

October 25, 2019

RE: Proposed creation of N.D. Admin. Code chapter 75-09.1-12
Licensing Standards for Medication Units

TO WHOM IT MAY CONCERN:

The Department of Human Services is proposing the creation of N.D. Admin. Code chapter 75-09.1-12, Licensing Standards for Medication Units. The department has adopted procedures to assure public input into the formulation of the rules prior to adoption.

In conformity with those procedures, we are providing you with a copy of the proposed rules and are requesting that you provide any written data, views, or arguments no later than 5:00 p.m. on December 19, 2019.

The department has scheduled an oral hearing for December 9, 2019. Further information concerning the public hearing is included in the attached notice of proposed rulemaking and public hearing.

Your participation is welcomed, as are your suggestions. Please send all written data, views, or arguments to: Rules Administrator, Department of Human Services, State Capitol - Judicial Wing, 600 E. Boulevard Ave., Bismarck, ND 58505-0250.

Sincerely,



Christopher Jones,
Executive Director

CDJ/rs

Enclosures

cc: Vonette Richter, Legislative Council
Pamela Sagness, Behavioral Health

EXECUTIVE OFFICE

GOVERNOR
Doug Burgum

EXECUTIVE DIRECTOR
Christopher Jones

NOTICE OF INTENT TO CREATE
ADMINISTRATIVE RULES RELATING TO
N.D.A.C. CHAPTER 75-09.1-12
LICENSING STANDARDS FOR MEDICATION UNITS

TAKE NOTICE that the North Dakota Department of Human Services will hold a public hearing to address proposed creation of N.D. Admin. Code chapter 75-09.1-12 at 3:00 p.m. on Monday, December 9, 2019, in Bismarck, N.D. in AV Room 210, located on the second floor of the Judicial Wing of the State Capitol.

The proposed creation of N.D. Admin. Code chapter 75-09.1-12, Licensing Standards for Medication Units, is necessary to comply with House Bill No. 1103, passed during the 2019 Legislative Session. The addition of this administrative rule allows for the creation of Medication Units to be licensed by the Behavioral Health Division, increasing access to treatment for individuals with an opioid use disorder.

The proposed changes are as follows:

Section 75-09.1-12-01 is created to provide definitions regarding licensing standards for medication units. Definitions created include “condition”, “corrective action plan”, “department”, “division”, “home-base opioid treatment program”, “interim license”, “medication unit”, “medication unit license”, “patient”, and “recommendation”.

Sections 75-09.1-12-02 is created to provide requirements for medication unit licensure. The section requires the medication unit to hold a current license in good standing as an opioid treatment program under chapter 75-09.1-01. The section also establishes criteria that must be reviewed within an assessment of need for the proposed location of a medication unit, requires the applicant to obtain written approval from the behavioral health division, and establishes what must be contained in the contents of a medication unit application. This section also permits the behavioral health division to grant an interim license to the prospective medication unit and the prospective medication unit to submit certain required documentation. The section also establishes a process for renewing a medication unit license.

Section 75-09.1-12-03 is created to outline when the behavioral health division shall issue a license to a medication unit. The section also establishes a one-year licensure period after initial approval and three-year licensure period for subsequent approvals.

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Section 75-09.1-12-04 is created to outline the situations under which the behavioral health division shall deny an applicant's license.

Section 75-09.1-12-05 is created to outline the licensing review requirements that the behavioral health division shall implement. This includes a review within one year of the initial license and at least every three years thereafter. The section also permits scheduled or unscheduled visits at times other than routine licensing reviews and outlines what must be contained in a licensure review report. The section also describes what a medication unit must do upon receiving a condition and details what must be done in a corrective action plan to address any conditions.

Section 75-09.1-12-06 is created to establish procedures for suspension and revocation of a license for a medication unit. The section also permits an applicant for or a holder of a license to appeal a decision to deny, suspend, or revoke a license.

Section 75-09.1-12-07 is created to provide requirements for the operation of all licensed medication units, including development of policies and processes regarding: medication dosing; development of a policy on the physical operations of a medication unit in conjunction with services at the home-based opioid treatment program; policy identifying criteria for a patient to receive services at the medication unit; identification of services received; patient orientation; treatment plans; a continuity of care process; employee requirements; cleanliness; and protection of patient confidentiality.

Section 75-09.1-12-08 is created to require a medication unit to: maintain health and safety policies and procedures; develop and implement a written emergency plan; have staff certified in basic first aid and basic cardiac life support; have overdose reversal medication readily available; make available first-aid equipment and supplies; and to implement a written policy that addresses the use of nicotine products.

Section 75-09.1-12-09 is created to establish procedures that a home-based opioid treatment program should take if a medication unit closes voluntarily or involuntarily, including procedures relating to continuity of care and providing notice of the anticipated closure.

