CHAPTER 19-24.1
MEDICAL MARIJUANA

19-24.1-01. Definitions.

As used in this chapter, unless the context indicates otherwise:

1. "Advanced practice registered nurse" means an advanced practice registered nurse defined under section 43-12.1-02.
2. "Agent" means an individual who is authorized to act for, in place of, or on behalf of a compassion center.
3. "Allowable amount of usable marijuana" means the amount of usable marijuana a registered qualifying patient or registered designated caregiver may purchase in a thirty-day period under this chapter.
   a. Except as provided under subdivision b:
      (1) During a thirty-day period, a registered qualifying patient may not purchase or have purchased by a registered designated caregiver more than two and one-half ounces [70.87 grams] of dried leaves or flowers of the plant of the genus cannabis in a combustible delivery form.
      (2) At any time a registered qualifying patient, or a registered designated caregiver on behalf of a registered qualifying patient, may not possess more than three ounces [85.05 grams] of dried leaves or flowers of the plant of the genus cannabis in a combustible delivery form.
   b. Notwithstanding subdivision a, if a registered qualifying patient has a registry identification card authorizing an enhanced allowable amount:
      (1) During a thirty-day period a registered qualifying patient may not purchase or have purchased by a registered designated caregiver more than six ounces [170.01 grams] of dried leaves or flowers of the plant of genus cannabis in a combustible delivery form.
      (2) At any time a registered qualifying patient, or a registered designated caregiver on behalf of a registered qualifying patient, may not possess more than seven and one-half ounces [212.62 grams] of dried leaves or flowers of the plant of the genus cannabis in a combustible delivery form.
   c. A registered qualifying patient may not purchase or have purchased by a registered designated caregiver more than the maximum concentration or amount of tetrahydrocannabinol permitted in a thirty-day period. The maximum concentration or amount of tetrahydrocannabinol permitted in a thirty-day period for a cannabinoid concentrate or medical cannabinoid product, or the cumulative total of both, is six thousand milligrams.
4. "Bona fide provider-patient relationship" means a treatment or counseling relationship between a health care provider and patient in which all the following are present:
   a. The health care provider has reviewed the patient's relevant medical records and completed a full assessment of the patient's medical history and current medical condition, including a relevant, in-person, medical evaluation of the patient.
   b. The health care provider has created and maintained records of the patient's condition in accordance with medically accepted standards.
   c. The patient is under the health care provider's continued care for the debilitating medical condition that qualifies the patient for the medical use of marijuana.
   d. The health care provider has a reasonable expectation that provider will continue to provide followup care to the patient to monitor the medical use of marijuana as a treatment of the patient's debilitating medical condition.
   e. The relationship is not for the sole purpose of providing written certification for the medical use of marijuana.
5. "Cannabinoid" means a chemical compound that is one of the active constituents of marijuana.
6. "Cannabinoid capsule" means a small, soluble container, usually made of gelatin, which encloses a dose of a cannabinoid product or a cannabinoid concentrate intended for consumption. The maximum concentration of amount of

tetrahydrocannabinol permitted in a serving of a cannabinoid capsule is fifty milligrams.

7. "Cannabinoid concentrate" means a concentrate or extract obtained by separating cannabinoids from marijuana by a mechanical, chemical, or other process.
8. "Cannabinoid edible product" means a food or potable liquid into which a cannabinoid concentrate or the dried leaves or flowers of the plant of the genus cannabis is incorporated.
9. "Cannabinoid solution" means a solution consisting of a mixture created from cannabinoid concentrate and other ingredients. A container holding a cannabinoid solution for dispensing may not exceed thirty milliliters.
10. "Cannabinoid topical" means a cannabinoid product intended to be applied to the skin or hair. The maximum concentration or amount of tetrahydrocannabinol permitted in a cannabinoid topical is six percent.
11. "Cannabinoid transdermal patch" means an adhesive substance applied to the skin which contains a cannabinoid product or cannabinoid concentrate for absorption into the bloodstream. The maximum concentration or amount of tetrahydrocannabinol permitted in a serving of a cannabinoid transdermal patch is fifty milligrams.
12. "Cardholder" means a qualifying patient, designated caregiver, or compassion center agent who has been issued and possesses a valid registry identification card.
13. "Compassion center" means a manufacturing facility or dispensary.
14. "Compassion center agent" means a principal officer, board member, member, manager, governor, employee, volunteer, or agent of a compassion center. The term does not include a lawyer representing a compassion center in civil or criminal litigation or in an adversarial administrative proceeding.
15. "Contaminated" means made impure or inferior by extraneous substances.
16. "Debilitating medical condition" means one of the following:
    a. Cancer;
    b. Positive status for human immunodeficiency virus;
    c. Acquired immune deficiency syndrome;
    d. Decompensated cirrhosis caused by hepatitis C;
    e. Amyotrophic lateral sclerosis;
    f. Posttraumatic stress disorder;
    g. Agitation of Alzheimer's disease or related dementia;
    h. Crohn's disease;
    i. Fibromyalgia;
    j. Spinal stenosis or chronic back pain, including neuropathy or damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity;
    k. Glaucoma;
    l. Epilepsy;
    m. Anorexia nervosa;
    n. Bulimia nervosa;
    o. Anxiety disorder;
    p. Tourette syndrome;
    q. Ehlers-Danlos syndrome;
    r. Endometriosis;
    s. Interstitial cystitis;
    t. Neuropathy;
    u. Migraine;
    v. Rheumatoid arthritis;
    w. Autism spectrum disorder;
    x. A brain injury;
    y. A terminal illness; or
    z. A chronic or debilitating disease or medical condition or treatment for such disease or medical condition that produces one or more of the following:
        (1) Cachexia or wasting syndrome;

(2) Severe debilitating pain that has not responded to previously prescribed medication or surgical measures for more than three months or for which other treatment options produced serious side effects;
(3) Intractable nausea;
(4) Seizures; or
(5) Severe and persistent muscle spasms, including those characteristic of multiple sclerosis.

17. "Department" means the department of health and human services.
18. "Designated caregiver" means an individual who agrees to manage the well-being of a registered qualifying patient with respect to the qualifying patient's medical use of marijuana.
19. "Dispensary" means an entity registered by the department as a compassion center authorized to dispense usable marijuana to a registered qualifying patient and a registered designated caregiver.
20. "Enclosed, locked facility" means a closet, room, greenhouse, building, or other enclosed area equipped with locks or other security devices that permit access limited to individuals authorized under this chapter or rules adopted under this chapter.
21. "Health care provider" means a physician, a physician assistant, or an advanced practice registered nurse.
22. "Manager" means an individual who administers or supervises the day-to-day operations and affairs of a compassion center.
23. "Manufacturing facility" means an entity registered by the department as a compassion center authorized to produce and process and to sell usable marijuana to a dispensary.
24. "Marijuana" means all parts of the plant of the genus cannabis; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, the seeds of the plant, or the resin extracted from any part of the plant. The term marijuana does not include:
    a. Hemp as regulated under section 4.1-18.1-01; or
    b. A prescription drug approved by the United States food and drug administration under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355].
25. "Maximum concentration or amount of tetrahydrocannabinol" means the total amount of tetrahydrocannabinol and tetrahydrocannabinolic acid in a medical cannabinoid product or a cannabinoid concentrate.
26. "Medical cannabinoid product" means a product intended for human consumption or use which contains cannabinoids.
    a. Medical cannabinoid products are limited to the following forms:
        (1) Cannabinoid solution;
        (2) Cannabinoid capsule;
        (3) Cannabinoid transdermal patch; and
        (4) Cannabinoid topical.
    b. "Medical cannabinoid product" does not include:
        (1) A cannabinoid edible product;
        (2) A cannabinoid concentrate by itself; or
        (3) The dried leaves or flowers of the plant of the genus cannabis by itself.
27. "Medical marijuana product" means a cannabinoid concentrate or a medical cannabinoid product.
28. "Medical marijuana waste" means unused, surplus, returned, or out-of-date usable marijuana; recalled usable marijuana; unused marijuana; or plant debris of the plant of the genus cannabis, including dead plants and all unused plant parts and roots.
29. "Medical use of marijuana" means the acquisition, use, and possession of usable marijuana to treat or alleviate a qualifying patient's debilitating medical condition.
30. "Member" means an individual who has a ten percent or more ownership interest in the compassion center limited liability company, limited liability partnership, or partnership.
31. "Minor" means an individual under the age of nineteen.

32. "North Dakota identification" means a North Dakota driver's license or comparable state of North Dakota or federal issued photo identification card verifying North Dakota residence.
33. "Owner" means an individual or an organization with an ownership interest in a compassion center.
34. "Ownership interest" means an aggregate ownership interest of five percent or more in a compassion center, unless the interest is solely a security, lien, or encumbrance, or an individual who will be participating in the direction, control, or management of the compassion center.
35. "Pediatric medical marijuana" means a medical marijuana product containing cannabidiol which may not contain a maximum concentration or amount of tetrahydrocannabinol of more than six percent.
36. "Physician" means a physician licensed under chapter 43-17 to practice medicine in the state of North Dakota.
37. "Physician assistant" means an individual licensed under chapter 43-17 to practice as a physician assistant in the state.
38. "Posttraumatic stress disorder" means a patient meets the diagnostic criteria for posttraumatic stress disorder under the "Diagnostic and Statistical Manual of Mental Disorders", American psychiatric association, fifth edition, text revision (2013).
39. "Processing" or "process" means the compounding or conversion of marijuana into a medical marijuana product.
40. "Producing", "produce", or "production" mean the planting, cultivating, growing, trimming, or harvesting of the plant of the genus cannabis or the drying of the leaves or flowers of the plant of the genus cannabis.
41. "Qualifying patient" means an individual who has been diagnosed by a health care provider as having a debilitating medical condition.
42. "Registry identification card" means a document issued by the department which identifies an individual as a registered qualifying patient, registered designated caregiver, or registered compassion center agent.
43. "Substantial corporate change" means:
    a. For a corporation, a change of ten percent or more of the officers or directors, or a transfer of ten percent or more of the stock of the corporation, or an existing stockholder obtaining ten percent or more of the stock of the corporation;
    b. For a limited liability company, a change of ten percent or more of the managing members of the company, or a transfer of ten percent or more of the ownership interest in the company, or an existing member obtaining a cumulative of ten percent or more of the ownership interest in the company; or
    c. For a partnership, a change of ten percent or more of the managing partners of the company, or a transfer of ten percent or more of the ownership interest in the company, or an existing member obtaining a cumulative of ten percent or more of the ownership interest in the company.
44. "Terminal illness" means a disease, illness, or condition of a patient:
    a. For which there is not a reasonable medical expectation of recovery;
    b. Which as a medical probability, will result in the death of the patient, regardless of the use or discontinuance of medical treatment implemented for the purpose of sustaining life or the life processes; and
    c. As a result of which, the patient's health care provider would not be surprised if death were to occur within six months.
45. "Tetrahydrocannabinol" means tetrahydrocannabinols naturally contained in a plant of the genus cannabis, and synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of the plant, including synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, including:
    a. (1) Delta-1 cis or trans tetrahydrocannabinol, and their optical isomers. Other names: Delta-9-tetrahydrocannabinol.

(2) Delta-6 or trans tetrahydrocannabinol, and their optical isomers. Other names: Delta-8 tetrahydrocannabinol.
(3) Delta-3, 4 cis or trans tetrahydrocannabinol, and its optical isomers.

(Since nomenclature of these substances is not intentionally standardized, compounds of these structures, regardless of numerical designation or atomic positions covered.)

b. Tetrahydrocannabinol does not include:
(1) The allowable amount of total tetrahydrocannabinol found in hemp as defined in chapter 4.1-18.1; or
(2) A prescription drug approved by the United States food and drug administration under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355].

46. "Total tetrahydrocannabinol" means the sum of the percentage by weight of tetrahydrocannabinolic acid multiplied by eight hundred seventy-seven thousandths plus the percentage of weight of tetrahydrocannabinol.
47. "Usable marijuana" means a medical marijuana product or the dried leaves or flowers of the plant of the genus cannabis in a combustible delivery form. However, the term does not include a cannabinoid edible product. In the case of a registered qualifying patient who is a minor, "usable marijuana" is limited to pediatric medical marijuana.
48. "Verification system" means the system maintained by the department under section 19-24.1-31 for verification of registry identification cards.
49. "Written certification" means a form established by the department which is executed, dated, and signed by a health care provider within ninety calendar days of the date of application, stating the patient has a debilitating medical condition. A health care provider may authorize an enhanced amount of dried leaves or flowers of the plant of the genus cannabis in a combustible delivery form to treat or alleviate the patient's debilitating medical condition of cancer. A written certification may not be made except in the course of a bona fide provider-patient relationship.

19-24.1-02. Medical marijuana program.

The department shall establish and implement a medical marijuana program under this chapter to allow for production and processing, the sale and dispensing of usable marijuana, and medical use of marijuana. A person may not produce or process or sell, possess, transport, dispense, or use marijuana or usable marijuana under the medical marijuana program unless the person is authorized to do so as a compassion center, a cardholder, or otherwise authorized by rule adopted under this chapter.

19-24.1-03. Qualifying patients - Registration.

1. A qualifying patient is not eligible to purchase, use, or possess usable marijuana under the medical marijuana program unless the qualifying patient has a valid registry identification card.
2. A qualifying patient application for a registry identification card is complete and eligible for review if an applicant submits to the department:
a. A nonrefundable application fee in an amount not to exceed twenty-five dollars.
b. An original written certification, which must include:
(1) The name, address, and telephone number of the practice location of the applicant's health care provider;
(2) The health care provider's North Dakota license number;
(3) The health care provider's medical or nursing specialty;
(4) The applicant's name and date of birth;
(5) The applicant's debilitating medical condition and the medical justification for the health care provider's certification of the patient's debilitating medical condition;
(6) Attestation the written certification is made in the course of a bona fide provider-patient relationship;
(7) Whether the health care provider authorizes the patient to use an enhanced amount of the dried leaves or flowers of the plant of the genus cannabis in a

combustible delivery form to treat or alleviate the patient's debilitating medical condition of cancer; and

(8) The health care provider's signature and the date.

c. An original qualifying patient application for a registry identification card form established by the department which must include all of the following:

(1) The applicant's name, address, and date of birth.

(2) The name, address, and date of birth of the applicant's proposed designated caregiver, if any.

(3) A photographic copy of the applicant's North Dakota identification. The North Dakota identification must be available for inspection and verification upon request of the department. If the applicant is a minor, a certified copy of a birth record or a photographic copy of the minor's North Dakota identification is required.

(4) The applicant's or guardian's signature and the date, or in the case of a minor, the signature of the minor's parent or legal guardian with responsibility for health care decisions and the date.

(5) A disclosure that possession of a firearm by a person who possesses marijuana may be a violation of federal law.

d. A signed consent for release of medical information related to the applicant's debilitating medical condition, on a form provided by the department.

e. A recent two-by-two inch [5.08-by-5.08 centimeter] photograph of the applicant.

f. Any other information or material required by rule adopted under this chapter.

3. If the applicant is unable to submit the required application information due to age or medical condition, the individual responsible for making medical decisions for the applicant may submit the application on behalf of the applicant. The individual responsible for making medical decisions:

a. Must be identified on the qualifying patient application for a registry identification card; and

b. Shall provide a photographic copy of the individual's department-approved identification. The identification must be available for inspection and verification upon the request of the department.

4. If the applicant is a minor, the department may waive the application or renewal fee if:

a. The parent or legal guardian of the applicant is the applicant's registered designated caregiver; and

b. The applicant resides with the applicant's registered designated caregiver.

19-24.1-03.1. Qualifying patients - Veterans.

In lieu of the written certification required under section 19-24.1-03, a veteran receiving treatment from a federal veterans' affairs entity may submit to the department a copy of the veterans' affairs medical records identifying a diagnosis of a debilitating medical condition and a copy of military discharge documents. The department may use the medical records and discharge documents in place of a written certification to approve or deny the application under section 19-24.1-05. The department shall issue a registry identification card within thirty calendar days of approving an application under this section.

19-24.1-03.2. Qualifying patients - Hospice program.

In lieu of the written certification required under section 19-24.1-03, an individual admitted into the hospice program as defined in chapter 23-17.4 may submit to the department a copy of the individual's medical records identifying a designation of being admitted into the hospice program. The department may use medical records in place of a written certification to approve or deny the application under section 19-24.1-05. The department shall issue a registry identification card within fourteen calendar days of approving an application under this section. The department shall waive the registration fee for a qualifying patient applicant admitted into the hospice program.

19-24.1-04. Designated caregivers - Registration.

1. A designated caregiver is not eligible to purchase, assist in the use of, or possess usable marijuana under the medical marijuana program unless the designated caregiver has a valid registry identification card.
2. A designated caregiver application is complete and eligible for review if an applicant submits to the department all of the following:
   a. An original designated caregiver application for a registry identification card form established by the department which must include all of the following:
      (1) A photographic copy of the applicant's North Dakota identification. The North Dakota identification must be available for inspection and verification upon request of the department.
      (2) The name, address, telephone number, and date of birth of the qualifying patient.
      (3) The name, address, and telephone number of the applicant.
      (4) The applicant's signature and the date.
      (5) A disclosure that possession of a firearm by a person who possesses marijuana may be a violation of federal law.
   b. An original designated caregiver authorization form established by the department which must be executed by a registered qualifying patient providing the designated caregiver applicant with the responsibility of managing the well-being of the registered qualifying patient with respect to the registered qualifying patient's medical use of marijuana. The form must include:
      (1) The name and date of birth of the designated caregiver applicant; and
      (2) The registered qualifying patient's signature and the date.
   c. A recent two-by-two inch [5.08-by-5.08 centimeter] photograph of the applicant.
   d. Any other information or material required by the department by rule.
3. Except as provided in section 19-24.1-04.1, a criminal history record check conducted under section 12-60-24 must be performed upon initial application and biennially thereafter and at any other time upon the request of the department. All fees associated with the criminal history record check must be paid by the department.
4. An individual convicted of a drug-related misdemeanor offense within the five years preceding the date of application or of a felony offense is prohibited from serving as a designated caregiver.
5. An applicant shall submit a separate and complete application for each of the applicant's registered qualifying patients. A registered designated caregiver may assist no more than five registered qualifying patients. A registered designated caregiver who is a registered qualifying patient may assist no more than four additional registered qualifying patients.
6. A registered designated caregiver may not purchase or possess more than the allowable amount of usable marijuana for each of the registered designated caregiver's registered qualifying patients and for the registered designated caregiver if the caregiver is a registered qualifying patient.

19-24.1-04.1. Designated caregivers - Criminal history record check exemption.

The department may waive the requirement for a registered designated caregiver to obtain a criminal history record check under section 12-60-24 if the registered designated caregiver is solely assisting a registered qualifying patient whose debilitating medical condition is a terminal illness or if the registered designated caregiver is solely assisting a registered qualifying patient who is admitted into the hospice program. A registered designated caregiver seeking a waiver under this section shall provide the department with a written statement attesting the caregiver has not been convicted of a drug-related misdemeanor offense within the five years preceding the date of application or a felony offense. If a waiver is issued under this section, the registered designated caregiver's registry identification card is valid for a period not to exceed six months.

19-24.1-05. Qualifying patients and designated caregivers - Identification cards - Issuance and denial.

1. Upon receipt of a complete application for or renewal of a qualifying patient or designated caregiver registry identification card, the department shall verify the submitted information.
2. The verification methods used by the department on an application or renewal and accompanying documentation may include:
   a. Contacting an applicant by telephone or mail, or if proof of identity is uncertain, the department shall require a face-to-face meeting and the production of additional identification materials;
   b. Contacting the North Dakota board of medicine or North Dakota board of nursing to verify the certifying health care provider is licensed in the state and is in good standing; and
   c. Contacting the health care provider to obtain additional documentation verifying the qualifying patient applicant's medical diagnosis and medical condition qualify the applicant for participation in the medical marijuana program.
3. Upon verification of the information contained in an application or renewal, the department shall approve or deny the application or renewal.
4. Except as provided in subsection 5, the department shall issue a registry identification card within thirty calendar days of approving an application or renewal. A designated caregiver must have a registry identification card for each of the designated caregiver's registered qualifying patients.
5. The department may not issue a registry identification card to a qualifying patient who is a minor unless:
   a. The department receives documentation the minor's health care provider has explained to the parent or legal guardian with responsibility for health care decisions for the minor the potential risks of the use of pediatric medical marijuana; and
   b. The department receives documentation the parent or legal guardian with responsibility for health care decisions for the minor consents in writing to:
      (1) Allow the minor's use of pediatric medical marijuana to treat or alleviate the debilitating medical condition;
      (2) Serve as the minor's designated caregiver or identifies a registered designated caregiver to act as the minor's designated caregiver;
      (3) Control the acquisition of usable marijuana and control the dosage and frequency of the use of usable marijuana by the minor; and
      (4) If serving as the minor's designated caregiver, prevent the minor from accessing the usable marijuana by storing the usable marijuana in an enclosed, locked facility.
6. If the department denies an application or renewal, the applicant may not reapply for one year from the date of the denial, unless otherwise authorized by the department, and the applicant is prohibited from all lawful privileges provided under this chapter.
7. The department shall deny an application for or renewal of a qualifying patient's registry identification card if the applicant:
   a. Does not meet the requirements of this section or section 19-24.1-03;
   b. Did not provide the required information and materials;
   c. Previously had a registry identification card revoked which involved unauthorized minor transfer, use, or access to usable marijuana or the use of usable marijuana which allowed the smoke or vapor to be inhaled by a minor;
   d. Provided false or falsified information or made a material misstatement; or
   e. Previously had a registry identification card revoked three times.
8. The department shall deny an application for or renewal of a designated caregiver registry identification card if the designated caregiver applicant:
   a. Does not meet the requirements of this section or section 19-24.1-04;
   b. Did not provide the required information and materials;

c. Previously had a registry identification card revoked which involved unauthorized minor transfer, use, or access to usable marijuana or the use of usable marijuana which allowed the smoke or vapor to be inhaled by a minor;
d. Provided false or falsified information or made a material misstatement; or
e. Previously had a registry identification card revoked three times.

9. Notwithstanding subsection 8, the department shall deny an application for or renewal of a qualifying patient or designated caregiver registry identification card for one year from the date of an initial revocation and five years from the date of a second revocation.
10. A registered qualifying patient may have no more than five registered designated caregivers.
11. The department shall notify, in writing, the qualifying patient or designated caregiver applicant of the reason for denying an application or renewal.
12. The department shall notify the following in writing:
    a. A registered qualifying patient if that patient's designated caregiver's application or renewal is denied; and
    b. A registered designated caregiver if that caregiver's qualifying patient's application or renewal is denied.
13. The cardholder may appeal a denial or revocation of a registry identification card, within thirty days after notice has been given, to the district court of Burleigh County for hearing. The court may authorize the cardholder to appear by reliable electronic means.

19-24.1-06. Registry identification cards - Renewal.

To prevent interruption of possession of a valid registry identification card, a registered qualifying patient or registered designated caregiver shall apply for a registry identification card renewal by submitting a complete reapplication as provided under section 19-24.1-03 or 19-24.1-04 no less than forty-five calendar days before the expiration date of the existing registry identification card.

19-24.1-07. Registry identification cards - Nontransferable.

A registry identification card is not transferable, by assignment or otherwise, to another person. If a person attempts to transfer a card in violation of this section, the registry identification card is void and the person is prohibited from all privileges provided under this chapter.

19-24.1-08. Qualifying patients and designated caregivers - Voluntary withdrawal.

A registered qualifying patient or registered designated caregiver may voluntarily withdraw from participation in the medical marijuana program. A registered qualifying patient or registered designated caregiver seeking to withdraw from the medical marijuana program shall notify the department in writing no less than thirty calendar days before withdrawal.

19-24.1-09. Cardholders - Eligibility and compliance.

1. A cardholder shall provide the department or the department's designee immediate access to any material and information necessary for determining eligibility and compliance with this chapter.
2. Failure of a cardholder to provide the department access to the material, or information as provided under this chapter may result in the department taking action, which may include the revocation of the cardholder registry identification card and referral to state or local law enforcement.
3. Failure of a cardholder to comply with the requirements under this section which is documented by the department, may result in sanctions, including suspension, revocation, nonrenewal, or denial of registration, and referral to state or local law enforcement.

4. The department may refer credible criminal complaints against a cardholder to appropriate state or local law enforcement authorities.
5. a. If a violation of the requirements under this section is cited as a result of compliance monitoring, the department shall provide the cardholder with written notice of the findings following the compliance monitoring visit.
   b. Unless otherwise specified by the department, the cardholder shall correct the violation within five calendar days of receipt of the notice citing the violation.
   c. The department shall verify whether the cardholder corrected the violation.
   d. The violation is not deemed corrected until the department provides written verification the corrective action is satisfactory.
   e. If the violation is not corrected within the required time, the department may revoke the registry identification card of the cardholder.

19-24.1-10. Cardholders - Notification of change.

1. Within ten calendar days of the change, in a manner prescribed by the department, a registered qualifying patient or registered designated caregiver shall notify the department of any of the following:
   a. A change in the cardholder's name or address;
   b. Knowledge of a change that would render the registered qualifying patient no longer eligible to participate in the medical marijuana program;
   c. Knowledge of a change that results in the registered qualifying patient's health care provider no longer meeting the definition of the term "health care provider" as defined under section 19-24.1-01; or
   d. Knowledge of a change that renders the registered qualifying patient's registered designated caregiver no longer eligible to participate in the medical marijuana program.
2. If a registered qualifying patient seeks to change the patient's designated caregiver, the registered qualifying patient shall notify the department in writing of this change.
3. If a cardholder loses the cardholder's registry identification card, the cardholder shall notify the department in writing within twenty-four hours of becoming aware of the loss.
4. If a registered qualifying patient is unable to make a notification required under this section due to age or medical condition, that patient's registered designated caregiver or the individual responsible for making medical decisions for that patient shall provide the notification.
5. If the department receives notification of an item listed in this section and the nature of the item reported does not affect a cardholder's eligibility, the department may issue the cardholder a new registry identification card within twenty calendar days of approving the updated information and the cardholder may pay a fee, not to exceed twenty-five dollars. If a cardholder notifying the department is a registered qualifying patient who has a registered designated caregiver, the department shall issue the patient's registered designated caregiver a new registry identification card within twenty calendar days of approving the updated information.
6. If the department receives notification of an item listed in this section and the nature of the item reported makes the cardholder ineligible, the cardholder's registry identification card becomes void immediately upon notification of the department and the registered cardholder shall dispose of any usable marijuana in the cardholder's possession within fifteen calendar days, in accordance with rules adopted under this chapter.
7. A registered qualifying patient's certifying health care provider may notify the department in writing if the health care provider's registered qualifying patient no longer has a debilitating medical condition. The health care provider may notify the department if a bona fide provider-patient relationship ceases to exist. Except if the bona fide provider-patient relationship is terminating due to the health care provider moving to a location where it is not suitable to continue the bona fide provider-patient relationship, the qualifying patient's registry identification card becomes void immediately upon the health care provider's notification of the department. If the bona

fide provider-patient relationship is terminating due to the health care provider moving to a location where it is not suitable to continue the bona fide provider-patient relationship, the qualifying patient's registry identification card is void if the registered qualifying patient fails to establish a new bona fide provider-patient relationship within sixty days of the department receiving notice from the original health care provider. If the registry identification card is voided under this subsection, the registered qualifying patient shall dispose of any usable marijuana in the cardholder's possession within fifteen calendar days, in accordance with rules adopted under this chapter.

19-24.1-11. Registry identification cards.

1. The contents of a registry identification card must include:
   a. The name of the cardholder;
   b. A designation as to whether the cardholder is a qualifying patient, designated caregiver, or compassion center agent;
   c. A designation as to whether a qualifying patient is a minor;
   d. A designation as to whether a qualifying patient or a designated caregiver's qualifying patient is authorized to use an enhanced amount of dried leaves or flowers of the plant of the genus cannabis to treat or alleviate the patient's debilitating medical condition of cancer;
   e. The date of issuance and expiration date;
   f. A random ten-digit alphanumeric identification number containing at least four numbers and at least four letters which is unique to the cardholder;
   g. If the cardholder is a designated caregiver, the random identification number of the qualifying patient the designated caregiver is authorized to assist;
   h. A photograph of the cardholder; and
   i. The phone number or website address at which the card can be verified.
2. Except as otherwise provided in this section or rule adopted under this chapter, a registry identification card expiration date must be one year after the date of issuance.
3. If a health care provider limits the written certification until a specified date, less than one year, the registry identification card expires on that date.

19-24.1-12. Compassion centers.

1. A person may not process or produce or dispense usable marijuana or otherwise act as a compassion center in this state unless the person is registered as a compassion center.
2. Except as otherwise provided under this section, the department shall register no more than:
   a. Two compassion centers with the sole purpose of operating as a manufacturing facility; and
   b. Eight compassion centers with the sole purpose of operating as a dispensary.
3. The department shall establish an open application period for the submission of compassion center applications. At the completion of the open application period, the department shall review each complete application using a competitive process established in accordance with rules adopted under this chapter and shall determine which applicants to register as compassion centers.
4. The department may register additional compassion centers if the department determines additional compassion centers are necessary to increase access to usable marijuana by registered qualifying patients and registered designated caregivers.
5. If the department revokes or does not renew a compassion center registration certificate, the department may establish an open application period for the submission of compassion center applications.
6. The department of commerce may not certify a compassion center as a primary sector business.

19-24.1-13. Compassion centers - Authority.

1. The activities of a manufacturing facility are limited to producing and processing and to related activities, including acquiring, possessing, storing, transferring, and transporting marijuana and usable marijuana, for the sole purpose of selling usable marijuana to a dispensary.
2. The activities of a dispensary are limited to purchasing usable marijuana from a manufacturing facility, and related activities, including storing, delivering, transferring, and transporting usable marijuana, for the sole purpose of dispensing usable marijuana to a registered qualifying patient, directly or through the registered qualifying patient's registered designated caregiver. The activities of a dispensary include providing educational material and selling usable marijuana related supplies to a registered qualifying patient or a registered designated caregiver.
3. An individual or organization may not hold an ownership interest in:
   a. More than one manufacturing facility.
   b. More than four dispensaries.
   c. More than one dispensary within a twenty-mile [32.19 kilometer] radius of another dispensary.
4. An agreement may not be entered between a manufacturing facility and dispensary whereby a dispensary agrees to limit purchases or sales of usable marijuana to one manufacturing facility.

19-24.1-14. Compassion centers - Application.

1. The department shall establish forms for an application to be registered as a compassion center. For a compassion center registration application to be complete and eligible for review, the applicant shall submit to the department all of the following:
   a. A nonrefundable application fee, not to exceed five thousand dollars, made payable to the "North Dakota Department of Health and Human Services, Medical Marijuana Program".
   b. The legal name, articles of incorporation or articles of organization, and bylaws or operating agreement of the proposed compassion center applicant.
   c. Evidence of the proposed compassion center applicant's registration with the secretary of state and certificate of good standing.
   d. The physical address of the proposed location of the proposed compassion center and:
      (1) Evidence of approval from local officials as to the proposed compassion center applicant's compliance with local zoning laws for the physical address to be used by the proposed compassion center; and
      (2) Evidence the physical address of the proposed compassion center is not located within one thousand feet [304.80 meters] of a property line of a pre-existing public or private school.
   e. For a manufacturing facility applicant, a description of the enclosed, locked facility that would be used in the production and processing of marijuana, including steps that will be taken to ensure the production and processing is not visible from the street or other public areas.
   f. The name, address, and date of birth of each principal officer and board member, or of each member-manager, manager, or governor, of the proposed compassion center applicant and verification each officer and board member, or each member-manager, manager, or governor, has consented to a criminal history record check conducted under section 12-60-24.
   g. For each of the proposed compassion center applicant's principal officers and board members, or for each of the proposed compassion center applicant's member-managers, managers, or governors, a description of that individual's relevant experience, including training or professional licensing related to medicine, pharmaceuticals, natural treatments, botany, food science, food safety, production, processing, and the individual's experience running a business entity.

h. A description of proposed security and safety measures, which demonstrate compliance with the security and safety requirements under section 19-24.1-25.
i. An example of the design and security features of usable marijuana containers which demonstrates compliance with section 19-24.1-21.
j. A complete operations manual, which demonstrates compliance with section 19-24.1-27.
k. A description of the plans for making usable marijuana available on an affordable basis to registered qualifying patients with limited financial resources.
l. A list of all individuals and business entities having direct or indirect authority over the management or policies of the proposed compassion center applicant.
m. A list of all individuals and business entities having an ownership interest in the proposed compassion center applicant, 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.
n. The identity of any creditor holding a security interest in the proposed compassion center premises.

2. The department is not required to review an application submitted under this section unless the department determines the application is complete. The criteria considered by the department in reviewing an application must include:
   a. The suitability of the proposed compassion center location, including compliance with any local zoning laws, and the geographic convenience to access compassion centers for registered qualifying patients and registered designated caregivers from throughout the state;
   b. The character and relevant experience of the principal officers and board members, or of the member-managers, managers, or governors, including training or professional licensing and business experience;
   c. The applicant's plan for operations and services, including staffing and training plans, whether the applicant has sufficient capital to operate, and the applicant's ability to provide an adequate supply of usable marijuana to registered qualifying patients and registered designated caregivers;
   d. The sufficiency of the applicant's plans for recordkeeping;
   e. The sufficiency of the applicant's plans for safety, security, and the prevention of diversion, including the proposed location and security devices employed;
   f. The applicant's plan for making usable marijuana available on an affordable basis to registered qualifying patients with limited financial resources;
   g. The applicant's plan for safe and accurate packaging and labeling of usable marijuana; and
   h. The applicant's plans for testing usable marijuana and marijuana.
3. Following completion of the review under subsection 2, the department shall select the applicants eligible for registration under section 19-24.1-15.

19-24.1-15. Compassion centers - Registration.

1. Upon receipt of notification by the department a compassion center application is eligible for registration, the applicant shall submit all of the following additional items to the department to qualify for registration:
   a. A certification fee, made payable to the "North Dakota Department of Health and Human Services, Medical Marijuana Program", in an amount not to exceed ninety thousand dollars for a dispensary and one hundred ten thousand dollars for a manufacturing facility.
   b. A financial assurance or security bond to ensure the protection of the public health and safety and the environment in the event of abandonment, default, or other inability or unwillingness to meet the requirements of this chapter.
   c. The physical address of the proposed compassion center; confirmation the information in the application regarding the physical location of the proposed compassion center has not changed, and if the information has changed the department shall determine whether the new information meets the requirements

of this chapter; and a current certificate of occupancy, or equivalent document, to demonstrate compliance with the provisions of state and local fire code for the physical address of the proposed compassion center. It is not necessary for an applicant to resubmit any information provided in the initial application unless there has been a change in that information.

d. An update to previously submitted information, including information about compassion center agents and compliance with section 19-24.1-18.

2. If an applicant complies with subsection 1, the department shall issue the applicant a registration certificate.

19-24.1-16. Compassion centers - Renewal.

1. A compassion center registration certificate expires two years after issuance. A compassion center may submit a renewal application at any time beginning ninety calendar days before the expiration of the registration certificate. A compassion center shall submit a renewal application a minimum of sixty calendar days before the expiration of the registration certificate to avoid suspension of the certificate.
2. The department shall approve a compassion center's renewal application within sixty calendar days of submission, if the following conditions are satisfied:
   a. The compassion center submits a renewal fee, in an amount not to exceed ninety thousand dollars for a dispensary and one hundred ten thousand dollars for a manufacturing facility, which the department shall refund if the department rejects the renewal application;
   b. The compassion center submits a complete renewal application;
   c. The department has at no time suspended the compassion center's registration for violation of this chapter;
   d. Inspections conducted under this chapter do not raise any serious concerns about the continued operation of the compassion center; and
   e. The compassion center continues to meet all the requirements for the operation of a compassion center as set forth in this chapter and rules adopted under this chapter.
3. If a compassion center does not meet the requirements for renewal, the department may not issue a registration certificate and the department shall provide the compassion center with written notice of the determination. If a compassion center's certificate is not renewed, the compassion center shall dispose all marijuana and usable marijuana in accordance with rules adopted under this chapter.

19-24.1-17. Compassion centers - Registration certificates nontransferable - Notification of changes.

1. Upon application of a compassion center to the department, a registration certificate of a compassion center may be amended to authorize a change in the authorized physical location of the compassion center, or to amend the ownership or organizational structure of the compassion center with the registration certificate. A compassion center shall provide the department written notice of any change described under this section at least sixty calendar days before the proposed effective date of the change.
2. A registration certificate authorizing the operation of a compassion center is void by a change in ownership, substantial corporate change, change in location, or discontinued operation, without prior approval of the department. The department may adopt rules allowing for certain types of changes in ownership without the need for prior written approval from the department.
3. The department shall authorize the use of additional structures located within five hundred feet [152.40 meters] of the location described in the original application, unless the department makes an affirmative finding the use of additional structures would jeopardize public health or safety or would result in the cannabis business being within one thousand feet [304.80 meters] of a property line of a pre-existing public or

private school. The department may waive all or part of the required advance notice to address emergent or emergency situations.

19-24.1-18. Compassion centers - Agents - Registry identification cards.

1. Upon issuance of a compassion center registry certificate, the department shall issue a registry identification card to each qualified compassion center agent associated with the compassion center.
2. To qualify to be issued a registry identification card, each compassion center agent must be at least twenty-one years of age and shall submit all of the following registry identification card application material to the department:
   a. A photographic copy of the agent's department-approved identification. The agent shall make the identification available for inspection and verification by the department.
   b. A recent two-by-two inch [5.08-by-5.08 centimeter] photograph of the agent.
   c. A written and signed statement from an officer or executive staff member of the compassion center stating the applicant is associated with the compassion center and the capacity of the association.
   d. The name, address, and telephone number of the agent.
   e. The name, address, and telephone number of the compassion center with which the agent is associated.
   f. The agent's signature and the date.
   g. A nonrefundable application or renewal fee not to exceed the amount of two hundred dollars.
3. Each compassion center agent shall consent to a criminal history record check conducted under section 12-60-24 to demonstrate compliance with the eligibility requirements.
   a. All applicable fees associated with the required criminal history record checks must be paid by the department.
   b. A criminal history record check must be performed upon initial application and biennially upon renewal. A compassion center agent shall consent to a criminal history record check at any time the department determines necessary.
   c. An individual convicted of a drug-related misdemeanor offense within the five-year period before the date of application or a felony offense is prohibited from being a compassion center agent.
4. The department shall notify the compassion center in writing of the purpose for denying a compassion center agent application for a registry identification card. The department shall deny an application if the applicant fails to meet the registration requirements or to provide the information required, if the applicant previously had a registry identification card revoked, or if the department determines the information provided is false. The cardholder may appeal a denial or revocation of a registry identification card, within thirty days after notice has been given, to the district court of Burleigh County. The court may authorize the cardholder to appear by reliable electronic means.
5. The department shall issue a compassion center agent a registry identification card within thirty calendar days of approval of an application.
6. A compassion center agent with a registry identification card shall notify the department of any of the following within ten calendar days of the change, in a manner prescribed by the department:
   a. A change in the cardholder's name or address; and
   b. Knowledge of a change that would render the compassion center agent no longer eligible to be a cardholder.
7. If a compassion center agent loses the agent's registry identification card, that agent shall notify the department in writing within twenty-four hours of becoming aware the card has been lost.
8. If a cardholder notifies the department of items listed in this section but the nature of the item reported results in the cardholder remaining eligible, the department shall

issue the cardholder a new registry identification card with a new random ten-digit alphanumeric identification number within twenty calendar days of approving the updated information and the cardholder shall pay a fee, not to exceed twenty-five dollars. If a cardholder notifies the department of an item that results in the cardholder being ineligible, the registry identification card immediately becomes void.

9. A compassion center shall notify the department in writing within two calendar days of the date a compassion center agent ceases to work for or be associated with the compassion center. Upon receipt of the notification, that individual's registry identification card becomes void immediately.
10. The registry identification card of a compassion center agent expires one year after issuance or upon the termination of the compassion center's registration certificate, whichever occurs first. To prevent interruption of possession of a valid registry identification card, a compassion center agent shall renew a registry identification card by submitting a complete renewal application no less than forty-five calendar days before the expiration date of the existing registry identification card.

19-24.1-19. Cardholders - Compassion centers - Revocation.

1. The department may suspend or revoke a cardholder's registry identification card or a compassion center's registration certificate for a material misstatement by an applicant in an application or renewal.
2. The department may suspend or revoke a registry identification card or registration certificate for a violation of this chapter or rules adopted under this chapter.
3. If a compassion center agent or a compassion center sells or otherwise transfers marijuana or usable marijuana to a person not authorized to possess marijuana or usable marijuana under this chapter, the department shall revoke the cardholder's registry identification card or the compassion center's registration certificate, or both. If the department revokes a cardholder's registry identification card under this subsection, the cardholder may not reapply for one year from the date of an initial revocation and five years from the date of a second revocation. Upon a third revocation or if the revocation under this subsection involved unauthorized minor transfer, use, or access to usable marijuana or the use of usable marijuana which allowed the smoke or vapor to be inhaled by a minor, the cardholder is disqualified from further participation under this chapter.
4. The department shall provide written notice of suspension or revocation of a registry identification card or registration certificate.
   a. A suspension may not be for a period longer than six months.
   b. A manufacturing facility may continue to produce and process and to possess marijuana and usable marijuana during a suspension, but may not transfer or sell usable marijuana.
   c. A dispensary may continue to possess usable marijuana during a suspension, but may not purchase, dispense, or transfer usable marijuana.
   d. The cardholder or the compassion center may appeal a denial or revocation of a registry identification card or registry certificate, within thirty days after notice has been given, to the district court of Burleigh County. The court may authorize the cardholder or compassion center to appear by reliable electronic means.

19-24.1-20. Cardholders - Compassion centers - Violations - Penalties.

1. A cardholder or compassion center that fails to provide a notice as required under this chapter shall pay to the department a fee in an amount established by the department, not to exceed one hundred fifty dollars.
2. In addition to any other penalty applicable in law, a manufacturing facility or a manufacturing facility agent is guilty of a class B felony for intentionally selling or otherwise transferring marijuana or usable marijuana in any form, to a person other than a dispensary, or for intentionally selling or otherwise transferring marijuana in any form other than usable marijuana, to a dispensary. A person convicted under this

subsection may not continue to be affiliated with a compassion center and is disqualified from further participation under this chapter.

3. In addition to any other penalty applicable in law, a dispensary or a dispensary agent is guilty of a class B felony for intentionally selling or otherwise transferring usable marijuana, to a person other than a registered qualifying patient or a registered designated caregiver, to a registered qualifying patient who is a minor, or in a form not allowed under this chapter. A person convicted under this subsection may not continue to be affiliated with a compassion center and is disqualified from further participation under this chapter.
4. In addition to any other penalty applicable in law, a dispensary or a dispensary agent is guilty of a class B felony for intentionally selling or otherwise transferring usable marijuana, in a form other than pediatric medical marijuana, to a registered designated caregiver, for use by a registered qualifying patient who is a minor. A person convicted under this subsection may not continue to be affiliated with a compassion center and is disqualified from further participation under this chapter.
5. A compassion center or compassion center agent that knowingly submits false records or documentation required by the department to certify a compassion center under this chapter is guilty of a class C felony. A person convicted under this subsection may not continue to be affiliated with a compassion center and is disqualified from further participation under this chapter.
6. In addition to any other penalty applicable in law, if a compassion center violates this chapter the department may fine the compassion center up to one thousand dollars for each violation.
7. In addition to any other penalty applicable in law, a registered qualifying patient who intentionally sells or otherwise transfers usable marijuana, to another person, is guilty of a class B felony. An individual convicted under this subsection is disqualified from further participation under this chapter.
8. In addition to any other penalty applicable in law, a registered designated caregiver who intentionally sells or otherwise transfers usable marijuana, to a person other than a registered qualifying patient to which the caregiver is associated with registration, is guilty of a class B felony. An individual convicted under this subsection is disqualified from further participation under this chapter.
9. An individual who knowingly submits false records or documentation required by the department to receive a registry identification card under this chapter is guilty of a class A misdemeanor. An individual convicted under this subsection may not continue to be affiliated with a compassion center and is disqualified from further participation under this chapter.
10. A health care provider who holds a financial interest in a compassion center may not knowingly refer a patient to a compassion center or to a registered designated caregiver, advertise in a compassion center, or issue a written certification. A health care provider who violates this subsection must be fined up to one thousand dollars.

19-24.1-21. Compassion centers - Dispensing.

1. A compassion center shall comply with the dispensing requirements of this section.
2. Design and security features of usable marijuana containers must be in accordance with rules adopted under this chapter.
3. A manufacturing facility or agent of the manufacturing facility may not dispense marijuana or usable marijuana, except the manufacturing facility or agent may sell usable marijuana to a dispensary.
4. A dispensary or agent of the dispensary may not dispense usable marijuana unless the dispensary first uses the verification system to confirm the registered qualifying patient or registered designated caregiver identification card is valid. A dispensary or agent of the dispensary:
   a. May not dispense usable marijuana to a person other than a registered qualifying patient or a registered qualifying patient's registered designated caregiver. If a registered qualifying patient is a minor:

(1) The dispensary or agent of the dispensary may not dispense usable marijuana to a minor; and
(2) The usable marijuana dispensed to the minor's designated caregiver must be in the form of pediatric medical marijuana.

b. May not dispense to a registered qualifying patient or registered designated caregiver more than the allowable amount of usable marijuana and may not dispense an amount if it is known that amount would cause the recipient to purchase or possess more usable marijuana than is permitted under this chapter.

19-24.1-22. Compassion centers - Inspections.

1. A compassion center is subject to random inspection by the department. During an inspection, the department may review the compassion center's records, including the compassion center's financial and dispensing records, which may track transactions according to registered qualifying patient and registered designated caregiver registry identification numbers.
2. The department shall conduct inspections of compassion centers to ensure compliance with this chapter. The department shall conduct inspections of manufacturing facilities for the presence of contaminants. The department shall select a certified laboratory to conduct random quality sampling testing, in accordance with rules adopted under this chapter. A compassion center shall pay the cost of all random quality sampling testing.

19-24.1-23. Compassion centers - Pesticide testing.

A manufacturing facility shall test marijuana at a manufacturing facility for the presence of pesticides. If a marijuana pesticide test or a random quality sampling test under section 19-24.1-22 indicates the presence of a pesticide, the manufacturing facility shall report the test result immediately to the department and to the agriculture commissioner. Upon the order of the department or agriculture commissioner, the manufacturing facility immediately shall destroy all affected or contaminated marijuana and usable marijuana inventory in accordance with rules adopted under this chapter, and shall certify to the department and to the agriculture commissioner that all affected or contaminated inventory has been destroyed.

19-24.1-24. Compassion centers - Cannabis plants.

1. A manufacturing facility shall grow an amount of marijuana sufficient to meet the qualifying patient population demands. For every five hundred plants in excess of one thousand plants a manufacturing facility possesses, the manufacturing facility shall pay the department an additional certification fee not to exceed seven thousand five hundred dollars. This fee is due at the time of increase and again at renewal of the compassion center registration certificate under section 19-24.1-16.
2. A dispensary may not possess more than three thousand five hundred ounces [99.22 kilograms] of usable marijuana at any time, regardless of formulation.
3. The department shall adopt rules to allow a manufacturing facility to possess no more than an additional fifty plants for the exclusive purpose of department-authorized research and development related to production and processing. These plants are not counted in a manufacturing facility possession amount and are not subject to an additional fee.

19-24.1-25. Compassion centers - Security and safety.

1. In compliance with rules adopted under this chapter, a compassion center shall implement appropriate security and safety measures to deter and prevent the unauthorized entrance to areas containing marijuana and containing usable marijuana and to prevent the theft of marijuana and usable marijuana.
2. A compassion center shall limit to authorized personnel entry to an area in which production or producing takes place or in which marijuana or usable marijuana is held.

3. A compassion center must have a fully operational security alarm system at the authorized physical address which includes an electrical support backup system for the alarm system to provide suitable protection against theft and diversion.
4. A compassion center shall maintain documentation in an auditable form for:
   a. All maintenance inspections and tests conducted under this section, and any servicing, modification, or upgrade performed on the security alarm system;
   b. An alarm activation or other event that requires response by public safety personnel; and
   c. Any breach of security.

19-24.1-26. Compassion centers - Inventory control.

1. A compassion center shall comply with the inventory control requirements provided under this section and rules adopted under this chapter.
   a. A manufacturing facility shall:
      (1) Employ a bar coding inventory control system to track batch, strain, and amounts of marijuana and usable marijuana in inventory and to track amounts of usable marijuana sold to dispensaries; and
      (2) Host a secure computer interface to transfer inventory amounts and dispensary purchase information to the department.
   b. A dispensary shall:
      (1) Employ a bar coding inventory control system to track batch, strain, and amounts of usable marijuana in inventory and to track amounts sold to registered qualifying patients and registered designated caregivers; and
      (2) Host a secure computer interface to transfer inventory amounts and registered qualifying patient and registered designated caregiver purchase information to the department.
2. A compassion center shall store the compassion center's marijuana and usable marijuana in an enclosed locked facility with adequate security, in accordance with rules adopted under this chapter.
3. A compassion center shall conduct inventories of marijuana and usable marijuana at the authorized location at the frequency and in the manner provided by rules adopted under this chapter. If an inventory results in the identification of a discrepancy, the compassion center shall notify the department immediately and appropriate law enforcement authorities within seventy-two hours. A compassion center shall document each inventory conducted by the compassion center.

19-24.1-27. Compassion centers - Operating manual - Training.

1. A compassion center shall maintain a current copy of the compassion center's operating manual that meets the requirements of rules adopted under this chapter.
2. A compassion center shall develop, implement, and maintain on the premises an onsite training curriculum or shall enter contractual relationships with outside resources capable of meeting compassion center agent training needs. A compassion center shall ensure each compassion center agent receives training that includes:
   a. Education regarding professional conduct, ethics, and state and federal laws regarding patient confidentiality;
   b. Informational developments in the field of medical use of marijuana;
   c. All safety and security measures required under section 19-24.1-25;
   d. Specific procedural instructions for responding to an emergency, including robbery or violent accident; and
   e. The compassion center's operating manual and all requirements related to recordkeeping.

19-24.1-28. Compassion centers - Bylaws and operating agreements.

As part of a proposed compassion center's initial application, the applicant shall provide to the department a current copy of the applicant's bylaws or operating agreement. Upon receipt of

a registration certificate, a compassion center shall maintain the bylaws or operating agreement in accordance with this chapter. In addition to any other requirements, the bylaws or operating agreement must include the ownership or management structure of the compassion center; the composition of the board of directors, board of governors, member-managers, or managers; and provisions relative to the disposition of revenues and earnings.

19-24.1-29. Compassion centers - Retention of and access to records and reports.

A compassion center shall keep detailed financial reports of proceeds and expenses. A compassion center shall maintain all inventory, sales, and financial records in accordance with generally accepted accounting principles. The compassion center shall maintain for a period of seven years all reports and records required under this section. A compassion center shall allow the department, or an audit firm contracted by the department, access at all times to all books and records kept by the compassion center.

19-24.1-30. Compassion centers - Recordkeeping - Compassion center agents - Registry identification cards.

1. Each compassion center shall maintain:
   a. In compliance with rules adopted under this chapter, a personnel record for each compassion center agent for a period of at least three years following termination of the individual's affiliation with the compassion center. The personnel record must comply with minimum requirements set by rule adopted under this chapter.
   b. A record of the source of funds that will be used to open or maintain the compassion center, including the name, address, and date of birth of any investor.
   c. A record of each instance in which a current or prospective board member, member-manager, manager, or governor, who managed or served on the board of a business or not-for-profit entity and in the course of that service was convicted, fined, or censured or had a registration or license suspended or revoked in any administrative or judicial proceeding.
2. Each compassion center agent shall hold a valid registry identification card.

19-24.1-31. Verification system.

1. The department shall maintain a confidential list of cardholders and each cardholder's address, phone number, and registry identification number.
2. The department shall establish a secure verification system. The verification system must allow law enforcement personnel, health care providers, pharmacists, compassion centers, and compassion center agents twenty-four-hour access to enter a registry identification number to determine whether the number corresponds with a current valid registry identification card. The system may disclose:
   a. Whether an identification card is valid;
   b. The name of the cardholder;
   c. Whether the cardholder is a registered qualifying patient, registered designated caregiver, or registered compassion center agent;
   d. Whether a registered qualifying patient is a minor; and
   e. The registry identification number of any affiliated registered qualifying patient, registered designated caregiver, or compassion center.

19-24.1-32. Protections.

Except as provided in sections 19-24.1-20 and 19-24.1-33:

1. A registered qualifying patient is not subject to arrest or prosecution or the denial of any right or privilege, including a civil penalty or disciplinary action by a court or occupational or professional regulating entity for the acquisition, use, or possession of usable marijuana or related supplies under this chapter.

2. A registered designated caregiver is not subject to arrest or prosecution or the denial of any right or privilege, including a civil penalty or disciplinary action by a court or occupational or professional regulating entity:
    a. For assisting a registered qualifying patient with the acquisition, use, or possession of usable marijuana or related supplies under this chapter, if the registered designated caregiver is connected to the registered qualifying patient through the department's registration process.
    b. For receiving compensation for costs associated with assisting a registered qualifying patient with the acquisition, use, or possession of usable marijuana or related supplies under this chapter, if the registered designated caregiver is connected to the registered qualifying patient through the department's registration process.
3. It is presumed a registered qualifying patient is engaged in, or a registered designated caregiver is assisting with, the acquisition, use, or possession of usable marijuana or related supplies in accordance with this chapter if the registered qualifying patient or registered designated caregiver is in possession of a valid registry identification card and is not in possession of usable marijuana in an amount that exceeds what is authorized under this chapter. This presumption may be rebutted by evidence the conduct related to acquisition, use, or possession of usable marijuana or related supplies was not for the purpose of treating or alleviating the registered qualifying patient's debilitating medical condition under this chapter.
4. A person is not subject to arrest or prosecution or the denial of any right or privilege, including a civil penalty or disciplinary action by a court or occupational or professional regulating entity, for being in the presence or vicinity of the medical use of marijuana authorized under this chapter.
5. A manufacturing facility is not subject to prosecution, search or inspection, or seizure, except by the department or a department designee, under this chapter for acting under this chapter to:
    a. Produce or process or to conduct related activities for the sole purpose of selling usable marijuana to a dispensary; or
    b. Transfer, transport, or deliver marijuana or usable marijuana to and from a department designee or manufacturing facility in accordance with this chapter.
6. A dispensary is not subject to prosecution, search or inspection, or seizure, except by the department or a department designee, under this chapter for acting under this chapter to:
    a. Purchase usable marijuana from a manufacturing facility and conducting related activities for the sole purpose of dispensing usable marijuana, selling related supplies, and providing educational materials to registered qualifying patients and designated caregivers; or
    b. Transfer usable marijuana to and from a department designee or related marijuana facility in accordance with this chapter.
7. A registered compassion center agent is not subject to arrest or prosecution or the denial of any right or privilege, including a civil penalty or disciplinary action by a court or occupational or professional regulating entity, for working or volunteering for a compassion center if the action performed by the compassion center agent on behalf of the compassion center is authorized under this chapter.
8. The sale and possession of marijuana paraphernalia by a dispensary is lawful if in accordance with this chapter.
9. The medical use of marijuana by a registered cardholder or the producing and processing and the dispensing of usable marijuana by a compassion center is lawful if in accordance with this chapter.
10. A health care provider is not subject to arrest or prosecution or the denial of any right or privilege, including a civil penalty or disciplinary action by a court or occupational or professional regulating entity, solely for providing a written certification or for stating in the health care provider's professional opinion a patient is likely to receive therapeutic or palliative benefit from the medical use of usable marijuana to treat or alleviate the

patient's debilitating medical condition or for refusing to provide written certification or a statement. This chapter does not release a health care provider from the duty to exercise a professional standard of care for evaluating or treating a patient's medical condition.

11. A cardholder or registered compassion center is not subject to arrest or prosecution for use of drug paraphernalia or possession with intent to use drug paraphernalia in a manner consistent with this chapter.
12. A person in possession of medical marijuana waste in the course of transporting or disposing of the waste under this chapter and rules adopted under this chapter may not be subject to arrest or prosecution for that possession or transportation.
13. A person in possession of marijuana, usable marijuana, or medical marijuana waste in the course of performing laboratory tests as provided under this chapter and rules adopted under this chapter may not be subject to arrest or prosecution for that possession or testing.

19-24.1-33. Limitations.

This chapter does not authorize a person to engage in, and does not prevent the imposition of any civil liability or criminal liability or other penalties for engaging in the following conduct:

1. Undertaking an activity under the influence of marijuana if doing so would constitute negligence or professional malpractice.
2. Possessing or consuming usable marijuana:
   a. On a school bus or school van that is used for school purposes;
   b. On the grounds of any public or private school;
   c. At any location while a public or private school sanctioned event is occurring at that location;
   d. On the grounds of a correctional facility; or
   e. On the grounds of a child care facility or licensed home day care, unless authorized under rules adopted by the department.
3. Undertaking any activity prohibited by section 23-12-09, 23-12-10, 23-12-10.2, 23-12-10.4, 23-12-10.5, or 23-12-11.
4. Using a combustible delivery form of usable marijuana or vaporizing usable marijuana under this chapter if the smoke or vapor would be inhaled by a minor who is not the registered qualifying patient for whom the usable marijuana is intended.
5. Operating, navigating, or being in actual physical control of a motor vehicle, aircraft, train, or motorboat, while under the influence of marijuana. However, a registered qualifying patient may not be considered to be under the influence of marijuana solely because of the presence of metabolites or components of marijuana that appear in insufficient concentration to cause impairment.

19-24.1-34. Acts not prohibited - Acts not required.

1. This chapter does not require:
   a. A government medical assistance program or private insurer to reimburse a person for costs associated with the medical use of marijuana;
   b. A person in lawful possession of property to allow a guest, client, customer, or other visitor to possess or consume usable marijuana on or in that property;
   c. A landlord to allow production or processing on rental property; or
   d. A health care provider to provide a written certification or otherwise recommend marijuana to a patient.
2. This chapter does not prohibit an employer from disciplining an employee for possessing or consuming usable marijuana in the workplace, working while under the influence of marijuana, or working with marijuana in the employee's system.

19-24.1-35. Facility restrictions.

1. A basic care facility, nursing facility, assisted living facility, adult day care facility, or adult foster care home licensed in the state may adopt reasonable restrictions on the

medical use of marijuana by residents or individuals receiving inpatient services, including:

a. The facility will not store or maintain the registered qualifying patient's supply of usable marijuana.
b. The facility, caregivers, or hospice agencies serving the facility's residents are not responsible for providing the usable marijuana for registered qualifying patients or assisting with the medical use of marijuana.
c. Usable marijuana can be consumed by a method other than vaporizing or combustion.
d. Consumption of usable marijuana is limited to a place specified by the facility.

2. A facility listed in subsection 1 may not unreasonably limit a registered qualifying patient's medical use of marijuana as authorized under this chapter unless failing to do so would cause the facility to lose a monetary or licensing-related benefit under federal law or regulations.

19-24.1-36. Rules.

1. The department shall adopt rules as necessary for the implementation and administration of this chapter, including transportation and storage of marijuana and usable marijuana, advertising, packaging and labeling, standards for testing facilities, inventory management, and accurate recordkeeping.
2. The department may adopt rules regarding the operation and governance of additional categories of registered medical marijuana establishments.
3. The department shall adopt rules to establish requirements for reporting incidents of individuals not authorized to possess marijuana or usable marijuana under this chapter and who are found in possession of marijuana or usable marijuana. The rules must identify professionals required to report, the information the reporter is required to report, and actions the reporter shall take to secure the marijuana or usable marijuana.
4. The department shall adopt rules to establish requirements for law enforcement officials and health care professionals to report to the department incidents involving overdose or adverse reaction related to the use of usable marijuana.

19-24.1-37. Confidentiality.

1. Except as provided under subsection 2, information kept or maintained by the department is confidential, including information in a registration application or renewal and supporting information submitted by a qualifying patient, designated caregiver, compassion center, proposed compassion center, or compassion center agent, including information on designated caregivers and health care providers.
2. Information kept or maintained by the department may be disclosed as necessary for:
   a. The verification of registration certificates and registry identification cards under this chapter;
   b. Submission of the annual report required by this chapter;
   c. Submission to the North Dakota prescription drug monitoring program;
   d. Notification of state or local law enforcement of apparent criminal violation;
   e. Notification of state and local law enforcement about falsified or fraudulent information submitted for purposes of obtaining or renewing a registry identification card;
   f. Notification of the North Dakota board of medicine or North Dakota board of nursing if there is a reason to believe a health care provider provided a written certification and the department has reason to believe the health care provider otherwise violated this chapter; or
   g. Data for statistical purposes in a manner such that an individual or compassion center is not identified.
3. Upon a cardholder's written request, the department may confirm the cardholder's status as a registered qualifying patient or a registered designated caregiver to a third party, such as a landlord, school, medical professional, or court.

4. Information submitted to a local government to demonstrate compliance with any security requirements required by local zoning ordinances or regulations is confidential.

19-24.1-38. Advisory board.

1. The governor shall appoint six members to serve on an advisory board as follows:
   a. One health care provider;
   b. One representative of the department;
   c. One representative of the manufacturing facilities;
   d. One representative of the dispensaries;
   e. One registered qualifying patient; and
   f. One licensed pharmacist.
2. The chairman of the legislative management shall appoint two members of the legislative assembly to serve on the advisory board, one member from each chamber. The legislative council shall pay the compensation and expense reimbursement for the legislative members. The terms of members of the appointed advisory board are for two years and members may be reappointed by the appointing entity. The state health officer or designee shall serve as an ex officio voting member and as chairman of the advisory board.
3. The advisory board:
   a. Shall advise the department in implementation of the medical marijuana program.
   b. May receive reports from the department on the status and activities of the medical marijuana program.
   c. May provide recommendations to the department and the legislative management on the medical marijuana program.

19-24.1-39. Report to legislative management.

Annually, the department shall submit to the legislative management a report that does not disclose any identifying information about registered cardholders, compassion centers, or health care providers, but contains the following information:

1. The number of registry identification card applications and renewals;
2. The number of registered qualifying patients, registered designated caregivers, and registered compassion center agents;
3. The nature of the debilitating medical conditions of the registered qualifying patients;
4. The number of registry identification cards revoked;
5. The number of health care providers providing written certifications for qualifying patients;
6. The number of compassion centers;
7. Any expenses incurred and revenues generated by the department from the medical marijuana program; and
8. Data for statistical purposes in a manner so that an individual person is not identifiable.

19-24.1-40. Medical marijuana fund - Continuing appropriation.

The medical marijuana fund is established in the state treasury. The department shall deposit in the fund all fees collected under this chapter. The department shall administer the fund. Moneys in the fund are appropriated to the department on a continuing basis for use in administering this chapter.

ARTICLE 33-44
MEDICAL MARIJUANA

CHAPTER 33-44-01
MEDICAL MARIJUANA

33-44-01-01. Definitions.

In this chapter, unless the context otherwise requires:

1. "Activation time" means the amount of time it is likely to take for an individual to begin to feel the effects of ingesting or inhaling usable marijuana.

2. "Adverse reaction" means an unwanted, unexpected, or dangerous effect caused by the administration of usable marijuana dispensed pursuant to North Dakota Century Code chapter 19-24.1.

3. "Analyte" means a component, substance, or chemical or microbiological constituent that is of interest in an analytical procedure or test.

4. "Batch" means a quantity of dried leaves and flowers from a harvest lot, a quantity of cannabinoid concentrate, or medical cannabinoid product from a process lot.

5. "Compliance test" means a test required by these rules to be performed by a laboratory selected by the department in order to allow the transfer or sale of usable marijuana.

6. "Container" means a sealed, hard- or soft-bodied receptacle in which usable marijuana is placed.

7. "Container identification number" means the identification number that was generated by the manufacturing facility at the time the usable marijuana was packaged and labeled for sale to the dispensary.

8. "Cotyledons" means an embryonic leaf of a plant, one or more of which are the first leaves to appear.

9. "Date of harvest" means the date the mature marijuana plants in a harvest lot were removed from the soil or other growing media. If the harvest occurred on more than one day, the "date of harvest" is the day the last mature marijuana plant in the harvest lot was removed from the soil or other growing media.

10. "Degradation compound" or "Pesticide degradate" means a resultant product from the transformation of a parent compound to a product with different physical and chemical properties, the fate and significance of which, is altered due to the structural changes.

11. "Harvest lot" means a specifically identified quantity of the same strain of marijuana that is cultivated utilizing the same growing practices, harvested within a seventy-two-hour period at the same location, and cured under uniform conditions.

12. "Hazardous waste" means the same as defined in North Dakota Century Code chapter 23-20.3.

13. "Laboratory" means a laboratory selected by the department in accordance with section 33-44-01-36 to sample and conduct tests in accordance with these rules.

14. "Medical marijuana waste" means the same as defined in North Dakota Century Code chapter 19-24.1.

15. "Net weight" means the gross weight minus the tare weight of the packaging.

16. "Parent compound" means the original molecular structure from which other compounds can be derived through a chemical reaction or natural breakdown process.

17. "Pediatric symbol" means the image, established by the department and made available to manufacturing facilities, indicating the product complies with the pediatric medical marijuana maximum concentration limit as defined in North Dakota Century Code chapter 19-24.1.

18. "Plant" means a marijuana plant that has produced cotyledons or a cutting of a marijuana plant that has produced cotyledons.

19. "Process lot" means any amount of:

    a. Cannabinoid concentrate of the same type and processed within a forty-eight-hour period, unless prior written authorization is received from the department, using the same extraction methods, standard operating procedures, and batches, not to exceed three, of the same strain from the same or a different harvest lot; or

    b. Medical cannabinoid product of the same type and processed within a forty-eight-hour period, unless prior written authorization is received from the department, using the same ingredients, standard operating procedures, and a process lot or process lots, not to exceed three, of cannabinoid concentrate as defined in subsection a.

20. "Product identity" means a common name of the product that is contained in the package.

21. "Remediation" means a process used by a manufacturing facility to remedy a lot or batch that has failed testing.

22. "Sterilization" means the removal of all micro-organisms and other pathogens from usable marijuana by treating it with approved chemicals or subjecting it to high heat.

23. "Tentatively identified compounds" means compounds detected in a sample using gas chromatography mass spectrometry or liquid chromatography mass spectrometry that are not among the target analytes for the residual solvent analysis and pesticide and mycotoxin analysis.

24. "Test sample" means anything collected by a laboratory from a compassion center for testing.

25. "Unit of sale" means an amount of usable marijuana commonly packaged in a container for transfer to a registered qualifying patient or registered designated caregiver, or capable of

being packaged in a container for transfer to a registered qualifying patient or registered designated caregiver.

26. "Universal symbol" means the image, established by the department and made available to manufacturing facilities, indicating the product contains marijuana.

27. "Water activity" means a measure of the free moisture in usable marijuana and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol a_w.

28. "Written notice" means a notice provided to the department via letter, electronic mail, or other electronic form or medium made available on the department's website.

History: Effective April 1, 2018; amended effective October 1, 2019; July 1, 2022.
General authority: NDCC 19-24.1-01
Law Implemented: NDCC 19-24.1-01

33-44-01-02. Cardholder notification of change.

A registered qualifying patient or registered designated caregiver who is required to provide notification in accordance with subsection 1 of North Dakota Century Code section 19-24.1-10 shall provide the department written notice.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-10
Law Implemented: NDCC 19-24.1-10

33-44-01-03. Fees for failure to provide notice.

A compassion center that fails to provide notice as required by North Dakota Century Code chapter 19-24.1 and these rules, is subject to a fee in the amount of one hundred fifty dollars.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-20
Law Implemented: NDCC 19-24.1-20

33-44-01-03.1. Minor application.

The department may process a qualifying patient application for a registry identification card without the signature of the minor's parent or legal guardian if the applicant is eighteen years of age and the department determines the minor has no parent or legal guardian with responsibility for health care decisions of the minor.

History: Effective July 1, 2022.
General Authority: NDCC 19-24.1-03
Law Implemented: NDCC 19-24.1-03

33-44-01-03.2. Application fees for registry identification cards.

The department shall collect nonrefundable original application fees and nonrefundable renewal application fees for registry identification cards as follows:

1. For qualifying patient applications, twenty-five dollars.

2. For compassion center agent application fees, two hundred dollars.

History: Effective October 1, 2022.
General Authority: NDCC 19-24.1-03, 19-24.1-18

Law Implemented: NDCC 19-24.1-03, 19-24.1-18

33-44-01-03.3. Replacement fees for registry identification cards.

The department shall collect fees for issuing new registry identification cards when an original application or renewal application is not submitted as follows:

1. For a lost qualifying patient registry identification card or compassion center registry identification card, twenty-five dollars.

2. For a change in name of a registered qualifying patient or registered compassion center agent, five dollars.

History: Effective October 1, 2022.
General Authority: NDCC 19-24.1-10, 19-24.1-18
Law Implemented: NDCC 19-24.1-10, 19-24.1-18

33-44-01-04. Cardholder disposal of usable marijuana.

1. An individual who is no longer registered with the department or a cardholder who is no longer eligible shall dispose of any usable marijuana in their possession by:

   a. Returning it to a dispensary; or

   b. Rendering it unusable in accordance with subsection 4 of section 33-44-01-15.

2. Except as provided in this section, an individual who is no longer registered with the department or a cardholder who is no longer eligible may not transfer, share, give, sell, or deliver any usable marijuana in their possession to anyone, regardless of whether the individual possesses a valid registry identification card.

3. An individual who is no longer registered with the department or a cardholder who is no longer eligible may not dispose of usable marijuana in any manner other than as permitted by these rules.

4. After the death of a registered qualifying patient, any usable marijuana that was in the cardholder's possession or in the possession of the registered qualifying patient's registered designated caregiver must be disposed of within fifteen days. The registered qualifying patient's registered designated caregiver or next of kin shall dispose of any usable marijuana by rendering it unusable in accordance with subsection 4 of section 33-44-01-15.

5. After the death of a registered designated caregiver, any usable marijuana that was in the cardholder's possession must be disposed of within fifteen days. The registered designated caregiver's next of kin shall dispose of any usable marijuana by:

   a. Allowing the registered qualifying patient for whom it was dispensed to take possession of the usable marijuana; or

   b. Rendering it unusable in accordance with subsection 4 of section 33-44-01-15.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-10
Law Implemented: NDCC 19-24.1-10

33-44-01-05. Expiration of registry identification cards.

An initial registry identification card expires one year after the date of issuance, unless the health care provider's written certification identifies the benefit from the medical use of marijuana is less than a

year. To prevent interruption of possession of a valid registry identification card, a renewal of a registry identification card may have an expiration date from date of issuance in excess of one year.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-11
Law Implemented: NDCC 19-24.1-11

33-44-01-06. Compassion center application process.

1. The department shall announce the open application period for the submission of compassion center applications. The announcement may be made using the department's website, electronic mail, press release, or any other means determined by the department. The announcement must include:

   a. Instructions;

   b. Forms;

   c. Deadline for submission;

   d. Criteria and score sheet to be used to review applications;

   e. Number, and category, of compassion centers eligible for registration; and

   f. Department contact information.

2. The department shall announce a change to the application requirements in the same manner used to announce the open application period.

3. The department may use a separate open application period for each category of compassion center.

4. Each proposed compassion center must be a separate legal entity and must submit a complete application.

5. The department shall establish a panel to evaluate all complete compassion center applications received before the deadline. The panel must be comprised of at least three, but no more than five, members. Panel members shall execute a conflict of interest form developed by the department. An individual with a conflict of interest, as determined by the department, may not participate as a panel member.

6. The panel shall evaluate all complete compassion center applications using an impartial and numerical scoring system. The panel must include the criteria in subsection 2 of North Dakota Century Code section 19-24.1-14 when reviewing compassion center applications. The department may include additional criteria in the review as long as the criteria is included in the open application period announcement.

7. Each panel member shall review and score every complete application.

8. 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.

9. The department shall notify, in writing, the highest scoring applicants for each category of compassion center of their eligibility for registration. Upon approval of the criteria in subsection 1 of North Dakota Century Code section 19-24.1-15 the department shall issue a compassion center registration certificate to the eligible compassion centers in each category. A separate legal entity may possess only one compassion center registration certificate. The

department shall notify, in writing, compassion center applicants who are not selected for registration.

10. The department shall determine the amount and acceptable evidence of the financial assurance or security bond required in subsection 1 of North Dakota Century Code section 19-24.1-15. The amount may not exceed one hundred thousand dollars for a dispensary and may not exceed one million dollars for a manufacturing facility.

11. If a compassion center applicant eligible for registration does not meet the criteria in subsection 1 of North Dakota Century Code section 19-24.1-15, the department may select the next highest scoring compassion center applicant in the category for registration, or establish a new open application period.

History: Effective April 1, 2018; amended effective October 1, 2022.
General Authority: NDCC 19-24.1-12
Law Implemented: NDCC 19-24.1-12

33-44-01-07. Establishing additional compassion centers.

If the department determines additional compassion centers are necessary to increase access to usable marijuana by registered qualifying patients and registered designated caregivers, the department may register additional compassion centers as follows:

1. The application and selection process for establishing additional compassion centers must be in accordance with section 33-44-01-06.

2. In addition to the criteria in subsection 2 of North Dakota Century Code section 19-24.1-14, the department also shall consider the location of the proposed compassion center, including its proximity to previously approved compassion centers of the same category and whether the population of registered qualifying patients supports the need for an additional facility in the area.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-12
Law Implemented: NDCC 19-24.1-12

33-44-01-07.1. Additional categories of registered medical marijuana establishments.

The department may use the compassion center application and selection process in accordance with North Dakota Century Code chapter 19-24.1 and section 33-44-01-06 to register a manufacturing facility as a specific category of a medical marijuana establishment. A manufacturing facility selected and registered as a specific category of medical marijuana establishment shall comply with applicable compassion center requirements of North Dakota Century Code chapter 19-24.1 and these rules. The category of medical marijuana establishments are as follows:

1. A production only authorized manufacturing facility is a specific category of manufacturing facility. The activities of a production only authorized manufacturing facility are limited to producing and to related activities, including acquiring, possessing, storing, transferring, and transporting marijuana and the dried leaves or flowers of the plant of the genus cannabis in a combustible delivery form for the sole purpose of selling dried leaves or flowers of the plant of the genus cannabis in a combustible delivery form to a dispensary.

2. A medical marijuana product processor only authorized manufacturing facility is a specific category of manufacturing facility. The activities of a medical marijuana product processor only authorized manufacturing facility are limited to producing and processing and to related activities, including acquiring, possessing, storing, transferring, and transporting marijuana

and medical marijuana products for the sole purpose of selling medical marijuana products to a dispensary.

History: Effective October 1, 2022.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-07.2. Compassion center application fees.

The department shall collect nonrefundable application fees for compassion centers as follows:

1. For a manufacturing facility, three thousand dollars.

2. For a dispensary, two thousand dollars.

History: Effective October 1, 2022; amended effective October 1, 2023.
General Authority: NDCC 19-24.1-14
Law Implemented: NDCC 19-24.1-14

33-44-01-07.3. Compassion center certification fees.

The department shall collect certification fees for compassion center registrations as follows:

1. For a manufacturing facility, seventy-five thousand dollars.

2. For a dispensary, sixty thousand dollars.

3. For a production only authorized manufacturing facility, forty thousand dollars.

4. For a medical marijuana product processor only authorized manufacturing facility, twenty thousand dollars.

History: Effective October 1, 2022; amended effective October 1, 2023.
General Authority: NDCC 19-24.1-15
Law Implemented: NDCC 19-24.1-15

33-44-01-07.4. Compassion center additional certification fees.

The department shall collect an additional certification fee of five thousand dollars for every five hundred plants in excess of one thousand plants a manufacturing facility possesses.

History: Effective October 1, 2023.
General Authority: NDCC 19-24.1-15
Law Implemented: NDCC 19-24.1-15

33-44-01-08. Compassion center inventory limits.

1. A manufacturing facility shall grow an amount of marijuana sufficient to meet the qualifying patient population demands. A manufacturing facility may possess up to fifty plants for the purpose of department-authorized research and development related to production and processing. Plants for research and development shall:

   a. Be included in inventory;

   b. Be located in a restricted area separate from the restricted area containing plants used for producing and processing of usable marijuana; and

   c. Not be used in the production and processing of usable marijuana that is sold to a dispensary for patient consumption unless authorized by the department in writing.

2. A manufacturing facility with a registration certificate may use additional structures located within five hundred feet [152.40 meters] of the location described in the original application. Prior to using additional structures, the manufacturing facility shall submit a written request to the department. The written request must include the reason the structures are necessary, verification the additional structures do not jeopardize public health or safety, and evidence from the appropriate local government official that the additional structures are at least one thousand feet [304.80 meters] from a property line of a pre-existing public or private school. The department shall approve or deny a request within thirty calendar days. The department shall deny a request if the department makes an affirmative finding the use of additional structures would jeopardize public health or safety or the additional structures are within one thousand feet [304.80 meters] of a property line of a pre-existing public or private school.

3. A dispensary may not possess more than three thousand five hundred ounces [99.22 kilograms] of usable marijuana at any time, regardless of formulation.

History: Effective April 1, 2018; amended effective October 1, 2019.
General Authority: NDCC 19-24.1-17, 19-24.1-24
Law Implemented: NDCC 19-24.1-17, 19-24.1-24

33-44-01-09. Use of pesticides prohibited.

Except for minimum-risk pesticides identified in North Dakota Century Code section 4.1-34-10, the use of pesticides, as defined in North Dakota Century Code section 4.1-34-01, in the production, processing, or storage of marijuana is prohibited. Prior to using any minimum-risk pesticide a compassion center must receive written approval from the department.

History: Effective April 1, 2018; amended effective October 1, 2019.
General Authority: NDCC 19-24.1-22
Law Implemented: NDCC 19-24.1-22

33-44-01-10. Pesticide presence.

All marijuana or usable marijuana inventory affected or contaminated, as defined by these rules, by pesticides must be disposed of in accordance with these rules, or as required by the department of agriculture.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-23
Law Implemented: NDCC 19-24.1-23

33-44-01-11. Operations manual.

1. A compassion center operations manual must include:

    a. Procedures for the oversight of the compassion center, including documentation of the reporting and management structure of the compassion center. The procedures must include a business continuity plan.

    b. Procedures to ensure accurate recordkeeping.

    c. Employee security policies, including information related to the unauthorized entrance into restricted access areas.

    d. Personal safety and crime prevention techniques.

    e. Safety and security procedures, including a disaster plan with procedures to be followed in case of fire, security breach, or other emergency. Security breach procedures must

include an event occurring during the transportation of marijuana, usable marijuana, and marijuana waste.

f. An overview of the inventory control provisions consistent with North Dakota Century Code section 19-24.1-26 and these rules.

g. A job description or employment contract developed for all employees and volunteers which includes duties, responsibilities, authority, qualification, and supervision.

h. An alcohol-free and drug-free workplace policy.

i. A description of the usable marijuana containers the compassion center utilizes in accordance with North Dakota Century Code section 19-24.1-21 and these rules.

j. A description of the documentation required to accompany a registered compassion center agent while transporting marijuana, usable marijuana, and medical marijuana waste on behalf of the compassion center. Documentation must be in accordance with these rules.

k. Procedures for the mandatory, or voluntary, recall of usable marijuana in accordance with these rules.

l. Any other information requested by the department.

2. A manufacturing facility's operations manual must also include:

a. Detailed procedures regarding the producing, processing, and testing of marijuana and usable marijuana. The procedures must include a description of how marijuana will be sampled and tested in accordance with these rules.

b. Procedures for ensuring compliance with quality control and quality assurance requirements in accordance with these rules.

c. Procedures for ensuring manufacturing areas are maintained in a clean and orderly condition.

d. Procedures for addressing infestation by insects, rodents, birds, or vermin of any kind.

e. A description of the types of usable marijuana produced and processed by the manufacturing facility.

3. A dispensary's operations manual also must include:

a. Procedures for safely dispensing usable marijuana to registered qualifying patients and registered designated caregivers.

b. A distribution plan to provide registered qualifying patients and registered designated caregivers access to usable marijuana.

c. A description of the dispensary's outreach activities for registered qualifying patients and registered designated caregivers which must include:

(1) Offering each new registered qualifying patient who visits the dispensary with a department-issued document that explains the state and federal law limitations of usable marijuana;

(2) Offering information regarding the forms of usable marijuana available at the dispensary;

(3) Offering information regarding potential side effects of marijuana use; and

(4) A plan regarding the implementation of outreach activities.

4. A compassion center shall maintain and follow its operations manual at all times. A compassion center shall provide the department with written notice of any updates or revisions to the operations manual within thirty days of the changes.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-27
Law Implemented: NDCC 19-24.1-27

33-44-01-12. Restricted access areas.

1. Except as provided in section 33-44-01-13, compassion center restricted access areas include:

   a. All areas containing marijuana, usable marijuana, and medical marijuana waste.

   b. All areas used for production and processing.

2. A compassion center shall use an electronic controlled access system to limit entrance to all restricted access areas of its facility.

   a. An electronic controlled access system must:

      (1) Limit access to authorized individuals.

      (2) Track specific personnel entry and exit times.

      (3) Lock down the facility in the event of a security threat.

      (4) Store data for retrieval.

      (5) Remain operable in the event of power failure.

      (6) Enable remote administration.

   b. A compassion center immediately shall submit stored controlled-access-system data to the department upon request.

   c. Restricted access areas must be identified with a sign that states: "Do Not Enter - Restricted Access Area - Access Limited to Authorized Personnel Only."

3. Individuals authorized to enter restricted access areas include:

   a. Compassion center agents;

   b. Laboratory agents;

   c. Authorized department personnel;

   d. Individuals accompanied by a compassion center agent when the compassion center agent has received written authorization from authorized department personnel; and

   e. Individuals accompanied by authorized department personnel.

4. A compassion center shall maintain documentation of access to restricted areas for individuals included in paragraphs b, c, d, and e of subsection 3. The documentation must include date of

entry, time of entry, time of exit, name of individual, reason for access, and any other information required by the department. The documentation must be retained for at least three years.

5. Law enforcement, fire personnel, or emergency medical service professionals may enter restricted access areas in the event of an emergency requiring immediate action.

History: Effective April 1, 2018; amended effective October 1, 2019.
General Authority: NDCC 19-24.1-25
Law Implemented: NDCC 19-24.1-25

33-44-01-13. Dispensary display areas.

1. A dispensary may have a display area where usable marijuana is displayed in enclosed locked cases accessible only by compassion center agents. The purpose of the display area is to provide registered qualifying patients and registered designated caregivers the opportunity to view usable marijuana and receive education regarding its use. Usable marijuana may not be visible from the street or other public areas.

2. Individuals authorized to enter dispensary display areas include:

   a. Registered qualifying patients;

   b. Registered designated caregivers;

   c. Compassion center agents;

   d. Authorized department personnel;

   e. Individuals accompanied by a compassion center agent when the compassion center agent has received written authorization from authorized department personnel; and

   f. Individuals accompanied by authorized department personnel.

3. Before allowing an individual to enter a dispensary display area, the dispensary shall verify the validity of a cardholder's registry identification card.

4. A dispensary shall post department-provided signs or materials regarding warnings, recalls, and education materials in a display area or lobby.

History: Effective April 1, 2018; amended effective October 1, 2019; July 1, 2022.
General Authority: NDCC 19-24.1-25
Law Implemented: NDCC 19-24.1-25

33-44-01-14. Usable marijuana take back.

1. A dispensary may accept at no charge unused, excess, or contaminated usable marijuana for disposal. A dispensary shall maintain a written record of returned usable marijuana that includes:

   a. The name of the registered qualifying patient;

   b. The registered qualifying patient's registry identification number;

   c. The date the usable marijuana was returned;

   d. The quantity of usable marijuana returned; and

   e. The type of usable marijuana returned.

2. A dispensary shall dispose of the returned usable marijuana as follows:

   a. In accordance with these rules; or

   b. By transferring it to a manufacturing facility for disposal in accordance with these rules. A dispensary shall maintain a written record that includes the amount of returned usable marijuana transferred to a manufacturing facility for disposal and the date.

3. A manufacturing facility may accept returned usable marijuana from a dispensary. Any returned usable marijuana accepted from a dispensary must be disposed of in accordance with these rules. A manufacturing facility shall maintain a written record that includes the amount of returned usable marijuana and the date accepted by a manufacturing facility for disposal.

History: Effective April 1, 2018; amended effective July 1, 2022.
General Authority: NDCC 19-24.1-10
Law Implemented: NDCC 19-24.1-10

33-44-01-15. Medical marijuana waste disposal.

1. All medical marijuana waste generated during production, processing, and testing, must be stored, managed, and disposed of in accordance with these rules.

2. All medical marijuana waste generated during production, processing, and testing must be evaluated against the state's hazardous waste regulations to determine if the medical marijuana waste is designated as hazardous waste. It is the responsibility of each medical marijuana waste generator to properly evaluate their medical marijuana waste to determine if it is designated as hazardous waste. If a generator's medical marijuana waste is designated as hazardous waste, the medical marijuana waste is subject to the hazardous waste management standards in North Dakota Century Code chapter 23-20.3.

3. Medical marijuana waste not designated as hazardous waste must be rendered unusable in accordance with subsection 4 prior to disposal. Medical marijuana waste rendered unusable must be disposed of in accordance with subsection 5.

4. The required method for rendering medical marijuana waste unusable is by grinding the medical marijuana waste and incorporating it with other ground materials so the volume of the resulting mixture is less than fifty percent medical marijuana waste. All other methods for rendering medical marijuana waste unusable must be approved by the department before implementation. Medical marijuana waste to be disposed in a landfill may be mixed with soil or other material as approved by the department.

5. Medical marijuana waste rendered unusable in accordance with subsection 4 can be disposed.

   a. Disposal of the medical marijuana waste rendered unusable may be delivered to a permitted and state-approved solid waste facility for final disposition.

   b. A compassion center or laboratory shall maintain a record of the final destination of medical marijuana waste rendered unusable. The record shall be maintained for a period of seven years.

History: Effective April 1, 2018; amended effective July 1, 2022.
General Authority: NDCC 19-24.1-16, 19-24.1-23
Law Implemented: NDCC 19-24.1-16, 19-24.1-23

33-44-01-16. Recall procedures.

Each compassion center shall establish a procedure for issuing voluntary and mandatory recalls for usable marijuana.

1. Factors that require a recall include:

   a. Defective or potentially defective usable marijuana.

   b. Usable marijuana that has failed laboratory testing in accordance with these rules.

   c. Reasonable probability that use of the usable marijuana or exposure to the usable marijuana will cause serious adverse health consequences.

   d. Any other instances as determined by the department that would warrant a recall.

2. The procedure must include:

   a. The compassion center agents who are responsible for overseeing the recall.

   b. The procedures for notifying everyone affected by a recall, including registered qualifying patients, registered designated caregivers, and other compassion centers.

   c. Instructions for registered qualifying patients, registered designated caregivers, and other compassion centers, regarding proper product handling of any recalled usable marijuana.

3. A dispensary shall maintain a list of registered qualifying patients and registered designated caregivers and current contact information to provide notice in the event of a recall.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-17. Surveillance requirements.

1. To prevent unauthorized access to marijuana and usable marijuana, the compassion center shall have video surveillance equipment to deter the unauthorized entrance into restricted access areas.

   a. The compassion center shall operate, monitor, and maintain in good working order a closed-circuit television surveillance system on all of its premises, which must operate at all times and visually record:

      (1) All phases of production and processing.

      (2) All compassion center points of entry and exit, sales and display areas, and garages.

      (3) The entrance to the video surveillance room.

      (4) Any parking lot, which must have appropriate lighting for the normal conditions of the area under surveillance.

   b. Video surveillance systems must:

      (1) Capture clear and certain identification of any person entering or exiting a compassion center.

      (2) Have the ability to produce a clear, color, still photo either live or from a recording.

(3) Have an embedded date-and-time stamp on all recordings which must be synchronized and not obscure the picture.

(4) Continue to operate during a power outage.

c. Video recording specifications include:

(1) A video recording must export still images in an industry standard image format, including .jpg, .bmp, and .gif.

(2) Exported video must be archived in a proprietary format that ensures authentication and guarantees the recorded image has not been altered.

(3) Exported video must be saved in an industry standard file format that can be played on a standard computer operating system.

(4) Upon completion of the required retention period, all recordings must be erased or destroyed before disposal.

2. The compassion center shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

3. The compassion center shall ensure that twenty-four hour recordings from all video cameras are:

a. Available for viewing by the department through a secure internet connection.

b. Retained for a period of at least ninety calendar days during the first year of operation, and upon department approval, for at least sixty calendar days thereafter.

c. Maintained free of alteration or corruption.

d. Retained longer if the compassion center is given notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

History: Effective April 1, 2018; amended effective October 1, 2019.
General Authority: NDCC 19-24.1-25
Law Implemented: NDCC 19-24.1-25

33-44-01-18. Alarm system requirements.

1. A compassion center shall install and maintain a professionally monitored security alarm system that provides intrusion and fire detection of all:

a. Facility entrances and exits.

b. Rooms with exterior windows.

c. Rooms with exterior walls.

d. Roof hatches.

e. Skylights.

2. A security alarm system means a device or series of devices that summons law enforcement personnel during, or as a result of, an alarm condition. Devices may include:

a. Hardwired systems and systems interconnected with a radio frequency method, such as cellular or private radio signals that emit or transmit a remote or local audio, visual, or electronic signal.

b. Motion detectors.

c. Pressure switches.

d. A duress alarm.

e. A panic alarm.

f. A holdup alarm.

g. An automatic voice dialer.

h. A failure notification system that provides an audio, text, or visual notification of any failure in the surveillance system.

3. A compassion center's security alarm system and all devices must continue to operate during a power outage.

4. The compassion center shall test the security alarm system and all devices on a monthly basis and maintain a record of all tests.

5. The compassion center's security alarm system must be inspected and all devices tested annually by a qualified alarm vendor.

History: Effective April 1, 2018; amended effective October 1, 2019.
General Authority: NDCC 19-24.1-25
Law Implemented: NDCC 19-24.1-25

33-44-01-19. Inventory control measures.

1. The department shall maintain a computer information system for inventory control and registry identification card verification.

2. A compassion center inventory control system shall interface with the computer information system maintained by the department. All costs associated with interfacing are the responsibility of the compassion center. If the compassion center's inventory control system does not adequately, as determined by the department, interface with the computer information system maintained by the department, the department may require the compassion center to use the system maintained by the department.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-26
Law Implemented: NDCC 19-24.1-26

33-44-01-20. Conducting inventory.

1. Each compassion center, prior to commencing business, shall:

a. Conduct an initial inventory of all marijuana and usable marijuana at the compassion center. If a compassion center commences business with no marijuana or usable marijuana, the compassion center shall record the initial inventory as zero.

b. After the initial inventory, a compassion center shall conduct an inventory of marijuana and usable marijuana once a week for a period of at least six months, and upon department approval, at least monthly thereafter.

c. Conduct each inventory in a manner that includes two individuals. One of the two individuals may not be involved in the production and processing of marijuana, the dispensing of usable marijuana, or the preparation of the compassion center financial records. One of the two individuals must be a supervisor or manager.

2. Inventory documentation must include:

a. The date of the inventory;

b. Detailed inventory results; and

c. The name, signature, and title of the individuals who conducted the inventory and an attestation by both individuals as to the accuracy of the inventory.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-26
Law Implemented: NDCC 19-24.1-26

33-44-01-21. Personnel record retention.

1. Personnel records maintained by the compassion center must include:

a. Recruiting and screening documents, such as:

(1) Application.

(2) Resume.

b. Job descriptions.

c. Records relating to job offers, promotion, demotion, transfer, layoff, and education and training.

d. Records related to other employment practices, such as policy acknowledgments and agreements.

e. Letters of recognition.

f. Warnings, counseling, and disciplinary notices.

g. Performance evaluation and goal setting records.

h. Termination records.

i. References and background checks.

2. Records must be retained longer than as required by North Dakota Century Code section 19-24.1-30, if the compassion center is given notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the record may contain relevant information.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-30
Law Implemented: NDCC 19-24.1-30

33-44-01-22. Compassion center and laboratory incidents.

1. Compassion centers and the laboratory shall contact 911 in the event of an emergency and contact law enforcement or 911 to report criminal activities.

2. Compassion centers and the laboratory shall provide the department with written notice, within twenty-four hours, of any of the following:

   a. A breach of security;

   b. Failures of, or tampering with, security and surveillance equipment, cameras, or recordings;

   c. Power failures lasting longer than two hours;

   d. Embezzlement or fraud;

   e. Contacting 911 or contact with law enforcement;

   f. Incidents that occur while transporting marijuana, usable marijuana, and medical marijuana waste;

   g. Attempts to obtain marijuana or usable marijuana in a manner not prescribed by North Dakota Century Code chapter 19-24.1 and these rules; and

   h. Violations of North Dakota Century Code chapter 19-24.1 and these rules.

History: Effective April 1, 2018; amended effective October 1, 2019; July 1, 2022.
General Authority: NDCC 19-24.1-25
Law Implemented: NDCC 19-24.1-25

33-44-01-23. Advertising and marketing.

1. A dispensary may:

   a. Display its business name and logo on labels, signs, websites, and informational material provided to registered qualifying patients and registered designated caregivers. The name or logo may not include:

      (1) Images of marijuana or marijuana paraphernalia.

      (2) Colloquial references to marijuana.

      (3) Names of marijuana plant strains.

      (4) Medical symbols that bear a reasonable resemblance to established medical associations, including the American medical association or American academy of pediatrics.

   b. Maintain a website that may contain:

      (1) The facility name.

      (2) Contact information.

      (3) Hours of operation.

      (4) The usable marijuana offered.

(5) Product pricing.

(6) Other information as approved by the department.

2. A manufacturing facility may display its business name and logo on labels, websites, and informational material.

   a. The name or logo may not include:

      (1) Images of marijuana or marijuana paraphernalia.

      (2) Colloquial references to marijuana.

      (3) Names of marijuana plant strains.

      (4) Medical symbols that bear a reasonable resemblance to established medical associations, including the American medical association or American academy of pediatrics.

   b. Maintain a website that may contain:

      (1) The facility name.

      (2) Phone number.

      (3) Other information as approved by the department.

3. A dispensary only may dispense usable marijuana when it has been purchased by a registered qualifying patient or registered designated caregiver. A dispensary may not provide free usable marijuana to a registered qualifying patient or registered designated caregiver.

4. All marketing or advertising activities not covered under subsections 1 and 2, are subject to department approval. The compassion center shall request approval from the department, and the department shall approve or deny the request within thirty calendar days.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-24. Strain or brand names.

A manufacturing facility may not use strain or brand names containing any words that refer to products commonly associated with minors, marketed to minors, or any names that are false or misleading.

History: Effective April 1, 2018; amended effective October 1, 2019.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-24.1. Medical cannabinoid product formulation.

A manufacturing facility must have a certificate of authenticity or similar documentation approved by the department for all ingredients used in formulating a medical cannabinoid product. A certificate of authenticity or similar documentation approved by the department must include the date of expiration.

History: Effective July 1, 2022.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-25. Usable marijuana packaging.

All usable marijuana packaging used by a manufacturing facility must be approved by the department. A manufacturing facility shall package all usable marijuana intended for distribution according to the following standards:

1. Usable marijuana containers must be:

   a. Plain.

   b. Tamper-evident.

   c. Child-resistant.

2. Usable marijuana must be packaged to minimize its appeal to children.

History: Effective April 1, 2018; amended effective October 1, 2019.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-26. Manufacturing facility labeling.

1. A manufacturing facility shall label all usable marijuana in accordance with the following before their sale or transfer to a dispensary:

   a. A container holding dried leaves and flowers must include the following information:

      (1) Manufacturers' business or trade name and registry certification number;

      (2) Container identification number;

      (3) Batch number;

      (4) Date of harvest;

      (5) Name of strain;

      (6) Net weight in United States customary or metric units;

      (7) Concentration of total tetrahydrocannabinol and total cannabidiol as identified by the laboratory selected by the department in accordance with section 33-44-01-36;

      (8) Activation time expressed in words or through a pictogram;

      (9) Expiration date;

      (10) Universal symbol; and

      (11) Consumer warnings that state:

         (a) "This product is not approved by the Food and Drug Administration to treat, cure, or prevent any disease."

         (b) "For use by North Dakota registered qualifying patients only."

         (c) "Keep out of reach of children."

         (d) "It is illegal to drive or to be in actual physical control of a motor vehicle while under the influence of marijuana."

b. A container holding a cannabinoid concentrate must include the following information:

(1) Manufacturing facility's business or trade name and registry certification number;

(2) Container identification number;

(3) Process lot number;

(4) Product identity;

(5) Date the concentrate was made;

(6) Net weight or volume in United States customary or metric units;

(7) If applicable, serving size and number of servings per container or amount suggested for use by the consumer or patient at any one time;

(8) Concentration or amount of total tetrahydrocannabinol, and the concentration or amount of total cannabidiol, by weight or volume in the container as identified by the laboratory selected by the department in accordance with section 33-44-01-36;

(9) Activation time, expressed in words or through a pictogram;

(10) Expiration date;

(11) A disclosure of the type of extraction process used and any solvent, gas, or other chemical used in the extraction process;

(12) Universal symbol;

(13) Pediatric symbol, if applicable; and

(14) Consumer warnings that state:

(a) "This product is not approved by the Food and Drug Administration to treat, cure, or prevent any disease."

(b) "For use by North Dakota registered qualifying patients only."

(c) "Keep out of reach of children."

(d) "It is illegal to drive or to be in actual physical control of a motor vehicle while under the influence of marijuana."

c. A container holding a medical cannabinoid product must include the following information:

(1) Manufacturers' business or trade name and registry certification number;

(2) Container identification number;

(3) Process lot number;

(4) Product identity;

(5) Date the product was made;

(6) Net weight or volume in United States customary or metric units;

(7) If applicable, serving size and number of servings per container;

(8) Concentration or amount of total tetrahydrocannabinol, and the concentration or amount of total cannabidiol, by weight or volume in each serving and in each container as identified by the laboratory selected by the department in accordance with section 33-44-01-36;

(9) List of ingredients in descending order or predominance by weight or volume used to process the medical cannabinoid product;

(10) Activation time, expressed in words or through a pictogram;

(11) Expiration date;

(12) A disclosure of the type of extraction process used and any solvent, gas, or other chemical used in the extraction process;

(13) Universal symbol;

(14) Pediatric symbol, if applicable; and

(15) Consumer warnings that state:

(a) "This product is not approved by the Food and Drug Administration to treat, cure, or prevent any disease."

(b) "For use by North Dakota registered qualifying patients only."

(c) "Keep out of reach of children."

(d) "It is illegal to drive or to be in actual physical control of a motor vehicle while under the influence of marijuana."

2. Usable marijuana labels required in accordance with this section must be no smaller than eight point, arial or calibri, font. If, due to the size of the container, sufficient space does not exist for a label containing all of the required information, the manufacturing facility may:

a. Use a peel-back or accordion label if, the peel-back or accordion label is easily identified as containing the required information; or

b. Reduce the size of the required information to six point font.

3. Usable marijuana labels may not contain the word "organic".

History: Effective April 1, 2018; amended effective October 1, 2019; July 1, 2022.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-27. Dispensary labeling.

1. All usable marijuana delivered to a dispensary from a manufacturing facility must meet the labeling requirements in section 33-44-01-26.

2. A dispensary shall affix a label to all usable marijuana distributed to registered qualifying patients and registered designated caregivers that includes:

a. The registered qualifying patient's name and department-issued registry identification card number.

b. The name of the dispensary.

c. Date dispensed.

3. Usable marijuana labels required in accordance with this section must be no smaller than eight point, arial or calibri, font. If, due to the size of the container, sufficient space does not exist for a label containing all of the required information, the dispensary may:

   a. Use a peel-back or accordion label if, the peel-back or accordion label is easily identified as containing the required information; or

   b. Reduce the size of the required information to six point font.

History: Effective April 1, 2018; amended effective July 1, 2022.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-28. Removal of product labels.

All usable marijuana labels affixed by a compassion center must remain on the packaging. The department may revoke or suspend a cardholder's registry identification if the cardholder alters, obliterates, or destroys any label affixed to a usable marijuana package or container.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-29. Transportation authorization.

1. Transportation of marijuana, usable marijuana, and medical marijuana waste by a manufacturing facility is authorized as follows:

   a. A manufacturing facility may transport usable marijuana:

      (1) From its manufacturing facility to a dispensary;

      (2) From its manufacturing facility to its quality control and quality assurance testing location; and

      (3) From a dispensary to its manufacturing facility.

   b. A manufacturing facility may transport marijuana or medical marijuana waste:

      (1) From its manufacturing facility to its quality control and quality assurance testing location;

      (2) From its manufacturing facility or a dispensary to a waste disposal site; and

      (3) From a dispensary to its manufacturing facility.

2. Transportation of usable marijuana and medical marijuana waste by a dispensary is authorized as follows:

   a. A dispensary may transport usable marijuana:

      (1) From a manufacturing facility to its dispensary;

      (2) From its dispensary to a manufacturing facility; and

      (3) From its dispensary to a registered qualifying patient or registered designated caregiver.

b. A dispensary may transport medical marijuana waste:

(1) From its dispensary to a manufacturing facility; and

(2) From its dispensary to a waste disposal site.

3. A laboratory may transport marijuana, usable marijuana, or medical marijuana waste:

a. From a manufacturing facility or a dispensary to its laboratory;

b. From its laboratory to a manufacturing facility; and

c. From its laboratory to a waste disposal site.

History: Effective April 1, 2018; amended effective July 1, 2022.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-30. Transportation requirements.

1. Any compassion center or laboratory transporting marijuana, usable marijuana, or medical marijuana waste shall use a manifest system, approved by the department, to track transportation. The manifest must be in a vehicle transporting marijuana, usable marijuana, or medical marijuana waste. The manifest must be provided to law enforcement upon request.

a. The manifest system must include a chain of custody that records:

(1) The name and address of the destination.

(2) The description of each individual container that is part of the shipment and the total number of individual containers.

(3) The date and time the shipment is placed into the transport vehicle.

(4) The date and time the shipment is accepted at the delivery destination.

(5) The person's identity, and the circumstances, duration, and disposition of any other person who had custody or control of the shipment.

(6) Any handling or storage instructions.

b. Before transporting marijuana, usable marijuana, or medical marijuana waste, a compassion center or laboratory shall:

(1) Complete a manifest on a form approved by the department.

(2) Transmit a copy of the manifest to the receiving entity or individual.

c. The manifest must be signed by:

(1) A compassion center agent or laboratory agent upon departure.

(2) A compassion center agent, laboratory agent, an employee of a waste facility, registered qualifying patient, or registered designated caregiver upon its receipt.

d. A compassion center agent or laboratory agent receiving marijuana or usable marijuana shall:

(1) Verify and document the type and quantity of the transported marijuana, usable marijuana, or medical marijuana waste, against the manifest.

(2) Return a copy of the signed manifest to the originating entity upon completion.

e. A compassion center also shall record the marijuana or usable marijuana that is received as inventory in accordance with section 33-44-01-20.

f. A compassion center or laboratory shall maintain all manifests for at least seven years and make them available upon request by the department.

2. A compassion center or laboratory shall ensure that marijuana, usable marijuana, or medical marijuana waste, except for medical marijuana waste that has been rendered unusable in accordance with section 33-44-01-15, is transported as follows:

a. Packaged in tamper-evident containers.

b. Transported so it is not visible or recognizable from outside the vehicle.

c. Transported in a vehicle that does not bear any markings to indicate the vehicle contains marijuana, usable marijuana, or medical marijuana waste, or bear the name or logo of the compassion center or laboratory.

d. Transported in an enclosed, locked storage compartment that is secured, or affixed, to the vehicle.

3. Compassion center agents or laboratory agents who are transporting marijuana, usable marijuana, or medical marijuana waste shall:

a. Travel directly to the designation specified on the manifest.

b. Document on the manifest refueling and all other stops during transit, including:

(1) The reason for the stop;

(2) The duration of the stop;

(3) The location of the stop; and

(4) All activities of compassion center agents or laboratory agents exiting the vehicle.

c. If an emergency requires stopping the vehicle, the compassion center agent or laboratory agent shall contact 911.

d. Under no circumstances may any person other than the designated compassion center agent or laboratory agent have physical control of the motor vehicle that is transporting the marijuana, usable marijuana, or medical marijuana waste.

e. A compassion center shall staff all motor vehicles with a minimum of two compassion center agents when transporting usable marijuana between compassion centers. At least one agent shall remain with the motor vehicle at all times when the motor vehicle contains usable marijuana.

f. A single compassion center agent may transport medical marijuana waste between compassion centers or to a waste facility. A single dispensary agent may transport usable marijuana to a registered qualifying patient or registered designated caregiver. A single laboratory agent may transport marijuana, usable marijuana, or medical marijuana waste to its laboratory, to a manufacturing facility, or to a waste facility.

g. Each compassion center agent or laboratory agent in a transport motor vehicle must have communication access with the compassion center or laboratory and have the ability to contact law enforcement through the 911 emergency system.

h. A compassion center agent or laboratory agent shall carry their registry identification card at all times when transporting marijuana, usable marijuana, or medical marijuana waste.

i. A compassion center agent or laboratory agent may not leave a vehicle that is transporting marijuana, usable marijuana, or medical marijuana waste unattended overnight.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-31. Compassion center inspections and compliance.

The department, or a department designee, shall conduct inspections of compassion centers to ensure compliance with North Dakota Century Code chapter 19-24.1 and these rules. Compassion centers shall receive the results of an inspection in writing. Issues of noncompliance and concerns about the continued operation of the compassion center may result in a plan of correction, suspension, or revocation of a registry identification card or registration certificate.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-22
Law Implemented: NDCC 19-24.1-22

33-44-01-32. Plan of correction.

1. Upon request, a compassion center shall submit to the department a plan of correction addressing issues of noncompliance and concerns identified during an inspection.

2. A plan of correction must include:

   a. How the corrective action will be accomplished;

   b. What changes will be made to ensure the issues of noncompliance and concerns identified during an inspection do not recur; and

   c. How the compassion center will monitor the corrective actions to ensure the issues of noncompliance and concerns identified during an inspection are corrected and do not recur.

3. A compassion center shall provide the department with a plan of correction within ten business days of receipt of the department request.

4. A plan of correction is subject to acceptance, acceptance with revisions, or rejection by the department.

5. A compassion center shall complete all corrections within thirty calendar days of acceptance of the correction plan by the department, unless an alternative schedule of correction has been specified by the department.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-22
Law Implemented: NDCC 19-24.1-22

33-44-01-33. Data reporting.

Data related to usable marijuana dispensed for a registered qualifying patient use must be submitted to the North Dakota prescription drug monitoring program. The department shall submit the data to the prescription drug monitoring program.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-37
Law Implemented: NDCC 19-24.1-37

33-44-01-34. Law enforcement reportable incidents.

1. Law enforcement shall notify the department within five business days, using a form developed by the department, if an individual who is not a registered cardholder is found in possession of usable marijuana dispensed pursuant to North Dakota Century Code chapter 19-24.1 or if a registered qualifying patient or a registered designated caregiver is found in possession of an amount greater than the allowable amount of usable marijuana in accordance with state law. Unlawful possession of usable marijuana includes:

   a. Possession of usable marijuana by anyone other than a registered cardholder.

   b. Possession of usable marijuana by a registered qualifying patient or registered designated caregiver not in possession of a valid registration card.

   c. Possession of usable marijuana by a registered cardholder if the registration card is no longer valid due to suspension, revocation, or expiration.

2. Law enforcement shall secure all confiscated usable marijuana in accordance with adopted evidence policies and procedures.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-35. Reporting adverse reactions.

1. Incidents involving overdose or adverse reaction related to the use of usable marijuana must be reported to the department. The department shall provide an electronic form for reporting incidents involving overdose or adverse reactions to the department.

2. Individuals required to report incidents involving overdose or adverse reactions to the department include:

   a. Registered qualifying patients.

   b. A registered qualifying patient's registered designated caregiver.

   c. Compassion center agents.

   d. Law enforcement.

   e. Health care professionals.

   f. Emergency medical services professionals.

   g. Emergency department personnel at any health care facility in which a patient presents for treatment of an incident involving overdose or adverse reaction related to the use of usable marijuana.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-36. Laboratory procurement process.

The department may contract with a laboratory or laboratories to conduct random quality sampling testing of a compassion center's marijuana and usable marijuana. The department shall procure the laboratory testing services in accordance with North Dakota Century Code chapter 54-44.4. An awarded laboratory must be properly accredited as determined by the department.

History: Effective April 1, 2018; amended effective October 1, 2019.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-37. Laboratory authority.

The activities of a department-awarded laboratory include providing laboratory services and related activities, including acquiring, possessing, storing, transferring, and transporting marijuana, usable marijuana, and medical marijuana waste in accordance with North Dakota Century Code chapter 19-24.1 and these rules.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-38. Laboratory agent registry identification cards.

1. Each laboratory agent who performs activities in accordance with North Dakota Century Code chapter 19-24.1 and these rules shall obtain a registry identification card.

2. Upon initial award of a contract, the department shall provide the laboratory a registration form to complete for each laboratory agent. Except for the fee, the form must require the laboratory to provide the same information for laboratory agents as required for compassion centers agents in subsection 2 of North Dakota Century Code section 19-24.1-18. The laboratory shall submit to the department:

   a. A complete agent registration form for each laboratory agent;

   b. All documents required for conducting a criminal history record check under North Dakota Century Code section 12-60-24 for each laboratory agent; and

   c. Payment of all applicable fees associated with the criminal history record check.

3. The laboratory shall complete additional laboratory agent registration forms as required by this section.

4. Upon approval of a laboratory agent registration form and verification of compliance with the requirements in subdivision c of subsection 3 of North Dakota Century Code section 19-24.1-18, the department shall issue, within thirty calendar days and at no cost, a laboratory agent registry identification card. The expiration date of the laboratory agent registry identification card must coincide with the contract expiration date. Only registered agents of an awarded laboratory have the authority to provide services authorized in section 33-44-01-37.

5. Each laboratory agent registry identification card must include the following information:

   a. The name of the cardholder;

b. A designation the cardholder is a laboratory agent;

c. The date of issuance and expiration date;

d. A random ten-digit alphanumeric identification number containing at least four numbers and at least four letters which is unique to the cardholder;

e. A photograph of the cardholder; and

f. The phone number or website address at which the card can be verified.

6. The laboratory is responsible for distributing and collecting laboratory agent registry identification cards that are no longer valid or belong to employees who no longer have responsibilities requiring a valid registry identification card. The laboratory shall shred collected laboratory agent registry identification cards. The laboratory shall notify the department in writing within two calendar days of the date a laboratory agent registry identification card is destroyed.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-39. Laboratory inspection.

An awarded laboratory is subject to random inspection by the department, or a department designee, to ensure compliance with North Dakota Century Code chapter 19-24.1 and these rules.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-22
Law Implemented: NDCC 19-24.1-22

33-44-01-40. Usable marijuana testing.

1. A manufacturing facility shall have all usable marijuana tested in accordance with sections 33-44-01-42, 33-44-01-43, and 33-44-01-44 by a laboratory selected by the department as described in section 33-44-01-36. The manufacturing facility shall pay all costs of testing usable marijuana in accordance with these rules.

2. A manufacturing facility may not transfer usable marijuana to a dispensary until it is tested and passes compliance testing in accordance with these rules.

3. A dispensary may not accept usable marijuana from a manufacturing facility unless it is tested and passes compliance testing in accordance with these rules.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-41. Ordering tests.

1. A manufacturing facility shall provide a laboratory with the following information, at a minimum, prior to the laboratory taking samples:

a. The name, address, and contact information of the manufacturing facility;

b. Type of usable marijuana;

c. Batch numbers to be tested;

d. Harvest lot number or numbers associated with the batch numbers;

e. Process lot number associated with the batch numbers, if applicable;

f. Total mass or volume of each batch to be tested;

g. For medical cannabinoid products, the unit of sale;

h. Concentration information, if known; and

i. Identification of the test or tests the manufacturing facility is requesting the laboratory to conduct.

2. The manufacturing facility shall order the tests necessary to comply with North Dakota Century Code chapter 19-24.1 and these rules.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-42. Compliance testing requirements for dried leaves and flowers.

A manufacturing facility shall have every batch from a harvest lot of dried leaves and flowers, to be packaged in a container for transfer to a dispensary, tested for the following:

1. Pesticides and degradation compounds in accordance with section 33-44-01-47.

2. Microbiological contaminants and mycotoxins in accordance with section 33-44-01-48.

3. Heavy metals in accordance with section 33-44-01-48.1.

4. Water activity and moisture content in accordance with section 33-44-01-50.

5. Concentration in accordance with section 33-44-01-51.

History: Effective April 1, 2018; amended effective October 1, 2019.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-43. Compliance testing requirements for cannabinoid concentrates.

1. A manufacturing facility shall have every process lot of cannabinoid concentrate, to be packaged in a container for transfer to a dispensary, tested for the following:

   a. Pesticides and degradation compounds in accordance with section 33-44-01-47.

   b. Microbiological contaminants and mycotoxins in accordance with section 33-44-01-48.

   c. Heavy metals in accordance with section 33-44-01-48.1.

   d. Solvents in accordance with section 33-44-01-49.

   e. Concentration in accordance with section 33-44-01-51.

