23.0476.02001

Sixty-eighth
Legislative Assembly
of North Dakota

HOUSE BILL NO. 1202

Introduced by

Representatives Vetter, Beltz, Cory, Dobervich, O'Brien, M. Ruby, Schneider, Steiner

Senators Hogan, Meyer, Rummel

A BILL for an Act to create and enact section 19-24.1-24.1 and a new subsection to section 19-24.1-36 of the North Dakota Century Code, relating to regulating edible medical marijuana products; to amend and reenact section 19-24.1-01 of the North Dakota Century Code, relating to definitions relating to medical marijuana products; to provide a contingent effective date; and to declare an emergency.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Section 19-24.1-01 of the North Dakota Century Code is amended and reenacted as follows:

19-24.1-01. Definitions.

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

1. "Advanced practice registered nurse" means an advanced practice registered nurse defined under section 43-12.1-02.
2. "Allowable amount of usable marijuana" means the amount of usable marijuana a registered qualifying patient or registered designated caregiver may purchase in a thirty-day period under this chapter.
   a. Except as provided under subdivision b:
      (1) During a thirty-day period, a registered qualifying patient may not purchase or have purchased by a registered designated caregiver more than two and one-half ounces [70.87 grams] of dried leaves or flowers of the plant of genus cannabis in a combustible delivery form.
      (2) At any time, a registered qualifying patient, or a registered designated caregiver on behalf of a registered qualifying patient, may not possess more than three ounces [85.05 grams] of dried leaves or flowers of the plant of the genus cannabis in a combustible delivery form.

~~(3) At any time, a registered qualifying patient, or a registered designated caregiver on behalf of a registered qualifying patient, may not possess more than five hundred milligrams of an edible marijuana product.~~

b. Notwithstanding subdivision a, if a registered qualifying patient has a registry identification card authorizing an enhanced allowable amount:

(1) During a thirty-day period, a registered qualifying patient may not purchase or have purchased by a registered designated caregiver more than six ounces [170.01 grams] of dried leaves or flowers of the plant of genus cannabis in a combustible delivery form.

(2) At any time, a registered qualifying patient, or a registered designated caregiver on behalf of a registered qualifying patient, may not possess more than seven and one-half ounces [212.62 grams] of dried leaves or flowers of the plant of the genus cannabis in a combustible delivery form.

~~(3) At any time, a registered qualifying patient, or registered designated caregiver on behalf of a registered qualifying patient, may not possess more than five hundred milligrams of an edible marijuana product.~~

c. A registered qualifying patient may not purchase or have purchased by a registered designated caregiver more than the maximum concentration or amount of tetrahydrocannabinol permitted in a thirty-day period. The maximum concentration or amount of tetrahydrocannabinol permitted in a thirty-day period for a cannabinoid concentrate or medical cannabinoid product, or the cumulative total of both, is four thousand milligrams. At any given time, a registered qualifying patient, or a registered designated caregiver on behalf of a registered qualifying patient, may not purchase or possess more than three hundred ten milligrams of tetrahydrocannabinol in the form of a cannabinoid edible product.

3. "Bona fide provider-patient relationship" means a treatment or counseling relationship between a health care provider and patient in which all the following are present:

a. The health care provider has reviewed the patient's relevant medical records and completed a full assessment of the patient's medical history and current medical condition, including a relevant, in-person, medical evaluation of the patient.

b. The health care provider has created and maintained records of the patient's condition in accordance with medically accepted standards.

c. The patient is under the health care provider's continued care for the debilitating medical condition that qualifies the patient for the medical use of marijuana.

d. The health care provider has a reasonable expectation that provider will continue to provide followup care to the patient to monitor the medical use of marijuana as a treatment of the patient's debilitating medical condition.

e. The relationship is not for the sole purpose of providing written certification for the medical use of marijuana.

4. "Cannabinoid" means a chemical compound that is one of the active constituents of marijuana.

5. "Cannabinoid capsule" means a small, soluble container, usually made of gelatin, which encloses a dose of a cannabinoid product or a cannabinoid concentrate intended for consumption. The maximum concentration ~~of~~for amount of tetrahydrocannabinol permitted in a serving of a cannabinoid capsule is fifty milligrams.

