



DISCLAIMER: This Policy has been replaced by the **Opioid Policy (December 2018)** and is only available for reference purposes until December 2019.

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Methadone Maintenance Treatment (MMT) and Dispensing Policy

POLICY

Published: September 2010

Revised: June 2014

Legislative References:

- Drug and Pharmacies Regulation Act R.S.O. 1990, c.H.4
- Narcotics Safety and Awareness Act, 2010, SO 2010, c22
- Controlled Drugs and Substances Act, S.C., 1996, c. 19

Additional References:

- College of Physicians and Surgeons of Ontario
 - Methadone Maintenance Treatment (MMT) for Opioid Dependence
 - MMT Program Standards and Clinical Guidelines
- Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorder (CAMH)

College Contact: Pharmacy Practice

Update May 19, 2018 - *Practitioners no longer need a Section 56 exemption to prescribe methadone. See details [here](#). Therefore, pharmacists are no longer required to verify that the prescriber (physician, nurse practitioner) has an exemption from Health Canada. **All other parts of the policy still apply.***

Introduction

This policy applies to members participating in methadone maintenance treatment (MMT) programs and who employ any of the models of dispensing methadone for MMT. The policy takes into account the introduction of a manufactured product (2014) indicated for the treatment of opioid dependence. An appendix is attached which addresses methadone dispensing for pain management.

Background

The College recognizes MMT as an effective form of treatment for opioid dependence and is committed to ensuring that Ontarians receive this treatment in a safe manner. The best MMT programs are done in partnership recognizing the unique role of the patient, physician, pharmacist and other health care providers in ensuring patient and public safety.

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Background *(continued from previous page)*

Methadone for the treatment of opioid dependence is regulated by Health Canada in partnership with the Ministry of Health and Long Term Care, the College of Physicians and Surgeons of Ontario (CPSO) and the Ontario College of Pharmacists (OCP).

Physicians who wish to prescribe methadone must apply through Health Canada for exemption under section 56 of the Controlled Drugs and Substances Act (CDSA). Exemptions can apply to either methadone maintenance treatment (MMT) for opioid dependence or to the treatment of malignant and chronic non-malignant pain.

Physicians who wish to provide methadone for both MMT and pain must obtain separate exemptions. Physicians may also seek authorization through CPSO to delegate the administration component of MMT in a medical office or clinic to qualified health care professionals under a "delegation exemption".

Methadone is dispensed according to the principles and guidelines established by the Centre for Addiction and Mental Health. Pharmacists in an accredited pharmacy are permitted to dispense methadone in individually labelled and fully diluted daily doses for the treatment of opioid dependence pursuant to a written prescription from an exempted physician. In order to enable the administration of methadone in a medical office or clinic, Health Canada has issued an exemption allowing pharmacists in Ontario to transfer custody of such doses, in a secure manner, to a physician or their delegate at the treatment location according to the policies and guidelines developed by both CPSO and OCP.

Pharmacists are reminded that it is not permissible to compound a commercially available product as per the Health Canada Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051).

Principles

Both OCP and CPSO concur with the following:

1. The ideal model for methadone maintenance treatment is one which supports the integration of the patient, physician and pharmacist within the community to ensure the availability of local and accessible solutions for patients requiring methadone maintenance treatment for opioid dependence.
2. The pharmacist practices in accordance with the provisions of the Drug and Pharmacies Regulations Act (DPRA), Narcotics Safety and Awareness Act, Standards of Practice, Code of Ethics, OCP policies and guidelines, and federal legislation, in particular the CDSA and the Narcotic Control Regulations.
3. The physician practices in accordance with CPSO policies and guidelines and meets the requirements of other relevant legislation for the prescribing, dispensing and storage of methadone in Ontario.
4. The pharmacist and the physician play an important and complimentary role in the interdisciplinary model of methadone maintenance treatment. This includes joint development of written policies and procedures to ensure continuity of patient care and secure custody and storage of methadone.
5. According to the Narcotic Control Regulations, the pharmacist, physician and his/her delegate must take all reasonable steps necessary to protect any quantities of methadone on the premises or under their control against loss or theft. When dispensing methadone, pharmacists are responsible for the safety and integrity of the drug until such time as they have dispensed directly to the patient or transferred its custody to an exempted physician or his/her delegate. When the provision of methadone has been entrusted to a delegate, the accountability and responsibility for the administration of methadone doses continues to rest with the physician.

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Principles *(continued from previous page)*

6. The role of the pharmacist is to optimize the patient's drug therapy and establish a therapeutic pharmacist-patient relationship with all patients for whom s/he dispenses drugs. The pharmacist must be responsive to prescribed changes in the patient's methadone treatment and able to provide methadone in a timely manner.
7. The Designated Manager (DM) and all pharmacy staff employ the same respectful, professional approaches and attitudes towards MMT patients as they would toward any other patient of the pharmacy.

