

**ARTICLE 33-44
MEDICAL MARIJUANA**

Chapter
33-44-01 Medical Marijuana

**CHAPTER 33-44-01
MEDICAL MARIJUANA**

Section	
33-44-01-01	Definitions
33-44-01-02	Cardholder Notification of Change
33-44-01-03	Fees for Failure to Provide Notice
<u>33-44-01-03.1</u>	<u>Minor Application</u>
33-44-01-04	Cardholder Disposal of Usable Marijuana
33-44-01-05	Expiration of Registry Identification Cards
33-44-01-06	Compassion Center Application Process
33-44-01-07	Establishing Additional Compassion Centers
33-44-01-08	Compassion Center Inventory Limits
33-44-01-09	Use of Pesticides Prohibited
33-44-01-10	Pesticide Presence
33-44-01-11	Operations Manual
33-44-01-12	Restricted Access Areas
33-44-01-13	Dispensary Display Areas
33-44-01-14	Usable Marijuana Take Back
33-44-01-15	Medical Marijuana Waste Disposal
33-44-01-16	Recall Procedures
33-44-01-17	Surveillance Requirements
33-44-01-18	Alarm System Requirements
33-44-01-19	Inventory Control Measures
33-44-01-20	Conducting Inventory
33-44-01-21	Personnel Record Retention
33-04-01-22	Compassion Center and Laboratory Incidents
33-44-01-23	Advertising and Marketing
33-44-01-24	Strain or Brand Names
<u>33-44-01-24.1</u>	<u>Medical Cannabinoid Product Formulation</u>
33-44-01-25	Usable Marijuana Packaging
33-44-01-26	Manufacturing Facility Labeling
33-44-01-27	Dispensary Labeling
33-44-01-28	Removal of Product Labels
33-44-01-29	Transportation Authorization
33-44-01-30	Transportation Requirements
33-44-01-31	Compassion Center Inspections and Compliance
33-44-01-32	Plan of Correction
33-04-01-33	Data Reporting
33-44-01-34	Law Enforcement Reportable Incidents
33-44-01-35	Reporting Adverse Reactions
33-44-01-36	Laboratory Procurement Process
33-44-01-37	Laboratory Authority
33-44-01-38	Laboratory Agent Registry Identification Cards
33-44-01-39	Laboratory Inspection
33-44-01-40	Usable Marijuana Testing
33-44-01-41	Ordering Tests
33-44-01-42	Compliance Testing Requirements for Dried Leaves and Flowers

33-44-01-43	Compliance Testing Requirements for Cannabinoid Concentrates
33-44-01-44	Compliance Testing Requirements for Medical Cannabinoid Products
33-44-01-44.1	Terpene Analysis
33-44-01-45	Batch Requirements for Compliance Testing
33-44-01-46	Manufacturing Facility Requirements for Labeling, Storing, and Securing Usable Marijuana Batches
33-44-01-47	Standards for Pesticides and Degradation Compounds Compliance Testing
33-44-01-48	Standards for Microbiological Contaminants and Mycotoxin Compliance Testing
33-44-01-48.1	Standards for Heavy Metals Compliance Testing
33-44-01-49	Standards for Solvents Compliance Testing
33-44-01-50	Standards for Water Activity and Moisture Content Compliance Testing
33-44-01-51	Standards for Concentration Compliance Testing
33-44-01-52	Failed Test Samples
33-44-01-53	Tentative Identification of Compounds
33-44-01-54	Random Testing
33-44-01-55	Manufacturing Facility Quality Control and Quality Assurance Program

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; amended effective.

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

General Authority: NDCC 19-24.1-03

Law Implemented: NDCC 19-24.1-03

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 five, but no more than twelve, 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.

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

33-44-01-08. 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; amended effective.

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 ~~shall~~ 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 .

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. There are two categories of ground material that can be incorporated with medical marijuana waste: compostable mix waste and noncompostable mix waste.

