

NOV 03 2017



OFFICE OF STATE HEALTH OFFICER
600 East Boulevard Avenue, Dept. 301
Bismarck, N.D. 58505-0200
www.ndhealth.gov



November 3, 2017

Hand Delivered

Ms. Vonette Richter, Code Revisor
North Dakota Legislative Council
State Capitol
600 East Boulevard Ave
Bismarck, ND 58505-0360

RE: Proposed Adoption of North Dakota Administrative Code Chapter 33-44-01 – Medical Marijuana

Dear Ms. Richter:

The Notice of Intent to Adopt Administrative Rules, a copy of the proposed rules, and an analysis and economic impact statement are enclosed as required by N.D.C.C. subsection 28-32-10(1).

Sincerely,

A handwritten signature in cursive script, reading "Mylynn K. Tufte".

Mylynn K. Tufte, MBA, MSIM, BSN
State Health Officer

MKT:irr
Enc.

NOTICE OF INTENT TO ADOPT ADMINISTRATIVE RULES

TAKE NOTICE that the North Dakota Department of Health will hold six public hearings to address proposed adoption of North Dakota Administrative Code Chapter 33-44-01 on the dates and at the locations listed in the table below (central time):

Date	Time	City	Location/Address
December 11, 2017	9:00 a.m.	Belcourt	Turtle Mountain Community College 10145 BIA Road 7
December 11, 2017	2:00 p.m.	Williston	Williston Area Recreation Center 822 18 th Street East
December 13, 2017	9:00 a.m.	Minot	First District Health Unit (Door B) 801 11 th Avenue Southwest
December 13, 2017	2:00 p.m.	Bismarck	Fort Totten Room, State Capitol 600 East Boulevard Ave
December 14, 2017	9:00 a.m.	Fargo	Fargo Cass Public Health 1240 25 th Street South
December 14, 2017	2:00 p.m.	Grand Forks	Grand Forks County Building Memorial Conference Rooms, 6 th Floor 151 South 4 th Street

The purpose of the proposed administrative rules is to establish rules as required by North Dakota Century Code (NDCC) Chapter 19-24.1 for the implementation and administration of the state's medical marijuana program. Senate Bill 2344 of the 65th Legislative Assembly created NDCC Chapter 19-24.1 ("Medical Marijuana") and was effective April 18, 2017. The proposed rules include requirements to be complied with by compassion centers, compassion center agents, a laboratory contracted with by the Department of Health, laboratory agents, qualifying patients, designated caregivers, health care provider professionals, law enforcement, emergency medical services professionals, and emergency department personnel. The proposed rules will impact the regulated community in excess of \$50,000.

The proposed rules may be reviewed in Room 202 at:

Department of Health
Division of Medical Marijuana
600 East Boulevard Ave, Department 301
Bismarck, ND 58505-0200.

A copy of the proposed rules and regulatory analysis may be requested by emailing medmarijuana@nd.gov or calling 701-328-1311. A copy of the proposed rules will also be available on the Division of Medical Marijuana website (www.ndhealth.gov/MM/).

Oral or written comments on the proposed rules provided at any of the six public hearings will be fully considered. Written comments on the proposed rules sent to the Division via email at medmarijuana@nd.gov or written comments sent to the above mailing address and received by December 26, 2017 will be fully considered. For written comments submitted via email, please include "Written Comments to Proposed Rules" in the subject line.

If you plan to attend a public hearing and will need specific facilities or assistance relating to a disability, please contact the Division of Medical Marijuana at 701-328-1311, via

PROPOSED ADDITION OF NORTH DAKOTA ADMINISTRATIVE CODE CHAPTER 33-44-01
(MEDICAL MARIJUANA)
ANALYSIS REQUIRED

As required by North Dakota Century Code (NDCC) Chapter 28-32, the following analysis was completed for the proposed addition of NDAC Chapter 33-44-01:

NDCC Section 28-32-08 – Regulatory analysis

- 1. Describe the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule:** The proposed rules will affect compassion centers, compassion center agents, a laboratory contracted with by the Department of Health (DoH), laboratory agents, qualifying patients, designated caregivers, health care provider professionals, law enforcement, emergency medical services professionals, and emergency department personnel. DoH does anticipate an impact to the regulated community (compassion centers) in excess of \$50,000. The compassion centers, including both manufacturing facilities and dispensaries, will be responsible for bearing the majority of costs of implementing the proposed rules. Registered qualifying patients will benefit from the proposed rules by being able to have access to usable marijuana under a well regulated program and the usable marijuana will have passed compliance testing standards. In addition, the public will benefit from a well regulated program that will prevent potential diversion and unlawful uses.
- 2. Describe the probable impact, including economic impact, of the proposed rule:** The probable impact of the proposed rules is having a well regulated medical marijuana program. The proposed rules were drafted to implement the medical marijuana program in a manner to protect the public's health and safety. The proposed rules assist in regulating marijuana, usable marijuana, and medical marijuana waste to prevent potential diversion and unlawful uses. The economic impact of the proposed rules is not able to be assessed at this point. The medical marijuana program has yet to be implemented.
- 3. Describe the probable costs to the agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues:** Currently, the Division of Medical Marijuana has three full-time equivalents (a program director, a program administrator, and an administrative assistant). It is anticipated an inspector will be hired to monitor compliance with proposed rules (approximately \$85,000 per year for salary and operating costs). The program director and program administrator will also be responsible for implementation and enforcement of the proposed rules. The fiscal note prepared for the 65th Legislative Assembly, identified for the 2017-19 biennium estimated revenue of approximately \$840,000 for DoH, \$1.7 million of increased sales and use tax revenue, and \$50,000 of revenue for the Office of the Attorney General (for conducting criminal history record checks). The proposed rules are expected to have no impact on the fiscal note.
- 4. Describe any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why the methods were rejected in favor of the proposed rule:** NDCC Chapter 19-24.1 requires administrative rules to be established. Therefore, no other alternative methods were seriously considered. In drafting the proposed rules, DoH reviewed and considered other states laws and rules.

NDCC Section 28-32-08.1(2) – Small entity regulatory analysis

1. **Was establishment of less stringent compliance and reporting requirements for small entities considered?** No. Regardless of the size of a manufacturing facility or a dispensary, the proposed rules need to be adhered to in order to have a well regulated program; protect the public health, safety, and welfare; and to prevent potential diversion and unlawful uses. Throughout the rule drafting process, DoH considered impacts of rules to the operations and costs of operations for manufacturing facilities and dispensaries. Also, the rules established for a laboratory contracted with by DoH were required in order for a laboratory to be properly authorized to conduct necessary testing.
2. **Was establishment of less stringent schedules or deadlines for compliance of reporting requirements for small entities considered?** No. To ensure proper regulation of the medical marijuana program, manufacturing facilities and dispensaries, regardless of size, need to comply with the proposed rules to protect the public health, safety, and welfare and to prevent potential diversion and unlawful uses.
3. **Was consolidation or simplification of compliance or reporting requirements for small entities considered?** No. To ensure proper regulation of the medical marijuana program, manufacturing facilities and dispensaries, regardless of size, need to comply with the proposed rules to protect the public health, safety, and welfare and to prevent potential diversion and unlawful uses.
4. **Was establishment of performance standards for small entities to replace design or operational standards required in the proposed rule considered?** No. Standards are the same for all manufacturing facilities and dispensaries.
5. **Was exemption of small entities from all or any part of the requirements contained in the proposed rule considered?** No. There are no exemptions in the proposed rules for manufacturing facilities or dispensaries.

NDCC Section 28-32-08.1(3) – Small entity economic impact statement

1. **Which small entities are subject to the proposed rules?** Manufacturing facilities, dispensaries, and a laboratory contracted with by DoH.
2. **What are the administrative and other costs required for compliance with the proposed rule?** The DoH is unable to determine what the costs will be for manufacturing facilities and dispensaries to implement the proposed rules.
3. **What is the probable cost and benefit to private persons and consumers who are affected by the proposed rule?** The probable costs to registered qualifying patients is unknown at this time. Costs incurred by manufacturing facilities to implement requirements in the proposed rules will need to be recouped through sales to dispensaries. Costs incurred by dispensaries to implement requirements in the proposed rules will need to be recouped through sales to registered qualifying patients and registered designated caregivers. Laboratory costs for testing are to be paid by manufacturing facilities. The benefits of the proposed rules are protecting the public health, safety, and welfare; preventing potential diversion and unlawful uses; and ensuring usable marijuana has passed compliance testing standards prior being dispensed to registered qualifying patients and registered designated caregivers.

4. **What is the probable effect of the proposed rule on state revenues?** The fiscal note prepared for the 65th Legislative Assembly, identified for the 2017-19 biennium estimated revenue of approximately \$840,000 for DoH, \$1.7 million of increased sales and use tax revenue, and \$50,000 of revenue for the Office of the Attorney General (for conducting criminal history record checks). The proposed rules are expected to have no impact on the fiscal note.
5. **Is there any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule?** No less intrusive or less costly alternative method of achieving the purpose of the proposed rules was identified.

NDCC Section 28-32-09 – Takings assessment

A takings assessment is not required as the proposed rules do not result in a taking as identified in NDCC Section 28-32-09.