

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

**N.D. Admin. Code Chapter)
75-09.1-10, Licensing and)
Treatment Standards for Opioid)
Treatment Programs)
(Pages 507-529))**

**REPORT OF THE
DEPT. OF HUMAN SERVICES
March 11, 2014**

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

1. The proposed creation of N.D. Admin. Code chapter 75-09.1-10 is necessary to comply with 2013 House Bill No. 1101.
2. These rules are not related to changes in a federal statute or regulation.
3. The Department of Human Services (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 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. A public hearing on the proposed rules was held in Bismarck on December 26, 2013. The record was held open until 5:00 p.m. on January 6, 2014, to allow written comments to be submitted. Three sets of written comments were received. The "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 \$2,149.44.
6. The proposed rules create chapter 75-09.1-10. The following specific changes were made:

Chapter 75-09.1-10. Chapter 75-09.1-10 is created to establish the licensing rules for opioid treatment programs and contains the following sections:

- | | |
|---------------|---|
| 75-09.1-10-01 | Definitions |
| 75-09.1-10-02 | Requirements for Opioid Treatment Program License – Application |
| 75-09.1-10-03 | Denial of Application for Opioid Treatment Program License |
| 75-09.1-10-04 | Issuing License to Opioid Treatment Program |
| 75-09.1-10-05 | Suspension and Revocation of License – Appeal |
| 75-09.1-10-06 | Subsequent Licensing Inspection and |

	Review
75-09.1-10-07	Opioid Treatment Program Requirements
75-09.1-10-08	Care of Adolescents in Opioid Treatment Program
75-09.1-10-09	Treatment
75-09.1-10-10	Opioid Treatment Program Administrative Organization and Responsibilities
75-09.1-10-11	Facility and Clinical Environment
75-09.1-10-12	Risk Management
75-09.1-10-13	Opioid Treatment Program Closure
75-09.1-10-14	Diversion Control
75-09.1-10-15	Medical and Behavioral Standards

7. No written requests for regulatory analysis have been filed by the Governor or by any agency. 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. There is no anticipated fiscal impact resulting from the implementation of the proposed amendments.
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:

Julie Leer
 Legal Advisory Unit
 North Dakota Department of Human Services
 March 11, 2014



Jack Dalrymple, Governor
Maggie D. Anderson, Executive Director

**SUMMARY OF COMMENTS RECEIVED
REGARDING PROPOSED CREATION OF
N.D. ADMIN. CODE CHAPTER 75-09.1-10
LICENSING AND TREATMENT STANDARDS FOR OPIOID TREATMENT PROGRAMS**

The North Dakota Department of Human Services (the Department) held a public hearing on December 26, 2013, in Bismarck, ND, concerning the proposed creation of N.D. Administrative Code chapter 75-09.1-10, Licensing and Treatment Standards for Opioid Treatment Programs.

Written comments on the rule could be offered through 5:00 p.m. on January 6, 2014.

Two individuals attended the public hearing. Three sets of written comments were received. The commentors were:

1. Roberta Griffin Stinson 4227 9th Ave South Fargo, ND 58103
2. Michele Holben 3825 N 24th St Phoenix, AZ 85016
3. Brendan Joyce 600 E. Boulevard Ave Dept. 325 Bismarck ND 58505
4. Howard C. Anderson PO Box 1354 Bismarck ND 58502-1354

SUMMARY OF COMMENTS

Comment: On page 10 of the opioid treatment program requirements, it says patients must receive appropriate, comprehensive behavioral therapy from a licensed clinical professional, such as a licensed addiction counselor, a LICSW psychologist and a licensed psychiatrist. Is that saying that all of those need to be providing service or one of those or is that including a psychiatrist along with one of the others. I am a little confused about how that is worded.

Response: The Department agrees and has changed the "and" to "or" in subsection 1 of section 75-09.1-10-07 to read as follows:

1. Patients must receive appropriate, comprehensive behavioral therapy from a licensed clinical professional, such as a licensed addiction counselor, a licensed independent clinical social worker, a licensed psychologist, or a licensed psychiatrist who is providing intervention beyond pharmacological management.

Comment: On page 15 b. it states an individual must have a one-year history of addiction and I feel like that's too long. Clients who come to us don't always have full year and they are needing that maintenance just as much as someone who has been addicted for much longer. I feel like that's excluding people who need the, who may need that level of treatment.

Response: The Department will not be making changes to this section because the proposed rule is based on federal guidelines for opioid treatment.

Comment: First and foremost, thank you for giving us the opportunity to contribute to the development of the North Dakota (ND) Opioid Treatment Program Standards. Below is a list of our recommendations along with some requests for clarification on a few of the items:

1) The proposed regulations note throughout the standards that a physician (Medical Doctor) is required to complete medical needs for clients. The recent draft revision of the CSAT Federal Guidelines for Opioid Treatment (available on the SAMHSA DPT website) notes in Section II (Opioid Treatment Standards) and again highlights in Appendix E that physicians, along with Physician Assistants and Nurse Practitioners (referred to as authorized health care professionals) are able to complete medical screenings, medication evaluations and other covered medical assessments for clients. This change will also allow, within the regulations of an Opioid Treatment Program, authorized health care professionals to prescribe Buprenorphine/Suboxone. With this upcoming change, would the ND regulations be able to include other authorized health care professionals licensed in the state of North Dakota, rather than limiting the medical care to physicians? The ability to use approved authorized healthcare providers, under the oversight of a Medical Director who is a Medical Doctor, would increase the availability of ongoing appropriate medical care, particularly in rural areas where such care may be limited,

Response: The Department agrees with this comment. To address this comment, the Department has defined "healthcare professional" and has included language acknowledging the appropriateness of the role of "healthcare professionals" throughout the rules where contextually appropriate.

Comment:

2) Section 75-09.1-10-02 1." An applicant for licensure to operate an opioid treatment program must hold a current license as a substance abuse treatment program under any of the following chapters." Is this requirement establishing that any agency that is interested in providing Opioid Treatment Services in ND must first be an established substance abuse program in North Dakota? If an interested agency has established substance abuse programs (specifically Opioid Treatment Programs) in other states, would that meet the requirement and/or intent of this standard? Additionally, if an out-of-state OTP were to hire a physician currently operating in North Dakota under a DEA license for prescribing Suboxone/Buprenorphine, would this fulfill said requirement?

Response: Yes – this requires an agency interested in providing opioid treatment services in North Dakota to be a licensed substance abuse treatment program in North Dakota. The Department is proposing changing this requirement to read as follows:

1. An applicant for licensure to operate an opioid treatment program, must hold a current license in good standing, or be eligible and become licensed prior to operating an opioid treatment program, as a substance abuse treatment program under any of the following chapters: 75-09.1-02, 75-09.1-02.1, 75-

N.D. Admin. Code Chapter 75-09.1-10
Summary of Comments
January 27, 2014

09.1-03, 75-09.1-03.1, 75-09.1-04, 75-09.1-04.1, 75-09.1-05, 75-09.1-05.1, 75-09.1-06, 75-09.1-06.1, 75-09.1-07, or 75-09.1-07.1. Chapter 75-09.1-01 applies to this chapter with the following exceptions:
a. 75-09.1-01-20. Discharge and transfer criteria
b. 75-09.1-01-25. Accreditation as a basis for licensing
c. 75-09.1-01-26. Sanctions

This change removes the "established" requirement and allows for an opioid treatment provider to obtain both licenses almost simultaneously. Operation of a substance abuse treatment program licensed in another state would not meet this requirement, nor would hiring a North Dakota physician fulfill this requirement. The Department does not have oversight over substance abuse treatment programs in other states and would be unable to use licensure in another state as an indicator of whether the out-of-state entity would be appropriate for licensure in North Dakota.

Comment:

3) Section 75-09.1-10-07, 1 "Patients must receive appropriate, comprehensive behavior therapy from a licensed clinical professional, such as a licensed independent clinical social worker, a licensed psychologist and a licensed psychiatrist who is providing intervention beyond pharmacological management"

Section 75-09.1.10-11 1.a "Has sufficient space and adequate equipment for the provision of services, including diagnosis, evaluation and treatment of other medical, psychiatric, and behavioral disorders, if they are to be provided onsite"

There are two questions related to these standards:

A) Are all counseling staff, including behavioral health providers, required to be licensed? Are there standards for case managers or behavioral health technicians who are not licensed to work with clients under the supervision of licensed clinical and/or Medical staff?

B) Can the standards clarify whether a Psychiatrist is required to be on staff? Is the intent of the standard to require a psychiatrist only if services required by a psychiatrist are provided onsite?

Response: Note the earlier change to the language of 75-09.1-10-07(1) identified in response to the first comment.

A) Individuals providing behavioral health services need to be licensed or certified in accordance with ND CC for their specific profession. Examples are social workers, addiction counselors, professional counselors, psychologists. There are no license requirements in ND for mental health technician and case managers. No change is made in response to this comment.

B) The Department has changed the "and" in 75-09.1-10-07(1) to "or" in response to the first comment above. This clarifies that a psychiatrist is required to be on staff only if services required by a psychiatrist are going to be provided onsite.

Comment: Please consider incorporating language within the rules to require licensed OTPs to enroll with and bill Medicaid and Medicaid Expansion for covered services to ensure access for Medicaid and Medicaid Expansion recipients ("recipients"). If this requirement was not included, according to numerous anecdotes from other state Medicaid agencies, recipients could face significant access issues to needed care due to their low income and inability to pay cash for services. Also, without this requirement to enroll with Medicaid and Medicaid Expansion, any ancillary services associated with receiving OTP services would not be payable by Medicaid or Medicaid Expansion as they can only pay for services provided by and associated with enrolled providers. Thank you for your consideration.

Response: The Department agrees that there could be an access issue if an opioid treatment provider failed to be prepared to provide treatment to a recipient as described in this comment. To avoid creating a gap in access, the Department has added language to section 75-09.1-10-02 to address this concern:

6. An opioid treatment program shall enroll as an approved Medicaid provider in this state within ninety days of licensure under these rules.

Comment: 75-09.1-10-01 (18) Page 3 "Opioid Use Disorder" The term "doses greatly in excess" gives too much latitude for questionable activity. This determination would generally be made by peer review and removing the word greatly would make that determination easier to make from a standard of care perspective.

Response: This section is intended to define intent of the opioid use which is outside legitimate medical reason. Actual diagnosis requirements are found in subdivision a of subsection 1 or section 75-09.1-10-15. No change is made in response to this comment.

Comment: 75-09.1-10-02 (2)(c) Page 4 The use of "needed health care" at the end of this sub-section is too broad in this context, as the treatment program should be required to provide "opioid treatment Services" and not all types of health care.

Response: This section is identifying assessment requirements for the potential provider to justify its proposed location of the opioid treatment program. This is not descriptive of the proposed opioid treatment program's service offerings. The intent is to locate an opioid treatment program in an area where other healthcare services are located. No change is made in response to this comment.

Comment: 75-09.1-10-03 (1)(d)((1)) Page 6 It looks like we are missing an "of" in the use of "perpetrator of child abuse".

Response: Agree. The rule will be changed to add "of" as proposed by the comment.

Comment: 75-09.1-10-03 (1)(d)((9)) Page 6 "Does not meet criminal background requirements" does not give any indication about what those requirements are. Is it simply the performance of the check, agreeing to one, or are their specific results that would apply?

Response: The requirements for criminal background checks are found in section 75-09.1-01-17 and are required of all opioid treatment programs. No change is made in response to this comment.

Comment: 75-09.1-10-06 (6)(a) Page 9 It looks like we are missing an "of" in the use of "perpetrator of child abuse"

Response: Agree. The rule will be changed to add "of" as proposed by the comment.

Comment: 75-09.1-10-06 (6)(i) Page 10 "Does not meet criminal background requirements" does not give any indication about what those requirements are. Is it simply the performance of the check, agreeing to one, or are their specific results that would apply?

Response: The requirements for criminal background checks are found in section 75-09.1-01-17 and are required of all opioid treatment programs. No change is made in response to this comment.

Comment: 75-09.1-10-11(4) Page 12 I do not believe that a program should be allowed to operate without a medical director. Therefore the notice should be required immediately and the program not allowed to operate without a responsible physician to hold accountable.

Response: This section is referring to the timing of the written notification of the change, not the length of time during which an opioid treatment program may operate without a medical director. An opioid treatment program is required to have a medical director to maintain the program's licensure. No change is made in response this comment.

Comment: 75-09.1-10-12 (2) Page 13 This section brings up a significant inconsistency, in that it appears a licensed pharmacy is to be contracted to provide prescriptions for a patient in emergencies, whereas elsewhere all medication must be dispensed, or administered, by the program.

Response: To address the concern raised in this comment, the language will be changed to avoid confusion in the requirements for the opioid treatment program to have emergency procedures as follows:

2. Each opioid treatment program shall create and maintain a plan for continuity of care for patients, including emergency procedures for obtaining access to

medications in case of temporary program closure during service disruptions such as those that may occur due to a major disaster or a more routine event such as a snow storm. Each opioid treatment program shall develop and maintain an electronic database consisting of client identification, emergency contact information, patient's current dose, last date medication administered, and number of take-home doses allowed as part of the patient's plan and must include a mechanism for informing each patient of the emergency arrangements. If there is a service disruption, the opioid treatment program shall implement its emergency plan and shall forward its database and plan to the division.

75-09.1-10-15 (9)(e) Page 19 Sentence two. "An opioid treatment program must provide adequate testing of or analysis"

Response: Agree. An "or" has been added as suggested by this comment.

Comment: N.D.C.C 50-31-08 (4)says: . Each state-licensed opioid treatment program shall submit by electronic means information regarding each prescription dispensed for a controlled substance to the state's prescription drug monitoring program, unless specifically exempted by federal law.

I do not see this requirement reflected in the rules and believe that is should be there.

Response: The requirement exists in the North Dakota Century Code; it does not need to be repeated in the rule. No change is made in response to this comment.

Comment: Please consider adding a section that specifies that all services for a Medicaid patient be billed to the department and no cash payments are allowed for Medicaid recipients.

Response: In response to an earlier comment, the Department added subsection 6 to section 75-09.1-10-02 requiring an opioid treatment provider to enroll as an approved Medicaid provider. The Department believes that language will address the concern raised in this comment. No further change is made in response to this comment.

Prepared by:

Julie Leer, Director
Legal Advisory Unit
N.D. Dept. of Human Services

N.D. Admin. Code Chapter 75-09.1-10
Summary of Comments
January 27, 2014

In Consultation with: JoAnne Hoesel, DMHSAS
Lacresha Graham, DMHSAS
Pam Sagness, DMHSAS

January 27, 2014

Cc: JoAnne Hoesel, DMHSAS

MEMO

TO: Julie Leer, Director, Legal Advisory Unit

FROM: **JoAnne Hoesel, Director of DMHSAS**

RE: Regulatory Analysis of Proposed North Dakota Administrative Code chapter 75-09.1-10, Opioid Treatment Programs

DATE: June 28, 2013

The purpose of this regulatory analysis is to fulfill the requirements of HB1101, AN ACT to create and enact two new sections to chapter 50-31 of the North Dakota Century Code (NDCC), relating to opioid treatment programs; and to amend and reenact section 50-31-01 of the NDCC, relating to opioid treatment programs.. This analysis pertains to proposed to North Dakota Administrative Code Article 75-09.10.

Classes of Persons Who Will be Affected

The classes of person who will most likely be affected by these rules are:

Individuals in need of Opioid Treatment.

Providers choosing to implement an Opioid Treatment Program.

Consideration of Alternative Methods

There are no alternative methods since HB 1101 requires the rules be adopted.

MEMORANDUM

TO: Julie Leer, Director, Legal Advisory Unit

FROM: JoAnne Hoesel, Director, DMHSAS
Dawn Pearson, Program Administrator, DMHSAS

DATE: June 5, 2013

SUBJECT: Small Entity Regulatory Analysis Regarding Proposed North Dakota Administrative Code Chapter 75-09.1-10, Opioid Treatment Programs

The purpose of this small entity regulatory analysis is to fulfill the requirements of N.D.C.C. § 50-31. This regulatory analysis pertains to proposed N.D. Administrative Code Chapter 75-09.1-10.

Consistent with public health, safety, and welfare, the N.D. Department of Human Services has considered using regulatory methods that will accomplish the objectives of applicable statutes while minimizing adverse impact on small entities. For this analysis, the Department has considered the following methods for reducing the rules' impact on small entities:

1. Establishment of Less Stringent Compliance or Reporting Requirements

The small entities affected by these proposed new and amended rules are entities licensed as Opioid Treatment Program providers. Federal law regulates Opioid Treatment Programs and HB 1101 established the Division of Mental Health and Substance Abuse Services of the North Dakota Department of Human Services as the state opioid treatment authority and requires an opioid treatment program be granted a license from the department, certification from the US department of health and human services substance abuse and mental health service administration, and registration from the US department of justice drug enforcement administration. HB 1101 requires the department to adopt rules relating to the licensing and monitoring of opioid treatment programs. Licensed providers must meet, or assist the North Dakota Department of Human Services with meeting compliance and reporting requirements imposed by federal and state law. For these reasons, establishment of less stringent compliance or reporting requirements for these small entities was not considered.

2. Establishment of Less Stringent Schedules or Deadlines for Compliance or Reporting Requirements for Small Entities

The proposed amendments will not alter any required schedules or deadlines for compliance or reporting requirements for providers. For this reason, the establishment of less stringent schedules or deadlines for compliance or reporting requirements for these small entities was not considered.

