



Opioid Agonist Treatment:
Practice Directive for Community Pharmacy Professionals

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Introduction

The primary goal of the *Opioid Agonist Treatment: Practice Directive for Community Pharmacy Professionals* document is to enhance the safety, consistency, and effectiveness of the opioid agonist treatment (OAT) services provided by community pharmacy professionals in Prince Edward Island, contributing to improved patient and societal outcomes.

Scope

The *Opioid Agonist Treatment: Practice Directive for Community Pharmacy Professionals* provides specific directions regarding the provision of opioid agonist treatment. The Practice Directive does not provide clinical advice or guidance as there are clinical practice guidelines published by reputable organizations that can be referenced by pharmacy professionals.

Definitions

Opioid agonist treatment: In this document, opioid agonist treatment (OAT) is used to treat opioid use disorder (OUD). It most often includes methadone, buprenorphine or buprenorphine/naloxone, but may include other treatments such as slow-release oral morphine or injectable opioid agonist treatment (iOAT).

Pharmacy professionals: Individuals who are registered with PEICP as a pharmacist or a pharmacy technician. Also referred to as registrants or members.

Pharmacy staff: All individuals employed in a pharmacy, including regulated and non-regulated personnel.



Professional Roles and Responsibilities

Expected Role of the Pharmacist

Before engaging in the provision of OAT services, pharmacists need to consider the activities they are expected to undertake and establish a plan of how to address the associated time and physical space requirements.

It is essential that pharmacists providing opioid agonist treatment are competent in this clinical area and be aware of clinical practice guidelines.

The expected activities of pharmacists providing opioid agonist treatment include but are not limited to:

- Medication dispensing (including witnessed administration 7 days a week – see [Pharmacy Hours](#) under operational requirements for options)
- Observing patient dosing when required by the prescriber
- Educating and counselling patients on the use of their treatment including how the product should be stored to optimize efficacy and safety
- Patient monitoring and support
- Thorough record keeping
- Communicating progress of treatment to the prescriber (for example: missed/lost doses, patient behaviour, treatment plan changes) and recommending treatment options.

Expected Role of the Pharmacy Technician

The expected role of the pharmacy technician in opioid agonist treatment includes the technical aspects corresponding to the standards of practice for Canadian pharmacy technicians.

These responsibilities may include:

- Medication dispensing,
- Thorough record keeping, and
- Witnessing observed doses after the pharmacist has assessed the patient.

Pharmacists are responsible for assessing the appropriateness of opioid agonist treatment, counselling patients, and assessing patients before witnessing or delegating the witnessing of doses to a pharmacy technician.



It is important to note that pharmacy assistants may be involved in the provision of opioid agonist treatment through the preparation of doses. However, they are not permitted to witness observed doses.

Operational Requirements

The permit holder and managing pharmacist must ensure that the pharmacy operated under the permit issued by the PEI College of Pharmacy has the appropriate staffing, layout, security, and operating hours to ensure safe delivery of opioid agonist treatment.

Pharmacy Layout and Design

The pharmacy should be designed to allow for all pharmacist-patient discussions, witnessed doses and the provision of take-home doses to take place in a patient care environment that ensures privacy and confidentiality and that is clean and safe. The pharmacy must have an area where opioid agonist doses, in particular, methadone, can be prepared away from high traffic areas and free from distractions.

Pharmacy Registration

Managing pharmacists will ensure that the PEI College of Pharmacy is aware that their pharmacy is participating in the provision of medication for the treatment of opioid use disorder.

Pharmacy Hours

When a patient is prescribed daily witnessed ingestion of opioid agonist treatment, they should attend a pharmacy that is open every day of the week. Pharmacies that do not typically operate seven days a week must ensure that arrangements are made to enable the patient to access their medication on days the pharmacy is closed.

Security

All controlled drugs and substances, including preparations containing methadone and buprenorphine/naloxone should be stored in a locked and secure location. This includes prepared doses waiting to be released to a patient and refrigerated doses.

Staff Education

The managing pharmacist is responsible for ensuring that all staff in the pharmacy understand the scope of their role in the provision of medications for the treatment of opioid use disorder and have policies and procedures in place that clearly set out these responsibilities.



Staff Resources

The permit holder and managing pharmacist are responsible for ensuring that appropriate references are available for staff who providing opioid agonist treatment services, which may include access to clinical practice guidelines.

Provision of Therapy

While there are other forms of OAT that pharmacy professionals may dispense or recommend, **this section will focus on methadone due to its unique preparation and storage requirements.**

Methadone Solution

Pharmacists must use a commercially available 10mg/mL methadone solution when preparing individual patient doses because of:

- enhanced patient safety (fewer steps to be potentially impacted by human error);
- enhanced stability of commercial product; and
- the requirements of federal legislation governing manufacturing.

