

## MANITOBA OPIOID AGONIST THERAPY RECOMMENDED PRACTICE MANUAL

### **1.2 Application, Training, & Regulatory Requirements to Provide Opioid Agonist Therapy**

#### REGULATION OF OAT PRESCRIBING & DISPENSING

In Manitoba, specific training and a regulatory approval is required to prescribe Opioid Agonist Therapy (OAT), including buprenorphine/naloxone, other buprenorphine-containing OAT treatments, methadone, and slow-release oral morphine (SROM) when used as OAT. Training requirements must also be met to dispense these medications as a pharmacist. This chapter addresses the application, training, and approval processes involved in providing OAT from a tri-college perspective.

Please note that the federal exemption for prescribing methadone no longer exists. Both methadone and buprenorphine prescribing approvals/authorizations are now provincially regulated by the prescriber's regulatory authority. In Manitoba, this includes the College of Physicians & Surgeons of Manitoba (CPSM) for physicians and the College of Registered Nurses of Manitoba (CRNM) for RN(Nurse Practitioners).

In compliance with the Manitoba Pharmaceutical Regulation and the College of Pharmacists of Manitoba (CPhM), dispensing of OAT by a pharmacy requires that at least one of the pharmacists at the pharmacy has specialized training and is extensively knowledgeable to provide OAT. The pharmacist with specialized training at a pharmacy is then responsible for training all pharmacists who will be dispensing methadone and/or buprenorphine. All pharmacists dispensing methadone or buprenorphine for OAT must be knowledgeable in all pertinent aspects of OAT.

### *Tri-College Resources & Approved Courses*

Details of the application and training process, for both buprenorphine and methadone, are outlined in these tri-college documents from CPSM, CRNM, and CPhM:

- [OAT Approval Training Process](#)
- [OAT Approval Training Process Flow Chart](#)

To prescribe or dispense OAT, the prescriber or pharmacist must complete an approved, theoretical course tailored to their intended practice and complete all assigned readings as required. If the practitioner intends to provide both methadone and buprenorphine, they must complete the *OAT 101: An Introduction to Clinical Practice Workshop*. This course, along with other requirements, can qualify the practitioner to provide both OAT medications.

Practitioners interested in providing treatment with buprenorphine-containing OAT medications *only* have the option to take the OAT 101 Workshop or complete a College-approved online course (as listed below). As of December 2022, *physicians* applying to prescribe *only* buprenorphine are no longer required to provide proof of training to CPSM *prior* to being granted prescribing approval. However, an approved course remains **strongly recommended** by CPSM for physicians to ensure clinical competency in the treatment of opioid use disorder (OUD) with buprenorphine/naloxone.

Prescribers have an additional component of required training, clinical preceptorship (optional for pharmacists). While proof of completed preceptorship/mentorship is no longer required for *physicians* pursuing buprenorphine-only approval, it remains recommended by CPSM. Given the more complex pharmacology and greater risks associated with methadone compared to buprenorphine, the training requirements for methadone are more comprehensive than those for buprenorphine-only prescribing approval.

#### TRI-COLLEGE APPROVED OAT TRAINING COURSES

[Opioid Agonist Therapy 101: An Introduction to Clinical Practice](#), offered by the University of Manitoba's CPD Medicine Program. The required course for methadone prescribing and dispensing.

To prescribe or dispense buprenorphine *only*, practitioners can take the above course, or:

[Provincial Opioid Addiction Treatment Support Program](#), offered by the British Columbia Centre on Substance (BCCSU); or

[Buprenorphine Treatment for Opioid Use Disorder](#), offered by The Centre for Addiction and Mental Health (CAMH); or

[Addiction Care and Treatment Online Certificate](#), offered by the BCCSU. This is more of a time commitment for more detailed learning on other substance use disorders beyond OUD; or

[Buprenorphine Prescribing Course](#), offered by the Canadian Society of Addiction Medicine (CSAM). May be offered in conjunction with the CSAM Annual General Meeting (no link available).

## FOR PHYSICIAN PRESCRIBERS

As outlined in the CPSM Practice Direction for [Prescribing Methadone or Buprenorphine/naloxone](#), a physician can apply and train towards two approvals for the treatment of OUD:

1. Methadone Prescribing Approval and/or
2. Buprenorphine/naloxone Prescribing Approval.

### *Step One – Apply to the Registrar*

The first step towards either or both approvals is applying **by letter to the Registrar. In this application the physician must request permission to pursue prescribing approval(s) for OAT.**

This letter can be submitted electronically, via email, and should outline the applicant's:

- Educational background (year of graduation, residency, specialty).
- Current practice and location(s).
- Plans for OAT Training and how OAT can be incorporated into their practice (e.g., target population for treatment, settings, if working with other OAT providers).
- For **methadone**, this letter must also contain the contact information for **two physician references** who can speak to the applicant's character and competency. These do **not** need to be OAT prescribers. CPSM will contact these references directly.

### CPSM CRITERIA FOR METHADONE APPROVAL

1. Application by letter to the Registrar and 2 physician references of character and competency.
2. Proof of Completion of the Approved Theoretical Training Course.
3. Documentation of Clinical Preceptorship Completion.
4. Active registration as a Full-Regulated Member (or active provisional registration, with an OAT Practice Supervisor identified).

### CPSM CRITERIA FOR BUPRENORPHINE APPROVAL

1. Application by letter to the Registrar.
2. Active registration as a Full-Regulated Member (or active provisional registration, with an OAT Practice Supervisor identified).
3. Training/education towards clinical competency in the treatment of OUD with buprenorphine *strongly recommended*, but proof of same no longer required *prior* to approval.

A written application requesting permission to pursue prescribing approvals and the relevant training is an essential first step, as the *Registrar has the authority to decline a candidate's application to proceed with training*. Contacting CPSM *before* initiating the training process ensures that physicians' time and financial resources are invested appropriately.

For buprenorphine-only approval, the applicant's request will be reviewed by CPSM to ensure suitability to provide OAT to this vulnerable patient population, prior to Registrar approval.

**Physicians can start prescribing buprenorphine/naloxone upon receipt of a formal letter from the Registrar indicating their prescribing approval was granted. However, physicians must ensure they possess the knowledge, skills, and clinical judgment to prescribe buprenorphine safely to patients as OAT.** Therefore, *Step Two* and *Step Three* below are recommended to build clinical competency in the treatment of OUD with buprenorphine/naloxone.

### *Step Two – Complete an Approved Course*

Physicians pursuing training must select a theoretical course approved for the specific OAT approval(s) they are seeking. Physicians seeking a methadone prescribing approval must complete the OAT 101 Workshop as outlined above.

This course is also useful to build clinical competency in the treatment of OUD with buprenorphine/naloxone, but is not required for approval. While physicians are no longer required to submit proof of a completed course *prior* to buprenorphine prescribing approval, a CPSM-approved course remains strongly recommended.

### *Step Three – Complete Preceptorship for Methadone*

Again, given the more complex pharmacology and greater risks associated with methadone compared to buprenorphine, the preceptorship requirements for methadone approval are more comprehensive than the requirements for buprenorphine-only.

Physicians seeking a **methadone approval must complete four half-day preceptorship clinics**, shadowing an experienced OAT prescriber, selected from the CPSM-approved preceptor and site list. This list is available by contacting the CPSM Prescribing Practices Program (it is not available online for privacy reasons as preceptors provide personal contact information to arrange clinics). These four clinics should ideally be **completed within six months of the theoretical workshop**.

Typically, physicians seeking a methadone approval are also seeking a buprenorphine approval. This is strongly encouraged, given that buprenorphine is considered first-line therapy for treatment of OUD. Completion of the OAT 101 Workshop and preceptorship clinics would certainly support clinical competency in the treatment of OUD with both medications. Ideally, preceptorship clinics can expose the candidate to the full spectrum of methadone and buprenorphine care, including inductions, titrations, and maintenance care.

Physicians seeking **only buprenorphine prescribing approval are encouraged to seek preceptorship/mentorship as needed to build clinical competency** for the treatment of OUD with buprenorphine/naloxone. Proof of completed preceptorship or mentorship is no longer required by CPSM prior to approval.

Preceptorship clinics are also a practical way to learn the administrative, pragmatic, psychosocial, and therapeutic aspects of OAT care. These clinics can build connections and mentorship relationships with experienced providers.

### *Step Four – Notify CPSM of Completed Training for Methadone*

Once the theoretical course and preceptorship clinics are completed for **methadone training**, the applicant can notify CPSM by providing confirmation and specific details via email. Physicians should submit their certificate of completion for the OAT 101 Workshop. They should also provide details of their preceptorship, including the dates of the clinics, the site(s), and name(s) of the physician(s) shadowed.

Final approval will be confirmed with the Registrar. **Physicians can start prescribing methadone upon receipt of a formal letter from the Registrar indicating their prescribing approval was granted.**

### *Prescribing Renewals – Every Three Years*

CPSM prescribing approvals expire on a specified date over a three-year cycle, regardless of when a physician obtained the approvals. For example, the next expiry date is June 1, 2024, and every three years thereafter. Renewals are granted upon completion of a questionnaire to evaluate continued competency through ongoing prescribing and participation in Continuing Professional Development (CPD) relevant to OAT prescribing and addictions medicine.

### **FOR NURSE PRACTITIONER PRESCRIBERS**

RN (Nurse Practitioners) can review the tri-college training process documents linked above and the CRNM document [Prescribing Controlled Drugs and Substances](#).

### *Step One – Apply to CRNM*

The first step towards prescribing either methadone or buprenorphine for RN(NP)s is **submission of the relevant application form**; the [Methadone Prescribing for OUD](#) form (Part A) and/or the [Buprenorphine Prescribing for OUD](#) application form.

RN(NP)s seeking a methadone prescribing exemption must also **provide two references for character and competency**, who will be contacted directly by CRNM. One reference must be a supervising manager and the other a professional with whom the applicant has worked or trained with recently.

#### **CRNM CRITERIA FOR OAT PRESCRIBING AUTHORIZATION**

1. Submission of Application Forms to CRNM and 2 references of character and competency.
2. Proof of Theoretical Training Course Completion.
3. Documentation of Clinical Preceptorship Completion.
4. Active Registration with CRNM and authorization to prescribe controlled substances (including M3P and controlled substances education as directed by CRNM).

### *Step Two – Complete an Approved Course*

RN(NPs) pursuing training must select a theoretical course approved for the specific OAT authorization they are seeking. RN(NP)s seeking a methadone prescribing exemption must take the OAT 101 Workshop as outlined above. This will also qualify them for a buprenorphine authorization. RN(NP)s seeking an authorization to prescribe *only* buprenorphine can complete any one of the CRNM-approved courses listed above, including the online options.

### *Step Three – Complete Preceptorship*

The clinical preceptorship requirements for RN(NPs) seeking methadone exemption are the same as the requirements for physicians. Likewise, the requirements for methadone are more comprehensive than the requirements for a buprenorphine-only prescribing authorization.

RN(NPs) pursuing **methadone prescribing must complete four half-day preceptorship clinics**, shadowing an experienced OAT prescriber from the approved preceptor and site list. These four clinics should ideally be **completed within six months of the theoretical workshop**.

Typically, RN(NP)s seeking a methadone exemption are also seeking buprenorphine authorization. This is strongly encouraged, given that buprenorphine is considered first-line therapy for treatment of OUD. Completion of the OAT 101 Workshop and four preceptorship clinics would qualify a RN(NP) for both authorizations. Ideally, these preceptorship clinics should expose the candidate to the full spectrum of methadone and buprenorphine care, including inductions, titrations, and maintenance care.

The preceptorship is also a practical way to learn the administrative, pragmatic, psychosocial, and therapeutic aspects of OAT care. These clinics can build connections and mentorship relationships with experienced providers.

RN(NP)s pursuing *only* buprenorphine prescribing must complete **one half-day preceptorship clinic**, shadowing an approved buprenorphine prescriber, ideally within three months of finishing the theoretical course. RN(NP)s must also formally identify a **CRNM-approved mentor** (with OAT experience) for their first year prescribing buprenorphine, for support and guidance as needed. Contact CRNM at [practice@crnm.mb.ca](mailto:practice@crnm.mb.ca) for a list of approved preceptors and mentors. (Please note the CRNM requirements for buprenorphine-only prescribing authorization may be revised at a later date.)

Registrants must also continue to demonstrate the [Practice Expectations for RN\(NP\)s](#).