3. Consolidation or Simplification of Compliance or Reporting Requirements for Small Entities

The proposed amendments will not alter any required compliance or reporting requirements of providers. For this reason, the establishment of less stringent schedules or deadlines for compliance or reporting requirements for these small entities was not considered.

4. Establishment of Performance Standards for Small Entities to Replace Design or Operational Standards Required in the Proposed Rules

Licensed Opioid Treatment Providers are responsible to meet performance standards as well as operational standards imposed by federal and state law. The proposed new and amended rules do not impose any design standards or additional operational standards above and beyond those required by law. For this reason, the establishment of less stringent schedules or deadlines for compliance or reporting requirements for these small entities was not considered.

5. Exemption of Small Entities From All or Any Part of the Requirements Contained in the Proposed Rules

The requirements of the proposed amendments are imposed on licensed Opioid Treatment Program providers. For this reason, the proposed rules do not exempt them from all or any part of the requirements contained in the proposed rule.

MEMORANDUM

TO: Julie Leer, Director, Legal Advisory Unit

FROM: JoAnne Hoesel, Director, DMHSAS
Dawn Pearson, Program Administrator, DMHSAS

DATE: June 5, 2013

SUBJECT: Small Entity Economic Impact Statement Regarding Proposed Amendments to] N.D. Admin. Code Article 75-09.1.

The purpose of this small entity economic impact statement is to fulfill the requirements of N.D.C.C. § 50-31. This impact statement pertains to proposed amendments to N.D. Admin. Code Article 75-09.1. The proposed rules are mandated by federal law 42 CFR, Part 8 and House Bill 1101. The proposed rules could have an adverse economic impact on small entities.

1. Small Entities Subject to the Proposed Rules

The small entities that are subject to the proposed amended rules are licensed opioid treatment program providers.

2. Costs For Compliance

The administrative and other costs required for compliance with the proposed rule are expected to be: No administrative or other costs are required by the small entities for compliance with the proposed rules.

3. Costs and Benefits

The probable cost to private persons and consumers who are affected by the proposed rule: There will not be probable cost to private persons or consumers for the proposed rules.

The probable benefit to private persons and consumers who are affected by the proposed rule: No anticipated benefits to private persons or consumers by the proposed rules.

4. Probable Effect on State Revenue

The probable effect of the proposed rule on state revenues is expected to be: No effects on state revenue expected because of the proposed rules.

5. Alternative Methods

The Department considered whether there are any less intrusive or less costly alternative methods of achieving the purpose of the proposed rules. Because small entities will not experience administrative costs or other costs and no probable effect on State Revenue, exploring alternative methods was not necessary.



Jack Dalrymple, Governor
Maggie D. Anderson, Executive Director

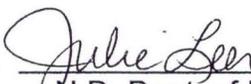
TAKINGS ASSESSMENT

concerning proposed creation of N.D. Admin. Code chapter 75-09.1-10.

This document constitutes the written assessment of the constitutional takings implications of this proposed rulemaking as required by N.D.C.C. § 28-32-09.

1. This proposed rulemaking does not appear to cause a taking of private real property by government action which requires compensation to the owner of that property by the Fifth or Fourteenth Amendment to the Constitution of the United States or N.D. Const. art. I, § 16. This proposed rulemaking does not appear to reduce the value of any real property by more than fifty percent and is thus not a "regulatory taking" as that term is used in N.D.C.C. § 28-32-09. The likelihood that the proposed rules may result in a taking or regulatory taking is nil.
2. The purpose of this proposed rule is clearly and specifically identified in the public notice of proposed rulemaking which is by reference incorporated in this assessment.
3. The reasons this proposed rule is necessary to substantially advance that purpose are described in the regulatory analysis which is by reference incorporated in this assessment.
4. The potential cost to the government if a court determines that this proposed rulemaking constitutes a taking or regulatory taking cannot be reliably estimated to be greater than \$0. The agency is unable to identify any application of the proposed rulemaking that could conceivably constitute a taking or a regulatory taking. Until an adversely impacted landowner identifies the land allegedly impacted, no basis exists for an estimate of potential compensation costs greater than \$0.
5. There is no fund identified in the agency's current appropriation as a source of payment for any compensation that may be ordered.
6. I certify that the benefits of the proposed rulemaking exceed the estimated compensation costs.

Dated this 28th day of June, 2013.

by: 
N.D. Dept. of Human Services