

**BEFORE THE
ADMINISTRATIVE RULES COMMITTEE
OF THE
NORTH DAKOTA LEGISLATIVE COUNCIL**

N.D. Admin. Code Chapter)	<u>REPORT OF THE</u>
75-09.1-12, Licensing Standards)	<u>DEPT. OF HUMAN SERVICES</u>
For Medication Units)	March 4, 2020
(Pages 220 and 222-226))	

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For its report, the North Dakota Department of Human Services (Department) states:

1. The proposed creation of N.D. Admin Code Chapter 75-09.1-12 is necessary to comply with 2019 House Bill No. 1103.
2. These rules are not related to a change in a federal statute or regulation.
3. The Department uses direct and electronic mail as the preferred ways of notifying interested persons of proposed rulemaking. The Department uses a basic mailing list for each rulemaking project that includes the human service zones directors (formerly known as county social service board directors), the regional human service centers, Legal Services offices in North Dakota, all persons who have asked to be on the basic list, and internal circulation within the Department. Additionally, the Department constructs relevant mailing lists for specific rulemaking. The Department also places public announcements in all county newspapers advising generally of the content of the rulemaking, of over 50 locations throughout the state where the proposed rulemaking documents may be reviewed, and stating the location, date, and time of the public hearing.

The Department conducts public hearings on all substantive rule-making. Oral comments are recorded. Oral comments, as well as any written comments that have been received, are summarized and presented to the Department's executive director, together with any response to the comments that may seem appropriate and a re-drafted rule incorporating any changes occasioned by the comments.

4. No comments were received at the public hearing held in Bismarck on December 9, 2019. The record was held open until December 19, 2019, to allow written comments to be submitted. No written comments were received during the comment period. A summary of comments is attached to this report.
5. The cost of giving public notice, holding a hearing, and the cost (not including staff time) of developing and adopting the rules was \$2382.57.
6. The rules were created to comply with 2019 House Bill No. 1103. The rules allow for the creation of Medication Units to be licensed by the Behavioral Health Division, increasing access to Medication Assisted Treatment for individuals with opioid use disorder. The following specific changes were made:
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.

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.

7. No written requests for regulatory analysis have been filed by the Governor or by any agency. The impact of the proposed amendments

are not expected to have an impact on the regulated community in excess of \$50,000. A regulatory analysis was prepared and is attached to this report.

8. A small entity regulatory analysis and small entity economic impact statement were prepared and are attached to this report.
9. The anticipated fiscal impact resulting from implementation of the proposed amendments is nominal.
10. A constitutional takings assessment was prepared and is attached to this report.
11. These rules were not adopted as emergency (interim final) rules.

Prepared by:

Jonathan Alm
Legal Advisory Unit
North Dakota Department of Human Services
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