

NEW

# POLICY FOR DISPENSING METHADONE



Larry Boggio, R.Ph., B.Sc.Pharm.  
Chair, Professional Practice Committee

## A NEED TO CREATE A METHADONE POLICY

Methadone dispensing for either methadone maintenance treatment (MMT) or pain management presents unique challenges for pharmacists and pharmacies.

Furthermore, much has happened since the College first published its 2002 *Methadone Maintenance Treatment Policy and Guidelines* for pharmacists dispensing or wishing to dispense methadone for the treatment of opioid dependence.

In 2004, the College of Physicians and Surgeons of Ontario published guidelines for methadone use for pain management. In its *Methadone for Pain Guidelines*, the CPSO outlines three types of patients requiring methadone for pain management. These guidelines were created to work alongside the CPSO's *Methadone Guidelines for Methadone Maintenance Treatment*.

## DRAFT POLICY REVIEW


In 2005, Council approved a draft policy for dispensing methadone that was published for pharmacist discussion and feedback. We received very helpful and specific responses from pharmacists who dispense methadone. The major changes in this policy include:

- Formalization of training requirements for pharmacists dispensing methadone
- Definitions of institutions
- Establishment of the concept of "clear provenance" in all documentation procedures

## ALL PHARMACISTS MUST NOW ADHERE TO THIS POLICY

Due to the complexities involved with methadone for pain management, which require a particular understanding of the condition and treatment protocols, all pharmacists dispensing methadone will now be required to adhere to the new methadone policy.

## NEW POLICY TO REPLACE GUIDELINES ON SEPTEMBER 1, 2006

The new *Policy for Dispensing Methadone*, on the following pages, replaces the 2002 MMT guidelines on September 1, 2006. 

# Policy for Dispensing Methadone

## PREAMBLE

The policy encompasses the dispensing of methadone for Methadone Maintenance Treatment (MMT) and Methadone for Pain (PAIN).

The pharmacist shall identify the indication for prescribing methadone. Patients treated with methadone for pain are categorized in the following three groups by the College of Physicians and Surgeons of Ontario (CPSO):

- 1. PAIN I:** Pain patients with no identified risk factors for addiction beyond that found in the general population.
- 2. PAIN II:** Pain patients with a past or active history of non-opioid drug or alcohol dependence.
- 3. PAIN III:** Pain patients with concurrent opioid addiction and their pain management should follow as closely as possible to MMT guidelines.

Where dispensing of methadone for MMT is addressed separately, it must be strictly adhered to. However, the treatment of patients categorized as either PAIN I or II may present unique clinical situations where, for individual patients, with appropriate documentation, practice may vary according to professional judgment. The treatment of PAIN III patients should follow as closely as possible to MMT policy.

Pharmacists are expected to be familiar with the current Methadone Guidelines from CPSO available on their website [www.cpso.on.ca](http://www.cpso.on.ca); also on the Ontario College of Pharmacists (OCP) website at [www.ocpinfo.com](http://www.ocpinfo.com).

Pharmacists in all practice settings shall verify whether a prescriber holds an exemption to prescribe methadone for either MMT or PAIN. A list of methadone prescribers that includes the expiry date of exemption is available to pharmacists from the Office of Controlled Substances (OCS), Health Canada. Pharmacists can verify a physician's prescribing exemption with the OCS and the CPSO. Temporary exemption to prescribe methadone may be requested from the OCS as described in the required reference, *Methadone Maintenance: a Pharmacist's Guide to Treatment* (CAMH), also known as the "CAMH Guidelines".

Pharmacists are expected to create institution-specific policy regarding methadone dispensing based on this policy. Institutions<sup>1</sup> include, but are not limited to, hospitals, licensed nursing homes and correctional facilities.

<sup>1</sup> An "institution" is defined as a facility that is licensed, approved or designated by a province in accordance with the laws of that province to provide care or treatment to persons or animals suffering from any form of disease or illness or is owned or operated by the Government of Canada or the government of a province and that provides health services.

