State of Minnesota

HOUSE OF REPRESENTATIVES

EIGHTY-EIGHTH SESSION

H. F. No. 1117

03/04/2013 Authored by Huntley
The bill was read for the first time and referred to the Committee on Health and Human Services Policy

A bill for an act

relating to human services; modifying provisions related to chemical and mental health and human services licensing; establishing methadone treatment program standards; modifying drug treatment provisions; amending Minnesota Statutes 2012, sections 254B.04, by adding a subdivision; 254B.05, subdivision 1b; proposing coding for new law in Minnesota Statutes, chapter 245A.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

ARTICLE 1

LICENSING

Section 1. **[245A.192] PROVIDERS LICENSED TO PROVIDE TREATMENT OF OPIOID ADDICTION.**

Subdivision 1. **Scope.** This section applies to services licensed under this chapter to provide treatment for opioid addiction. In addition to the requirements under Minnesota Rules, parts 9530.6405 to 9530.6505, a program licensed to provide treatment of opioid addiction must meet the requirements in this section. Where a standard exceeds that in administrative rule, the standards of this section apply.

Subd. 2. **Definitions.** (a) For purposes of this section, the terms defined in this subdivision have the meanings given them.

(b) "Diversion" means the use of a medication for the treatment of opioid addiction being diverted from its intended use.

(c) "Medication used for the treatment of opioid addiction" means a medication approved by the Food and Drug Administration for the treatment of opioid addiction.

(d) "Opioid treatment program" has the meaning given in Code of Federal Regulations, title 42, section 8.12, and includes programs licensed under Minnesota Rules, part 9530.6500.

(e) "Program" means an entity that is licensed under Minnesota Rules, part 9530.6500.

(f) "Unsupervised use" means the use of a medication for the treatment of opioid addiction dispensed for use by a client outside of the program setting. This is also referred to as a "take-home" dose.

(g) "Placing authority" has the meaning given in Minnesota Rules, part 9530.6605, subpart 21a.

(h) "Minnesota health care programs" has the meaning given in section 256B.0636, clause (3).

Subd. 3. **Medication orders.** Prior to the program administering or dispensing a medication used for the treatment of opioid addiction:

(1) a client-specific order must be received by an appropriately credentialed physician;

(2) the signed order must be documented in the client's record; and

(3) if the order is not directly issued by the physician, such as a verbal order, the physician that issued the order must review the documentation and sign the order in the client's record within 72 hours of the medication being administered or dispensed. The physician must document whether the medication was administered or dispensed as ordered. If the medication was not administered or dispensed as ordered, the license holder must report the incident to the commissioner.

Subd. 4. **Drug testing.** Each client enrolled in the program must receive a minimum of eight random drug abuse tests per 12 months of treatment. These tests must be reasonably disbursed over the 12-month period. A license holder may elect to conduct more drug abuse tests.

Subd. 5. **Criteria for unsupervised use.** (a) The medical director must determine whether a client may be dispensed medication used for the treatment of opioid addiction for unsupervised or take-home use outside of the program. The medical director must consider the criteria in this paragraph in determining whether a client may be permitted unsupervised or take-home use of such medications. The criteria must also be considered when determining whether dispensing medication for a client's unsupervised use is appropriate to increase or to extend the amount of time between visits to the program. The criteria includes:

(1) absence of recent abuse of drugs including but not limited to opioids, nonnarcotics, and alcohol;

(2) regularity of program attendance;

(3) absence of serious behavioral problems at the program;

(4) absence of known recent criminal activity such as drug dealing;

(5) stability of the client's home environment and social relationships;

(6) length of time in comprehensive maintenance treatment;

(7) reasonable assurance that take-home medication will be safely stored within the client's home; and

(8) whether the rehabilitative benefit the client derived from decreasing the frequency of program attendance outweighs the potential risks of diversion or unsupervised use.

(b) The determination, including the basis of the determination, must be consistent with the criteria in paragraph (a) and must be documented in the client's medical record.

Subd. 6. **Restrictions for unsupervised or take-home use.** (a) In cases where it is determined that a client meets the criteria in subdivision 5 and may be dispensed a medication used for the treatment of opioid addiction, the restrictions in paragraphs (b) to (g) must be followed.

(b) During the first 90 days of treatment, the take-home supply must be limited to a maximum of a single dose each week and the client shall ingest all other doses under direct supervision.

(c) In the second 90 days of treatment, the take-home supply must be limited to two doses per week.