The proposed amendments are not anticipated to have an impact on the regulated community in excess of \$50,000. No taking of real property is involved in this rulemaking action.

Copies of the proposed rules are available for review at county social services offices and at human service centers. Copies of the proposed rules and the regulatory analysis relating to these rules may be requested by telephoning (701) 328-2311. Written or oral data, views, or arguments may be entered at the hearing or sent to: Rules Administrator, North Dakota Department of Human Services, State Capitol - Judicial Wing, 600 E. Boulevard Ave., Dept. 325, Bismarck, ND 58505-0250. Written data, views, or arguments on the proposed rules must be received no later than 5:00 p.m. on Thursday, December 19, 2019.

ATTENTION PERSONS WITH DISABILITIES: If you plan to attend the hearing and will need special facilities or assistance relating to a disability, please contact the Department of Human Services at the above telephone number or address at least two weeks prior to the hearing.

Dated this 25th day of October, 2019.

SECTION 1. Chapter 75-09.1-12 is created as follows:

CHAPTER 75-09.1-12
LICENSING STANDARDS FOR MEDICATION UNITS

Section

<u>75-09.1-12-01</u>	<u>Definitions</u>
<u>75-09.1-12-02</u>	<u>Requirements for Medication Unit License – Application</u>
<u>75-09.1-12-03</u>	<u>Issuing License to Medication Unit</u>
<u>75-09.1-12-04</u>	<u>Denial of Application for Medication Unit</u>
<u>75-09.1-12-05</u>	<u>Licensing Review Requirements</u>
<u>75-09.1-12-06</u>	<u>Suspension and Revocation of License for Medication Unit – Appeal</u>
<u>75-09.1-12-07</u>	<u>Medication Unit Requirements</u>
<u>75-09.1-12-08</u>	<u>Health and Safety</u>
<u>75-09.1-12-09</u>	<u>Medication Unit Closures</u>

75-09.1-12-01. Definitions.

In this chapter, unless the context or subject matter otherwise requires:

1. “Condition” means a violation of the requirements of any applicable law or regulation has occurred.
2. “Corrective action plan” means a plan developed by the medication unit and submitted to the division identifying how the medication unit will correct a condition.
3. “Department” means the North Dakota department of human services.
4. “Division” means the behavioral health division of the department.
5. “Home-base opioid treatment program” means the opioid treatment program licensed according to chapter 75-09.1-10 to operate the medication unit.
6. “Interim license” means the proposed medication unit has met state requirements to move forward with federal requirements. A medication unit shall not perform the duties of a medication unit under an interim license.
7. “Medication unit” means a facility established as part of, but geographically separate from, an opioid treatment program from which licensed private medical practitioners or pharmacists dispense or administer an opioid agonist or antagonist treatment medication or collect biological specimen samples for drug testing or analysis. Medication units

are not required to be free-standing entities and can be located within other facilities, including a hospital, homeless shelter, correctional program, or public health location.

8. “Medication unit license” means a medication unit has met all state and federal requirements to operate the medication unit.
9. “Patient” means an individual who undergoes treatment in an opioid treatment program who may receive partial services at the medication unit.
10. “Recommendation” means a suggestion offered by the licensure team to strengthen and enhance the medication unit and services offered by the medication unit.

History: Effective April 1, 2020.

General Authority: NDCC 50-31-09

Law Implemented: NDCC 50-31-09

75-09.1-12-02. Requirements for medication unit license – Application.

1. A medication unit applicant for licensure to operate a medication unit shall hold a current license in good standing as an opioid treatment program under chapter 75-09.1-01.
2. Prior to applying for a license, the home-based opioid treatment program shall submit an assessment of need for the proposed location of a medication unit and obtain written approval by the division. The assessment of need must include an assessment of the following criteria:
 - a. A description of other existing services and medication units of the type proposed to meet the needs of the population proposed to be served in that location;
 - b. Justification for the need of a medication unit in the location;
 - c. Description of prospective operations for patient care at the medication unit; and
 - d. Community relations plan developed in consultation with the county, city, or tribal authority, or designees.
3. Following written approval from the division to pursue licensure, the prospective medication unit shall submit a medication unit application including required documentation and the application fee of one hundred fifty dollars to the department. Upon approval of the application

requirements, the prospective medication unit may receive an interim license.

4. Within ninety days of receiving the interim license, a prospective medication unit shall submit to the division the following items for review:
 - a. Documentation of the updated certification by the United States department of health and human services substance abuse and mental health services administration, including the application and required materials sent for certification; and
 - b. Registration from the United States department of justice, drug enforcement administration.

5. To renew a medication unit license, the following must occur:
 - a. A licensing renewal conducted by the division;
 - b. Submission of application with required documentation to the division; and
 - c. Application fee paid to the department.

History: Effective April 1, 2020.

