



PRINCE EDWARD ISLAND
COLLEGE OF PHARMACY

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Introduction

The primary goal of the *Opioid Agonist Maintenance Treatment: Practice Standards for Community Pharmacies* document is to enhance the safety, consistency, and effectiveness of the opioid agonist maintenance treatment (OAMT) services provided by community pharmacies in Prince Edward Island, contributing to improved patient and societal outcomes.

Scope

The *Opioid Agonist Treatment Practice Directive: Practice Standards for Community Pharmacies* provide 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 pharmacists.



Professional Requirements

Extended Practice Authorization - Pharmacists

All pharmacists (General, Special, Provisional) who are involved in dispensing methadone or buprenorphine/naloxone for the treatment of opioid use disorder must apply for an Extended Practice Authorization (EPA) from the PEI College of Pharmacy. Dispense in the context of the legislation includes the following activities:

- assessing the pharmaceutical and therapeutic suitability of the drug for its intended use;
- assessing the patient, the patient's health history and the patient's medication record;
- preparing, packaging and labelling a drug;
- providing the drug to the patient or a representative of the patient;
- counselling the patient or a representative of the patient on the use of a drug.

To apply for an EPA in Dispensing Opioid Agonist Treatment, pharmacists must complete the following:

- a) Complete and submit the EPA application in the registrant portal.
- b) Provide proof of successful completion of either the Centre for Addiction and Mental Health (CAMH) *Opioid Use Disorder Treatment (OUDT)* course or the *Optimizing Opioid Dependence Treatment* in PEI online course through Dalhousie Continuing Pharmacy Education.

Professional Roles and Responsibilities

Expected Role of the Pharmacist

Before engaging in the provision of OAMT 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 physician (for example: missed/lost doses, patient behaviour, treatment plan changes) and recommending treatment suggestions primary care providers.

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 use disorder 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 pharmacy manager 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

Pharmacy managers 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.

Options include:

- opening at selected pre-scheduled times on the day(s) the pharmacy is closed to provide service to patients who require witnessed daily doses,
- discussing with the patient and prescribers the option of take-home doses (if appropriate for the patient) on days the pharmacy is closed, or
- collaborating with the patient, prescribers, and another pharmacy to arrange witnessed dosing at a secondary pharmacy on days that the primary pharmacy is closed

Security

The security of the pharmacy should address the potential risks associated with the provision of medication for the treatment of opioid use disorder and the risks to the community that can result from theft of opioid agonist treatment. As with other controlled drugs and substances, preparations containing methadone and buprenorphine/naloxone should always be stored in a locked and secure location, including prepared doses waiting to be released to a patient, including refrigerated doses.

Staff Education

The pharmacy manager is responsible for ensuring that all pharmacists hold an Extended Practice Authorization in Dispensing Opioid Agonist Treatment prior to engaging in dispensing. The pharmacy manager is also 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 pharmacy manager 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

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;
- the expectation that large volume production is undertaken under the requirements of federal legislation governing manufacturing.

Compounded methadone solution may only be dispensed in cases of drug shortage where no Health Canada-approved product is available, or where a clinical reason, such 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.

Pharmacists and pharmacy technicians 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 pharmacist or pharmacy technician. It is preferable if these calculations are checked using an independent calculation performed by another pharmacist or pharmacy technician.



3. 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. For example, a dosage of 80 mg requires 8ml of a 10 mg/ml solution. Enough diluent is then added to make a final volume of 100ml. 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.
4. All individual patient doses will be bottled separately in 100 mL amber childproof bottles.
5. 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 pharmacist.

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 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 team.

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 in which providing a dose to the patient could place the patient at risk for harm, 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 Maintenance 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 (for complete patient counselling information, see the relevant product monograph).

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 should 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: Opioid Agonist Maintenance 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:
