

**245A.192 PROVIDERS LICENSED TO PROVIDE TREATMENT OF OPIOID ADDICTION.**

Subdivision 1. **Scope.** (a) 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.

(b) Where a standard in this section differs from a standard in an otherwise applicable administrative rule, the standards of this section apply.

(c) When federal guidance or interpretations have been issued on federal standards or requirements also required under this section, the federal guidance or interpretations shall 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) "Guest dose or 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.

(d) "Medical director" means a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and health care professionals functioning under the medical director's direct supervision.

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

(f) "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.

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

(h) "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.

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

(j) "Minnesota health care programs" has the meaning given in section 256B.0636.

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 from an appropriately credentialed physician who is enrolled as a Minnesota health care programs provider and meets all applicable provider standards;

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

(3) if the physician that issued the order is not able to sign the order when issued, the unsigned order must be entered in the client record at the time it was received, and the physician must review the documentation and sign the order in the client's record within 72 hours of the medication being ordered. The license holder

must report to the commissioner any medication error that endangers a patient's health, as determined by the medical director.

Subd. 3a. **High dose requirements.** A client being administered or dispensed a dose beyond that set forth in subdivision 5, paragraph (a), clause (1), that exceeds 150 milligrams of methadone or 24 milligrams of buprenorphine daily, and for each subsequent increase, must meet face-to-face with a prescribing physician. The meeting must occur before the administering or dispensing of the increased dose.

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) To limit the potential for diversion of medication used for the treatment of opioid addiction to the illicit market, any such medications dispensed to patients for unsupervised use shall be subject to the following requirements:

(1) any patient in an opioid treatment program may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and state and federal holidays; and

(2) treatment program decisions on dispensing medications used to treat opioid addiction to patients for unsupervised use beyond that set forth in clause (1) shall be determined by the medical director.

(b) A physician with authority to prescribe must consider the criteria in this subdivision 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 include:

(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.

(c) The determination, including the basis of the determination, must be consistent with the criteria in this subdivision and must be documented in the client's medical record.

Subd. 6. **Restrictions for unsupervised or take-home use of methadone hydrochloride.** (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 when the medication to be dispensed is methadone hydrochloride.

(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 of methadone hydrochloride, the license holder must comply with the requirements of Code of Federal Regulations, title 42, 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.** 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. Nonmedication treatment services; documentation.** (a) The program must offer at least 50 consecutive minutes of individual or group therapy treatment services as defined in Minnesota Rules, part 9530.6430, subpart 1, item A, subitem (1), per week, for the first ten weeks following admission, and at least 50 consecutive minutes per month thereafter. As clinically appropriate, the program may offer these services cumulatively and not consecutively in increments of no less than 15 minutes over the required time period, and for a total of 60 minutes of treatment services over the time period, and must document the reason for providing services cumulatively in the client's record. The program may offer additional levels of service when deemed clinically necessary.

(b) Notwithstanding the requirements of comprehensive assessments in Minnesota Rules, part 9530.6422, the assessment must be completed within 21 days of service initiation.

(c) Notwithstanding the requirements of individual treatment plans set forth in Minnesota Rules, part 9530.6425:

(1) treatment plan contents for maintenance clients are not required to include goals the client must reach to complete treatment and have services terminated;

(2) treatment plans for clients in a taper or detox status must include goals the client must reach to complete treatment and have services terminated;

(3) for the initial ten weeks after admission for all new admissions, readmissions, and transfers, progress notes must be entered in a client's file at least weekly and be recorded in each of the six dimensions upon the development of the treatment plan and thereafter. Subsequently, the counselor must document progress no less than one time monthly, recorded in the six dimensions or when clinical need warrants more frequent notations; and

(4) upon the development of the treatment plan and thereafter, treatment plan reviews must occur weekly, or after each treatment service, whichever is less frequent, for the first ten weeks after the treatment plan is developed. Following the first ten weeks of treatment plan reviews, reviews may occur monthly, unless the client has needs that warrant more frequent revisions or documentation.

Subd. 11. **Prescription monitoring program.** (a) The program must develop and maintain a policy and procedure that requires the ongoing monitoring of the data from the prescription monitoring program for each client. The policy and procedure must include how the program will meet the requirements in paragraph (b).

(b) If a medication used for the treatment of opioid addiction is administered or dispensed to a client, the license holder shall be subject to the following requirements:

(1) upon admission to a methadone clinic outpatient treatment program, clients must be notified in writing that the commissioner of human services and the medical director will monitor the prescription monitoring program to review the prescribed controlled drugs the clients have received;

(2) the medical director or the medical director's delegate must review the data from the Minnesota Board of Pharmacy prescription monitoring program (PMP) established under section 152.126 prior to the client being ordered any controlled substance, as defined under section 152.126, subdivision 1, paragraph (c), including medications used for the treatment of opioid addiction, and subsequent reviews of the PMP data must occur at least every 90 days;

(3) a copy of the PMP data reviewed must be maintained in the client file;

(4) when the PMP data contains a recent history of multiple prescribers or multiple prescriptions for controlled substances, the physician's review of the data and subsequent actions must be documented in the client's individual file within 72 hours and must contain the medical director's determination of whether or not the prescriptions place the client at risk of harm and the actions to be taken in response to the PMP findings. In addition, the provider must conduct subsequent reviews of the PMP on a monthly basis; and

(5) if at any time the medical director believes the use of the controlled substances places the client at risk of harm, the program must seek the client's consent to discuss the client's opioid treatment with other prescribers 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 prescriptions. If the information is not obtained within seven days, the medical director must document whether or not changes to the client's medication dose or number of take-home doses are necessary until the information is obtained.

(c) The commissioner shall collaborate with the Minnesota Board of Pharmacy to develop and implement an electronic system through which the commissioner shall routinely access the data from the Minnesota Board of Pharmacy prescription monitoring program established under section 152.126 for the purpose of determining whether any client enrolled in an opioid addiction treatment program licensed according to this section has also been prescribed or dispensed a controlled substance in addition to that administered or dispensed by the opioid addiction treatment program. When the commissioner determines there have been multiple prescribers or multiple prescriptions of controlled substances, the commissioner shall:

(1) inform the medical director of the opioid treatment program only that the commissioner determined the existence of multiple prescribers or multiple prescriptions of controlled substances; and

(2) direct the medical director of the opioid treatment program to access the data directly, review the effect of the multiple prescribers or multiple prescriptions, and document the review.

(d) If determined necessary, the commissioner shall seek a federal waiver of, or exception to, any applicable provision of Code of Federal Regulations, title 42, section 2.34(c), prior to implementing this subdivision.

Subd. 12. **Policies and procedures.** (a) License holders must develop and maintain the policies and procedures required in this subdivision.

(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 as required under subdivision 5, paragraph (a), clause (1).

(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, excluding those approved solely under subdivision 5, paragraph (a), clause (1), 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 unused 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.

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.

Subd. 15. **A program's duty to report suspected drug diversion.** (a) To the fullest extent permitted under Code of Federal Regulations, title 42, sections 2.1 to 2.67, a program shall report to law enforcement any credible evidence that the program or its personnel knows, or reasonably should know, that is directly related to a diversion crime on the premises of the program, or a threat to commit a diversion crime.

(b) "Diversion crime," for the purposes of this section, means diverting, attempting to divert, or conspiring to divert Schedule I, II, III, or IV drugs, as defined in section 152.02, on the program's premises.

(c) The program must document its compliance with the requirement in paragraph (a) in either a client's record or an incident report.

(d) Failure to comply with the duty in paragraph (a) may result in sanctions as provided in sections 245A.06 and 245A.07.

Subd. 16. **Variance.** The commissioner may grant a variance to the requirements of this section.

**History:** 2013 c 113 art 1 s 2; 2014 c 275 art 1 s 39-44; 2015 c 78 art 4 s 22-28