(d) In the third 90 days of treatment, the take-home supply must not exceed three doses per week.

(e) In the remaining months of the first year, a client may be given a maximum six-day supply of take-home medication.

(f) After one year of continuous treatment, a client may be given a maximum two-week supply of take-home medication.

(g) After two years of continuous treatment, a client may be given a maximum one-month supply of take-home medication, but must make monthly visits.

Subd. 7. **Restriction exceptions.** When a license holder has reason to accelerate the number of unsupervised or take-home doses, the license holder must comply with the requirements of Code of Federal Regulations, title 42, chapter 1, subchapter A, part 8, section 8.12, the criteria for unsupervised use in subdivision 5, and must use the exception process provided by the federal Center for Substance Abuse Treatment Division of Pharmacologic Therapies. For the purposes of enforcement of this subdivision, the commissioner has the authority to monitor for compliance with these federal regulations

and may issue licensing actions according to sections 245A.05, 245A.06, and 245A.07 based on the commissioner's determination of noncompliance.

Subd. 8. **Guest dosing.** For purposes of this subdivision, "guest dosing" means the practice of administering a medication used for the treatment of opioid addiction to a person who is not a client of the program that is administering or dispensing the medication. In order to receive a guest dose, the client must be enrolled in an opioid treatment program elsewhere in the state or country and be receiving the medication on a temporary basis because the client is not able to receive the medication at the program in which the client is enrolled. Such arrangements shall not exceed 30 consecutive days in any one program and must not be for the convenience or benefit of either program. Guest dosing may also occur when the client's primary clinic is not open and the client is not receiving take-home doses.

Subd. 9. **Data and reporting.** The license holder must submit data concerning medication used for the treatment of opioid addiction to a central registry. The data must be submitted in a method determined by the commissioner and must be submitted for each client at the time of admission and discharge. The program must document the date the information was submitted. This requirement is effective upon implementation of changes to the Drug and Alcohol Abuse Normative Evaluation System (DAANES) or development of an electronic system by which to submit the data.

Subd. 10. **Amount of treatment services.** The program must provide at least two individual or group therapy treatment services as defined in Minnesota Rules, part 9530.6430, subpart 1, item A, subitem (1), per week, or at least one treatment service per month if more than one week of take-home medication is dispensed to the client. Each treatment service must be at least 55 consecutive minutes in length.

Subd. 11. **Prescription monitoring program.** (a) The medical director or the medical director's delegate must review data from the Minnesota Board of Pharmacy, prescription monitoring program (PMP) established under section 152.126 prior to the client being prescribed any controlled substance as defined under section 152.126, subdivision 1, paragraph (b), including medications used for the treatment of opioid addiction. The subsequent reviews of the PMP data must occur monthly and be documented in the client's individual file. Additionally, any findings from the PMP data that are relevant to the medical director's course of treatment for the client must be documented in the client's individual file.

(b) In cases where the PMP data identifies that a client is receiving a medication that may be contraindicated if the client is also prescribed a medication used for the treatment of opioid addiction, the program must seek the client's consent to discuss the client's opioid treatment with the other prescriber and must seek consent for the other prescriber

to disclose to the opioid treatment program's medical director the client's condition that formed the basis of the other prescription.

(c) The commissioner shall pursue a waiver of, or exception to, Code of Federal Regulations, title 42, part 2, to permit programs licensed under this section to be required to meet the PMP reporting requirements under section 152.126 related to medications prescribed for the treatment of opioid addiction. If the federal waiver is granted, the commissioner, in consultation with the Minnesota Board of Pharmacy, shall propose legislation directing the opioid treatment programs' participation in the PMP.

Subd. 12. **Policies and procedures.** (a) License holders must develop and maintain the policies and procedures required in this subdivision. Where a standard exceeds that in administrative rule, the standards of this subdivision apply.

(b) For programs that are not open every day of the year, the license holder must maintain a policy and procedure that permits clients to receive a single unsupervised use of medication used for the treatment of opioid addiction for days that the program is closed for business, including, but not limited to, Sundays and state and federal holidays. The criteria for unsupervised use in subdivision 5, paragraph (a), do not apply to unsupervised use under this paragraph.

(c) The license holder must maintain a policy and procedure that includes specific measures to reduce the possibility of medication used for the treatment of opioid addiction being diverted from its intended treatment use. The policy and procedure must:

(1) specifically identify and define the responsibilities of the medical and administrative staff for carrying out diversion control measures; and

(2) include a process for contacting no less than five percent of clients who have unsupervised use of medication used for the treatment of opioid addiction to require them to physically return to the program each month. The system must require clients to return to the program within a stipulated time frame and turn in all medication containers related to opioid addiction treatment. The license holder must document all related contacts on a central log and the outcome of the contact for each client in the individual client's record.

(d) Medications used for the treatment of opioid addictions must be ordered, administered, and dispensed according to applicable state and federal regulations and the standards set by applicable accreditation entities. In addition, when an order requires assessment by the person administering or dispensing the medication to determine the amount to be administered or dispensed, the assessment must be completed by an individual whose professional scope of practice permits such assessment. For the purposes of enforcement of this paragraph, the commissioner has the authority to monitor for compliance with these state and federal regulations and the relevant standards of

the license holder's accreditation agency and may issue licensing actions according to sections 245A.05, 245A.06, and 245A.07 based on the commissioner's determination of noncompliance.

(e) The program must maintain a policy to address the treatment needs of clients for whom it is their first treatment episode for opioid addiction. For clients for whom the opioid treatment is their first chemical dependency treatment, the program must provide clients educational information concerning treatment alternatives to medication used for the treatment of opioid addiction. The education must include the risk and benefits of the alternatives and the clients' participation in the education must be documented. If a client refuses the educational information, the program must attempt at least weekly for the first six weeks of treatment to provide the education. This is in addition to providing education according to Minnesota Rules, part 9530.6430, subpart 1, item A, subitem (1).

Subd. 13. **Quality improvement plan.** The license holder must develop and maintain a quality improvement process and plan. The plan must:

(1) include evaluation of the services provided to clients with the goal of identifying issues that may improve service delivery and client outcomes;

(2) include goals for the program to accomplish based on the evaluation;

(3) be reviewed annually by the management of the program to determine whether the goals were met and if not, whether additional action is required;

(4) be updated at least annually to include new or continued goals based on an updated evaluation of services; and

(5) identify two specific goal areas, in addition to others identified by the program including:

(i) a goal concerning oversight and monitoring of the premises around and near the exterior of the program to reduce the possibility of medication used for the treatment of opioid addiction being inappropriately used by clients, including but not limited to the sale or transfer of the medication to others; and

(ii) a goal concerning community outreach, including but not limited to communications with local law enforcement and county human services agencies with the goal of increasing coordination of services and identification of areas of concern to be addressed in the plan.

Subd. 14. **Placing authorities.** Programs must provide certain notification and client-specific updates to placing authorities for clients who are enrolled in Minnesota health care programs. At the request of the placing authority, the program must provide client-specific updates, including but not limited to informing the placing authority of

positive drug screenings and changes in medications used for the treatment of opioid addiction ordered for the client.

ARTICLE 2

CHEMICAL AND MENTAL HEALTH

Section 1. Minnesota Statutes 2012, section 254B.04, is amended by adding a subdivision to read:

Subd. 2b. **Eligibility for placement in opioid treatment programs.** Notwithstanding provisions of Minnesota Rules, part 9530.6622, subpart 5, related to a placement authority's requirement to authorize services or service coordination in a program that complies with Minnesota Rules, part 9530.6500, or Code of Federal Regulations, title 42, part 8, a placement authority may authorize services or service coordination or otherwise place an individual in an opioid treatment program.

Sec. 2. Minnesota Statutes 2012, section 254B.05, subdivision 1b, is amended to read:

Subd. 1b. **Additional vendor requirements.** (a) Vendors must comply with the following duties:

(1) maintain a provider agreement with the department;

(2) continually comply with the standards in the agreement;

(3) participate in the Drug Alcohol Normative Evaluation System;

(4) submit an annual financial statement which reports functional expenses of chemical dependency treatment costs in a form approved by the commissioner;

(5) report information about the vendor's current capacity in a manner prescribed by the commissioner; and

(6) maintain adequate and appropriate insurance coverage necessary to provide chemical dependency treatment services, and at a minimum:

(i) employee dishonesty in the amount of $10,000 if the vendor has or had custody or control of money or property belonging to clients; and

(ii) bodily injury and property damage in the amount of $2,000,000 for each occurrence.

(b) For vendors of opioid treatment services, the medical director or the medical director's designee must review data from the prescription monitoring program (PMP) established under section 152.126, and conduct monthly reviews of all prescriptions of controlled substances dispensed to all clients served by their clinics. The client files must include documentation of the reviews.

APPENDIX
Article locations in 13-0150