General Authority: NDCC 50-31-03.1, 50-31-09

Law Implemented: NDCC 50-31-03.1, 50-31-09

75-09.1-12-03. Issuing license to medication unit.

The division shall issue a license following:

1. A review and approval of application materials for up to one year and subsequent licenses for three years;
2. A licensing review with no conditions issued; or
3. A review and approval of implementation of any corrective action plan required as a result of a licensing review or investigation.

History: Effective April 1, 2020.

General Authority: NDCC 50-31-09

Law Implemented: NDCC 50-31-09

75-09.1-12-04. Denial of application for medication unit.

The division shall deny an applicant's license:

1. When applicant fails to meet the requirements of this chapter; or
2. The home-base opioid treatment program's license is not in good standing or has been suspended or revoked.

History: Effective April 1, 2020.

General Authority: NDCC 50-31-09

Law Implemented: NDCC 50-31-09

75-09.1-12-05. Licensing review requirements.

1. The division shall conduct a licensing review within one year of the initial license and at least every three years thereafter to determine continued compliance with the standards contained in this chapter.
2. The division may conduct scheduled or unscheduled visits at times other than routine licensing reviews.
3. Within thirty days of the licensing review, the division shall send a licensure review report to the medication unit.
4. A licensure review report must contain a description of:
 - a. The medication unit reviewed;
 - b. Any conditions issued; and
 - c. Any recommendations.
5. A medication unit receiving a condition shall submit to the division a corrective action plan within thirty days from receipt identifying how the medication unit will become compliant with the standards contained in this article.
6. The medication unit shall have sixty days after the corrective action plan is submitted to implement the actions to become compliant with the standards contained in this chapter.
7. The division shall require documentation or conduct an on-site review or both to ensure the medication unit has implemented its corrective action plan.

History: Effective April 1, 2020.

General Authority: NDCC 50-31-09

Law Implemented: NDCC 50-31-09

75-09.1-12-06. Suspension and revocation of license for medication unit – Appeal.

1. The division may suspend or revoke a license for one or more of the following reasons:
 - a. The home-base opioid treatment program’s license has been suspended or revoked;
 - b. The medication unit has violated any rules of the department; or
 - c. If the medication unit fails to correct conditions or fails to provide a sufficient explanation for its failure to take action, the division may suspend or revoke the medication unit’s license or require other corrective measures from the medication unit.
2. An applicant for or a holder of a license may appeal a decision to deny, suspend, or revoke a license as set forth in section 75-09.1-01-27.

History: Effective April 1, 2020.

General Authority: NDCC 50-31-09

Law Implemented: NDCC 50-31-09

75-09.1-12-07. Medication unit requirements.

All licensed medication units shall:

1. Provide medication dosing and may provide urine screen collection and shall adhere to all state and federal regulations for those services. Any other services provided at the medication unit must have prior approval by the division;
2. Develop and implement a policy on the physical operations of a medication unit in conjunction with services at the home-based opioid treatment program;
3. Develop and implement a policy identifying the criteria a patient must meet to receive services offered at the medication unit;
4. Identify in a patient’s treatment plan the services received at a medication unit;
5. Provide orientation to each patient regarding the services offered through the medication unit;
6. Develop treatment plans that reflect the utilization of a medication unit;

7. Develop and implement a process for a patient's continuity of care between services conducted at the medication unit and the home-based opioid treatment program;
8. Ensure all employee requirements required in chapter 75-09.1-10 occur for employees of the medication unit;
9. Ensure the facility is clean and well-maintained; and
10. Provide protection of patient confidentiality, in accordance with federal and state confidentiality requirements.

History: Effective April 1, 2020.

General Authority: NDCC 50-31-09

Law Implemented: NDCC 50-31-09

75-09.1-12-08. Health and safety.

A medication unit shall:

1. Maintain health and safety policies and procedures;
2. Develop and implement a written emergency plan that addresses provisions for dealing with bomb threats, active shooter and other violent actions, fires, medical emergencies, natural disasters, and power failures;
3. Have staff certified in basic first aid and basic cardiac life support, and trained to respond to a suspected overdose;
4. Have overdose reversal medication readily available;
5. Make readily available first-aid equipment and supplies; and
6. Implement a written policy that addresses the use of nicotine products.

History: Effective April 1, 2020.

General Authority: NDCC 50-31-09

Law Implemented: NDCC 50-31-09

75-09.1-12-09. Medication unit closures.

If a medication unit closes involuntarily or voluntarily, the home-based opioid treatment program shall:

1. Provide the division with a plan detailing the procedures to ensure continuity of care for patients; and

2. Notify the division of the anticipated closure at least ninety days prior to the closure and identify the rationale for closure and the efforts to establish continuity of care for patients.

History: Effective April 1, 2020.

General Authority: NDCC 50-31-09

Law Implemented: NDCC 50-31-09