



# Methadone Maintenance Treatment for Opioid Dependence

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- COLLEGE CONTACT:** Public and Physician Advisory Service

# Methadone Maintenance Treatment for Opioid Dependence

## DEFINITIONS

**Methadone maintenance treatment:** The daily oral administration of methadone over a prolonged period as an oral substitute for heroin or other morphine-like drugs for patients who are dependent on or addicted to these drugs.

**Methadone exemption:** Methadone is a controlled drug under the *Controlled Drugs and Substances Act*, S.C. 1996, c. 16. Physicians who wish to provide methadone to their patients must obtain a special exemption from Health Canada. The exemption can apply to either methadone maintenance treatment for opioid dependence, or to the treatment of malignant and chronic non-malignant pain. Physicians who wish to provide methadone for both methadone maintenance treatment and pain must obtain separate exemptions.

Physicians who possess an exemption for methadone maintenance treatment may apply to the College of Physicians and Surgeons of Ontario for additional permission to delegate authority for the administration component of methadone maintenance treatment to other properly qualified health-care professionals.

**Methadone administration:** The provision of a dose of methadone to a patient for consumption by the patient under direct observation in a medical office or clinic, or for delayed consumption by the patient (in the form of take-home or carry doses) for the treatment of opioid dependence.

**Properly qualified health-care professional:** In the context of this policy, these are regulated health-care professionals other than physicians who possess the appropriate knowledge, skill and judgment needed to safely administer methadone to patients, and who meet the additional minimum requirements set out in this policy.

## BACKGROUND

Methadone maintenance treatment is an effective treatment for opioid dependence. In the interest of ensuring that methadone maintenance treatment is delivered in a safe and consistent manner, it is regulated by Health Canada through the *Controlled Drugs and Substances Act*, S.C. 1996, c. 16 (*CDSA*), in partnership with the province of Ontario, the College of Physicians and Surgeons of Ontario (CPSO) and the Ontario College of Pharmacists (OCP). Physicians who wish to provide methadone maintenance treatment must obtain a general methadone maintenance treatment exemption from Health Canada under section 56 of the *CDSA*. The general exemption permits physicians to prescribe, administer or sell methadone. The general exemption also permits the dispensing of methadone subject to conditions and limitations, as set out in this policy.

Physicians in possession of the general exemption may apply to the CPSO for a “delegation exemption”, which grants physicians permission to delegate authority for the administration component of methadone maintenance treatment to other properly qualified health-care professionals. This is intended to improve access to care.

In 2007, the CPSO and the OCP developed the Framework for the Implementation of the New “Delegation” Exemption: Safety, Security and Transfer of Methadone Doses, which sets out expectations for delegating authority for methadone administration pursuant to a “delegation exemption”. That document was intended to complement the CPSO’s Methadone Administration in the Treatment of Opioid Dependence policy. The present policy replaces both of those documents. In addition to this policy, physicians should consult the Methadone Maintenance Guidelines for further information.



## PURPOSE

This policy articulates the CPSO's expectations of physicians who provide methadone maintenance treatment, including expectations for delegating the authority for methadone administration to other properly qualified health-care professionals.

## SCOPE

This policy applies to physicians who, pursuant to a methadone maintenance treatment exemption under section 56 of the *CDSA*, deliver methadone maintenance treatment in medical offices or clinics outside a pharmacy. It also applies to physicians who, pursuant to a "delegation exemption" delegate authority for methadone administration to other properly qualified health-care professionals.

## PRINCIPLES

1. Physicians should always act in patients' best interests to deliver safe and effective care.
2. Physicians should carry out methadone maintenance treatment in an appropriate manner. This includes following statutory provisions designed to ensure patient safety and clinical efficacy.
3. Physicians should collaborate with other health-care professionals as a means of delivering and increasing access to safe and effective care.
4. Physicians are accountable for other health-care professionals to whom they delegate aspects of treatment. Physicians should ensure that their delegates are properly qualified to deliver safe and effective care.

## POLICY

### 1. Qualifications for the Delivery of Methadone Maintenance Treatment

Physicians may only deliver methadone maintenance treatment if they have obtained a general exemption for methadone maintenance treatment from Health Canada pursuant to Section 56 of the *CDSA*. Absent the additional "delegation exemption", physicians with the general exemption cannot delegate the administration of methadone to other qualified health-care professionals. More information about delegation appears in subsection 7 – "Delegating Authority for Methadone Administration" and subsection 8 – "Properly Qualified Health-care Professionals" of this policy.

### 2. Prescription

Any new dose or change of dose of methadone requires a new prescription and must be dispensed by a pharmacist. Once dispensed by the pharmacist, a physician must not alter individually labelled doses.

