

HOUSE OF REPRESENTATIVES

EIGHTY-EIGHTH SESSION

H. F. No. **1117**

03/04/2013 Authored by Huntley, Lesch and Paymar

The bill was read for the first time and referred to the Committee on Health and Human Services Policy

03/13/2013 Adoption of Report: Pass as Amended and re-referred to the Committee on Civil Law

03/20/2013 Adoption of Report: Pass as Amended and Read Second Time

1.1 A bill for an act
1.2 relating to human services; modifying provisions related to chemical and mental
1.3 health and human services licensing; establishing methadone treatment program
1.4 standards; modifying drug treatment provisions; amending Minnesota Statutes
1.5 2012, sections 152.126, subdivision 6; 254B.04, by adding a subdivision;
1.6 proposing coding for new law in Minnesota Statutes, chapter 245A.

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

1.8 **ARTICLE 1**

1.9 **LICENSING**

1.10 Section 1. **[245A.1915] OPIOID ADDICTION TREATMENT EDUCATION**
1.11 **REQUIREMENT FOR PROVIDERS LICENSED TO PROVIDE CHEMICAL**
1.12 **DEPENDENCY TREATMENT SERVICES.**

1.13 All programs licensed by the commissioner must provide educational information
1.14 concerning treatment options for opioid addiction, including the use of a medication for
1.15 the use of opioid addiction, to clients identified as having or seeking treatment for opioid
1.16 addiction. The commissioner shall develop educational materials that are supported by
1.17 research and updated periodically that must be used by programs to comply with this
1.18 requirement.

1.19 Sec. 2. **[245A.192] PROVIDERS LICENSED TO PROVIDE TREATMENT OF**
1.20 **OPIOID ADDICTION.**

1.21 Subdivision 1. **Scope.** (a) This section applies to services licensed under this chapter
1.22 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, 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 from 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. The license holder must report to the commissioner any medication error that endangers a patient's health, as determined by the medical director.

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 paragraph (a), clause (1), shall be determined by the medical director.

(b) The medical director must consider the criteria in paragraph (a) 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;

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

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

4.5 (c) The determination, including the basis of the determination, must be consistent
4.6 with the criteria in paragraph (a), clause (2), and must be documented in the client's
4.7 medical record.

4.8 **Subd. 6. Restrictions for unsupervised or take-home use of methadone**
4.9 **hydrochloride.** (a) In cases where it is determined that a client meets the criteria in
4.10 subdivision 5, paragraph (a), clause (2), and may be dispensed a medication used for the
4.11 treatment of opioid addiction, the restrictions in paragraphs (b) to (g) must be followed
4.12 when the medication to be dispensed is methadone hydrochloride.

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

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

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

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

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

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

4.26 **Subd. 7. Restriction exceptions.** When a license holder has reason to accelerate
4.27 the number of unsupervised or take-home doses of methadone hydrochloride, the license
4.28 holder must comply with the requirements of Code of Federal Regulations, title 42, chapter
4.29 1, subchapter A, part 8, section 8.12, the criteria for unsupervised use in subdivision 5,
4.30 and must use the exception process provided by the federal Center for Substance Abuse
4.31 Treatment Division of Pharmacologic Therapies. For the purposes of enforcement of
4.32 this subdivision, the commissioner has the authority to monitor for compliance with
4.33 these federal regulations and may issue licensing actions according to sections 245A.05,
4.34 245A.06, and 245A.07 based on the commissioner's determination of noncompliance.

4.35 **Subd. 8. Guest dosing.** In order to receive a guest dose, the client must be enrolled
4.36 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 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) treatment plan reviews must occur weekly, or after each treatment service, whichever is less frequent, for the first ten weeks of treatment for all new admissions, readmissions, and transfers. Following the first ten weeks of treatment, treatment plan

6.1 reviews may occur monthly, unless the client has needs that warrant more frequent
6.2 revisions or documentation.

6.3 Subd. 11. **Prescription monitoring program.** (a) Upon admission to a methadone
6.4 clinic outpatient treatment program, clients shall be notified that the Department of Human
6.5 Services and the medical director will monitor the prescription monitoring program to
6.6 review the prescribed controlled drugs the clients have received. The medical director or
6.7 the medical director's delegate must review data from the Minnesota Board of Pharmacy,
6.8 prescription monitoring program (PMP) established under section 152.126 prior to the
6.9 client being ordered any controlled substance as defined under section 152.126, subdivision
6.10 1, paragraph (b), including medications used for the treatment of opioid addiction. The
6.11 subsequent reviews of the PMP data must occur quarterly and be documented in the
6.12 client's individual file. When the PMP data shows a recent history of multiple prescribers
6.13 or multiple prescriptions for controlled substances, then subsequent reviews of the PMP
6.14 data must occur monthly and be documented in the client's individual file. If, at any time,
6.15 the medical director believes the use of the controlled substances places the client at risk
6.16 of harm, the program must seek the client's consent to discuss the client's opioid treatment
6.17 with other prescribers and must seek consent for the other prescriber to disclose to the
6.18 opioid treatment programs' medical director the client's condition that formed the basis of
6.19 the other prescriptions. Additionally, any findings from the PMP data that are relevant to
6.20 the medical director's course of treatment for the client must be documented in the client's
6.21 individual file. A review of the PMP is not required for every medication dose adjustment.