6. "Cannabinoid concentrate" means a concentrate or extract obtained by separating cannabinoids from marijuana by a mechanical, chemical, or other process.

7. "Cannabinoid edible product" means a ~~food or potable liquid~~soft or hard lozenge in a geometric square shape into which a cannabinoid concentrate or the dried leaves or flowers of the plant of the genus cannabis is incorporated.

a. The maximum concentration or amount of tetrahydrocannabinol permitted in a serving of a cannabinoid edible product is ~~ten~~five milligrams.

b. The term does not include a soft or hard lozenge in a geometric square shape into which a cannabinoid concentrate or the dried leaves or flowers of the plant of the genus cannabis is incorporated if the form, packaging, or labeling is target marketed to minors.

8. "Cannabinoid solution" means a solution consisting of a mixture created from cannabinoid concentrate and other ingredients. A container holding a cannabinoid solution for dispensing may not exceed thirty milliliters.

9. "Cannabinoid topical" means a cannabinoid product intended to be applied to the skin or hair. The maximum concentration or amount of tetrahydrocannabinol permitted in a cannabinoid topical is six percent.

10. "Cannabinoid transdermal patch" means an adhesive substance applied to the skin which contains a cannabinoid product or cannabinoid concentrate for absorption into the bloodstream. The maximum concentration or amount of tetrahydrocannabinol permitted in a serving of a cannabinoid transdermal patch is fifty milligrams.

11. "Cardholder" means a qualifying patient, designated caregiver, or compassion center agent who has been issued and possesses a valid registry identification card.

12. "Compassion center" means a manufacturing facility or dispensary.

13. "Compassion center agent" means a principal officer, board member, member, manager, governor, employee, volunteer, or agent of a compassion center. The term does not include a lawyer representing a compassion center in civil or criminal litigation or in an adversarial administrative proceeding.

14. "Contaminated" means made impure or inferior by extraneous substances.

15. "Debilitating medical condition" means one of the following:

    a. Cancer;

    b. Positive status for human immunodeficiency virus;

    c. Acquired immune deficiency syndrome;

    d. Decompensated cirrhosis caused by hepatitis C;

    e. Amyotrophic lateral sclerosis;

    f. Posttraumatic stress disorder;

    g. Agitation of Alzheimer's disease or related dementia;

    h. Crohn's disease;

    i. Fibromyalgia;

    j. Spinal stenosis or chronic back pain, including neuropathy or damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity;

    k. Glaucoma;

    l. Epilepsy;

    m. Anorexia nervosa;

n. Bulimia nervosa;

o. Anxiety disorder;

p. Tourette syndrome;

q. Ehlers-Danlos syndrome;

r. Endometriosis;

s. Interstitial cystitis;

t. Neuropathy;

u. Migraine;

v. Rheumatoid arthritis;

w. Autism spectrum disorder;

x. A brain injury;

y. A terminal illness; or

z. A chronic or debilitating disease or medical condition or treatment for such disease or medical condition that produces one or more of the following:

(1) Cachexia or wasting syndrome;

(2) Severe debilitating pain that has not responded to previously prescribed medication or surgical measures for more than three months or for which other treatment options produced serious side effects;

(3) Intractable nausea;

(4) Seizures; or

(5) Severe and persistent muscle spasms, including those characteristic of multiple sclerosis.

16. "Department" means the department of health and human services.

17. "Designated caregiver" means an individual who agrees to manage the well-being of a registered qualifying patient with respect to the qualifying patient's medical use of marijuana.

18. "Dispensary" means an entity registered by the department as a compassion center authorized to dispense usable marijuana to a registered qualifying patient and a registered designated caregiver.

19. "Enclosed, locked facility" means a closet, room, greenhouse, building, or other enclosed area equipped with locks or other security devices that permit access limited to individuals authorized under this chapter or rules adopted under this chapter.

20. "Health care provider" means a physician, a physician assistant, or an advanced practice registered nurse.

