
# Prescription Monitoring Program State Profiles - Minnesota

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# MINNESOTA

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- Status of Program – operational
- Housing Entity – Board of Pharmacy
- Advisory Commission – yes
- Funding – board fees, special revenue fund, grants, private funds
- Drugs Monitored – Schedules II – IV
- Who's Required to Report Dispensing Information – all dispensers; persons authorized by law to dispense a controlled substance
- Exemptions from Reporting – dispensing to hospital inpatients; veterinarians; dispensing to individuals in certain health care facilities when drug is distributed through the use of an automated drug distribution system; drug samples
- Nonresident Pharmacies Required to Report – yes
- Veterinarians Required to Report – no
- Data Collection Interval – daily/24 hours
- Notice to Consumers – yes
- Interstate Sharing – authorized users in other states
- Persons Authorized to Receive Information – county coroners and medical examiners; law enforcement officials; licensing/regulatory boards; personnel of the medical assistance program; patient or parent of minor child; health care agent; prescribers; dispensers; substance abuse professionals to licensed health care providers
- Delegates Allowed – yes
- De-identified Data Provided – no
- Unsolicited Reports – to prescribers and pharmacists
- Training Required – no
- Mandatory Enrollment – no
- Mandatory Access – yes; the medical director of a methadone outpatient clinic or his delegate must review the PMP data prior to the patient being ordered any controlled substance and must subsequently review the PMP data quarterly

Minnesota Statutes Annotated (2014)
Health (Ch. 144-159)
Chapter 152. Drugs; Controlled Substances
Prescriptions

§ 152.126. Prescription monitoring program.

Subdivision 1. Definitions. (a) For purposes of this section, the terms defined in this subdivision have the meanings given.

(b) "Board" means the Minnesota State Board of Pharmacy established under chapter 151.

(c) "Controlled substances" means those substances listed in section 152.02, subdivisions 3 to 6, and those substances defined by the board pursuant to section 152.02, subdivisions 7, 8, and 12. For the purposes of this section, controlled substances includes tramadol and butalbital.

(d) "Dispense" or "dispensing" has the meaning given in section 151.01, subdivision 30. Dispensing does not include the direct administering of a controlled substance to a patient by a licensed health care professional.

(e) "Dispenser" means a person authorized by law to dispense a controlled substance, pursuant to a valid prescription. For the purposes of this section, a dispenser does not include a licensed hospital pharmacy that distributes controlled substances for inpatient hospital care or a veterinarian who is dispensing prescriptions under section 156.18.

(f) "Prescriber" means a licensed health care professional who is authorized to prescribe a controlled substance under section 152.12, subdivision 1 or 2.

(g) "Prescription" has the meaning given in section 151. 01, subdivision 16.

Subd. 1a. Treatment of intractable pain. This section is not intended to limit or interfere with the legitimate prescribing of controlled substances for pain. No prescriber shall be subject to disciplinary action by a health-related licensing board for prescribing a controlled substance according to the provisions of section 152.125.

Subd. 2. Prescription electronic reporting system. (a) The board shall establish by January 1, 2010, an electronic system for reporting the information required under subdivision 4 for all controlled substances dispensed within the state.

(b) The board may contract with a vendor for the purpose of obtaining technical assistance in the design, implementation, operation, and maintenance of the electronic reporting system.

Subd. 3. Prescription Monitoring Program Advisory Task Force. (a) The board shall appoint an advisory task force consisting of at least one representative of:

(1) the Department of Health;

(2) the Department of Human Services;

(3) each health-related licensing board that licenses prescribers;

(4) a professional medical association, which may include an association of pain management and chemical dependency specialists;

(5) a professional pharmacy association;

(6) a professional nursing association;

(7) a professional dental association;

(8) a consumer privacy or security advocate;

(9) a consumer or patient rights organization; and

(10) an association of medical examiners and coroners.

(b) The advisory task force shall advise the board on the development and operation of the prescription monitoring program, including, but not limited to:

(1) technical standards for electronic prescription drug reporting;

(2) proper analysis and interpretation of prescription monitoring data;

(3) an evaluation process for the program; and

(4) criteria for the unsolicited provision of prescription monitoring data by the board to prescribers and dispensers.

(c) The task force is governed by section 15.059. Notwithstanding section 15.059, subdivision 5, the task force shall not expire.

Subd. 4. Reporting requirements; notice. (a) Each dispenser must submit the following data to the board or its designated vendor:

(1) name of the prescriber;

(2) national provider identifier of the prescriber;

(3) name of the dispenser;

(4) national provider identifier of the dispenser;

(5) prescription number;

(6) name of the patient for whom the prescription was written;

(7) address of the patient for whom the prescription was written;

(8) date of birth of the patient for whom the prescription was written;

(9) date the prescription was written;

(10) date the prescription was filled;

(11) name and strength of the controlled substance;

(12) quantity of controlled substance prescribed;

(13) quantity of controlled substance dispensed; and

(14) number of days supply.

(b) The dispenser must submit the required information by a procedure and in a format established by the board. The board may allow dispensers to omit data listed in this subdivision or may require the submission of data not listed in this subdivision provided the omission or submission is necessary for the purpose of complying with the electronic reporting or data transmission standards of the American Society for Automation in Pharmacy, the National Council on Prescription Drug Programs, or other relevant national standard-setting body.

(c) A dispenser is not required to submit this data for those controlled substance prescriptions dispensed for:

(1) individuals residing in a health care facility as defined in section 151.58, subdivision 2, paragraph (b), when a drug is distributed through the use of an automated drug distribution system according to section 151.58; and

(2) individuals receiving a drug sample that was packaged by a manufacturer and provided to the dispenser for dispensing as a professional sample pursuant to Code of Federal Regulations, title 21, part 203, subpart D.

(d) A dispenser must provide to the patient for whom the prescription was written a conspicuous notice of the reporting requirements of this section and notice that the information may be used for program administration purposes.

Subd. 5. Use of data by board. (a) The board shall develop and maintain a database of the data reported under subdivision 4. The board shall maintain data that could identify an individual prescriber or dispenser in encrypted form. Except as otherwise allowed under subdivision 6, the database may be used by permissible users identified under subdivision 6 for the identification of:

(1) individuals receiving prescriptions for controlled substances from prescribers who subsequently obtain controlled substances from dispensers in quantities or with a frequency inconsistent with generally recognized standards of use for those controlled substances, including standards accepted by national and international pain management associations; and

(2) individuals presenting forged or otherwise false or altered prescriptions for controlled substances to dispensers.

(b) No permissible user identified under subdivision 6 may access the database for the sole purpose of identifying prescribers of controlled substances for unusual or excessive prescribing patterns without a valid search warrant or court order.

(c) No personnel of a state or federal occupational licensing board or agency may access the database for the purpose of obtaining information to be used to initiate or substantiate a disciplinary action against a prescriber.

(d) Data reported under subdivision 4 shall be made available to permissible users for a 12-month period beginning the day the data was received and ending 12 months from the last day of the month in which the data was received, except that permissible users defined in subdivision 6, paragraph (b), clauses (6) and (7), may use all data collected under this section for the purposes of administering, operating, and maintaining the prescription monitoring program and conducting trend analyses and other studies necessary to evaluate the effectiveness of the program. Data retained beyond 24 months must be de-identified.

(e) The board shall not retain data reported under subdivision 4 for a period longer than four years from the date the data was received.

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

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

(1) a prescriber or an agent or employee of the prescriber to whom the prescriber has delegated the task of accessing the data, to the extent the information relates specifically to a current patient, to whom the prescriber is:

(i) prescribing or considering prescribing any controlled substance;

(ii) providing emergency medical treatment for which access to the data may be necessary; or

(iii) providing other medical treatment for which access to the data may be necessary and the patient has consented to access to the submitted data, and with the provision that the prescriber remains responsible for the use or misuse of data accessed by a delegated agent or employee;

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

(3) a licensed pharmacist who is providing pharmaceutical care for which access to the data may be necessary to the extent that the information relates specifically to a current patient for whom the pharmacist is providing pharmaceutical care if the patient has consented to access to the submitted data;

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

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

(6) personnel of the board engaged in the collection, review, and analysis of controlled substance prescription information as part of the assigned duties and responsibilities under this section;

(7) authorized personnel of a vendor under contract with the state of Minnesota who are engaged in the design, implementation, operation, and maintenance of the prescription monitoring program as part of the assigned duties and responsibilities of their employment, provided that access to data is limited to the minimum amount necessary to carry out such duties and responsibilities, and subject to the requirement of de-identification and time limit on retention of data specified in subdivision 5, paragraphs (d) and (e);

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

(9) personnel of the Minnesota health care programs assigned to use the data collected under this section to identify and manage recipients whose usage of controlled substances may warrant restriction to a single primary care provider, a single outpatient pharmacy, and a single hospital;

(10) personnel of the Department of Human Services assigned to access the data pursuant to paragraph (h); and

(11) personnel of the health professionals services program established under section 214.31, to the extent that the information relates specifically to an individual who is currently enrolled in and being monitored by the program, and the individual consents to access to that information. The health professionals services program personnel shall not provide this data to a health-related licensing board or the Emergency Medical Services Regulatory Board, except as permitted under section 214.33, subdivision 3.

For purposes of clause (4), access by an individual includes persons in the definition of an individual under section 13.02.

(c) A permissible user identified in paragraph (b), clauses (1), (2), (3), (6), (7), (9), and (10) may directly access the data electronically. If the data is directly accessed electronically, the permissible user shall implement and maintain a comprehensive information security program that contains administrative, technical, and physical safeguards that are appropriate to the user's size and complexity, and the sensitivity of the personal information obtained. The permissible user shall identify reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, or other compromise of the information and assess the sufficiency of any safeguards in place to control the risks.

(d) The board shall not release data submitted under subdivision 4 unless it is provided with evidence, satisfactory to the board, that the person requesting the information is entitled to receive the data.

(e) The board shall maintain a log of all persons who access the data for a person of at least three years and shall ensure that any permissible user complies with paragraph (c) prior to attaining direct access to the data.

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

(g) The board may participate in an interstate prescription monitoring program data exchange system provided that permissible users in other states have access to the data only as allowed under this section, and that section 13.05, subdivision 6, applies to any contract or memorandum of understanding that the board enters into under this paragraph. The board shall report to the chairs and ranking minority members of the senate and house of representatives committees with jurisdiction over health and human services policy and finance on the interstate prescription monitoring program by January 5, 2016.

(h) With available appropriations, the commissioner of human services shall establish and implement a system through which the Department of Human Services shall routinely access the data for the purpose of determining whether any client enrolled in an opioid treatment program licensed according to chapter 245A has been prescribed or dispensed a controlled substance in addition to that administered or dispensed by the opioid 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.

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

(i) The board shall review the data submitted under subdivision 4 on at least a quarterly basis and shall establish criteria, in consultation with the advisory task force, for referring information about a patient to prescribers and dispensers who prescribed or dispensed the prescriptions in question if the criteria are met. The board shall report to the chairs and ranking minority members of the senate and house of representatives committees with jurisdiction over health and human services policy and finance on the criteria established under this paragraph and the review process by January 5, 2016. This paragraph expires August 1, 2016.

Subd. 7. Disciplinary action. (a) A dispenser who knowingly fails to submit data to the board as required under this section is subject to disciplinary action by the appropriate health-related licensing board.

(b) A prescriber or dispenser authorized to access the data who knowingly discloses the data in violation of state or federal laws relating to the privacy of health care data shall be subject to disciplinary action by the appropriate health-related licensing board, and appropriate civil penalties.

Subd. 9. Immunity from liability; no requirement to obtain information. (a) A pharmacist, prescriber, or other dispenser making a report to the program in good faith under this section is immune from any civil, criminal, or administrative liability, which might otherwise be incurred or imposed as a result of the report, or on the basis that the pharmacist or prescriber did or did not seek or obtain or use information from the program.

(b) Nothing in this section shall require a pharmacist, prescriber, or other dispenser to obtain information about a patient from the program, and the pharmacist, prescriber, or other dispenser, if acting in good faith, is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting, receiving, or using information from the program.

Subd. 10. Funding. (a) The board may seek grants and private funds from nonprofit charitable foundations, the federal government, and other sources to fund the enhancement and ongoing

operations of the prescription monitoring program established under this section. Any funds received shall be appropriated to the board for this purpose. The board may not expend funds to enhance the program in a way that conflicts with this section without seeking approval from the legislature.

(b) Notwithstanding any other section, the administrative services unit for the health-related licensing boards shall apportion between the Board of Medical Practice, the Board of Nursing, the Board of Dentistry, the Board of Podiatric Medicine, the Board of Optometry, the Board of Veterinary Medicine, and the Board of Pharmacy an amount to be paid through fees by each respective board. The amount apportioned to each board shall equal each board's share of the annual appropriation to the Board of Pharmacy from the state government special revenue fund for operating the prescription monitoring program under this section. Each board's apportioned share shall be based on the number of prescribers or dispensers that each board identified in this paragraph licenses as a percentage of the total number of prescribers and dispensers licensed collectively by these boards. Each respective board may adjust the fees that the boards are required to collect to compensate for the amount apportioned to each board by the administrative services unit.

Minnesota Statutes Annotated (2014)
Public Welfare and Related Activities
Chapter 245A. Human Services Licensing

§ 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, 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 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 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 paragraph (a), clause (2), 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, paragraph (a), clause (2), 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 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 of treatment for all new admissions, readmissions, and transfers. Following the first ten weeks of treatment, treatment plan reviews may occur monthly, unless the client has needs that warrant more frequent revisions or documentation.

Subd. 11. Prescription monitoring program. (a) Upon admission to a methadone clinic outpatient treatment program, clients shall be notified that the Department of Human Services and the medical director will monitor the prescription monitoring program to review the prescribed controlled drugs the clients have received. 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 ordered 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 quarterly and be documented in the client's individual file. When the PMP data shows a recent history of multiple prescribers or multiple prescriptions for controlled substances, then subsequent reviews of the PMP data must occur monthly and be documented in the client's individual file. 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. 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. A review of the PMP is not required for every medication dose adjustment.

(b) 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.

(c) 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, paragraph (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.