2. A manufacturing facility is exempt from testing for solvents under this section if the manufacturing facility did not use any solvent or the department provides the manufacturing facility with a written exemption if the manufacturing facility uses a closed loop carbon dioxide extraction method.

History: Effective April 1, 2018; amended effective October 1, 2019.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-44. Compliance testing requirements for medical cannabinoid products.

A manufacturing facility shall have every process lot of a medical cannabinoid product, to be packaged in a container for transfer to a dispensary, tested for the following:

1. Pesticides and degradation compounds in accordance with section 33-44-01-47.
2. Microbiological contaminants and mycotoxins in accordance with section 33-44-01-48.
3. Heavy metals in accordance with section 33-44-01-48.1.
4. Solvents in accordance with section 33-44-01-49.
5. Concentration in accordance with section 33-44-01-51.

History: Effective April 1, 2018; amended effective October 1, 2019.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-44.1. Terpene analysis.

Upon a manufacturing facility's request, a terpene analysis may be performed by a laboratory selected by the department as described in section 33-44-01-36. The manufacturing facility shall pay all costs associated with a terpene analysis. A manufacturing facility may include terpenoid profile information on the label of a container holding dried leaves and flowers, a cannabinoid concentrate, or medical cannabinoid product only when a terpene analysis is performed under this section.

History: Effective October 1, 2019.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-45. Batch requirements for compliance testing.

1. For compliance testing of dried leaves and flowers, a manufacturing facility shall separate each harvest lot into no larger than ten-pound batches.
2. For compliance testing of cannabinoid concentrates, a process lot is considered a batch.
3. For compliance testing of medical cannabinoid products, a manufacturing facility shall separate process lots into not larger than five thousand unit of sale batches.
4. A manufacturing facility shall assign each batch a unique batch number and that unique batch number must be:
    a. Documented and maintained in the manufacturing facilities records, including the compassion center's inventory control system;
    b. Provided to the laboratory agent responsible for taking samples; and
    c. Included on the batch label as required in section 33-44-01-46.
5. A manufacturing facility may not reuse a unique batch number.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36

Law Implemented: NDCC 19-24.1-36

33-44-01-46. Manufacturing facility requirements for labeling, storing, and securing usable marijuana batches.

When samples are taken from a harvest or process lot batch, a manufacturing facility shall:

1. Store and secure the batch in a manner that prevents the product from being tampered with or transferred prior to required tests being completed.

2. Be able to easily locate a batch stored and secured under subsection 2 and provide that location to the department or a laboratory upon request.

History: Effective April 1, 2018; amended effective October 1, 2019; July 1, 2022.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-47. Standards for pesticides and degradation compounds compliance testing.

1. A batch fails pesticide and degradation compound testing if a sample does not satisfy the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in subpart C of the United States environmental protection agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR 180, in effect as of January 1, 2018. A batch of dried leaves and flowers failing pesticide and degradation compound testing is considered affected or contaminated.

2. A degradation compound identified in testing must be reported to and reviewed by the department. The department, in consultation with the laboratory, shall determine whether the batch is considered to be affected or contaminated and fails pesticide and degradation testing.

3. If the samples do not pass testing standards for pesticides and degradation compounds, the manufacturing facility shall comply with section 33-44-01-52.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-48. Standards for microbiological contaminants and mycotoxin compliance testing.

1. Usable marijuana required to be tested for microbiological contaminants under sections 33-44-01-42, 33-44-01-43, and 33-44-01-44 must be sampled using appropriate aseptic techniques.

2. For purposes of the microbiological test, a usable marijuana sample is deemed to have passed if it meets the following standards for microbial and fungal limits in colony forming units per gram (CFU/g):

	Concentrates	**Dried Leaves or Flowers and Medical Cannabinoid Products**
Total viable aerobic bacteria	10^4 CFU/g	10^5 CFU/g
Total yeast and mold	10^3 CFU/g	10^4 CFU/g
Total coliforms	10^2 CFU/g	10^3 CFU/g
Bile-tolerant gram-negative bacteria	10^2 CFU/g	10^3 CFU/g
Escherichia coli (pathogenic	Not detected in one gram	Not detected in one gram

strains) and salmonella species		

3. For purposes of the mycotoxin test, a usable marijuana sample is deemed to have passed if it meets the following standards:

   a. The total of aflatoxin B1, B2, G1, and G2 is less than 20 µg/kg of substance; and

   b. Ochratoxin A is less than 20 µg/kg of substance.

4. If the samples do not pass testing standards for microbiological contaminants or mycotoxins, the manufacturing facility shall comply with section 33-44-01-52.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-48.1. Standards for heavy metals compliance testing.

A batch fails heavy metals testing if the presence of one of the following metals, at a minimum, is above the following listed limit:

	Parts per Million (ppm)
Inorganic arsenic	0.4
Cadmium	0.3
Lead	1.0
Mercury	0.2

History: Effective October 1, 2019.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-49. Standards for solvents compliance testing.

1. A batch fails solvent testing if the presence of one of the following solvents, at a minimum, is above the action level listed in the published International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidance for industry Impurities: Residual Solvents Q3C(R6) in effect as of January 1, 2018:

   a. 1,4-Dioxane.

   b. 2-Butanol.

   c. 2-Ethoxyethanol.

   d. 2-Propanol (IPA).

   e. Acetone.

   f. Acetonitrile.

   g. Benzene.

   h. Cumene.

   i. Cyclohexane.

   j. Dichloromethane.

k. Ethyl acetate.

l. Ethyl ether.

m. Ethylene glycol.

n. Heptane.

o. Hexanes.

p. Isopropyl acetate.

q. Methanol.

r. Pentanes.

s. Tetrahydrofuran.

t. Toluene.

u. Xylenes.

2. In addition to subsection 1, a batch fails solvent testing if the presence of one of the following solvents exceeds the limits in the following table:

	Parts Per Million (ppm)
Butanes	5,000
Ethylene oxide	50
Propane	5,000

3. A manufacturing facility must receive written approval from the department prior to using any solvent not listed in subsection 1 and subsection 2. The department shall include in the written approval an action level, not to be exceeded, that is to be used as the standard for solvent testing.

4. A manufacturing facility only may use a solvent that is at least ninety-nine percent purity or is food-grade.

5. If the samples do not pass testing standards for solvents, the manufacturing facility shall comply with section 33-44-01-52.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-50. Standards for water activity and moisture content compliance testing.

1. Dried leaves and flowers to be packaged in a container for transfer to a dispensary, must be tested for:

   a. Water activity; and

   b. Moisture content.

2. If a sample has a water activity rate of more than 0.65 a_w the sample fails.

3. If a sample has a moisture content of more than fifteen percent the sample fails.

4. If the samples do not pass testing standards for water activity and moisture content, the manufacturing facility shall comply with section 33-44-01-52.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-51. Standards for concentration compliance testing.

1. Usable marijuana concentration testing must include:

   a. Tetrahydrocannabinol (THC).

   b. Tetrahydrocannabinolic acid (THCA).

   c. Cannabidiol (CBD).

   d. Cannabidiolic acid (CBDA).

2. The total tetrahydrocannabinol and total cannabidiol must be calculated as follows:

   a. Total tetrahydrocannabinol, where M is the mass or mass fraction of tetrahydrocannabinol or tetrahydrocannabinolic acid:

      M total THC = THC + (0.877 x M THCA)

   b. Total cannabidiol, where M is the mass or mass fraction of cannabidiol and cannabidiolic acid:

      M total CBD = M CBD + (0.877 x M CBDA)

3. Test results must report tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and cannabidiolic acid content by dry weight calculated as follows:

   a. P THC(dry) = P THC(wet) / [1-(P moisture/100)].

   b. P THCA(dry) = P THCA(wet) / [1-(P moisture/100)].

   c. P CBD(dry) = P CBD(wet) / [1-(P moisture/100)].

   d. P CBDA(dry) = P CBDA(wet) / [1-(P moisture/100)].

4. The concentration test fails if the total amount of tetrahydrocannabinol and tetrahydrocannabinolic acid, as calculated pursuant to this section, exceeds the maximum concentration or amounts permitted in North Dakota Century Code chapter 19-24.1.

5. The concentration test fails if the tetrahydrocannabinol or cannabidiol content of a medical cannabinoid product is determined through testing not to be homogenous. A medical cannabinoid product is considered not to be homogenous if ten percent of the infused portion of the medical cannabinoid product contains more than twenty percent of the total tetrahydrocannabinol or cannabidiol contained within the entire medical cannabinoid product.

6. If the samples do not pass testing standards for concentration, the manufacturing facility must comply with section 33-44-01-52.

History: Effective April 1, 2018; amended effective October 1, 2019; July 1, 2022.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-52. Failed test samples.

1. If a sample fails any test, the manufacturing facility may submit a written request to the department for a reanalysis. The request must be received by the department within seven calendar days from the date the laboratory sent notice of the failed test to the manufacturing facility. The department, in consultation with the laboratory, shall determine whether a reanalysis will be performed on the samples held by the laboratory or a new sample will be selected from the batch. The reanalysis must be completed by the laboratory within thirty days from the date the reanalysis request was received.

2. If a sample fails a test or a reanalysis under subsection 1:

   a. The batch may be remediated or sterilized in accordance with this section; or

   b. If the batch is not or cannot be remediated or sterilized under this section, the batch must be disposed of in accordance with section 33-44-01-15.

3. If a sample from a batch of dried leaves and flowers, cannabinoid concentrate, or cannabinoid product fails pesticide or degradation compound testing, the batch may not be remediated and must be disposed of as ordered by the department or the department of agriculture. An affected or contaminated batch may not be destroyed without obtaining written permission from the department or the department of agriculture.

4. A manufacturing facility shall comply with the following requirements when a sample fails to meet the standards for microbiological contaminant or mycotoxin testing:

   a. If a sample from a batch of dried leaves and flowers fails microbiological contaminant or mycotoxin testing, the batch may be used to make a cannabinoid concentrate if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon-based solvent or a carbon dioxide closed loop system, or the processing method selectively removes the mycotoxins from the batch.

   b. If a sample from a batch of a cannabinoid concentrate fails microbiological contaminant or mycotoxin testing, the batch may be further processed if:

      (1) The processing method effectively sterilizes the batch, such as a method using a hydrocarbon-based solvent or a carbon dioxide closed loop system; or

      (2) The processing method selectively removes the mycotoxins from the batch.

   c. If a sample from a batch of a medical cannabinoid product fails microbiological contaminant or mycotoxin testing, the batch may be remediated if written approval from the department is obtained prior to remediation.

   d. A batch that is remediated in accordance with subdivision a, b, or c of subsection 4 must be sampled and tested in accordance with these rules.

   e. A batch that fails microbiological contaminant or mycotoxin testing after undergoing remediation in accordance with subdivision a, b, or c of subsection 4 must be disposed of in accordance with section 33-44-01-15.

5. If a sample from a batch of dried leaves and flowers, cannabinoid concentrate, or cannabinoid product fails heavy metals testing, the batch may be remediated if written approval from the department is obtained prior to remediation. A batch that is remediated must be sampled and tested in accordance with these rules. A batch that fails heavy metals testing after undergoing remediation must be disposed of in accordance with section 33-44-01-15.

6. A manufacturing facility shall comply with the following requirements when a sample fails to meet the standards for solvent testing:

   a. If a sample from a batch fails solvent testing, the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level established in these rules.

   b. A batch that is remediated in accordance with subdivision a of subsection 6 must be sampled and tested in accordance with these rules.

   c. A batch that fails solvent testing after undergoing remediation in accordance with subdivision a must be disposed of in accordance with section 33-44-01-15.

7. A manufacturing facility shall comply with the following requirements when a sample fails to meet the standards for water activity and moisture testing:

   a. If a sample from a batch of dried leaves and flowers fails for water activity or moisture testing, the batch from which the sample was taken may:

      (1) Be used to make a cannabinoid concentrate or a medical cannabinoid product and must comply with testing requirements established in these rules; or

      (2) Continue to dry or cure.

   b. A batch that undergoes additional drying or curing as described in paragraph 2 of subdivision a must be sampled and tested in accordance with these rules.

8. A manufacturing facility shall comply with the following requirements when a sample fails to meet the standards for concentration testing:

   a. A batch that has a sample failing concentration testing under subsection 4 of section 33-44-01-51 may be remediated to meet the concentration limits permitted in North Dakota Century Code chapter 19-24.1.

   b. If a sample from a batch of pediatric medical marijuana fails concentration testing, the manufacturing facility may use the batch for nonpediatric usable marijuana rather than remediating the pediatric medical marijuana in accordance with subdivision a. No additional testing is required if the manufacturing facility does not label the usable marijuana for pediatric use and does no further processing with a batch of pediatric medical marijuana failing concentration testing. Any usable marijuana processed with a batch from a failed pediatric medical marijuana concentration test must be sampled and tested in accordance with these rules.

   c. A batch that has a sample failing concentration testing under subsection 5 of section 33-44-01-51 may be remediated or the manufacturing facility may use the concentration test results of the laboratory for labeling purposes.

   d. A batch that has a sample failing concentration testing under subsection 6 of section 33-44-01-51 may be remediated.

   e. A batch that is remediated in accordance with subdivision a, c, or d must be sampled and tested in accordance with these rules.

9. A manufacturing facility shall, as applicable:

   a. Have detailed written procedures for remediation processes to be used pursuant to this section.

b. Document all remediation processes used pursuant to this section.

History: Effective April 1, 2018; amended effective October 1, 2019; July 1, 2022.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-53. Tentative identification of compounds.

1. A laboratory shall report tentatively identified compounds to the manufacturing facility and the department.

2. Following the receipt of a tentatively identified compounds report, the department may initiate an investigation. The investigation may include requiring a sample be selected of marijuana or usable marijuana of a manufacturing facility. Testing of samples may include testing for analytes that are not required by these rules. Costs of tests performed under this section must be paid by the manufacturing facility.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-54. Random testing.

The department may require, at any time, a manufacturing facility to permit sampling of marijuana, usable marijuana, or medical marijuana waste to determine whether a manufacturing facility is in compliance with North Dakota Century Code chapter 19-24.1 and these rules. Costs of tests performed under this section must be paid by the manufacturing facility.

History: Effective April 1, 2018.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36

33-44-01-55. Manufacturing facility quality control and quality assurance program.

1. A manufacturing facility shall develop and follow a written quality control and quality assurance program. The program must be established to protect qualifying patient health and implemented in a manner to assist in complying with testing required in sections 33-44-01-42, 33-44-01-43, and 33-44-01-44. A manufacturing facility is not prohibited by these rules to test marijuana and usable marijuana as part of a quality control and quality assurance program.

2. A quality control and quality assurance program must include an assessment of the profile of the active ingredients, including expiration date, and the presence of inactive ingredients and contaminants. Testing results must be used to determine appropriate conditions and expiration dates.

3. A manufacturing facility shall develop and follow written procedures for sampling marijuana and usable marijuana. Procedures must be developed related to sampling methods, sample collection, and documentation of sampling. Test results from random samples must be retained for at least three years.

4. The manufacturing facility shall develop and follow written procedures for performing stability testing of usable marijuana to determine product expiration date. Once an expiration date has been determined through testing described in subsection 5, a manufacturing facility must perform periodic stability testing to verify expiration dates.

5. If stability testing has not been completed within one year of production, a manufacturing facility may assign a tentative expiration date based on available stability information. Stability

testing is to include, at a minimum, an assessment of microbiological contaminants and mycotoxins, heavy metals, and concentration. When applicable, the stability testing must include water activity and moisture content or solvents. If an expiration date is one year or less, at a minimum, a stability test must be performed once before fifty percent of the period has expired and at the end of the expiration date. If an expiration date is more than one year, at a minimum, a stability test must be performed at no less than six-month intervals and at the end of the expiration date. After the manufacturing facility verifies the tentative expiration date, or determines the appropriate expiration date, the manufacturing facility shall include the expiration date on each batch of marijuana or usable marijuana.

6. A manufacturing facility shall retain a uniquely labeled reserve sample representing each harvest lot, process lot of cannabinoid concentrate to be packaged in a container for transfer to a dispensary, and process lot of medical cannabinoid product for at least one year following the expiration date. The reserve sample must be stored in the same immediate container-closure system the usable marijuana is packaged in for dispensaries, or in one that has similar characteristics. The reserve sample must consist of at least twice the quantity necessary to perform all required tests.

History: Effective April 1, 2018; amended effective October 1, 2019.
General Authority: NDCC 19-24.1-36
Law Implemented: NDCC 19-24.1-36