Models for Dispensing Methadone to Patients for the Treatment of Opioid Dependence

The pharmacist prepares individually labelled doses of methadone using a manufactured product (10 mg/mL solution) pursuant to a prescription and diluted to 100mL of a vehicle which does not lend itself to injection (e.g. Tang®) and then the pharmacist either:

1. Dispenses to patients in a pharmacy accredited by OCP pursuant to the DPRA;
2. Transfers doses in a secure manner to a physician or his/her delegate for custody of and administration to patients; or
3. Takes the doses to the patient at the treatment location and observes the ingestion by the patient.

For the purposes of dispensing methadone in a pharmacy, the pharmacy may be physically located in the treatment location. If the pharmacy is not open seven days a week, pharmacists may open the pharmacy for a restricted time or collaborate with a hospital or another pharmacy to provide weekend access to patients requiring daily doses

Collaboration and Seamless Care

Collaboration and regular communication between pharmacists and prescribers and other members of the MMT team have an important positive impact on patient care and safety. In order to ensure safe and uninterrupted treatment, pharmacists must communicate and collaborate intra-professionally with other pharmacists during their patients' transitions into or out of institutions and when patients change pharmacies.

Patient Agreement

A pharmacy – patient agreement is required for patients treated for MMT. Templates may be found in "Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorder" from the Centre for Addiction and Mental Health (CAMH). Issues to be addressed in agreement may include:

- Expectations of all parties (i.e. pharmacy/clinic hours of operation, consequences of inappropriate behaviour of patient);
- Patient's consent to access and share personal health information with other health professionals involved in their care;
- Notice to the patient that methadone dose will be withheld if the patient appears to be intoxicated or under the influence of other substances;
- Patient's consent to provide identification, if requested, when picking up their medication; and
- Notice to the patient that missed, lost, stolen or wasted doses will not be replaced without a prescription.

The agreement should be in place for the duration of treatment unless circumstances require a re-evaluation of the document. The agreement must be re-signed where a pharmacy makes substantial changes to policies or procedures regarding methadone.

Requirements for Dispensing Methadone in a Pharmacy

1. Written Prescription for Methadone

A prescription written by an exempted prescriber is required. The Office of Controlled Substances (Health Canada) may be contacted to confirm that the prescriber has the appropriate methadone exemption (i.e. MMT or pain).

2. Preparation of Methadone

The methadone is prepared in a manner and form required for dispensing to a patient in accordance with the:

- CAMH Guide: "Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorder";
- Prescriber's instructions;
- Standards of Practice;
- Drug and Pharmacies Regulations Act and Regulations; and
- Narcotic Control Regulations.

2.1 Preparation of Final Dosage Form

Daily doses of methadone (drink and carries) must be prepared using a manufactured product (10 mg/mL solution) diluted to 100 mL of a vehicle that does not lend itself to injection such as orange flavoured Tang® or another suitable drink.

Methadone doses must be accurately measured using a device that is able to deliver 0.1mL increments. The reliability of graduated cylinders can vary significantly and such devices are not suitable for accurate dose measurement.

Methadone solution for carries must be dispensed with child-proof safety caps.

2.2 Labelling

Labels on all dispensed methadone must be in accordance with the DPRA, section 156. In addition the label of each unit dose of methadone, i.e. drink or carry, must include:

- The total dose in mg of methadone contained in the bottle;
- A notation: "Drink entire contents of bottle";
- The date for ingestion for carries;
- "Keep refrigerated" auxiliary label for carries; and one of the following auxiliary labels must be used:
 - Methadone may cause serious harm to someone other than the intended patient. Not to be used by anyone other than the patient for whom it was intended. MAY BE FATAL TO CHILD OR ADULT.
 - Methadone may cause serious harm to someone other than the intended patient. MAY BE FATAL TO CHILD OR ADULT.

3. Transferring Custody

When pharmacists transfer custody of individually labelled doses of methadone, to a physician or his/her delegate, the physician or delegate must sign the patient manifest on a daily basis to confirm that they have received each correct dose.

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3. Transferring Custody *(continued from previous page)*

Pharmacists must either directly hand the doses of methadone to the physician or his/her delegate, or use a method of transportation that ensures they are aware of and can track who has had custody of the drug at any given time to ensure safekeeping of the methadone while in transit (i.e. a chain-of-signatures and tamper proof boxes). All methadone must be transported in an accountable and secure manner, as described above, and in such a manner as to avoid extremes in temperature or delays in transport which could compromise the drug.

4. Administration of Methadone Dose

Refer to CAMH Guide: "Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorder"

In all instances, the patient must be positively identified prior to observing the ingestion of methadone. After the daily dose of methadone is prepared, the pharmacist does one of the following:

- Observes the ingestion by the patient in the pharmacy; Observes the ingestion of the first dose of the maintenance prescription by the patient in the pharmacy and provides authorized carries to the patient;
 - Takes the dose to the patient and observes the ingestion of the dose; or
 - Takes the doses to the patient and observes the ingestion of the first dose of the maintenance prescription by the patient and provides authorized carries.
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5. Documentation

The observation of methadone ingestion is documented daily in the patient record so that it can be determined where each dose of methadone went, for both patient care and auditing purposes. Documentation of methadone ingestion must include the patient's name, daily dose, date, time and place where the administration was observed. When a physician or delegate administers the methadone, the dispensing pharmacist must be provided with copies of such records daily.

