# **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
33-44-01-03.1	Minor Application
33-44-01-03.2	Application Fees for Registry Identification Cards
33-44-01-03.3	Replacement Fees for Registry Identification Cards
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
33-44-01-07.1	Additional Categories of Registered Medical Marijuana Establishments
33-44-01-07.2	Compassion Center Application Fees
33-44-01-07.3	Compassion Center Certification Fees
33-44-01-07.4	Compassion Center Additional Certification Fees
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
33-44-01-24.1	Medical Cannabinoid Product Formulation
33-44-01-24.2	Cannabinoid Edible Product
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
00 44 04 4=	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
_	3 , , , , , , , , , , , , , , , , , , ,

**SECTION 1.** Section 33-44-01-03.2 is amended as follows:

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

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

- 1. For <u>resident</u> qualifying patient applications, <u>twenty-fiveforty</u> dollars.
- 2. For nonresident qualifying patient applications, forty dollars.

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

History: Effective October 1, 2022; amended effective October 1, 2025.

General Authority: NDCC 19-24.1-03, 19-24.1-18

Law Implemented: NDCC 19-24.1-03, 19-24.1-18, Section 7 of 2025 Senate Bill No. 2294

**SECTION 2.** Section 33-44-01-03.3 is amended as follows:

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

TheFor a cardholder's first time losing a qualifying patient registry identification card or compassion center agent registry identification card, the department shall collect no fees for issuing a new registry identification cards when an original application or renewal application is not submitted as follows:card.

- 1. For a lostcardholder's second and subsequent times losing a qualifying patient registry identification card or compassion center registry identification card, the department shall collect a twenty-five dollars.
- 2. For a change in name of a registered qualifying patient or registered compassion center agent, five dollars dollar fee for issuing a new registry identification card.

History: Effective October 1, 2022; amended effective October 1, 2025.

**General Authority:** NDCC 19-24.1-10, 19-24.1-18 **Law Implemented:** NDCC 19-24.1-10, 19-24.1-18

**SECTION 3.** Section 33-44-01-20 is amended as follows:

#### 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; amended effective October 1, 2025.

**General Authority:** NDCC 19-24.1-26 **Law Implemented:** NDCC 19-24.1-26

SECTION 4. Section 33-44-01-23 is amended as follows:

## 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 of a compassion center are prohibited from being marketed to a minor.
- 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; amended effective October 1, 2025.

General Authority: NDCC 19-24.1-36

Law Implemented: NDCC 19-24.1-36, NDCC 19-24.1-24.1

**SECTION 5.** Section 33-44-01-24.1 is amended as follows:

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. All non-marijuana ingredients shall be of food-grade quality for a medical cannabinoid product intended for ingestion.

History: Effective July 1, 2022; amended effective October 1, 2025.

General Authority: NDCC 19-24.1-36

Law Implemented: NDCC 19-24.1-36, 19-24.1-24.1

#### **SECTION 6.** A new section is created as follows:

### 33-44-01-24.2. Cannabinoid edible product.

- 1. A cannabinoid edible product must be marked, stamped, or otherwise imprinted with the letters 'THC' or other marking approved by the department.
- 2. A cannabinoid edible product may not be covered or coated with sugar, candy, or a flavor enhancing ingredient. With written department approval, a cannabinoid edible product may be covered or coated in a nonflavored enhancing wax or oil to enhance shelf-stability or usage of the product.
- 3. Depictions of the product, cartoons, or images other than the universal symbol, pediatric symbol, or manufacturing facility logo may not be included on the cannabinoid edible product packaging.

<u>History: Effective October 1, 2025.</u> **General Authority:** NDCC 19-24.1-36

Law Implemented: NDCC 19-24.1-36, 19-24.1-24.1

SECTION 7. Section 33-44-01-25 is amended as follows:

#### 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 and opaque.
  - b. Tamper-evident.
  - c. Child-resistant.

- 2. Usable marijuana must be packaged to minimize its appeal to childrenminors.
- 3. Usable marijuana packaging may not be similar to or bear a reasonable resemblance to any commercially available product.
- 4. Usable marijuana packaging must be resealable if intended for more than a single use.

History: Effective April 1, 2018; amended effective October 1, 2019; October 1, 2025.

General Authority: NDCC 19-24.1-36

Law Implemented: NDCC 19-24.1-36, 19-24.1-24.1

**SECTION 8.** Section 33-44-01-51 is amended as follows:

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

- 1. Usable marijuana concentration testing must include:
  - a. Tetrahydrocannabinol (THC).
  - b. Tetrahydrocannabinolic acid (THCA).
  - c. Cannabidiol (CBD).
  - d. Cannabidiolic acid (CBDA).
- 2. The total tetrahydrocannabinol and total cannabidiol must be calculated as follows:
  - a. Total tetrahydrocannabinol, where M is the mass or mass fraction of tetrahydrocannabinol or tetrahydrocannabinolic acid:

M total THC = THC + 
$$(0.877 \times M \text{ THCA})$$

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

M total CBD = M CBD + 
$$(0.877 \times M CBDA)$$

- 3. Test results must report tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and cannabidiolic acid content by dry weight calculated as follows:
  - a. P THC(dry) = P THC(wet) / [1-(P moisture/100)].

- b. P THCA(dry) = P THCA(wet) / [1-(P moisture/100)].
- c. P CBD(dry) = P CBD(wet) / [1-(P moisture/100)].
- d. P CBDA(dry) = P CBDA(wet) / [1-(P moisture/100)].
- 4. The concentration test fails if the total amount of tetrahydrocannabinol and tetrahydrocannabinolic acid, as calculated pursuant to this section, exceeds the maximum concentration or amounts permitted in North Dakota Century Code chapter 19-24.1.
- 5. The concentration test fails if the tetrahydrocannabinol or cannabidiol content of a medical cannabinoid product is determined through testing not to be homogenous. A medical cannabinoid product is considered not to be homogenous if ten percent of the infused portion of the medical cannabinoid product contains more than twenty percent of the total tetrahydrocannabinol or cannabidiol contained within the entiretest results identify a total tetrahydrocannabinol or cannabidiol variation of plus or minus fifteen percent. A medical cannabinoid product intended for ingestion must include concentration homogeneity testing.
- 6. If the samples do not pass testing standards for concentration, the manufacturing facility must comply with section 33-44-01-52.

History: Effective April 1, 2018; amended effective October 1, 2019; July 1, 2022; October 1, 2025.

**General Authority:** NDCC 19-24.1-36 **Law Implemented:** NDCC 19-24.1-36

**SECTION 9.** Section 33-44-01-55 is amended as follows:

# 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 yearsix months 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; October 1, 2025.

**General Authority:** NDCC 19-24.1-36 **Law Implemented:** NDCC 19-24.1-36