### *Step Four – Notify CRNM of Completed Training*

Once the theoretical course and preceptorship are completed, the applicant can notify CRNM by submitting any outstanding application forms, a mentor's name as applicable, and relevant completed course certificates to [practice@crnm.mb.ca](mailto:practice@crnm.mb.ca). RN(NP)s will receive a formal email from CRNM confirming their methadone and/or buprenorphine prescribing privileges.

## FOR PHARMACISTS

Pharmacists seeking to dispense methadone and/or buprenorphine can review the tri-college training documents linked above and complete the required readings as found in the [OAT Guidelines for Manitoba Pharmacists](#).

### *Step One – Complete an Approved Course*

The Manitoba Pharmaceutical Regulation states that a member may only engage in the aspects of pharmacy practice for which they have the requisite knowledge, skill, and judgment to provide or perform, and that are appropriate to their area of practice.

At least one pharmacist must be extensively knowledgeable at each pharmacy that provides OAT. Similar to prescribers, the pharmacist must complete a theoretical training course approved for the specific OAT they plan to dispense:

- If the pharmacist wishes to dispense methadone, they are required to take the OAT 101 Workshop. This will also qualify them for buprenorphine dispensing.
- If the pharmacist wants to dispense *only* buprenorphine, they can complete any one of the tri-college approved online courses already listed. (Please note these CPhM requirements for buprenorphine-only dispensing are presently being revised.)

The pharmacist with specialized training is then responsible for training all pharmacists who will be dispensing OAT at their pharmacy.

If a pharmacy must provide OAT for continuation of care and it is not possible for the pharmacist to complete the approved specialized training in advance, they must have a formal agreement with a pharmacist with specialized training at another pharmacy who agrees to act as a mentor. Training must be completed within 6 months.

### *Step Two – Preceptorship, Mentorship, & Documentation*

Clinical preceptorship or mentorship is optional for Pharmacists.

Additionally, pharmacists do not need to provide confirmation of completed clinical training to CPhM. However, they must maintain documentation of completion of the required training for record keeping and compliance with the Regulation. Proof of completion may be requested at a later date.

While not a formal requirement, pharmacists who are new to dispensing OAT can also seek a mentor; another trained pharmacist can be helpful in setting up early practice and for guidance as needed. Contact CPhM if assistance is needed in finding a mentor.



## PROVIDING OTHER FORMS OF OAT

To prescribe other formulations of buprenorphine, such as Sublocade® (buprenorphine extended-release injection) or Probuphine® (buprenorphine implant), prescribers must hold a buprenorphine/naloxone prescribing approval/authorization from their respective College and pursue additional training as outlined below.

If third-line options such as slow-release oral morphine (SROM) or injectable OAT (iOAT) are considered, prescribers must already hold both methadone and buprenorphine/naloxone approvals/authorizations. Prescribers **MUST** discuss such treatment *in consultation with an addiction medicine specialist*.

Additionally, see [Recommendations for Sublocade®](#) and [Alternative Treatment Approaches including SROM \(Kadian®\)](#) for further guidance.

Pharmacists should contact CPhM for more information on training requirements for dispensing other forms of OAT.

### INFORMATION ON SUBLOCADE® TRAINING

More information on Sublocade® use and administration is available **for prescribers and pharmacists** in this document: [Joint Guidance on Sublocade Administration](#).

- Prescribers must hold a current, active buprenorphine/naloxone prescribing approval/authorization from CPSM/CRNM to prescribe Sublocade®.
- Currently, approved/authorized prescribers wanting to prescribe Sublocade® must complete the non-accredited certification program, **a Health Canada requirement**, available at [www.sublocadecertification.ca](http://www.sublocadecertification.ca). The completed program certificate must be faxed to the pharmacy along with the M3P prescription when prescribers first order Sublocade® from a particular pharmacy.

### INFORMATION ON PROBUPHINE® TRAINING

More information on Probuphine® (buprenorphine implant) is available **for prescribers and pharmacists** by contacting the CPSM's Prescribing Practices Program directly.

- Please note that prescribers must hold a current, active buprenorphine/naloxone prescribing approval/authorization from CPSM/CRNM to prescribe/implant Probuphine®.
- Because of the risks associated with insertion and removal, Probuphine® must be prescribed, implanted, and removed only by trained prescribers who have successfully completed a training program on the insertion and removal of Probuphine®.