All documentation pertaining to methadone must provide an audit trail and be readily retrievable.

6. Changes in Dosing

Any new doses or changes of methadone dose require a new prescription.

7. Unused Doses of Methadone

Unused individually labelled doses of methadone:

- Remain in the pharmacy and are managed in accordance with applicable laws, standards of practice, and OCP policy (where the patient did not attend the pharmacy for his dose, or where the patient was refused the dose because of safety concerns); or
 - Are returned to the pharmacy by the physician or his/her delegate, preferably on a daily basis, signed for upon receipt, entered into the appropriate record, and destroyed in the pharmacy in accordance with applicable laws, standards of practice and OCP policy.
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8. Daily Reconciliation (pertains to transfer of custody only)

A daily reconciliation of the methadone dispensed to and received from a treatment location is conducted in such a manner that would allow for immediate detection of any losses or diverted quantities.

9. Maintaining Patient Confidentiality and Privacy

Patient administration of methadone in a pharmacy must be done in an area and manner which ensures patient confidentiality and privacy.

Exceptional Dispensing of a Compounded Product

Compounding is permitted in the event of a therapeutic need or lack of product availability and must be completed according to the OCP Guidelines for Compounding Preparations. In the event that, pursuant to a prescription, a patient requires a concentration of methadone that is less than that provided by the manufactured product (10 mg/mL solution) or where a patient is unable to tolerate the commercially manufactured product, the pharmacist is permitted to compound a solution at the required concentration for that patient.

Institutional Services

Institutional deliveries are not considered transfers of custody and should be treated similarly to any narcotic delivery, i.e. auditable and traceable. In those instances where a pharmacy provides methadone services to institutions such as long term care facilities, correctional institutions, or hospitals, specific policies and procedures are to be established by the institution. At a minimum, the pharmacy should be assured that the institution has established policies which outline the secure handing and safe administration of methadone doses.

Reporting to the College

The owner/designated manager of a pharmacy that dispenses methadone must provide the College with the following information within seven days using the approved form:

- Notification of the intention to dispense methadone;
 - Whether they are accepting new patients;
 - The names of pharmacists who are trained to dispense methadone;
 - Hours of operation and days of the week the pharmacy is open, including holidays;
 - Whether they are preparing methadone doses for the transfer of custody; and
 - Any changes in this status.
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Education and Training

Pharmacists dispensing methadone must be familiar with the principles and guidelines outlined in both the CAMH publication, Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorder and the CPSO Methadone Maintenance Treatment Program Standards and Clinical Guidelines. The DM must be trained in methadone via the CAMH Opioid Dependence Treatment Course (ODT Core Course or equivalent course) or approved course within six months of beginning a methadone practice.

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Education and Training *(continued from previous page)*

In addition to the DM, within one year, at least one staff pharmacist must complete these training requirements. Training must be updated at a minimum of every 5 years. Ideally all pharmacists providing methadone services should participate in educational training in MMT. It is the DM's responsibility to inform all pharmacists working in a pharmacy, including relief and casual pharmacists, if that pharmacy provides methadone services.

Required References

Pharmacies dispensing methadone for MMT must maintain as a required reference the most recent edition of:

- Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorder (CAMH)
- Methadone Maintenance Treatment: Program Standards and Clinical Guidelines (CPSO)
- Methadone Maintenance Treatment for Opioid Dependence (CPSO)

Other References

- The 2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain
- OCP: Methadone and Buprenorphine Practice Tools
- Fact Sheet: Key Requirements for Methadone Dispensing

Appendix

Methadone Dispensing for Pain Management

Methadone may also be dispensed for pain management in patients. Although, there is no formal training (i.e. CAMH, ODT certification) required for dispensing methadone for pain, pharmacists need to be aware of the requirements regarding methadone. Pharmacists are expected to be familiar with the current Methadone Maintenance Treatment: Program Standards and Clinical Guidelines from CPSO. Pharmacists in all practice settings shall verify whether a prescriber holds an exemption to prescribe methadone for either MMT, Pain, or both.

The owner/designated manager of a pharmacy that dispenses methadone for either MMT or Pain shall inform the College within seven days.

With the exception of the differences outlined below, the same principles and policies apply to the documentation, dispensing, administration and labelling of methadone for both MMT and Pain management.

- Methadone may be dispensed using manufactured products (liquid or tablets) rather than diluted in flavoured drink. Observed doses usually will not be necessary and to facilitate self administration, the pharmacist will provide the patient with appropriate measuring device (i.e. oral syringe) with capacity and accuracy to deliver prescribed doses and provide instructions on the use of such devices.
- Labels shall include directions for the frequency of the dosing as prescribed
- In the exceptional cases where a compounded product is dispensed, pharmacist shall label with expiry date and concentration.

Required Reference

- CPSO Methadone Maintenance Treatment: Program Standards and Clinical Guidelines

Other References

- The 2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain