivery of products? If so, who will be writing those checks? (The dispensaries or the department) As a manufacturer, can we offer a floor plan program to dispensaries? (Manufacturer would maintain a stock of their products at the dispensary but only get paid when they are sold)

    Response: The Department of Health has no statutory authority regarding payments between dispensaries and manufacturing facilities.

8. Question: Form C must be completed by "each principal officer, board member, member-manager, manager, or governor of the proposed manufacturing facility." What is a governor?

    Response: An entity interested in becoming a registered manufacturing facility must be structured as a corporation or a limited liability company. NDCC Chapter 10-19.1 and NDCC Chapter 10-32.1 include definitions for certain terms included on Form C.

9. Question: Is there a word or character limit for the Operations Manual? Can the Operations Manual include graphs, charts, diagrams, or photos? If yes, do these count against any word counts that exist? Does Form G have a character count or word limit?

    Response: There are no word, character, or similar limits for the Operations Manual. A complete copy of the manual is to be included (references to business/entity names, personnel names, and other similar identifying information is to be removed from the manual). Form G will expand as necessary to fit information provided. There is no character count or word limit.

10. Question: I understand that the application must be delivered by mail. Is it acceptable to use FedEx, UPS, DHL, or should we stick to USPS? If going to be dropped off, is anybody qualified to drop off the application or must it be an owner or member of the organization?

    Response: Applications may be hand delivered to the Accounting Division within the Department of Health (Room #207 of the Judicial Wing, State Capitol). Delivery method to

be used is a decision to be made by the applicant. Regardless of delivery method used, applications must be received by 4:00 p.m. (central standard time) on April 19, 2018.

11. Question: How many copies of the final application does the Department require? Can I also send an electronic copy via thumb drive?

    Response: Applicants are not required to submit additional copies or an electronic copy of the application. Applicants are reminded they are solely responsible for submitting a complete application.

12. Question: If we apply for a manufacturing facility, do we need to file our LLC as a Farming LLC?

    Response: The Department of Health is unable to provide legal advice. Applicability of the corporate farming law requires a fact-based analysis that should be conducted with an applicant's private legal counsel.

13. Question: Will security officers be allowed to possess guns on the facility? While on Transport? We like to use off-duty local law enforcement officials when possible. If we use someone from law enforcement, does that change the answer?

    Response: The Department of Health has no statutory authority related to possession of firearms at a manufacturing facility or related to transportation. Applicants should be knowledgeable of state laws and requirements in this area.

14. Question: Will manufacturing facilities be permitted to include information about the products they offer or how to use those products on their website?

    Response: North Dakota Administrative Code (NDAC) Section 33-44-01-23, Subsection 2 includes information related to a manufacturing facility's website.

15. Question: Will North Dakota allow a licensed waste hauler to take properly mixed medical cannabis waste to a disposal site?

    Response: NDAC Section 33-44-01-15 includes requirements for waste disposal. A manufacturing facility agent is required to transport medical marijuana waste rendered unusable to a facility for final disposition.

16. Question: Is CO2 considered a solvent that needs to be tested for?

    Response: CO2 is considered a solvent. Since CO2 is not listed in NDAC Section 33-44-01-49, the Department of Health must provide written approval to the manufacturing facility to use CO2. As part of the written approval, the Department of Health will establish what, if any, action level is to be used and the impact the level has on requiring, or not requiring, a solvent test.

17. Question: How many manufacturing facility applications does the Department anticipate receiving?

    Response: The Department of Health does not know how many applications will be received.

18. Question: Should applicants strictly use the forms provided or can applications be presented in other formats? If restricted to the forms, and due to the short window established to evaluate applications, does the Department prefer that applicants limit responses to the space provided and/or limit page count?

    Response: Please see 'How to Apply' on Pages 5 through 8 of the application instructions. Forms will expand as necessary to fit information provided and there is no limit on pages.

19. Question: Are there any length or format restrictions that should be applied to the Operations Manual?

    Response: There are no word, character, length, or similar limits for the Operations Manual. A complete copy of the manual is to be included (references to business/entity names, personnel names, and other similar identifying information is to be removed from the manual).

20. Question: Does the opportunity exist to supply supplemental attachments and other value-add content to our application or should we restrict content to the attachments requested in the forms?

    Response: Only information relevant to specific categories identified in the forms will be scored by the review panel. All identifying information must be redacted as required by the sections. Forms will expand as necessary to fit information provided.

