

## **New Requirements for Treatment of Opioid Addiction**

Legislation was passed in 2013 to strengthen the regulation of methadone clinics and improve treatment for people who are addicted to opiates. The new laws incorporate some federal standards into state licensing laws, making requirements clearly enforceable at the state level, and allowing DHS to act on violations more quickly and effectively.

**Opioid Addiction Treatment Education.** Effective August 1, 2013, [Minnesota Statutes, section 245A.1915](#) requires all programs licensed by the commissioner to provide educational information concerning treatment options for opioid addiction to clients identified as having or seeking treatment of opioid addiction. The commissioner shall develop the educational materials.

**Opioid Addiction Provider Licensing Requirements.** Effective August 1, 2013, in addition to compliance with Minnesota Rules parts 9530.6405 to 9530.6505, a program licensed to provide treatment of opioid addiction must comply with [Minnesota Statutes, section 245A.192](#) : which includes the following:

1. Definition of the following terms:
  - a. "Diversion"
  - b. "Guest dose or dosing"
  - c. "Medical director," including qualifications and responsibilities
  - d. "Medication used for the treatment of opioid addiction"
  - e. "Minnesota health care programs"
  - f. "Opioid treatment program"
  - g. "Placing authority"
  - h. "Program"
  - i. "Unsupervised use"
2. Describes the medication order requirements the license holder must meet prior to administering or dispensing a medication used for the treatment of opioid addiction.
3. Requires a minimum of eight random drug tests, reasonably disbursed over a 12-month period for clients in the program. A license holder may elect to conduct more drug tests.
4. Specifies the criteria that must be met before a client may be dispensed medication for unsupervised or take-home use outside of the program to limit the potential for diversion of medications used for treatment of opioid addiction to the illicit market.
5. Imposes restrictions and timelines for clients who meet the criteria required for unsupervised or take-home use when the medication to be dispensed is methadone hydrochloride.
6. Requires a provider to meet certain federal requirements in order to accelerate the number of unsupervised or take-home doses of methadone hydrochloride. The commissioner is given authority to monitor for compliance and may issue licensing actions for noncompliance.
7. Allows individuals enrolled in an opioid treatment program elsewhere to receive guest doses of medication used to treat opioid addiction on a temporary basis not to exceed 30 consecutive days when the client is not able to receive the medication at the program in which the client is enrolled, or when the client's primary clinic is not open and the client is not receiving take home doses. Guest dosing must not be for the convenience or benefit of either clinic.
8. Requires the license holder to submit data regarding medication used for treatment of opioid addiction to a central registry, effective upon implementation of the changes to DAANES or the development of an electronic system to which the data can be submitted.
9. Modifies the non-medication treatment services that a program must offer, including the amount of individual or group therapy, and clarifies contents of the treatment plan and

progress notes, and the frequency of progress notes and treatment plan reviews, in the client's file.

10. Provides that, upon admission, the client will be notified that the medical director and DHS will be monitoring the Board of Pharmacy's Prescription Monitoring Program (PMP) to review prescribed controlled drug use by the client before ordering any controlled substance for the client, and that subsequent reviews will occur quarterly, unless there is recent history of multiple prescribers, which would result in monthly reviews. If the use of controlled substances places the client at risk of harm, the medical director must seek the client's consent to contact the other prescribers to discuss the client's opioid treatment and to allow the other prescriber to disclose to the medical director the condition that formed the basis of the prescription for the controlled substance.
11. Requires the commissioner to collaborate with the Minnesota Board of Pharmacy to develop and implement an electronic system by which the commissioner shall routinely access the data from the prescription monitoring program to determine if a client has been prescribed controlled substances in addition to the prescriptions by the opioid treatment program. Sets forth requirements when the commissioner determines there are multiple prescribers or prescriptions, and states that if determined necessary, the commissioner will seek any federal waiver of, or exception to, Code of Federal Regulation, title 42, part 2.34, item (c).
12. Requires license holders to develop and maintain the policies and procedures in this subdivision, which includes a policy and procedure to provide a single unsupervised use of medication used to treat opioid addiction when the program is closed, to reduce the possibility of the medication being diverted from its intended use.
13. 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.
14. Requires the license holder to develop and maintain a quality improvement process and plan, as specified in this subdivision.
15. Requires programs to provide notification and client-specific updates to placing agencies for clients who are enrolled in Minnesota health care programs. At the request of the placing agency, the program must provide client-specific updates, including positive drug screenings and changes in medications.

### **Opioid Treatment Program Eligibility**

Effective August 1, 2013, Minnesota Statutes, [section 254B.04, subdivision 2b, paragraphs \(a\) and \(b\)](#) is amended as follows to:

- Allow but does not require the placement authority, after taking into account an individual's preference for placement in an opioid treatment program, to place the individual in an opioid treatment program. If applicable, the placing authority must consult with the current treatment provider.
- Require the assessor to provide educational information, prior to placement, concerning treatment options for opioid addiction. The commissioner shall develop and periodically update the educational materials that must be used by the assessors.

### **Prescription Monitoring Program Database Access Granted to DHS**

Effective August 1, 2013, Minnesota Statutes, [section 152.126, subdivision 6](#), was amended, as follows:

- Paragraphs (b)(9) and (h) adds DHS to the list of permissible users who are allowed to access the private data in the Prescription Monitoring Program (PMP) if DHS establishes and implements a system for routinely accessing the PMP to determine if an individual enrolled in an opioid treatment program has been prescribed a controlled substance outside of the program. If the individual has a non-programmatic controlled substance prescription, the medical director of the patient's program will be notified by DHS of the existence of multiple prescriptions and directed to access the data directly and review the effect of the multiple prescribers or prescription of multiple controlled substances and document the review.