21. "Manufacturing facility" means an entity registered by the department as a compassion center authorized to produce and process and to sell usable marijuana to a dispensary.

22. "Marijuana" means all parts of the plant of the genus cannabis; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, the seeds of the plant, or the resin extracted from any part of the plant. The term marijuana does not include:

    a. Hemp as regulated under section 4.1-18.1-01; or

    b. A prescription drug approved by the United States food and drug administration under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355].

23. "Maximum concentration or amount of tetrahydrocannabinol" means the total amount of tetrahydrocannabinol and tetrahydrocannabinolic acid in a medical cannabinoid product or a cannabinoid concentrate.

24. "Medical cannabinoid product" means a product intended for human consumption or use which contains cannabinoids.

    a. Medical cannabinoid products are limited to the following forms:

        (1) Cannabinoid solution;

        (2) Cannabinoid capsule;

        (3) Cannabinoid transdermal patch; ~~and~~

        (4) Cannabinoid topical; and

        (5) Cannabinoid edible products.

    b. "Medical cannabinoid product" does not include:

        (1) ~~A cannabinoid edible product;~~

        ~~(2)~~ A cannabinoid concentrate by itself; or

        ~~(3)~~(2) The dried leaves or flowers of the plant of the genus cannabis by itself.

25. "Medical marijuana product" means a cannabinoid concentrate or a medical cannabinoid product.
26. "Medical marijuana waste" means unused, surplus, returned, or out-of-date usable marijuana; recalled usable marijuana; unused marijuana; or plant debris of the plant of the genus cannabis, including dead plants and all unused plant parts and roots.
27. "Medical use of marijuana" means the acquisition, use, and possession of usable marijuana to treat or alleviate a qualifying patient's debilitating medical condition.
28. "Minor" means an individual under the age of nineteen.
29. "North Dakota identification" means a North Dakota driver's license or comparable state of North Dakota or federal issued photo identification card verifying North Dakota residence.
30. "Owner" means an individual or an organization with an ownership interest in a compassion center.
31. "Ownership interest" means an aggregate ownership interest of five percent or more in a compassion center, unless the interest is solely a security, lien, or encumbrance, or an individual who will be participating in the direction, control, or management of the compassion center.
32. "Pediatric medical marijuana" means a medical marijuana product containing cannabidiol which may not contain a maximum concentration or amount of tetrahydrocannabinol of more than six percent.
33. "Physician" means a physician licensed under chapter 43-17 to practice medicine in the state of North Dakota.
34. "Physician assistant" means an individual licensed under chapter 43-17 to practice as a physician assistant in the state.
35. "Posttraumatic stress disorder" means a patient meets the diagnostic criteria for posttraumatic stress disorder under the "Diagnostic and Statistical Manual of Mental Disorders", American psychiatric association, fifth edition, text revision (2013).
36. "Processing" or "process" means the compounding or conversion of marijuana into a medical marijuana product.

37. "Producing", "produce", or "production" mean the planting, cultivating, growing, trimming, or harvesting of the plant of the genus cannabis or the drying of the leaves or flowers of the plant of the genus cannabis.

38. "Qualifying patient" means an individual who has been diagnosed by a health care provider as having a debilitating medical condition.

39. "Registry identification card" means a document issued by the department which identifies an individual as a registered qualifying patient, registered designated caregiver, or registered compassion center agent.

40. "Substantial corporate change" means:

    a. For a corporation, a change of ten percent or more of the officers or directors, or a transfer of ten percent or more of the stock of the corporation, or an existing stockholder obtaining ten percent or more of the stock of the corporation;

    b. For a limited liability company, a change of ten percent or more of the managing members of the company, or a transfer of ten percent or more of the ownership interest in the company, or an existing member obtaining a cumulative of ten percent or more of the ownership interest in the company; or

    c. For a partnership, a change of ten percent or more of the managing partners of the company, or a transfer of ten percent or more of the ownership interest in the company, or an existing member obtaining a cumulative of ten percent or more of the ownership interest in the company.