21. Question: May applicants propose multiple locations within their application? If only one location is permitted per application, may applicants submit multiple applications with the understanding that a single location would be selected in the event that both applications score highly?

    Response: A separate complete application must be submitted for a specific proposed location. An entity may submit more than one application following the "How to Apply' requirements listed in the application instructions on Pages 5 through 8. However, a legal entity is not authorized to possess more than one registration certificate.

22. Question: The application requests that we "provide a description of the plans for testing usable marijuana and marijuana". Could you please clarify whether the Department is referring to onsite testing or testing to be done at the state sanctioned laboratory?

    Response: Applicants should include their plans for testing marijuana and usable marijuana as part of a quality control and quality assurance program. Applicants may also provide information regarding compliance testing as required in NDAC Chapter 33-44-01.

23. Question: Does the Department have a geographic preference for the location of the manufacturing facilities?

    Response: There are no preference points for location. The facility must be located in North Dakota.

24. Question: If a city/county requires that a conditional use or special use permit be obtained, in addition to meeting setback and permitted district location rules, would the applicant be

required to have received the conditional/special use permit prior to submitting an application to meet zoning requirements or is complying with location and setback requires sufficient for the purpose of the application?

Response: Applicants are required to have an authorized zoning representative complete Form B.

25. Question: Will compassion centers be charged or need to purchase licenses for the implementation and use of BioTrackTHC?

    Response: Please review the requirements for inventory control measures included in NDAC Section 33-44-01-19.

26. Question: Is there market predictions for patients that would use these products. Is that where the 1000 plants per grower came from?

    Response: The number of qualifying patients participating in the Medical Marijuana Program is unknown. The Department of Health does not provide any assurances regarding the demand for usable marijuana under the Medical Marijuana Program. The 1,000 plant maximum for a manufacturing facility is established in NDCC Section 19-24.1-24.

27. Question: Is it 1000 plants for production total? Or 1000 plants including plants for crossing, etc.?

    Response: NDCC Section 19-24.1-24 establishes a 1,000 plant maximum and an additional 50 plants for the exclusive purpose of department-authorized research and development related to production and processing. NDAC Section 33-44-01-08 provides additional information on inventory limits.

28. Question: What yield is the state using per plant to determine that 1000 plants number?

    Response: The 1,000 plant maximum is established in NDCC Section 19-24.1-24.

29. Question: What type of entity is required?

    Response: A compassion center must be structured as a corporation or as a limited liability company. Registration of a business is through the ND Secretary of State. They can be contacted at (701) 328-2900 (Option 2).

30. Question: On page 5 of the instructions for application, line item 6 states AFFORDABILITY. Can you please better define and, or, advise as to what the intent of this is.

    Response: NDCC Section 19-24.1-14 requires an applicant to include a description of the plans for making usable marijuana available on an affordable basis to registered qualifying patients with limited financial resources. Affordability is not defined in NDCC Chapter 19-24.1 or NDAC Chapter 33-44-01.

31. Question: If someone has a criminal history will that disqualify them from consideration? I'm am thinking about applying and I have some blemishes on my record.

Response: Compassion center agent is defined in NDCC Section 19-24.1-01. The requirements to qualify to be issued a registry identification card are included in NDCC Section 19-24.1-18. Individuals listed on Form C and Form C1 must be able to possess a registry identification card. If an individual listed on Form C or Form C1 is not qualified according to NDCC Section 19-24.1-18 to possess a registry identification card, the individual will not be eligible to be considered by the panel in the review of application materials.

32. Question: Do I understand correctly that the $5000.00 check is not refunded to applicants not selected to participate.

    Response: A nonrefundable $5,000 check must be submitted with an application. No refunds are provided regardless of an applicant's selection or nonselection to be eligible for registration.

33. Question: Does the LLC entity applying for the Compassion Center need to be a North Dakota entity or can they be an LLC in another state?

    Response: This is a ND Secretary of State question. They can be contacted at (701) 328-2900 (Option 2).

34. Question: Can you offer any assurance as to the unbiased nature of the review panel?

    Response: The application process requirements are described in NDAC Section 33-44-01-06. Panel members will be responsible for performing as fair an evaluation as possible of applications.

35. Question: In a community as small as North Dakota, how can identifying information about applicants be sufficiently redacted without also redacting some of their significant qualifications? For instance, if one of an applicant's qualifications is that they served as the attorney general of the state of North Dakota during the farm crisis of the 1980's, how could that be redacted without taking away from their very specific credentials?

