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MANITOBA OPIOID AGONIST THERAPY RECOMMENDED PRACTICE MANUAL

1.5 The Relationship with Pharmacy & Prescriptions for Opioid Agonist Therapy

GENERAL CONSIDERATIONS

Pharmacy staff are integral members of the care team and play a crucial role in the provision of Opioid Agonist Therapy (OAT). A trusting professional relationship between the patient and pharmacist plays an important role in promoting treatment goals, while reinforcing boundaries and patient safety. The pharmacy team will see patients more frequently than other members of the OAT care team and they can be a great source of support to patients. They can also provide valuable collateral information to the OAT prescriber and clinic team to augment the care provided in the clinic setting.

Although the pharmacy team is often geographically removed from the clinic, they are part of the circle of care under the *Personal Health Information Act* (PHIA). Sharing information within the circle of care, to the patient's benefit, is permissible and still fulfills the duty of confidentiality[1]. As such, information required for the safe and effective provision of care should be shared freely between the pharmacist and prescriber/clinic staff.

Treatment agreements are effective tools to review behavioural and safety expectations with patients throughout the course of care, and these expectations extend to the pharmacy team. **The same respectful behaviour expected in clinic is also expected in and around the pharmacy**. This can be clearly communicated with patients when reviewing treatment agreements (see Comprehensive Assessment for further guidance). Disruptive behavior or theft from the pharmacy may result in the pharmacist terminating the patient relationship. Unacceptable behavior in pharmacy may also result in consequences and changes to the treatment plan with the clinic. For example, if a patient behaves in a threatening manner toward pharmacy staff, this may constitute grounds for involuntary withdrawal of treatment (see the Discontinuing Treatment chapter for detailed guidance).

Information sharing and collaboration between the pharmacy and clinic enables care providers at both locations to reinforce consistent boundaries and provide clear guidance on patients' rights and responsibilities when participating in treatment.

SPECIFIC RECOMMENDATIONS

PHARMACY & PRESCRIBER COMMUNIATION

Clear communication between the OAT prescriber/clinic staff and pharmacist is crucial. Issues that require prompt communication between prescriber and pharmacist are outlined below.

1) **Dose Changes**: All dose changes must be clearly communicated/highlighted to the pharmacist. Using an up (↑) or down (↓) arrow on the prescription instructions can be useful to indicate to the pharmacy that a dose change is intentional and not an error. This is particularly important during transitions between different pharmacies or treatment sites where the dose may have been adjusted (e.g., discharge from hospital or a residential treatment program).

2) **Missed Doses**: The pharmacist must report missed doses to the prescriber daily as they occur. The prescriber/clinic staff can then reach out to the patient to assess wellbeing and screen for issues that could be contributing to missed doses. This can also help providers plan ahead in case a prescription for a reduced OAT dose is needed in the near future. See the Ongoing Care section on MISSED OAT DOSES for specific recommendations.

3) **New Prescriptions for Concerning Medications**: The pharmacist must inform the OAT provider of any concerns when the patient is prescribed a medication by another prescriber that may interact with OAT, including all medications with sedating and/or psychoactive properties. This allows for collaborative discussion so that treatment adjustments can be made as necessary in the interest of patient safety. For example, the OAT prescriber may request that a new psychoactive medication be dispensed at intervals that match the witnessing schedule of the patient's OAT.

4) **Changes in Pharmacy Attendance**: A change of pharmacy or travel plans should be communicated promptly between the pharmacy and clinic team. This allows the clinic team to appropriately support the patient in planning for travel/guest dosing. It also prompts pharmacy staff to appropriately communicate with the new pharmacy, or the pharmacy responsible for guest dosing if indicated during travel.

5) **Take-home (Carry) Doses**: The schedule of take-home doses must be clearly communicated to the pharmacy. This can be done by either writing the instructions for witnessed and take-home doses directly on the prescription, or by sending it to the pharmacy as a separate note or letter (see **Appendix E** for an example). The latter is

especially useful when the current prescription is still valid and the treatment team wishes to authorize changes to take-home doses, such as a new permanent carry or one-time carry doses for travel or another reason. The schedule must indicate *both* the witness and take-home dates using specific days of the week (e.g., Monday, etc.) or calendar dates.

Take-home doses must be authorized by the prescriber or a member of the prescriber's treatment team. The pharmacist cannot authorize take-home doses, and the prescriber/clinic staff should clearly explain this to the patient to avoid misunderstanding. Pharmacists can often provide valuable input on the appropriateness of take-home doses. Discussion is thus encouraged, especially when the prescriber/clinic staff are questioning the safety of releasing carries in certain situations.

6) **Collateral About Stability**: As the pharmacy team interacts with the patient regularly between appointments, they can provide valuable observations regarding the patient's physical and mental health, apparent social stability, and episodes of intoxication/sedation. Concerning presentations or behaviors should be promptly communicated to the prescriber.

Occasionally, the prescriber/clinic team may elect to send a letter to the patient's pharmacy of choice at the start of treatment, or to facilitate guest dosing during travel. Such a letter serves to communicate the prescriber's treatment expectations to the pharmacy, as discussed with the patient. This may be particularly useful for out-of-province pharmacies who may operate with different expectations than Manitoba, or for pharmacies with minimal OAT experience (see **Appendix F** for an example letter). Pharmacists may also require patients on OAT to sign a pharmacy treatment agreement to outline expectations (contact the College of Pharmacists of Manitoba for an example).

It is also important for prescribers/clinic staff to discuss practical expectations about care with patients *periodically* to ensure understanding. This reinforces the safety measures, boundaries, and predictable structure that anchors OAT treatment.

OTHER CONSIDERATIONS FOR PHARMACY

Intoxicated Patients & Withholding Doses

Patients may present at the pharmacy for their dose appearing intoxicated from alcohol or other substance use. Concurrent use of sedative-hypnotics, such as benzodiazepines/Z-drugs, alcohol, or other opioids greatly increases the risk of overdose when combined with OAT medication.

Patients appearing somnolent, sedated, or intoxicated (slurred speech, stumbling gait, disorientation) will not be given their OAT dose if the pharmacist deems it unsafe, based on their assessment of the patient. The pharmacist may elect to ask the patient to return for

reassessment at a later time or the dose for that day may be withheld altogether. The pharmacist must inform the prescriber/clinic of such presentations as soon as they occur and may request additional collaboration from the prescriber/clinic to resolve the matter.

If a patient is administered their OAT dose and impairment/intoxication is noted after, the prescriber/clinic should be consulted and/or the pharmacist may choose to call 911 for emergency assistance. Consideration may also be given to clinic or emergency room attendance for assessment and further observation, as appropriate.

Management of Wrong Dose & Overdose

On occasion, dosing errors may occur at the pharmacy, and this may necessitate further assessment and monitoring. **Dosing errors must be reported to the OAT prescriber**. Particular caution must be taken with overdosing of methadone and slow-release oral morphine (SROM), given the full-agonist effects and comparatively greater risk of opioid toxicity.

The pharmacist, in consultation with the prescriber, should be actively involved in ensuring that the patient receives the appropriate medical intervention, which may include finding transportation to the OAT clinic, emergency department, or calling an ambulance.

Methadone and buprenorphine/naloxone can have peak effects that begin in 1-2 hours, and this can last for several hours. When an overdose occurs, adverse effects will be most apparent during these peak times. Early signs of toxicity include drowsiness or “nodding” during low stimulus activities. Ataxia, nausea/vomiting, slurred speech, euphoria, and slow or laboured breathing (respiratory depression) may be signs of progressive toxicity and require urgent medical attention.