Compounded methadone solution may only be used in cases of drug shortage where no Health Canada-approved product is available, or where a clinical reason, such as an allergy to a component of the commercially available product, exists.

Dispensing Equipment

Methadone doses must be prepared with a calibrated device that minimizes the measurement error rate to no greater than 0.1 ml. Devices must be used solely to prepare methadone and should be clearly labeled with “methadone only.” Graduated cylinders are not acceptable for preparing methadone.

Pharmacy professionals must ensure that the manufacturer’s instructions for the use of measuring devices are followed. This includes proper use, cleaning, maintenance, and storage of the device and associated equipment or software. Any required device calibration or quality control processes used to monitor the integrity of the device must be documented in a readily retrievable manner.

Preparing Witnessed and Take-Home Doses

Methadone



1. Calculations for the preparation of the patient's dose must be completed by a pharmacy professional. It is preferable if these calculations are checked using an independent calculation performed by another pharmacist or pharmacy technician.
2. The final dosage volume for each individual dose must not be less than 100 ml, both for on-site consumption and for take-home doses. This volume is sufficiently large to ensure the dose is not retained in the mouth and diverted. A consistent volume also enables patients to easily identify unanticipated changes in the taste of their solution.
3. All individual patient doses must be bottled separately in 100 mL light-resistant childproof bottles.
4. If individual patient doses are prepared in advance of being processed for dispensing, they must be clearly labelled with at least:
 - a. strength and quantity of methadone (i.e. methadone 8 mg in 100 mL of diluent);
 - b. prepared date/expiry date and;
 - c. initials of preparing pharmacy staff.

Storage and Stability

When storing individual doses of methadone, pharmacists must consider the following:

- The stability of commercially available methadone solution;
- Whether the individual doses have been diluted;
- The date the individual dose was prepared.

Releasing the OAT Prescription

Providing Witnessed Doses

The pharmacist is required to assess the patient prior to the ingestion of the dose. This function may not be delegated to a pharmacy technician or any other member of the pharmacy staff.

Prior to releasing the witnessed dose to the patient, the pharmacist must:

- Positively identify the patient. If uncertain as to the patient's identity, photo identification must be requested.
- Assess the patient for signs of intoxication or sedation. If it is determined that there are conditions under which providing a dose to the patient could place the patient at risk, it is advisable to withhold the dose. If such a determination is made, the primary care provider must be notified immediately (see sample [Appendix: Opioid Agonist Treatment Prescriber Fax Notification Form](#)).



- Review the patient's profile and administration log for notes, missed doses, documentation of returned bottles (if applicable), or any other applicable information.
- Counsel the patient appropriately.

Once the pharmacist determines that it is appropriate to release the witnessed dose, the pharmacist or a pharmacy technician must:

- Directly observe the patient ingesting the medication;
- Engage the patient in brief conversation to ensure the entire dose has been swallowed; and
- Appropriately document the dose on the Administration Log ([Appendix E: Patient Daily OAT Witness Ingestion and Carry Log](#)).

Providing Take-Home Doses

When providing take-home doses to the patient, the pharmacist must:

- Positively identify the patient. If uncertain as to the patient's identity, photo identification must be requested.
- Review the patient's profile and administration log for notes, missed doses, documentation of returned bottles (if required by the primary care provider), or any other applicable information.
- Counsel the patient appropriately.
- Appropriately document the provision of the take-home doses on the Administration Log.

It is important that patient take-home doses are safely secured while being transported from the pharmacy and stored within the patient's home. The patient's primary care provider or the treatment program where the patient receives care may require them to bring a locked box with them in which to place their take-home doses. Alternatively, the pharmacist may require that the patient pick up, transport to and from the pharmacy, and store their take-home doses in a locked box or secured container if the pharmacist determines, based on patient specific factors, that it is necessary for safety reasons.



Appendix A: Opioid Agonist Treatment Prescriber Fax Notification Form

To: _____
Prescriber _____ Fax # _____

Date: _____

RE: _____
Patient Name _____ PEI Health Card _____

From: _____
Pharmacy Name _____ Pharmacist _____

Phone # _____ Fax # _____

Type of Incident

- ☐ The patient missed dose on (date): _____
- ☐ The patient vomited a dose on (date): _____
- ☐ The patient reported a lost or stolen take-home dose on (date): _____
- ☐ The patient was refused a dose on (date): _____
because they presented at the pharmacy in an intoxicated or sedated state.

Additional Details:

Follow-up Plan:



Appendix B: Patient Daily OAT Witnessed Ingestion and Take-Home Dose Log

Patient: _____

Prescriber: _____

Date	Rx#	Dose (mg consumed)	# of take-home bottles/tablets given	# of take-home doses/tablets returned	Patient signature	Pharmacist signature

This log must be maintained as part of the patient record.

If the patient does not arrive for their witnessed ingestion or take-home doses, if the patient vomits their dose, refuses their dose, or consumes a portion of their dose it must be noted on this log.