- ~~a. Compostable mixed waste: medical marijuana waste to be disposed as compost feedstock or in another organic waste method, such as an anaerobic digester, may be mixed with:~~
 - ~~(1) Food waste.~~
 - ~~(2) Yard waste.~~
 - ~~(3) Vegetable-based grease or oils.~~
 - ~~(4) Other wastes as approved by the department.~~
- ~~b. Noncompostable mixed waste: medical marijuana waste to be disposed in a landfill or another disposal method, such as incineration, may be mixed with these materials:~~
 - ~~(1) Paper waste.~~
 - ~~(2) Cardboard waste.~~
 - ~~(3) Plastic waste.~~
 - ~~(4) Soil.~~
 - ~~(5) Other wastes 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. ~~Acceptable and department-approved permitted solid waste facilities include:~~

- ~~(1) Compostable mixed waste: compost, anaerobic digester, or other facility with the approval of the jurisdictional state or local health department.~~
- ~~(2) Noncompostable mixed waste: landfill, incinerator, or other facility with the approval of the jurisdictional state or local health department.~~

~~b. Disposal of the medical marijuana waste rendered unusable may be managed onsite by the generator in accordance with the standards of North Dakota Century Code chapter 23-29.~~

eb. 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.

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; ~~and~~
- 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; amended effective .

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

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) ~~Harvest lot~~Batch number;
 - (4) Date of harvest;
 - (5) Name of strain;
 - (6) Net weight in United States customary ~~and 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 ~~and 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 each amount suggested for use and~~ 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~~

~~(412)~~ Universal symbol;

~~(4213)~~ Pediatric symbol, if applicable; and

~~(4314)~~ 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 ~~and-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;~~

- (~~42~~13) Universal symbol;
- (~~13~~14) Pediatric symbol, if applicable; and
- (~~44~~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; amended effective.

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 registered designated caregiver's name and department-issued registry identification card number, if applicable.~~
 - ~~e~~b. The name of the dispensary.
 - ~~d~~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.

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.

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. Ensure the batch is labeled with the following information:~~

~~a. The manufacturing facility's name;~~

- ~~b. The harvest lot or process lot unique identification number;~~
- ~~c. The name of the laboratory that took samples;~~
- ~~d. The unique identification sample numbers; and~~
- ~~e. The date the samples were taken.~~

21. Store and secure the batch in a manner that prevents the product from being tampered with or transferred prior to required tests being completed.
32. 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.

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 strains) and salmonella species	Not detected in one gram	Not detected in one gram
--	--------------------------	--------------------------

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 ~~delta-9~~ tetrahydrocannabinol or ~~delta-9~~ tetrahydrocannabinolic acid:

$$M \text{ total } \del{\text{delta-9}}\text{-THC} = \del{\text{delta-9}}\text{-THC} + (0.877 \times M \del{\text{delta-9}}\text{-THCA})$$
 - b. Total cannabidiol, where M is the mass or mass fraction of cannabidiol and cannabidiolic acid:

$$M \text{ total CBD} = M \text{ CBD} + (0.877 \times M \text{ CBDA})$$
3. Test results must report tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and cannabidiolic acid content by dry weight calculated as follows:
 - a. $P \text{ THC(dry)} = P \text{ THC(wet)} / [1-(P \text{ moisture}/100)]$.
 - b. $P \text{ THCA(dry)} = P \text{ THCA(wet)} / [1-(P \text{ moisture}/100)]$.
 - c. $P \text{ CBD(dry)} = P \text{ CBD(wet)} / [1-(P \text{ moisture}/100)]$.
 - d. $P \text{ CBDA(dry)} = P \text{ CBDA(wet)} / [1-(P \text{ moisture}/100)]$.
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 concentration amount identified by the laboratory varies from the concentration amount identified by the manufacturing facility, if known, by more than plus or minus fifteen percent.~~
65. 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.

76. 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; amended effective.

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:
 - (1) ~~The batch is not combined with another batch of dried leaves and flowers to process a cannabinoid concentrate; and~~
 - (2) ~~The~~ 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.

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