41. "Terminal illness" means a disease, illness, or condition of a patient:

    a. For which there is not a reasonable medical expectation of recovery;

    b. Which as a medical probability, will result in the death of the patient, regardless of the use or discontinuance of medical treatment implemented for the purpose of sustaining life or the life processes; and

    c. As a result of which, the patient's health care provider would not be surprised if death were to occur within six months.

42. "Tetrahydrocannabinol" means tetrahydrocannabinols naturally contained in a plant of the genus cannabis, and synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of the plant, including synthetic

substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, including:

a. (1) Delta-1 cis or trans tetrahydrocannabinol, and their optical isomers. Other names: Delta-9-tetrahydrocannabinol.

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

(3) Delta-3, 4 cis or trans tetrahydrocannabinol, and its optical isomers.

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

b. Tetrahydrocannabinol does not include:

(1) The allowable amount of total tetrahydrocannabinol found in hemp as defined in chapter 4.1-18.1; or

(2) A prescription drug approved by the United States food and drug administration under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355].

43. "Total tetrahydrocannabinol" means the sum of the percentage by weight of tetrahydrocannabinolic acid multiplied by eight hundred seventy-seven thousandths plus the percentage of weight of tetrahydrocannabinol.

44. "Usable marijuana" means a medical marijuana product or the dried leaves or flowers of the plant of the genus cannabis in a combustible delivery form. ~~However, the term does not include a cannabinoid edible product.~~ In the case of a registered qualifying patient who is a minor, "usable marijuana" is limited to pediatric medical marijuana.

45. "Verification system" means the system maintained by the department under section 19-24.1-31 for verification of registry identification cards.

46. "Written certification" means a form established by the department which is executed, dated, and signed by a health care provider within ninety calendar days of the date of application, stating the patient has a debilitating medical condition. A health care provider may authorize an enhanced amount of dried leaves or flowers of the plant of the genus cannabis in a combustible delivery form to treat or alleviate the patient's debilitating medical condition of cancer. A written certification may not be made except in the course of a bona fide provider-patient relationship.

SECTION 2. Section 19-24.1-24.1 of the North Dakota Century Code is created and enacted as follows:

19-24.1-24.1. Compassion centers - Cannabinoid edible products.

1. A manufacturing facility may not manufacture a cannabinoid edible product unless the manufacturing facility has received the prior approval of the department.
2. A dispensary may not possess, market, or sell a cannabinoid edible product unless the dispensary has received the prior approval of the department.
3. The department may not approve the manufacturing, possession, marketing, or sale of a cannabinoid edible product unless the department has reviewed and approved the form, manufacturing, packaging, labeling, and marketing of the cannabinoid edible product.
   a. Manufacturing of a cannabinoid edible product must take place in a ~~department-licensed commercial kitchen that is inspected annually by the department~~manufacturing facility.
   b. Packaging of a cannabinoid edible product must be resealable, must be child resistant, and may not be transparent. The maximum concentration or amount of tetrahydrocannabinol permitted in a package is one hundred milligrams.
   c. Labeling of a cannabinoid edible product must be in black arial font which provides the name of the product, manufacturer's information, ingredient list, milligrams of tetrahydrocannabinol per serving, and number of servings per package. The labeling may not include an image other than text and the symbols required by rules adopted under this chapter.
   d. Marketing may not target market to minors.

SECTION 3. A new subsection to section 19-24.1-36 of the North Dakota Century Code is created and enacted as follows:

The ~~health council~~department shall adopt rules to regulate the form, manufacturing, packaging, labeling, and marketing of a cannabinoid edible product. The rules must prohibit the marketing of a cannabinoid edible product to a minor.

SECTION 4. CONTINGENT EFFECTIVE DATE. Section 2 of this Act becomes effective on the date the department of health and human services certifies to the legislative council that all

necessary administrative rules to regulate the form, manufacturing, packaging, labeling, and marketing of a cannabinoid edible product are in place.

SECTION 5. EMERGENCY. ~~This~~Sections 1 and 3 of this Act ~~is~~are declared to be an emergency measure.