In certain rare circumstances, a physician may dispense a dose of methadone, subject to the conditions and limitations outlined in subsection 6 – "Dispensing" below.

### 3. Administration

Physicians must follow the requirements for methadone administration outlined in the current CPSO Methadone Maintenance Guidelines, as well as those in this policy.

When administering methadone for methadone maintenance treatment, physicians must:

- Ensure that methadone is administered to their patients in the dose and manner that has been prescribed.

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- Witness doses provided for immediate consumption.
- Confirm the patient's identity prior to administering doses for observed consumption or for providing carries in order to ensure that the methadone is given to the correct individual. The physician should also verbally confirm the expected dose with the patient.

Information about delegating authority for administering methadone appears in subsection 7 – “Delegating Authority for Methadone Administration” and subsection 8 – “Properly Qualified Health-care Professionals” of this policy.

## 4. Responsibility for Doses

Under the OCP's Policy for Dispensing Methadone, a pharmacist is responsible for the safety and integrity of methadone until such time as he or she has dispensed directly to the patient or transferred custody of the methadone to an exempted physician or his or her delegate.

### Transportation and Transfer of Custody

OCP policy requires a pharmacist to transfer custody of the individually labelled doses of methadone dispensed pursuant to a prescription in a secure, tamper-proof manner to a physician who signs that he or she has received each correct dose on a daily basis on a patient manifest. The pharmacist must either directly hand the doses of methadone to the physician or his or her delegate, or use a method of transportation that ensures that he or she is aware of and tracks 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 such a manner as to avoid extremes in temperature or delays in transport which could compromise the drug.

Only the physician or his or her delegate may accept delivery of methadone doses. The physician who accepts the methadone must sign that he or she has received and has accepted custody of each dose. A record of the transfer of each dose must be maintained.

Once the physician has accepted custody of the methadone, the physician assumes responsibility for the safety and security of those methadone doses. The physician maintains responsibility and is fully accountable for all doses until provided to the patient for observed consumption, or as a carry. If a dose is unused, the physician maintains responsibility and is fully accountable until the dose is returned to the pharmacy.

### Destruction of Unused or Unserviceable Doses

All unused or unserviceable doses must be returned to the dispensing pharmacy for destruction on a daily basis. These doses must be transferred in a secure manner in accordance with the guidelines for transportation and custody set out above. Once the pharmacist accepts custody of the unused or partially used doses, the pharmacist is responsible for the safety, security and destruction of those doses.

### Safe and Secure Storage

Under section 55(f) of the federal Narcotic Control Regulations, physicians must take “adequate steps” to protect any quantities of methadone on the premises or under their control against theft or loss. The term “adequate” is not defined in the Narcotic Control Regulations, C.R.C., c. 1041. The CPSO is unable to offer advice on how this term may be interpreted. It is, however, the expectation of the CPSO that physicians will ensure that all methadone doses are stored in a locked cabinet or refrigerator in a secure area within the physician's office or clinic. Further, as required under



s. 55(d) of the Narcotic Control Regulations, physicians must permit an inspector to check all stocks of narcotics in their office or clinic.

### **Reconciling Doses and Accounting for Lost or Stolen Doses**

The physician or his or her delegate must conduct a daily reconciliation of doses received, administered and returned to the pharmacy. Preferably, this will occur both before the first dose and after the last dose for that day have been administered. Any loss of methadone (stolen or spilled) must be reported within 10 days of its discovery to the Compliance Monitoring Liaison Division, Office of Controlled Substances, by calling 613-954-1541, as required by section 55(g) of the Narcotic Control Regulations.

## **5. Documentation**

Maintenance of accurate and complete medical records is a crucial component of methadone maintenance treatment. For general documentation requirements, physicians should refer to the CPSO's Medical Records policy.

Documentation requirements specific to methadone maintenance treatment are as follows:

- The patient's informed consent to methadone maintenance treatment.
  - The patient's name, daily dose, and time and place where administration was observed.
  - Results of assessment prior to methadone administration, including, where applicable, signs of intoxication, observed abnormal behaviour, and symptoms of over-medication with methadone.
  - Record of urine sample, if provided, and results.
  - The name of the health-care professional administering the dose.
- Sign-off of drink and/or carry doses, including the date and time when methadone was given.
  - Missed doses, including refusal and vomiting of doses.
  - Partial doses taken.
  - Lost or stolen carry doses.
  - Suspected diversion of doses.
  - Guest dosing arrangements.
  - Other prescribed medications that may interfere with methadone.