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

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

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

7.1 (c) If determined necessary, the commissioner shall seek a federal waiver of, or
7.2 exception to, any applicable provision of Code of Federal Regulations, title 42, part 2.34,
7.3 item (c), prior to implementing this paragraph.

7.4 Subd. 12. **Policies and procedures.** (a) License holders must develop and maintain
7.5 the policies and procedures required in this subdivision. Where a standard in this section
7.6 differs from a standard in otherwise applicable administrative rule, the standards of this
7.7 subdivision apply.

7.8 (b) For programs that are not open every day of the year, the license holder must
7.9 maintain a policy and procedure that permits clients to receive a single unsupervised use
7.10 of medication used for the treatment of opioid addiction for days that the program is
7.11 closed for business, including, but not limited to, Sundays and state and federal holidays
7.12 as required under subdivision 5, paragraph (a), clause (1).

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

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

7.18 (2) include a process for contacting no less than five percent of clients who have
7.19 unsupervised use of medication used for the treatment of opioid addiction, excluding
7.20 those approved solely under subdivision 5, paragraph (a), clause (1), to require them to
7.21 physically return to the program each month. The system must require clients to return to
7.22 the program within a stipulated time frame and turn in all medication containers related to
7.23 opioid addiction treatment. The license holder must document all related contacts on a
7.24 central log and the outcome of the contact for each client in the individual client's record.

7.25 (d) Medications used for the treatment of opioid addictions must be ordered,
7.26 administered, and dispensed according to applicable state and federal regulations and the
7.27 standards set by applicable accreditation entities. In addition, when an order requires
7.28 assessment by the person administering or dispensing the medication to determine
7.29 the amount to be administered or dispensed, the assessment must be completed by
7.30 an individual whose professional scope of practice permits such assessment. For the
7.31 purposes of enforcement of this paragraph, the commissioner has the authority to monitor
7.32 for compliance with these state and federal regulations and the relevant standards of
7.33 the license holder's accreditation agency and may issue licensing actions according to
7.34 sections 245A.05, 245A.06, and 245A.07 based on the commissioner's determination
7.35 of noncompliance.

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

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

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

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

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

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

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

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

8.20 Subd. 14. **Placing authorities.** Programs must provide certain notification and
8.21 client-specific updates to placing authorities for clients who are enrolled in Minnesota
8.22 health care programs. At the request of the placing authority, the program must provide
8.23 client-specific updates, including but not limited to informing the placing authority of
8.24 positive drug screenings and changes in medications used for the treatment of opioid
8.25 addiction ordered for the client.

8.26 **ARTICLE 2**

8.27 **CHEMICAL AND MENTAL HEALTH**

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

8.30 Subd. 2b. **Eligibility for placement in opioid treatment programs.** (a)
8.31 Notwithstanding provisions of Minnesota Rules, part 9530.6622, subpart 5, related
8.32 to a placement authority's requirement to authorize services or service coordination
8.33 in a program that complies with Minnesota Rules, part 9530.6500, or Code of Federal
8.34 Regulations, title 42, part 8, and after taking into account an individual's preference for
8.35 placement in an opioid treatment program, a placement authority may, but is not required

9.1 to, authorize services or service coordination or otherwise place an individual in an opioid
9.2 treatment program. Prior to making a determination of placement for an individual, the
9.3 placing authority must consult with the current treatment provider, if any.

9.4 (b) Prior to placement of an individual who is determined by the assessor to require
9.5 treatment for opioid addiction, the assessor must provide educational information
9.6 concerning treatment options for opioid addiction, including the use of a medication
9.7 for the use of opioid addiction. The commissioner shall develop educational materials
9.8 supported by research and updated periodically that must be used by assessors to comply
9.9 with this requirement.

9.10 **ARTICLE 3**

9.11 **CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM**

9.12 Section 1. Minnesota Statutes 2012, section 152.126, subdivision 6, is amended to read:

9.13 Subd. 6. **Access to reporting system data.** (a) Except as indicated in this
9.14 subdivision, the data submitted to the board under subdivision 4 is private data on
9.15 individuals as defined in section 13.02, subdivision 12, and not subject to public disclosure.