## REPORTING TO THE COLLEGE

- The owner/designated manager of a pharmacy that dispenses methadone for either methadone maintenance treatment (MMT) or for pain (PAIN) shall inform the College within seven days:
  - of this practice
  - whether they are accepting new patients
  - of the names of pharmacists who are trained in the dispensing of methadone.
  - of changes in this status.
  - of hours of operation and days of the week the pharmacy is open, including holidays

## REQUIRED REFERENCES

- Pharmacies dispensing methadone for either MMT or PAIN shall maintain as a required reference the most recent edition of:
  - Methadone Maintenance: A Pharmacist's Guide to Treatment (CAMH)
  - Methadone for Pain Guidelines (CPSO)
  - Methadone Maintenance Guidelines (CPSO)

## PATIENT AGREEMENT

- For MMT & Pain III

A pharmacy-patient agreement is required for patients treated for MMT or Pain III. Agreements for patients treated for Pain I or Pain II are up to the pharmacist's discretion.

In addition, it is recommended that the physician and/or other health care providers be included in this agreement. The agreement:

- will outline the expectations of all parties.
- should be in place for the duration of treatment unless circumstances require a re-evaluation of the agreement.
- must be re-signed where a pharmacy makes substantial changes to policies or procedures regarding methadone
- will include consent to access and share personal health information with respect to methadone treatment.

It is expected that the Designated Manager will sign the agreement on behalf of the pharmacy. This may be delegated to another pharmacist where written policies and procedures are in place outlining the process for accepting new patients.

Where consent or an agreement may not be possible, (for example, due to a cognitive impairment or a unique clinical situation) pharmacists shall document the reasons for not obtaining a signed agreement.

## IDENTIFICATION OF PATIENT

- Prior to dispensing, the pharmacist shall positively identify each patient (may include photograph of patient) in the case of MMT & Pain III.
- In the case of patients categorized as PAIN I and II, where the methadone is provided to an agent, the pharmacist will document the identity of the agent.
- Where a pharmacy provides service to an institution, (e.g licensed nursing home, correctional institution, hospital), the pharmacist participates in the development of policies and procedures regarding the identification of and administration of methadone to the patient.

## COMPOUNDING AND DOCUMENTATION

- When preparing a stock solution a bulk-compounding log file shall be maintained:
  - This should include the date prepared, name (printed) and signature of the pharmacist responsible for preparing the stock solution, concentration, quantity and lot number of methadone used as well as final quantity of stock solution made.
  - A separate log file shall be maintained for each strength of stock solution.
  - The label on stock solution bottles shall be distinct and easily identified from other bottles and include the date of manufacture.

## DISPENSING AND ADMINISTRATION

- Daily doses of methadone (drink and carries) shall be diluted and dispensed in approximately 100 mL of a vehicle such as orange flavoured Tang® or other suitable drink that does not lend itself to injection.
- Where self administration is required, e.g. Pain I or Pain II, the pharmacists shall provide the patient with an appropriate measuring device (i.e. oral syringe) with the appropriate capacity and accuracy to deliver prescribed doses and provide instructions on the use of such devices.
- All methadone solution shall be dispensed with child-proof safety caps.
- A record of administration for MMT or Pain III patients shall be maintained. The cross-reference to stock solution used must be readily retrievable.
- All documentation pertaining to clear provenance must be readily retrievable. This includes but is not limited to, records of compounding, dispensing, administration, dates, storage conditions and handling.

## LABELLING

- Labels on all dispensed methadone shall be in accordance with the Drug and Pharmacies Regulations Act, section 156.
- In addition the label of each unit dose of methadone, i.e. drink or carry, shall indicate the total dose of methadone contained in the bottle and indicate the date for ingestion.
- The label directions shall instruct the patient to drink the entire contents of the bottle (MMT or Pain III). For Pain I and Pain II the directions for the frequency of the dosing as prescribed must be indicated.
- Where self administration is required, e.g. Pain I or Pain II, the pharmacist shall label solutions with an expiry date and concentration.
- One of the following auxiliary labels shall 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.*

## EDUCATION AND TRAINING

- All pharmacists dispensing methadone shall be familiar with the principles and guidelines outlined in the publication, Methadone Maintenance: A Pharmacist's Guide to Treatment by Centre for Addiction and Mental Health (CAMH). In addition, pharmacists should be familiar with the guidelines in the Methadone Maintenance Guidelines (CPSO) and the Methadone for Pain Guidelines by CPSO.
- The Pharmacy Manager shall be trained in methadone via the CAMH workshop or approved course within one year of beginning a methadone practice.
- At least one staff pharmacist shall be trained in methadone via the CAMH workshop or approved course. Training must be updated every 5 years. 