    Response: Applicants should provide information on qualifications in a manner to prevent an individual from being readily identifiable to panel review members. Individual names, names of companies, etc. should not be included in certain forms (such as Forms D, D1, G, and F). If necessary, applicants should reference prior titles and work performed accordingly. Applicants may reference states by name.

36. Question: Ethanol is not listed as a solvent. Water and CO2 are also not on the list of solvents. Given that these are among the most commonly used solvents in the cannabis extraction industry, can you clarify that these solvents are acceptable for use in this program?

    Response: Solvents to be used that are not listed in NDAC Section 33-44-01-49, require written approval from the Department of Health. As part of the written approval, the Department of Health will establish what, if any, action level is to be used and the impact the level has on requiring, or not requiring, a solvent test.

37. Question: Can you offer assurance that this subjective and unjustified delay in this legal process (registration with the state) will not interfere with the fairness of the application process?

    Response: The Department of Health will ensure the application process is fair.

38. Question: Will the manufacturing centers be required to collect sales tax from the dispensaries, and if so at what rate?

    Response: This is a ND Office of State Tax Commissioner question. They can be contacted at (701) 328-3011.

39. Question: What is the exact definition of a "school" in the context of NDCC Section 19-24.1-14(1)(d)(2)? Does it include daycares? Does it include nurseries? Does it include a distance learning facility where no classes are held? Does it include vocation school such as an adult art studio class? Does it include elementary, high school, secondary school, and colleges?

    Response: The Department of Health provided the following information in the "Frequently Asked Questions – Manufacturing Facilities and Dispensaries" document on the Division of Medical Marijuana website:

    North Dakota Century Code Chapter 19-24.1 does not provide a specific definition of "school." The common definition of school is (1) an institution of learning and education, especially for children; (2) The collective body of students under instruction in an institution of learning; (3) A group of people adhering to the same philosophy or system of beliefs. Based on the common meaning and the legislative history, the Department of Health interprets the definition of school to include the following:

    - An entity included on the Department of Public Instruction's "Approved Schools By City" or "Approved Schools By District" list (https://www.nd.gov/dpi/SchoolStaff/SAO/approval/)
    - An entity included on the Department of Public Instruction's "Head Start Sites" (https://www.nd.gov/dpi/SchoolStaff/ECE/HeadStart/HSsites/)
    - A public or private institution of higher education or career and technical education school.

40. Question: What type of criminal background event will disqualify an applicant's principal officer, board member, member-manager, manager or governor or a proposed manufacturing facility? I see that a "compassion center agent" may not have a drug related misdemeanor on their record for the preceding 5 years, or a felony, however, I cannot find any rule that controls what would disqualify an applicant?

    Response: Compassion center agent is defined in NDCC Section 19-24.1-01. The requirements to qualify to be issued a registry identification card are included in NDCC Section 19-24.1-18. Individuals listed on Form C and Form C1 must be able to possess a registry identification card. If an individual listed on Form C or Form C1 is not qualified according to NDCC Section 19-24.1-18 to possess a registry identification card, the individual will not be eligible to be considered by the panel in the review of application materials.

41. Question: How will applicants be vetted for providing false or misleading info? How will the state create a record of their vetting of incomplete, false, inaccurate, or misleading information?

Response: The Department of Health will verify certain information contained in the submitted application. The Department of Health is not informing applicants what information will be verified. The Department of Health will determine how to document such work performed.

42. Question: In Form D - Can the names of the companies or where the companies are located, that are a part of the applicant's experience, be used while describing their experience?

    Response: Applicants should provide information on qualifications in a manner to prevent an individual from being readily identifiable to panel review members. Individual names, names of companies, etc. should not be included in certain forms (such as Forms D, D1, G, and F). If necessary, applicants should reference prior titles and work performed accordingly. Applicants may reference states by name.

43. Question: In form E, if one of the 'business entities' that has direct or indirect authority has multiple minority owners, do we need to provide information for each owner? Is there a minimum ownership threshold for reporting in Forms C, D and E?

    Response: Form E only requires the list of individual or business entities with: 1) direct or indirect authority over the management or policies of the proposed manufacturing facility; and 2) an ownership interest in the proposed manufacturing facility, whether direct or indirect. There are no minimum ownership thresholds identified in NDCC Chapter 19-24.1. Form C and Form D must be completed for each principal officer and board member or for each member-manager, manager, or governor. Form C1 and Form D1 can be completed for each known employee, volunteer, and agent of the manufacturing facility.

44. Question: Will the applications and scores be made public documents at any point during the process?

    Response: Application information submitted is confidential under NDCC Section 19-24.1-37. Scoring sheets of panel members are open records.

45. Question: Will the state value the experience of company advisory board and consultants with long term engagements in the "character and experience" points in the scoring elements, even if they do not have ownership in the company? Can we include advisory board members, consultants and other company employees in Form D?

    Response: Form C and Form D are to only be used for providing information on each principal officer and board member or of each member-manager, manager, or governor of the proposed manufacturing facility. Two new forms have been added to the application to provide information on employees, volunteers, and agents of the proposed manufacturing facility (which includes consultants). Please review the revised instructions and complete Form C1 and Form D1 as necessary or if applicable.

46. Question: Can the state distinguish the difference in the type of material requested in the operations manual from the type of material requested in the Producer and processor plans (Form G)?

Response: Information in an Operations Manual may or may not be sufficient to cover all areas to be included in Form G. Applicants may reference pages in the Operations Manual as part of their responses in Form G.

47. Question: Is there information missing from the gray fields in Form G (producer and processor sections)?

    Response: Due to a recent update of Internet Explorer, the bottom portion of the gray field in Form G may appear to be cut off. There are eight bullets in both gray areas of Form G. The last bullet listed is “Research and development plans and processes.”

48. Question: Please clarify acceptable delivery methods. Specifically, can we hand-deliver the application on the closing date?

    Response: Applications may be hand delivered to the Accounting Division within the Department of Health (Room #207 of the Judicial Wing, State Capitol). Delivery method to be used is a decision to be made by the applicant. Regardless of delivery method used, applications must be received by 4:00 p.m. (central standard time) on April 19, 2018.

49. Question: Can the department identify which application forms match up with each line item in the scoring elements list? For example, "Types of usable marijuana transferred to a dispensary" in the scoring list is not exactly stated in any form in the application.

    Response: The Department of Health will not provide information related to what specific form or forms are to be used exclusively for determining a certain scoring category. Form F includes information related to usable marijuana. Please also refer to NDAC Section 33-44-01-11.

50. Question: What part(s) of the application forms account for the points for "Operations and services plan" in the scoring elements list?

    Response: The Department of Health will not provide information related to what specific form or forms are to be used exclusively for determining a certain scoring category.

51. Question: Are the points for "suitability of facility" earned with the response to form B only?

    Response: The Department of Health will not provide information related to what specific form or forms are to be used exclusively for determining a certain scoring category.

52. Question: Will the scoring of applications be made public?

    Response: Scoring sheets of panel members are open records.

53. Question: The application doesn't appear to allow the notation of content the applicant wishes to maintain as confidential (intellectual property for example) in the event of a public records request. Will the entirety of these applications be made public, or is there an option to mark sensitive content as such so it is not disclosed?

    Response: Application information submitted is confidential under NDCC Section 19-24.1-37.

54. Question: Can we include additional materials in our applications, such as character reference letters and other letters of support? Will they count towards scoring?

    Response: Only information relevant to specific categories identified in the forms will be scored by the review panel. All identifying information must be redacted as required by the sections. Forms will expand as necessary to fit information provided.

55. Question: What is the difference between a manufacturer's quality control/quality assurance testing procedures and the certified-laboratory testing required by the state?

    Response: The quality control and quality assurance program required under NDAC Section 33-44-01-55 is a manufacturing facility's internal program. The compliance testing required under NDAC Sections 33-44-01-42, 33-44-01-43, and 33-44-01-44 will be conducted by the Department of Health's contracted laboratory.

56. Question: Are the quality control/quality assurance testing procedures just to identify expiration dates?

    Response: No.

57. Question: Is "the profile of active ingredients" the cannabinoid potency?

    Response: The profile may include potency information as well as information required for labeling purposes (see NDAC Section 33-44-01-26).

58. Question: How does this inform the product's expiration date? Will the state establish these standards?

    Response: NDAC Section 33-44-01-55 requires manufacturing facilities to determine product expiration dates.

59. Question: What will be the standards the health department requires for issuing prescription cards for consumers of Medical Marijuana?
    a) Will there be a list of approved use cases the Department of Health will limit prescriptions to? If so what are those ailments?
    b) Will any professional that can currently write a prescription have the ability to prescribe marijuana to a person in medical need?

    Response: There are no prescriptions as part of the Medical Marijuana Program. Please review NDCC Chapter 19-24.1.

60. Question: What assurances do the 2 manufacturers have that the Department of Health will not issue further manufacturing licenses/permits increasing supply and driving prices down?

    Response: NDCC Section 19-24.1-12 and NDAC Section 33-44-01-07 address establishment of additional manufacturing facilities and/or dispensaries.

61. Question: Who will make up the panel that evaluates the applications and awards the licenses to the applicants? Who will choose the panel members?

Response: The panel has not been finalized at this time. The Department of Health will select the panel members.

62. Question: Will the panel members be ND residents?

    Response: Since the panel has yet to be finalized, it is unknown at this time what the residency of panel members will be.

63. Question: Can the Marijuana Manufacturing license be sold? Under what criteria or process can the license be sold?

    Response: Please see NDCC Section 19-24.1-17.

64. Question: What rate of taxation will the manufacturer pay to the state?

    Response: This is a ND Office of State Tax Commissioner question. They can be contacted at (701) 328-3011.

65. Question: Are there additional fees the manufacturer will be responsible for such as annual inspections?

    Response: Fees to be paid are included in NDCC Chapter 19-24.1 and NDAC Chapter 33-44-01. Other fees to operate a business in the state are the responsibility of the manufacturing facility.

66. Question: Can applicants disclose company names in Form D that are part of applicants' experience?

    Response: No. Applicants should provide information on qualifications in a manner to prevent an individual from being readily identifiable to panel review members. Individual names, names of companies, etc. should not be included in certain forms (such as Forms D, D1, G, and F). If necessary, applicants should reference prior titles and work performed accordingly. Applicants may reference states by name.

67. Question: Some business entities in ownership have many minority owners. Is there a minimum disclosure threshold?

    Response: There are no minimum disclosure threshold requirements in NDCC Chapter 19-24.1.

68. Question: Will company consultants' experience be valued for experience points?

    Response: Two new forms have been added to the application to provide information on employees, volunteers, and agents of the proposed manufacturing facility (which includes consultants). Please review the revised instructions and complete Form C1 and Form D1 as necessary or if applicable.

69. Question: Do only owners' experience count for experience points?

    Response: Form C and Form D are to only be used for providing information on each principal officer and board member or of each member-manager, manager, or governor of

the proposed manufacturing facility. Two new forms have been added to the application to provide information on employees, volunteers, and agents of the proposed manufacturing facility (which includes consultants). Please review the revised instructions and complete Form C1 and Form D1 as necessary or if applicable.

70. Question: What makes production/processing plans different from an operations manual? Don't they contain the same information?

    Response: Information in an Operations Manual may or may not be sufficient to cover all areas to be included in Form G. Applicants may reference pages in the Operations Manual as part of their responses in Form G.

71. Question: Can the state define the types of information required to be part of an operations manual, production plan and processing plan?

    Response: Please refer to NDAC Section 33-44-01-11 for Operations Manual. Please refer to NDCC Section 19-24.1-01 for definitions of processing and producing.

72. Question: Can materials be delivered in person on April 19?

    Response: Applications may be hand delivered to the Accounting Division within the Department of Health (Room #207 of the Judicial Wing, State Capitol). Delivery method to be used is a decision to be made by the applicant. Regardless of delivery method used, applications must be received by 4:00 p.m. (central standard time) on April 19, 2018.

73. Question: Can the department identify which each line items in the scoring elements list match with each application form?

    Response: The Department of Health will not provide information related to what specific form or forms are to be used exclusively for determining a certain scoring category.

74. Question: Can we mark parts of our application as "proprietary" or "trade secret" to prevent public disclosure?

    Response: Application information submitted is confidential under NDCC Section 19-24.1-37.

75. Question: Which form contains the points for "Types of usable marijuana transferred to a dispensary" in the scoring elements list?

    Response: The Department of Health will not provide information related to what specific form or forms are to be used exclusively for determining a certain scoring category. Form F includes information related to usable marijuana. Please also refer to NDAC Section 33-44-01-11.

76. Question: Can the applicant include letters of support and character references? Will the state award any points?

    Response: Only information relevant to specific categories identified in the forms will be scored by the review panel. All identifying information must be redacted as required by the sections. Forms will expand as necessary to enter information.

77. Question: What forms gain an applicant points for “suitability of facility”?

Response: The Department of Health will not provide information related to what specific form or forms are to be used exclusively for determining a certain scoring category.