The “Timeline” section of the “Application Instructions: Dispensaries” issued July 10, 2018 included a deadline for submission of application questions. Based on questions received, the Department of Health has made no changes to the application instructions and application forms. Responses to questions of a substantive nature submitted by the deadline are as follows.

1. **Question:** My question involves an interpretation of 19-24.1-21(3). Does this mean that a current manufacturing facility agent may not be a part of a dispensary application? To clarify, may a person who is currently a manufacturing facility agent, meaning a principal officer, board member, member, manager, owner, governor, employee, volunteer or agent of one of the two manufacturing facilities create a new entity and then apply for a dispensary license as a member of the new entity? Or does the above rule simply mean that a manufacturing facility agent in their capacity as a manufacturing facility agent may not dispense marijuana directly to a patient?

   **Response:** NDCC Section 19-24.1-21, Subsection 3 prohibits a manufacturing facility agent from dispensing marijuana and usable marijuana. NDCC Chapter 19-24.1 does not preclude an individual from having a registry identification card as a manufacturing facility agent and having a registry identification card as a dispensary agent. An individual holding two registry identification cards must have in their possession the appropriate card when performing related duties as authorized by state law as a manufacturing facility agent or a dispensary agent.

2. **Question:** The application refers to all of the key people as "Individual A," "Individual B," etc. We are curious if we need to change or redact the names of these people from resumes, State IDs, and other information that we may attach as exhibits.

   **Response:** No identifying information is to be redacted. The instructions do not include a requirement to redact names from materials submitted. No application forms include language to request applicants to remove names.

3. **Question:** If selected for a dispensary would applicant have time to build a new constructed facility, specifically what is the time line allowed to have cert of occupancy after selection is made?

   **Response:** NDCC Chapter 19-24.1 does not include a mandatory timeline. However, the review panel will take into consideration timeline information in the evaluation of complete applications.

4. **Question:** The City of Fargo has taken the position that our location is non-conforming because our proposed compassionate care center is within a building, which is within a lot whose property line is 888 feet from the property line of a lot which contains "The Salon Professional Academy," at its closest point. The City also says that the Academy technically falls within the definition of a school (see the attached picture and explanation from the city.) We would like to know if the Department intended for its regulation on distance from schools to be measured from lot line to lot line, and to include institutions
such as The Salon Professional Academy, and, if not, to give additional guidance on this regulation, as to measurement, definition of "school" or both.

Response: NDCC Section 19-24.1-14, Subsection 1(d) establishes the requirement that a dispensary is not to be located within 1,000 feet of a property line of a pre-existing public or private school. Under the guidance provided by the Department of Health regarding a definition of school, the Salon Professional Academy would be considered a school. The applicable local government will be measuring the distance from property line to property line to determine whether a proposed location is within 1,000 feet of a property line of a pre-existing public or private school.

5. Question: If the measurement is appropriate and The Salon Professional Academy is intended to be included in this regulation, we would like to know if this regulation can be waived by consent of the Academy; or if there is any other process to apply for an exception or a variance to this requirement, due to the minimal nature of the non-compliance.

Response: NDCC Section 19-24.1-14, Subsection 1(d) establishes the 1,000-foot requirement. The Department of Health does not have the authority to waive the requirement and there will be no exceptions granted for state law requirements.

6. Question: I have a question regarding Form B of the Dispensary Application. Three of the questions understandably relate to a possible requirement of a conditional use permit (CUP) and/or special use permit (SUP). In the event a CUP or SUP is required by the local municipality, will it still be possible for an applicant to receive the maximum possible points relating to the "Suitability of Facility Location" (8 points) if the CUP and/or SUP process hasn’t been started? I just want to make sure that I will not be penalized if I have spoken with the local zoning office about my project, had them complete Form B, but have not gone through any sort of zoning process. It would be a lot of work for the municipality to start the CUP/SUP process in the event I was not awarded the location in the Region that municipality is located within.

Response: The decision to begin a process related to meeting zoning requirements rests solely with the applicant. The review panel will take into consideration timeline information in the evaluation of complete applications.

7. Question: For physical submission, is it correct that all that needs to be submitted is:
   o One printed copy in a binder;
   o A USB with the operations manual on it; and
   o The application fee.

Response: Please refer to the instructions in the section entitled "How to Apply" on pages 6 through 9. All information required by laws and administrative rules must be submitted for an application to be complete and eligible for review.

8. Question: Is identifying information allowed in Form F: Operations Manual? The manufacturing facility application required applicants to remove all references to business/entity names, personnel names, and other similar identifying information. There is no such language in the dispensary application.
Response: No identifying information is to be redacted. The manufacturing facility application used a “blind” review process. The dispensary application is not using a “blind” review process.

9. Question: In the North Dakota Administrative Code, section 33-44-01-11, part 1i states that the operations manual must include “a description of the usable marijuana containers the compassion center utilizes in accordance with NDCC section 19-24.1 and these rules.” However, section 33-44-01-25 states that a manufacturing facility, not a dispensary shall package all usable marijuana. Is 33-44-01-11 part 1i not relevant for a dispensary operations manual?

Response: The requirement for a dispensary to include container information in an Operations Manual is applicable when a dispensary has a plan to use an additional container in which to place usable marijuana. If no additional container is planned to be used, the Operations Manual can reflect this (i.e. specifically stating no additional container will be used or indicating how products are dispensed in the containers from a manufacturing facility). A manufacturing facility will package all usable marijuana intended for dispensing into a container prior to transferring to a dispensary. A dispensary is not permitted to open these containers.

10. Question: Must the application be de-identified, or are we permitted to include individual and company names, company logos, etc.?

Response: No identifying information is to be redacted.

11. Question: Do any of the responses have page or word limitations, or may we include as much information as we see fit to respond to the question?

Response: Aside from the cover letter, there are no additional page or word restrictions or limitations. As identified in the application instructions “Application forms will expand to fit responses (text only, if other information is deemed necessary to submit as part of a response it may be included in the Operations Manual).”

12. Question: Is "central time" = "Central Daylight Time" on 8/7/18?

Response: Yes.

13. Question: Are there any square footage limitations for dispensaries?

Response: NDCC Chapter 19-24.1 and NDAC Chapter 33-44-01 do not include square footage limitations for dispensaries.

14. Question: Will forms be added to the dispensary application to facilitate a blind review? Or will the dispensary review be open?

Response: No forms will be added. There is not a “blind” review process for dispensary applications.

15. Question: Is "Word" a satisfactory program for the electronic version of the operations manual?
Response: Yes.

16. Question: Should the flash drive for the operations manual be identified in a particular way? or attached to a 3 ring binder in a specific way? or is including the entity name in the operations manual file sufficient for identification?

Response: No. The flash drive can simply be included in the envelope/box or similar packaging material. Since no redaction of information is required, the entity name is anticipated to be included in the Operations Manual. If necessary, we will be able to match up an electronic version of the Operations Manual to the printed copy of the Operations Manual included in the 3-ring binder.

17. Question: What is the contact information for the 2 Manufacturing Facilities?

Response: Manufacturing facility contact information will not be provided during the open application period for dispensaries. However, once a dispensary applicant is selected to move forward in the registration process, applicable information will be shared between manufacturing facilities and the dispensary applicant selected.

18. Question: Does the Operations Manual need to be redacted, or can the Operations Manual contain identifiable information concerning the company and its owners?

Response: No identifying information is to be redacted.

19. Question: What is the best process for establishing communications with the manufacturers and the laboratory? Is there official Department contact information for either of the manufacturers or the laboratory?

Response: Once a dispensary applicant is selected to move forward in the registration process, applicable information will be shared between manufacturing facilities and the dispensary applicant selected.

20. Question: Can the owner’s of the manufacturing or laboratory facilities obtain dispensary licenses (even if created under a new legal entity)? (Are monopolies and/or vertically integrated businesses allowed?)

Response: The same legal entity is not authorized to possess more than one registration certificate. The law does not prohibit the same individual, or organization, from having an ownership interest in more than one legal entity.

21. Question: Where can we find information regarding state regulations concerning firearms at the Compassion Center location and during the transportation process? (Are armed security services allowed?)

Response: Applicants should conduct their own reviews of state and federal laws and rules that may be applicable to their dispensary operations and consult with their own legal counsel.

22. Question: According to the rules on Advertising and Marketing in N.D.A.C. § 33-44-01-23(4), all marketing and advertising activities not covered by the rule must be approved by
the Department: Does this extend to patient outreach and education activities conducted by the Compassion Center?

Response: Patient outreach activities are addressed in NDAC Section 33-44-01-11, Subsection 3(c). Advertising and marketing activities are addressed in NDAC Section 33-44-01-23.

23. Question: Where can we find information on North Dakota’s rules regarding patient confidentiality and privacy?

Response: Applicants should conduct their own reviews of federal and state laws and rules that may be applicable to their dispensary operations and consult with their own legal counsel.

24. Question: Will the growers be required to transport medical marijuana products to the dispensaries or are dispensaries required to get it on their own? Will the growers be required to pick up any waste product and transport it to designated areas or is that the responsibility of the dispensary?

Response: NDAC Section 33-44-01-29 includes transportation authorization information.

25. Question: Will the product come from the growers in bulk, to be split up by the dispensaries, or will the product come prepackaged?

Response: NDAC Section 33-44-01-25 requires manufacturing facilities to package all usable marijuana intended for distribution prior to transferring to dispensaries. A dispensary is not permitted to open these containers.

26. Question: Will applicants be required to submit all of their individual financial records, or do you just want to see how the projected amount available for the dispensary will be funded?

Response: Applicants must provide information as instructed in completing Form E.

27. Question: Which forms (if any) are the Department of Health creating as part of required documentation and record keeping?

Response: The recordkeeping and format of the records is a decision of the dispensary. However, a dispensary must ensure compliance with state law and administrative rules related to records, reports, inventory, etc.

28. Question: Will medicinal dispensaries be allowed to obtain a recreational dispensary license if recreational is voted on and passed this November?

Response: The Department of Health only has authority over the Medical Marijuana Program.

29. Question: Is the cardholder verification system included in BioTrackTHC software or will this be a separate system?
Response: The data to be provided through the verification system as required by NDCC Section 19-24.1-31 will come from the BioTrackTHC system. What inventory system is being used at the dispensary will impact if a separate system will exist.

30. Question: What will the "special authorization" for dried leaves and flowers be from a health care provider? Is there a certain phrase that must be written on the recommendation such as "smoking?"

Response: Under NDCC Section 19-24.1-03, Subsection 2, the written certification must include whether the health care provider authorizes the patient to use the dried leaves or flowers of the plant of the genus cannabis in a combustible delivery form. While the written certification form is still in a draft phase, the Department of Health uses the same terminology in state law when developing application materials (i.e. application materials for manufacturing facility and dispensary applications).

31. Question: On form A, we need to attach the Operating Agreement for proposed dispensary. Do we also need to or would it be helpful, to provide the Operating Agreements for the entities that own the proposed dispensary?

Response: The Operating Agreement is a specific document attributed to a limited liability company and is defined in state law. The Operating Agreement of the entity listed on Form A under the 'Legal Name' must be submitted.

32. Question: If a "medical marijuana product" is defined as "a cannabinoid concentrate or a medical cannabinoid product" (19-24.1-01.25), and a "medical cannabinoid product' does not include: (2) a cannabinoid concentrate by itself" (19-24.1-01.24.b(2)), then what methods of extraction or forms of cannabis extract are allowed under the North Dakota Department of Health (NDDoH) Medical Marijuana Program?

Response: Please refer to the definitions under NDCC Section 19-24.1-01 including, but not limited to, the term “usable marijuana.” NDCC Section 19-24.1-13, Subsection 2 includes the authorized activities of a dispensary. The types of usable marijuana include dried leaves or flowers, a cannabinoid concentrate, cannabinoid tincture, cannabinoid capsule, cannabinoid transdermal patch, and cannabinoid topical.

33. Question: Under NDDoH’s Medical Marijuana Program, is transportation of medical cannabinoid products the responsibility of the manufacturing Compassion Center or the dispensary, or up to each Compassion Center?

Response: NDAC Section 33-44-01-29 includes transportation authorization information.

34. Question: Must an applicant for a Compassion Center as a dispensary demonstrate control of the proposed location, either through ownership or an option to lease or purchase, or is simply a complete “Form B: Local Zoning Approval” the sole requirement for location at the time of application?

Response: Form B is the required document to be included in the submitted application.

35. Question: In the application for a Compassion Center and in 33-44-01-11 covering the “Operations Manual” NDDoH uses the term “distribution plan”, given the importance of providing access to registered patients and their caregivers, can NDDoH clarify what the
definition is of a distribution plan and the parameters for a Compassion Center’s distribution plan?

Response: Dispensaries may have different plans on how they anticipate providing registered qualifying patients and registered designated caregivers access to usable marijuana. The dispensary’s Operations Manual should include information on aspects of their specific proposed plans regarding how usable marijuana will be accessible to patients and designated caregivers.

36. Question: Our team would like a clarification regarding the distribution plan required in the dispensary’s operations manual. Can you please define this distribution plan - it is a delivery plan or something else?

Response: Dispensaries may have different plans on how they anticipate providing registered qualifying patients and registered designated caregivers access to usable marijuana. The dispensary’s Operations Manual should include information on aspects of their specific proposed plans regarding how usable marijuana will be accessible to patients and designated caregivers. A home delivery option would only be one aspect of such a plan.