9.16 (b) Except as specified in subdivision 5, the following persons shall be considered
9.17 permissible users and may access the data submitted under subdivision 4 in the same or
9.18 similar manner, and for the same or similar purposes, as those persons who are authorized
9.19 to access similar private data on individuals under federal and state law:

9.20 (1) a prescriber or an agent or employee of the prescriber to whom the prescriber has
9.21 delegated the task of accessing the data, to the extent the information relates specifically to
9.22 a current patient, to whom the prescriber is prescribing or considering prescribing any
9.23 controlled substance and with the provision that the prescriber remains responsible for the
9.24 use or misuse of data accessed by a delegated agent or employee;

9.25 (2) a dispenser or an agent or employee of the dispenser to whom the dispenser has
9.26 delegated the task of accessing the data, to the extent the information relates specifically
9.27 to a current patient to whom that dispenser is dispensing or considering dispensing any
9.28 controlled substance and with the provision that the dispenser remains responsible for the
9.29 use or misuse of data accessed by a delegated agent or employee;

9.30 (3) an individual who is the recipient of a controlled substance prescription for
9.31 which data was submitted under subdivision 4, or a guardian of the individual, parent or
9.32 guardian of a minor, or health care agent of the individual acting under a health care
9.33 directive under chapter 145C;

9.34 (4) personnel of the board specifically assigned to conduct a bona fide investigation
9.35 of a specific licensee;

10.1 (5) personnel of the board engaged in the collection of controlled substance
10.2 prescription information as part of the assigned duties and responsibilities under this
10.3 section;

10.4 (6) authorized personnel of a vendor under contract with the board who are engaged
10.5 in the design, implementation, operation, and maintenance of the electronic reporting
10.6 system as part of the assigned duties and responsibilities of their employment, provided
10.7 that access to data is limited to the minimum amount necessary to carry out such duties
10.8 and responsibilities;

10.9 (7) federal, state, and local law enforcement authorities acting pursuant to a valid
10.10 search warrant; and

10.11 (8) personnel of the medical assistance program assigned to use the data collected
10.12 under this section to identify recipients whose usage of controlled substances may warrant
10.13 restriction to a single primary care physician, a single outpatient pharmacy, or a single
10.14 hospital.

10.15 For purposes of clause (3), access by an individual includes persons in the definition
10.16 of an individual under section 13.02.

10.17 (c) Any permissible user identified in paragraph (b), who directly accesses
10.18 the data electronically, shall implement and maintain a comprehensive information
10.19 security program that contains administrative, technical, and physical safeguards that
10.20 are appropriate to the user's size and complexity, and the sensitivity of the personal
10.21 information obtained. The permissible user shall identify reasonably foreseeable internal
10.22 and external risks to the security, confidentiality, and integrity of personal information
10.23 that could result in the unauthorized disclosure, misuse, or other compromise of the
10.24 information and assess the sufficiency of any safeguards in place to control the risks.

10.25 (d) The board shall not release data submitted under this section unless it is provided
10.26 with evidence, satisfactory to the board, that the person requesting the information is
10.27 entitled to receive the data.

10.28 (e) The board shall not release the name of a prescriber without the written consent
10.29 of the prescriber or a valid search warrant or court order. The board shall provide a
10.30 mechanism for a prescriber to submit to the board a signed consent authorizing the release
10.31 of the prescriber's name when data containing the prescriber's name is requested.

10.32 (f) The board shall maintain a log of all persons who access the data and shall ensure
10.33 that any permissible user complies with paragraph (c) prior to attaining direct access to
10.34 the data.

11.1 (g) Section 13.05, subdivision 6, shall apply to any contract the board enters into
11.2 pursuant to subdivision 2. A vendor shall not use data collected under this section for
11.3 any purpose not specified in this section.

11.4 (h) With available appropriations, the commissioner of human services shall
11.5 establish and implement a system through which the Department of Human Services shall
11.6 routinely access the data for the purpose of determining whether any client enrolled in
11.7 an opioid treatment program licensed according to chapter 245A has been prescribed or
11.8 dispensed a controlled substance in addition to that administered or dispensed by the
11.9 opioid treatment program. When the commissioner determines there have been multiple
11.10 prescribers or multiple prescriptions of controlled substances, the commissioner shall:

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

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

11.17 If determined necessary, the commissioner of human services shall seek a federal waiver
11.18 of, or exception to, any applicable provision of Code of Federal Regulations, title 42, part
11.19 2.34, item (c), prior to implementing this paragraph.

APPENDIX
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