In addition to the foregoing, section 69 of the Narcotic Control Regulations requires physicians to keep and retain for a period of two years from the date of the making of the record, a record of:

- the date and quantity of methadone received;
- the name and address of the person from whom the methadone was received; and
- the particulars of the use to which the methadone was put.

Section 69 of the Narcotic Control Regulations also requires that physicians provide access to these records, as well as furnish any information respecting methadone as may be required by the federal Minister of Health.

Physicians must also ensure that all dosing information is provided to the pharmacy to ensure accuracy and completeness of patient history. This should be done with the consent of the patient.

Where a physician delegates authority for methadone administration to other properly qualified health-care professionals, the physician must ensure that the patient consents to the delegation. This consent should be obtained and recorded each time methadone is administered by the delegate. The physician should also document the delegate's qualifications and training.

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## 6. Dispensing

Dispensing methadone is typically done by a pharmacist. However, Health Canada recognizes that in certain rare circumstances, it may be appropriate for a physician to dispense methadone. These rare circumstances are those wherein the physician determines it is necessary to dispense methadone due to a risk of withdrawal or overdose, and no pharmacist is able to provide the necessary dose in a period of time which would not compromise patient safety. For example, it may be appropriate for the physician to dispense methadone when a patient has already missed three or more consecutive days of dosing and requires stabilization to prevent further withdrawal, or when a patient has vomited a dose under direct observation, particularly in the case of pregnant patients where withdrawal may compromise the well-being of the fetus. Methadone for induction would not be viewed as a rare circumstance.

A physician who dispenses methadone in appropriate rare circumstances must do so in accordance with the requirements set out in the *Drug and Pharmacies Regulation Act*, R.S.O. 1990, c.H.4, this policy and the CPSO's Dispensing Drugs policy. Additional guidance can be found in the OCP's Policy for Dispensing Methadone.<sup>1</sup>

Pre-measured doses of methadone must be purchased from an accredited pharmacy and mixed by the physician with the appropriate diluent (e.g., Tang beverage) prior to ingestion.

When dispensing methadone in appropriate rare circumstances, the physician must only administer one dose. The physician must then immediately report to the

pharmacy or clinic where the patient usually received methadone and ensure that the necessary arrangements are made for subsequent doses to be administered at the pharmacy.

## 7. Delegating Authority for Methadone Administration

Only a physician who possesses the “delegation exemption” is permitted to delegate authority for methadone administration to other properly qualified health-care professionals under his or her control. Methadone administration is the only component of methadone maintenance treatment that may be delegated. Authority for prescribing, dispensing and selling methadone cannot be delegated.

Where a physician delegates authority for methadone administration, the physician must adhere to the direction set out in the CPSO's Delegation of Controlled Acts policy and this policy.

Accountability and responsibility for methadone administration rests with the physician at all times. The physician must ensure that if he or she delegates authority for methadone administration to other properly qualified health-care professionals, he or she must ensure that those delegates have the knowledge, skill and judgment to do so. This includes taking reasonable steps to ensure that delegates understand and comply with office or clinic policies and procedures regarding methadone administration. The physician must also provide the level of supervision necessary to ensure that delegates administer methadone safely and effectively.

Office/clinic policies and procedures for methadone

1. <http://www.ocpinfo.com/client/ocp/OCPhome.nsf/web/Policy+for+Dispensing+Methadone>.



administration must be accessible at all times and must clearly state that individuals administering methadone are charged with the following responsibilities:

- i. To administer methadone only when the patients does not exhibit any signs of sedation or intoxication.
  - ii. Where direct observation is prescribed, to observe the patient consuming the methadone and ensure that the dose has been consumed.
  - iii. To administer methadone precisely as prescribed by the physician.
- ii. Have successfully completed the Methadone Treatment Workshop at the Centre for Addiction and Mental Health or equivalent training approved by the CPSO in the safe and appropriate administration of methadone.
  - iii. Have demonstrated to the satisfaction of the physician an understanding of methadone maintenance treatment, including the risks associated with it.

## 8. Properly Qualified Health-care Professionals

Properly qualified health-care professionals are those who possess the appropriate knowledge, skill and judgment needed to safely administer methadone to patients. The following are the minimum requirements that individuals must possess:

### Nurses

Individuals must:

- i. Be either a Registered Practical Nurse or a Registered Nurse, including a Registered Nurse in the Extended Class.
- ii. Have demonstrated to the satisfaction of the physician an understanding of methadone maintenance treatment, including the risks associated with it.

### Other Health-care Professionals

Individuals must:

- i. Be another health-care professional regulated under Ontario's *Regulated Health Professions Act*, 1991, SO. 1991, c. 18.

# METHADONE MAINTENANCE TREATMENT FOR OPIOID DEPENDENCE



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