If the patient refuses to seek medical attention, such as attending their OAT clinic or hospital, the pharmacist and prescriber/clinic staff can collaborate on the following:

- Educate the patient on the risks involved.
- Involve a trusted person (e.g., family member or friend), as able, who can stay with them and monitor for adverse effects, particularly during dosing peaks.
- Ensure the patient has a naloxone kit and someone who can stay with them who knows how to use it.
- Educate the patient and/or trusted person regarding signs of overdose, naloxone kit use, and when to call 911.
- Instruct the patient to avoid any other sedative/psychoactive substances for the remainder of the day and/or until the peak effects are expected to subside.
- Contact the patient throughout the day to check in and provide further support.

OAT providers/clinics and pharmacies should have an **overdose response plan** in place. A clear protocol for appropriate action supports staff and increases safety. **For high dose ingestions or if the patient shows any signs of sedation, OAT providers/clinics should adhere to the following steps**:

- Ensure naloxone is available on-site and administered if needed.
- Monitor patient vitals accordingly.
- Clinic staff should recommend and help arrange transfer to an emergency department, and provide appropriate information to the receiving institution.
- Consider the need for involuntary transfer to a hospital if the prescriber or clinic staff have significant concerns.
- If the patient is referred to the emergency department, the OAT prescriber/clinic staff should communicate with the emergency room physician to advise that:
    - The patient should be observed for a minimum of 10 hours.
    - The patient should not be discharged with ongoing signs of lethargy or sedation.
    - The patient should not receive any other sedative/psychoactive medications.

The risk of opioid toxicity is also affected by other factors, such as the patient's age, stage of treatment, concurrent health conditions, prescribed medications, and/or concurrent substance use. **Patients in the early stabilization phase (e.g., first 2-3 weeks), using other sedative-hypnotic substances/medications, the elderly, and patients with respiratory illness are more prone to toxicity**. Even a small "extra" OAT dose could cause harm in such patients.

OAT PRESCRIPTION WRITING & TRANSMISSION

OAT Medications Are M3P Drugs

Methadone, buprenorphine, and SROM (Kadian®) are drugs covered by the Manitoba Prescribing Practices Program (M3P), and therefore prescriptions must be written in one of the approved M3P formats. See the CPSM Practice Direction for Manitoba Prescribing Practices Program and page 3 for a list of M3P drugs[2].

The following resources are available electronically by contacting the CPSM Prescribing Practices Program (phone 204-774-4344):

- Guidance on approved methods and formats for faxing M3P medications.
- Templates for faxing that can be tailored to prescribers' practice locations.
- Teaching examples of M3P OAT prescriptions.

Please note these instructional resources are not available online for forgery prevention.

The M3P form exists to minimize diversion of controlled and narcotic medications, and to facilitate communication among healthcare professionals. Historically, the original, hardcopy M3P form had to be received by pharmacies for the prescription to be valid. Since 2016, OAT prescribers were permitted and **strongly advised to fax OAT prescriptions directly to the pharmacy of the patient's choice**. This decreases the chance of prescriptions being lost, stolen, or altered, and improves access to care for patients on OAT, especially when providers are caring for patients over a distance. See *Faxing M3Ps* below for more details on faxing OAT prescriptions.

Since the COVID-19 pandemic, it has been permissible to fax prescriptions for all drugs on the M3P schedule directly to the patient's pharmacy of choice, *without sending the original*.

M3P prescriptions can now be faxed as the M3P form (from the duplicate prescription pad) affixed to a template, or the provider can generate an EMR or handwritten prescription for faxing, **provided all requirements are met per the M3P form** and the Joint Statement for Facsimile Transmission of Prescriptions.

OAT Prescription Requirements

OAT prescriptions must contain the following information, consistent with M3P form fields, including:

- Patient demographics (name, address, PHIN, DOB).
- Name and daily dosage of the drug, in numbers and words, e.g., methadone 30 (thirty) mg or Suboxone 18 (eighteen) mg.
- Total quantity of the drug to be dispensed, in numbers and words.
- First and last calendar date of the prescription.
- Specific days of the week or calendar dates for witnessed dosing and take-home doses.
- Therapeutic indication (e.g., opioid use disorder).
- Directions for use.
- Any special instructions specific to the patient.
- Date prescribed.
- Written and signed by an approved OAT prescriber.

Prescribers Must Complete Total Quantity

The total quantity on OAT prescriptions must be filled out (regardless of the faxing format used), including the **total milligram amount** of the entire prescription, written both **numerically** and **alphabetically**. Given the potential for harm to patients, **CPSM requires the total quantity to be completed by the prescriber**. This serves as an additional safety check to ensure the correct daily dose is dispensed to the patient and that the intentions of the prescriber are clear.

As above, OAT prescriptions must clearly state the first and last calendar date of the intended prescription, the indication for the medication (e.g., opioid use disorder), and the daily dose. Completing these fields on the M3P prescription *does not* preclude the prescriber from completing the total quantities field. If the total quantity is not specified, the pharmacy will need to contact the prescriber for clarification, while being mindful not to unnecessarily delay patient care.

Total Daily Dose vs Strength of Drug

It is strongly recommended to write the total *daily* dose in milligrams on the OAT prescription instead of the individual unit strength of the medication, to prevent dosing errors and to provide flexibility for pharmacists. For example, writing Suboxone 18 mg (instead specifying the 8 mg and/or 2 mg tablet strengths) gives the pharmacist flexibility to use the tablet strengths available to make up the dose. Likewise, writing methadone in milligrams (e.g., 30 mg) and not in millilitres (e.g., 3 mL) will help prevent dosing errors. Furthermore, writing the generic name "methadone" (instead of Methadose, for example) also gives the pharmacist options to use available formulations.

If the daily dose is written on an M3P form that is affixed to a prescription fax template, the daily dose must also be written in a *secondary area* on the faxed prescription, to ensure accuracy in case fax artifacts cover the primary notation.

Other Nuances of OAT Prescriptions

The following also applies for prescribers and pharmacists in managing OAT prescriptions:

- No doses are to be given beyond the last calendar date of the prescription (i.e., missed doses cannot be given past the prescription end date).
- Every new prescription must clearly state which doses are to be taken by witnessed self-administration and which may be dispensed as take-home doses.
- A new prescription must be written for any change(s) from a previous dose. Multiple doses written on the same prescription should be avoided. An example of an exception to this may be a pre-planned taper where a number of dose decreases over a specified period of time is clearly written on the same prescription.
- The practice of having pre-signed blank prescriptions in the clinic is unacceptable.
- Any new prescription cancels the previous prescription.
- If the patient is changing pharmacies, the previous prescription will be cancelled. There is an increased risk of error when OAT is regularly dispensed out of two or more pharmacies, and this should be done only rarely if no alternative exists (e.g., geographical constraints). The patient could potentially be double dosed, or the

pharmacist could be unaware of missed doses. As below, one prescriber (or identified group of prescribers) and one pharmacy is considered best practice.

STRONG RECOMMENDATION: ONE PRESCRIBER - ONE PHARMACY

It is best practice for ALL sedating/psychoactive medications to be prescribed by a single prescriber (or group of prescribers) and dispensed from a single community pharmacy. The prescriber (or group of prescribers) of these medications should generally be the OAT prescriber(s).

OAT prescribers are **strongly encouraged to provide their cell numbers** (or on-call number for a prescriber group) on *all* prescriptions to facilitate timely communication regarding urgent prescription issues and to minimize delays in patient care. These numbers can be marked as "private" to indicate to the pharmacy team that they should not be shared with patients.

Faxing M3Ps

The requirements outlined in the Joint Statement for Facsimile Transmission of Prescriptions must be met when M3P OAT prescriptions are faxed to the pharmacy of the patient's choice and the prescription must contain the usual signed certifications indicating that[3]:

i. The prescription represents the original of the prescription drug order,

ii. The addressee is the only intended recipient and there are no others, and

iii. The original prescription will be invalidated, securely filed, and not transmitted elsewhere at another time.

The original hardcopy M3P prescription *does not* need to be mailed or couriered to the pharmacy. Once successfully faxed, the original M3P prescription essentially becomes a "copy" and should be labelled as such before being added to a paper chart or scanned into an electronic medical record. The faxed M3P prescription received by the pharmacy is now regarded as the original valid M3P prescription.

Do not provide the original hardcopy M3P prescription to the patient to take to the pharmacy if it has been faxed. This prevents the patient from potentially taking the original hardcopy M3P prescription to a second pharmacy, other than the intended pharmacy.

Buprenorphine Formulations

Buprenorphine/naloxone is currently available as a sublingual tablet or film. While formulations contain both buprenorphine and naloxone at a ratio of 4:1, it should be noted that buprenorphine/naloxone products are commonly referred to by their buprenorphine component only (e.g., 2 mg instead of 2 mg/0.5 mg).

Depending on availability and coverage, the pharmacist will commonly use 2 mg and 8 mg tablets to make up the prescribed strength, however other options may be available. When films are prescribed, the pharmacist may choose from 2 mg, 4 mg, 8 mg, or 12 mg strengths, but may be limited in their choice depending on coverage and availability.

Methadone Formulations

Methadone is available in various formulations, but pharmacists *must* use designated 10 mg/mL liquid concentrates when filling prescriptions for opioid use disorder (OUD). Pharmacists are required to dilute some of these methadone concentrates with a crystalline diluent (e.g., Tang®), while some concentrates may be dispensed safely without further dilution (e.g., cherry-flavored concentrates). Pharmacists will prepare individual daily doses for their patients using this concentrate. An exception to using the methadone concentrate may be made for patients with long-term documented stability; they may be eligible for tablets or capsules at the discretion of the prescriber for reasons such as extended or international travel.

Methadone products are not interchangeable from a clinical perspective nor a coverage perspective. Changes occurred in the Pharmacare drug coverage for brand vs generic methadone products in 2021. Generic methadone products are now listed as a Part 1 (open) benefit. These generic methadone products are *not* interchangeable with each other nor with the brand name methadone products.

As of March 2023, brand name methadone products (e.g., Methadose™) are only a Part 2 benefit for patients who:

a) Are being treated with the same methadone product already, or

b) Have previously been treated with two or more generic methadone products listed under Part 1.

Please refer to the Manitoba Health website for updates to the Pharmacare coverage.

A safety review completed by Health Canada found that there may be a link between switching methadone-containing products used to treat OUD and the risk of lack of effect, which may present as withdrawal symptoms, although the reason for this is unclear. OAT providers and pharmacists should be aware that[4]:

- Some patients may experience withdrawal symptoms after being switched from one methadone-containing product to another; these patients should be clinically managed and monitored regularly.
- Dose adjustments may be necessary in some patients.
- Withdrawal symptoms can lead to a failure to remain in treatment and subsequent problematic substance use, which can lead to serious harms.

Particular caution should be exercised when the patient is switching between methadone products that require dilution with a crystalline diluent (e.g., Tang®) and ones that do not require dilution (e.g., cherry-flavored).

A new prescription would be required to switch a patient from one methadone product to another. If a patient is *new* to taking methadone and presents to a pharmacy with a prescription that does not specify the brand (i.e., written as "methadone"), the pharmacist can dispense whatever generic is usually used by the pharmacy. It is good practice for the pharmacist to notify the prescriber of the generic brand that is being used.

Writing new methadone prescriptions in this format (i.e., written as "methadone") is recommended, as it may prevent a delay in treatment at the pharmacy.

If the patient is *already* taking methadone and presents with a new prescription, consideration must be given to what brand the patient has been receiving and it may be necessary in some cases to avoid changing the brand, if possible. **If the patient receives a different methadone brand, the patient and prescriber must be made aware so that the patient can be monitored for dose equivalency. This often requires collaboration and communication between the prescriber, pharmacy team, and patient**.

As above, prescribers are **strongly encouraged** to provide their cell numbers (or on-call number for a prescriber group) on *all* OAT prescriptions to facilitate timely communication regarding urgent prescription issues and to minimize delays in patient care. These numbers can be marked as "private" to indicate to the pharmacy team that they should not be shared with patients.

References

1. College of Physicians & Surgeons of Manitoba. *Standard of Practice: Duty to Report Self, Colleagues, or Patients, Contextual Information and Resources*. CPSM; 2021.
2. College of Physicians & Surgeons of Manitoba. *Practice Direction: Manitoba Prescribing Practices Program (M3P)*. CPSM; 2018.
3. College of Pharmacists of Manitoba. *Joint Statement: Facsimile Transmission of Prescriptions.* CPhM; 1998 (Revised 2016).
4. Health Canada. *Methadone Treatment of Opioid Dependence and Potential Risk of Lack of Effect when Switching between Different Products*. Government of Canada; 2020. Available at: https://recalls-rappels.canada.ca/en/alert-recall/methadone-treatment-opioid-dependence-and-potential-risk-lack-effect-when-switching

Appendix E

AUTHORIZATION TO PHARMACY FOR OAT TAKE-HOME (CARRY) DOSES

Date:	
Pharmacy:	
Phone:	
Fax:	

Dear Pharmacist,

RE:	
DOB:	
PHIN:	
Clinic Phone:	Fax:

☐ Please be advised that the above-named patient has been authorized *one-time* carry dose(s) for the following date(s) _____.

OR

☐ Please be advised that the above-named patient has been authorized a *permanent* carry dose.

They would like to take home their OAT dose on: _____ (day of the week), starting on _____ (date).

The carry schedule moving forward will be:

Day	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Witnessed Dose (W)							
Carry Dose (C)							

Please call us as needed with any questions or concerns, at _____.

Sincerely,

_____

Prescriber or Clinician Signature, credentials

Appendix F

LETTER TO PHARMACY FOR PATIENTS STARTING OAT

Date:	
Pharmacy:	
Phone:	
Fax:	

Dear Pharmacist,

RE:	
DOB:	
PHIN:	
Clinic Phone:	Fax:

Our patient has chosen your pharmacy for Opioid Agonist Therapy (OAT).

We encourage regular communication between the pharmacist, OAT prescriber, and clinic staff, for the comprehensive and safe care of our patients. We also ask that the following **clinic expectations** be reinforced with our patients. Please contact the clinic with any questions or concerns at _____.

1) Patients are required to self-administer their OAT dose in front of the pharmacist, unless take-home (carry) doses are authorized.

2) Please inform us of any OAT doses missed by the patient.

3) Please withhold the OAT dose if the patient misses **≥ 3 consecutive doses of methadone** or **≥ 6 consecutive doses of buprenorphine/naloxone**, to prevent overdose due to loss of tolerance. The patient may need to be reassessed before OAT is restarted. Please notify us as soon as possible.

4) Please inform us of any diversion or attempted diversion.

5) If the patient appears somnolent, sedated, or intoxicated, their OAT dose will not be given if the pharmacist deems it unsafe, based on their assessment. The pharmacist may elect to ask the patient to return for reassessment at a later time or the dose for that day can be withheld altogether. Please notify us of such presentations.

6) Patients have been instructed to keep their medication(s) in a locked box or cabinet at home and when travelling. Please inform us of any lost or stolen doses, or if you have any concerns about the patient's ability to lock or secure their doses.

7) Changes to the witness/take-home dosing schedule can only be authorized by the prescriber/clinic. Patients are asked to arrange any requests for changes to the schedule directly with our clinic at least 24 hours in advance, if possible.

8) Please notify us if pharmacy staff observe the patient vomit their methadone dose within less than 30 minutes from ingesting their dose, or if the patient reports vomiting their dose otherwise.

9) Please notify us if you become aware that the patient is prescribed any new medications that interact with OAT, including any new prescriptions for other sedating/psychoactive medications.

Sincerely,

_____

Prescriber or Clinician Signature, credentials