SENATE
STATE OF MINNESOTA
NINETY-THIRD SESSION

S.F. No. 4104

(SENATE AUTHORS: KUPEC, Hoffman, Fateh, Abeler and Oumou Verbeten)

DATE	D-PG	OFFICIAL STATUS
02/22/2024	11711	Introduction and first reading Referred to Human Services

1.1 A bill for an act

1.2 relating to human services; modifying rules on opioid treatment program medication
1.3 dispensing for take-home uses; amending Minnesota Statutes 2022, section
1.4 245G.22, subdivision 6; Minnesota Statutes 2023 Supplement, section 245G.22,
1.5 subdivisions 2, 17; repealing Minnesota Statutes 2022, section 245G.22,
1.6 subdivisions 4, 7.

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

1.8 Section 1. Minnesota Statutes 2023 Supplement, section 245G.22, subdivision 2, is
1.9 amended to read:

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

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

1.14 (c) "Guest dose" means administration of a medication used for the treatment of opioid
1.15 addiction to a person who is not a client of the program that is administering or dispensing
1.16 the medication.

1.17 (d) "Medical director" means a practitioner licensed to practice medicine in the
1.18 jurisdiction that the opioid treatment program is located who assumes responsibility for
1.19 administering all medical services performed by the program, either by performing the
1.20 services directly or by delegating specific responsibility to a practitioner of the opioid
1.21 treatment program.

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

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

(g) "Opioid treatment program" has the meaning given in Code of Federal Regulations, title 42, section 8.12, and includes programs licensed under this chapter.

(h) "Practitioner" means a staff member holding a current, unrestricted license to practice medicine issued by the Board of Medical Practice or nursing issued by the Board of Nursing and is currently registered with the Drug Enforcement Administration to order or dispense controlled substances in Schedules II to V under the Controlled Substances Act, United States Code, title 21, part B, section 821. ~~Practitioner includes an advanced practice registered nurse and physician assistant if the staff member receives a variance by the state opioid treatment authority under section 254A.03 and the federal Substance Abuse and Mental Health Services Administration.~~

(i) "Unsupervised use" or "take-home doses" means the use of a medication for the treatment of opioid use disorder dispensed for use by a client outside of the program setting.

Sec. 2. Minnesota Statutes 2022, section 245G.22, subdivision 6, is amended to read:

Subd. 6. **Criteria for unsupervised use.** (a) To limit the potential for diversion of medication used for the treatment of opioid use disorder to the illicit market, medication dispensed to a client for unsupervised use shall be subject to the requirements of this subdivision. Any client in an opioid treatment program may receive ~~a single unsupervised use dose for a day that the clinic is closed for business, including Sundays and state and federal holidays~~ individualized take-home doses as ordered for days that the clinic is closed for business on one weekend day and state and federal holidays, no matter the client's length of time in treatment, as allowed under Code of Federal Regulations, title 42, section 8.12(i)(1).

(b) For take-home doses beyond those allowed in paragraph (a), a practitioner with authority to prescribe must review and document the criteria in ~~this paragraph and paragraph (c)~~ Code of Federal Regulations, title 42, section 8.12(i)(1), when determining whether dispensing medication for a client's unsupervised use is safe and when it is appropriate to implement, increase, or extend the amount of time between visits to the program. ~~The criteria are:~~

~~(1) absence of recent abuse of drugs including but not limited to opioids, non-narcotics, 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 unsupervised use 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 documented in the client's medical record.~~

Sec. 3. Minnesota Statutes 2023 Supplement, section 245G.22, subdivision 17, is amended to read:

Subd. 17. **Policies and procedures.** (a) A license holder must develop and maintain the policies and procedures required in this subdivision.

(b) For a program that is not open every day of the year, the license holder must maintain a policy and procedure that covers requirements under section 245G.22, subdivisions 6 and 7. Unsupervised use of medication used for the treatment of opioid use disorder for days that the program is closed for business, including ~~but not limited to Sundays~~ one weekend day and state and federal holidays, must meet the requirements under section 245G.22, subdivisions 6 and 7.

(c) The license holder must maintain a policy and procedure that includes specific measures to reduce the possibility of diversion. The policy and procedure must:

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

(2) include a process for contacting no less than five percent of clients who have unsupervised use of medication, excluding clients approved solely under subdivision 6, paragraph (a), to require clients 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 use disorder treatment. The license holder must document all related contacts on a central log and the outcome of the contact for each client in the client's record. The medical director must be informed of each outcome that results in a situation in which a possible diversion issue was identified.

4.1 (d) Medication used for the treatment of opioid use disorder must be ordered,
4.2 administered, and dispensed according to applicable state and federal regulations and the
4.3 standards set by applicable accreditation entities. If a medication order requires assessment
4.4 by the person administering or dispensing the medication to determine the amount to be
4.5 administered or dispensed, the assessment must be completed by an individual whose
4.6 professional scope of practice permits an assessment. For the purposes of enforcement of
4.7 this paragraph, the commissioner has the authority to monitor the person administering or
4.8 dispensing the medication for compliance with state and federal regulations and the relevant
4.9 standards of the license holder's accreditation agency and may issue licensing actions
4.10 according to sections 245A.05, 245A.06, and 245A.07, based on the commissioner's
4.11 determination of noncompliance.

4.12 ~~(e) A counselor in an opioid treatment program must not supervise more than 50 clients.~~

4.13 ~~(f) Notwithstanding paragraph (e),~~ (e) From July 1, 2023, to June 30, 2024, a counselor
4.14 in an opioid treatment program may supervise up to 60 clients. The license holder may
4.15 continue to serve a client who was receiving services at the program on June 30, 2024, at
4.16 a counselor to client ratio of up to one to 60 and is not required to discharge any clients in
4.17 order to return to the counselor to client ratio of one to 50. The license holder may not,
4.18 however, serve a new client after June 30, 2024, unless the counselor who would supervise
4.19 the new client is supervising fewer than 50 existing clients.

4.20 Sec. 4. **REPEALER.**

4.21 Minnesota Statutes 2022, section 245G.22, subdivisions 4 and 7, are repealed.

245G.22 OPIOID TREATMENT PROGRAMS.

Subd. 4. **High dose requirements.** A client being administered or dispensed a dose beyond that set forth in subdivision 6, paragraph (a), 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 practitioner. The meeting must occur before the administration or dispensing of the increased medication dose.

Subd. 7. **Restrictions for unsupervised use of methadone hydrochloride.** (a) If a medical director or prescribing practitioner assesses and determines that a client meets the criteria in subdivision 6 and may be dispensed a medication used for the treatment of opioid addiction, the restrictions in this subdivision must be followed when the medication to be dispensed is methadone hydrochloride. The results of the assessment must be contained in the client file. The number of unsupervised use medication doses per week in paragraphs (b) to (d) is in addition to the number of unsupervised use medication doses a client may receive for days the clinic is closed for business as allowed by subdivision 6, paragraph (a).

(b) During the first 90 days of treatment, the unsupervised use medication 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 unsupervised use medication supply must be limited to two doses per week.

(d) In the third 90 days of treatment, the unsupervised use medication 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 unsupervised use medication supply.

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

(g) After two years of continuous treatment, a client may be given a maximum one-month unsupervised use medication supply, but must make monthly visits to the program.