

**Methadone Distribution Guidelines
For a
Methadone Maintenance Program**

Approved by PEIPB

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I Introduction

The philosophy of a Methadone Treatment Program is based on harm reduction; thereby attempting to nurture an attitude of tolerance and understanding towards injection drug users in our community. Methadone maintenance is considered one component of a harm reduction approach to the health care of opiate drug users.

The purpose of these guidelines is to provide information and guidance to assist pharmacists involved in the dispensing of Methadone for opioid dependence, not for treatment of pain.

Generally, the goals of the Methadone Maintenance Program are to:

1. Reduce illicit opiate use and ideally become drug free
2. Reduce needle sharing
3. Reduce criminal activity associated with addiction
4. Maintain and improve quality of family life and personal productivity

This document is intended to provide pharmacists with information to generate some consistency concerning the proper dispensing practice of Methadone and other important patient-pharmacist issues.

Key points of the program include:

1. Pharmacist understanding of the pharmacology of Methadone
2. Patient understanding of the program rules and adherence to their responsibilities
3. Positive ID is required for all patients before administering a dose
4. Physicians must be authorized to prescribe Methadone
5. Prescriptions must be written appropriately and meet all the legal requirements
6. Daily dose ingestion is supervised

Success can only be achieved when the patients understand the requirements of their continued participation. In addition, pharmacists must apply the requirements in a fair and consistent manner. Therefore, these guidelines lay the framework for those requirements.

Patients are enrolled in the program voluntarily and are required to sign an agreement acknowledging their responsibilities and requirements for remaining in the program

These guidelines will be reviewed as new information about treatment protocols arises. Any comments and suggestions should be forwarded to the Board office.

II Patient Care

Program Consistency

Pharmacists report that their experience with the program can be improved by providing professional, respectful and consistent care and ensuring that patients clearly understand the requirements at their pharmacy.

Be consistent in following the bylaws and guidelines with methadone patients. State exactly what you are able to do and remain firm, as this sends a clear message to the patient about what is allowed and what is not.

Patients who demonstrate disruptive behavior or make requests for early or advance doses should be reminded of the requirements of the program. Some pharmacies find it useful to have a preset process for dealing with specific situations. A policy or plan can help dispensary staff prevent situations from escalating.

Treatment Agreement

A treatment agreement can help you to explain to your patients the goals of the program, your responsibility as their pharmacist and their responsibilities as a patient. The use of an agreement is not required, but some pharmacists find it provides an opportunity to discuss the patients' treatment goals and obligations. See appendix A

When a patient is new to the program they may be in severe physical discomfort or crisis, and may not be able to fully participate in a detailed discussion. It is important to be sensitive to these issues when reviewing the program expectations with a new patient.

Counseling

Pharmacists are required to have a brief conversation with the patient after they drink their methadone dose. This provides an opportunity to emphasize the benefits of methadone treatment and provide support for the patient. At the same time a discussion about the patient's treatment goals, compliance, adverse effects, and lifestyle choices can occur. By initiating dialogue with your patient you can have a positive impact on their treatment. Sufficient time and a private counseling area enable the pharmacist to maximize the benefits of patient counseling.

III Prescription

Authority to dispense methadone

In Prince Edward Island, dispensing of Methadone is regulated by:
The *Controlled Drugs and Substances Act and Narcotic Control Regulations*
The Prince Edward Island Pharmacy Board
The College of Physicians and Surgeons of Prince Edward Island

Prescriber Authority

As per the *Controlled Drugs and Substances Act and Narcotic Control Regulations*,

Methadone may ONLY be supplied to certain health professionals or DISPENSED to a person from whom the pharmacist has received a WRITTEN order or prescription, signed and dated by a practitioner of medicine who is authorized to prescribe methadone.

A physician who wishes to prescribe or administer Methadone must first obtain authorization from the Federal Minister of Health. An authorization is issued for a specific time period and for the specific indication of dependence or pain control. There are currently no restrictions on pharmacists as to who may dispense methadone.

The pharmacist is responsible for ensuring that the practitioner is authorized to prescribe Methadone prior to dispensing it to the patient. To confirm physician status, the pharmacists can call the Bureau of Dangerous Drugs at (613) 946-5139. A prescription for any narcotic, including Methadone, must have a specified total quantity stated on the prescription for it to be valid and legally filled by a pharmacist. A physician must state a specific total quantity to be dispensed.

In the *Narcotic Control Regulations* the definition of a prescription is as follows:

“Prescription” means, in respect of a narcotic an authorization given by a practitioner that a stated amount of a narcotic be dispensed for the person named in the prescription.”

A prescription for Methadone indicating that it continue to be filled until there is a dosage change, would violate Section 31 of the *Narcotic Control Regulations*. It is the responsibility of the pharmacist to ensure all orders or prescriptions are written legally.

Administration

Dispensing and administration of Methadone to patients must be done on a daily basis until carry privileges have been granted. For those patients receiving their dose of Methadone on a daily basis, the medication must be consumed under the direct supervision of a health professional. The health professional must ensure that the Methadone has been swallowed, for example by talking to the patient after they drink or having them drink water after their dose. **Have the patient sign the log record indicating receipt of the dose(Appendix B).** Because a single dose of Methadone is effective for 24 hours, Methadone patients should be counseled to attend the pharmacy at

the same time every day to receive their Methadone. This will result in more consistent blood levels and fewer adverse effects.

Therapy is usually started at 10mg to 30mg of Methadone per day for at least three days. If the patient has had no significant respiratory problems, the dose may be adjusted upward by 10mg per day, over several weeks, until the daily dose of 60mg has been reached, at which time the patient should be re-evaluated. Remember that it requires 4 doses to achieve a steady state due to the long half-life of Methadone. Most patients will be maintained on a 60-100mg daily dose.

It is recommended that a patient receive all methadone doses, including daily doses and carries, from the same pharmacy. Any alternate arrangements must involve communication between the prescribing physician and the dispensing pharmacies.

Carry Medication or Take-Homes

Take home medication or “carries” are given to stable patients to reduce disruption in and improve the quality of the patient’s daily life. The patient will usually drink the first dose at the pharmacy under observation and then take home the carry medication in properly labeled, childproof, unit dose containers for the determined number of days. Patients must be advised to keep all carries out of the reach of children as well as other family members. A dose of as little as 10mg can be fatal to a child. Carries should be refrigerated and taken on the day of the week indicated on the label.

All empty carry bottles are to be returned to the pharmacy by the patient at the time of the next visit. Patients with carries must be informed that they may be asked at any time to appear in the pharmacy and bring with them the remainder of their carry medication. This procedure may be used to deter patients from diverting their Methadone carry doses.

Carries must be labeled according to federal and provincial requirements and must include a warning that the amount of drug contained could cause serious harm or toxicity if taken by someone other than for which it was prescribed. Record carries in a similar manner as the daily administration records

As a pharmacist and member of the care team you may be contacted by the physician, addictions counselor or other member of the treatment team to offer your assessment of the patient’s progress in treatment and their compliance with the use of carry medications. It is therefore important that you understand the general criteria for carries.

Criteria for Carries

Carries are a progression of treatment. Once a patient has been stabilized on Methadone not all doses may have to be witnessed by a pharmacist and the physician may grant carries. A decision to grant carries by the physician should ideally be made in consultation with other professionals involved, such as counselors and pharmacists. Carries are for a maximum of 6 days with no total mg restriction.

Carries are issued to patients who are considered to be functionally stable and are assessed by the care team and physician for the following:

1. Program participation including:

- Attends the pharmacy on schedule for their Methadone dose
- Attends scheduled appointments with the physician, nurse or counselor; and
- Complies with the treatment agreement

2. Demonstrates cognitive stability to assume responsibility for the care and use of the medication

3. Use of drugs improves (as evidenced by acceptable urines for 3 months), either abstinence or non-harmful use of drugs (harm can be seen as a continuum and can result from a single use or from long term use of drugs).

4. Integrates socially via employment, school attendance, child-care responsibilities, and volunteer work.

Patients with carries must be able to accept responsibility for the carried doses, which includes proper security and use of the Methadone. A pharmacist may refuse to fill a prescription for a carry if there is concern for the safety of the patient or the safety of others is at risk. This decision must be communicated to the physician and addictions counselor.

The physician or pharmacist for any of the following reasons may discontinue carries:

- Evidence the patient has failed to meet the terms of the treatment agreement;
- Sustained use of unauthorized drugs;
- The patient has produced an unacceptable urine sample or has tampered with the collection of the urine sample;
- The patient has approached another Methadone treated patient suggesting or proposing to sell, buy or share any urine sample or tamper with any urine sample;
- The patient has diverted, or permitted to be diverted any part of the Methadone; or
- The patient has approached another Methadone treated patient suggesting or proposing to sell, buy or share Methadone.
- Disruptive behaviour by the client, the client's family or friends

Carries may not exceed 6 doses of methadone. An exemption to this restriction may be made given by the physician for the following reasons:

- The client is going on a vacation to an area where Methadone is not readily available
- Compassionate reasons
- The client travels to an area for employment where Methadone is not readily available.

IV Professional Practice

Care of the Methadone Patient

A non-judgmental and respectful approach, which builds a good rapport with the patient, will encourage them to stay motivated to continue treatment. Substance dependence is a chronic and relapsing disorder, not an acute condition that can be rapidly cured upon detoxification. Relapses are a common part of recovery. As the pharmacist will see the patient on a daily basis at the beginning of treatment, they are in a good position to assess the patient's progress and provide information to other members of the treatment team. The pharmacist must be aware of the treatment goal of the patient (reduction of harmful use vs abstinence).

Pharmacology and Drug Interactions

Methadone is extensively metabolized by cytochrome CYP3A4 in human liver microsomes (Chem Res Toxicology 1996;9:3 65-73). Most drug interactions with methadone are associated with drugs that either induce or inhibit these enzymes. A good on-line reference is <http://medicine.iupui.edu/flockhart/table.htm> for a complete list.

Drugs that may decrease methadone levels	Ascorbic Acid Carbamazepine Phenobarbital and other barbiturates Phenytoin Primidone Rifampin Ritonavir Urinary acidifiers
Drugs that may increase methadone levels	Ciprofloxacin Fluconazole Fluvoxamine maleate Urinary alkalinizers Drugs that inhibit CYP 3A4,5,7: Delaviridine, Indinavir, Nelfinavir, Ritonavir, Saquinavir (as well as Grapefruit Juice)
Drugs with levels affected by methadone	Zidovudine
Drugs that may precipitate methadone withdrawal	Opioid antagonists Mixed opioid agonist/antagonists

Side Effects and Adverse Events

Some of the more common side effects include sweating, constipation, sexual difficulties, sleepiness or drowsiness, and weight gain. Adverse effects such as respiratory depression, decreased bowel motility, miotic pupils, nausea and hypotension can occur. After abrupt discontinuation or administration of an antagonist such as naloxone, an abstinence syndrome can develop, consisting of lacrimation, rhinorrhea, sneezing, nausea, vomiting, fever, chills, tremor and tachycardia.

The most serious adverse effect is the potential for apnea, respiratory failure and hypoxia, leading to coma or death. Other adverse effects associated with long-term use of methadone can include appetite disturbance, abnormal menses, urinary retention, blurred vision, biliary pain, insomnia, gynecomastia and hepatotoxicity.

A patient presenting to an emergency room may appear to recover when given a dose of naloxone, however, due to the long half-life of Methadone, the potential for serious adverse events can persist for up to 24 hours and a naloxone drip is advised.

Contraindications / Intoxicated Patients

In most methadone related deaths, concurrent use of sedatives such as benzodiazepines and alcohol were found to have contributed to the cause of death. If an intoxicated patient presents at your pharmacy asking for their methadone dose, their physician should be contacted to discuss whether or not the dose should be administered that day.

Refusal to Fill a Prescription

At any time the pharmacist may refuse to fill a prescription for Methadone for any of the following reasons:

- **Threats** – the patient, family member or friend has threatened the safety or well being of any staff member or another patient or pharmacy customer by oral or written action
- **Disruptive Behaviour** – the patient, family member or friend has engaged in disruptive behaviour on the premises
- **Violent Behaviour** – the patient, family member or friend has engaged in violent behaviour towards a staff member, a patient or another person
- **Illegal Activity** – the patient, family member or friend has engaged in an illegal act on the premises
- **Diversion of Methadone** – the patient has diverted, or allowed to be diverted, any part of their Methadone
- **Contraindication of Methadone** – In the opinion of the prescriber, Methadone has become contraindicated for the patient
- **Missed Doses** – The patient has failed to pick up doses of Methadone for 2 consecutive days (unless alternative arrangements for pick-up have been made or there is convincing evidence that the failure to pick-up was beyond their control).

Missed Doses

Patients who miss their Methadone treatment for two or more consecutive days should be reported to their physicians and no further Methadone should be dispensed without their authorization. Due to the variability and unpredictable loss of tolerance experience with opioids, the physician should be contacted for a new prescription at a lower dose.

Use in Pregnancy

Methadone crosses the placenta and can cause fetal dependence; therefore, its use in pregnant women should be limited to those with opioid dependence. The primary intent of Methadone use is to create a stable environment for the pregnancy and to improve outcomes. Methadone has no teratogenic effects. Detoxification is not recommended

during pregnancy because fetal distress can occur. However, women who are dependent on opioids do better with Methadone than with no treatment. The advantages include longer gestational periods and higher birth weights, as well as a more moderate abstinence syndrome in the neonate. The newborn infant will need close monitoring for signs of withdrawal, and treatment if it occurs. Methadone will pass into the breast milk.

Split Dosing

Once stable, fast metabolisers, such as pregnant patients, patients taking antiepileptics, etc. may need split dosing even at relatively high doses. Splitting the daily dose 50/50 a.m./p.m. is often effective. Split doses are not recommended for new patients.

V Products

Preparing Oral Doses of Methadone

When compounding methadone solution from powder, it is recommended that a stock solution of Methadone be prepared by dissolving the Methadone crystals in bacteriostatic water at the strength of 10mg per ml. An expiry date of 30 days would be appropriate. Stock solution should be stored in a glass, light resistant container, in the refrigerator. The major issue of concern with Methadone solutions is bacterial growth, not stability. Check stock solutions when pouring doses for signs of bacterial growth. Orange drinks or other juices used for dilution are also susceptible to bacterial growth and some go rancid in just a few days. A stability chart is provided for your information. (Appendix C).

A volume of 100mls must be dispensed for on site consumption and take home carries. Individual dosages are prepared by measuring the required amount of the stock solution (example - a dosage of 90mg requires 9ml of stock solution) then qs to 100ml with liquid Tang. For lower doses, a more dilute stock solution may be prepared. You may wish to adjust the amount of water when preparing Tang to allow for the water in the stock solution. Tang is suggested, as Methadone should be dispensed in a vehicle that does not lend itself to injection (can't be boiled down). Patients have been known to "cheek" or "emesis" their dose and then inject it.

Alternatively, Methadone may be prepared using the commercially available PMS-Metadol 10mg/ml solution. Once the appropriate amount of Metadol is measured Tang can be added to the usual 100ml volume.

Long acting morphine may be prescribed until the patient's Methadone dose reaches a level, which controls withdrawal symptoms and cravings. The morphine is administered daily along with the Methadone in a manner which does not allow for diversion, such as splitting the capsules and placing the granules on a teaspoon or in the Methadone solution. (Note: these preparations are not soluble in solution and will clump at the bottom of the bottle requiring several rinses of the bottle with water to obtain the total dose.)

Cases of accidental poisoning have occurred in a pharmacy when a stock solution of Methadone was mistaken for distilled water. **All Methadone solutions should be labeled clearly and stored separately from the distilled water in a distinctive container. Colouring the stock solution is an acceptable option.**

The pharmacist is responsible for ensuring that patients receive their Methadone in person. The doses are not to be released to spouses, relatives or friends. Spilled, damaged, lost or stolen dosages are not replaced without a new prescription from the physician. The patients are responsible for protecting their doses. Records are kept for each daily dose administered to the patient and the patient must sign for each dosage administered including carries authorized by the physician. (Appendix D)

Methadone is rapidly absorbed when given orally. Consuming methadone slowly in small sips may decrease the risk of vomiting. When a patient reports that they vomited their dose, that dose should not automatically be replaced. The physician should be contacted and provided with as much information as possible about the incident (time the dose was taken, time of vomiting, etc.). Physicians can authorize replacement doses by sending a written or faxed authorization to the pharmacy. The authorization stays with the original prescription for the duration of the dispensing and storage requirements.

The following guideline is offered should it be agreed that the dose be reissued:

Emesis < 15 minutes after consumption Full dose
Emesis between 15 – 30 minutes after consumption, replace 50% of dose
Emesis > 30 minutes after consumption – no replacement

Methadone use in Hospitals

During an inpatient stay, the hospital staff should ensure the continuity of Methadone pharmacotherapy through its own pharmacy or by arrangement with the patient's community pharmacy. If the patient is discharged to continuing care facilities, arrangements for continued provision of Methadone should be part of the discharge plan.

If the physician ordering the patient's methadone is not the admitting physician, and there is no physician on staff authorized to prescribe methadone, the physician responsible for the patient in hospital must obtain a temporary exemption (for dependency or analgesia) to prescribe methadone for a patient already stabilized on methadone. It must be noted that only practitioners are eligible to receive a temporary exemption (e.g. medical residents may not receive an exemption). The exemption is granted for the period of the patient's hospitalization (up to 60 days) and expires on the earlier of the date on which the patient is discharged from the hospital or a maximum of 60 days. Should the patient be hospitalized longer than 60 days, the authorization may be extended.

A physician with a temporary exemption may not start new patients on methadone. A temporary exemption is only for patients who are already on methadone before hospitalization. The attending physician may obtain a temporary exemption by calling toll free 1-866-358-0453.

Appendix A: Patient Agreement

Information for patients on the methadone maintenance program

As your pharmacists, we believe in the principles of the methadone maintenance program, and the valuable role it can play in improving people's lives and their health. To help you succeed in the program we make the following promises.

- We will treat you professionally and respectfully at all times.
- We are part of your health care team and will communicate with other members of the healthcare team including your physician when necessary.
 - The kinds of issues we will discuss with your physician include:
 - Missing one or more doses,
 - refusal to drink the full prescribed dose of methadone
 - if you are intoxicated when you arrive at the pharmacy,
 - doses for replacement of lost, stolen or vomited methadone, and
 - if you see another physician and are prescribed mood-altering medications.
- We will provide methadone to you exactly as your physician has prescribed it. We are not able to give you extra doses, early doses, or methadone to take home unless your physician prescribes it.
- We are required to watch you drink your dose of methadone and have a conversation with you afterward, unless your physician specifically directs otherwise on your prescription.
- We will not dispense your methadone to anyone other than you unless directed to do so by your physician on your prescription.

As our patient, we have a number of expectations of you, too.

- You must not arrive at the pharmacy before the pharmacy is open.
- All of our patients are expected to be respectful of others, including staff, other patients and our neighbors.
- If you are prescribed take-home doses of methadone (carries) you must store them safely and securely in your home and return the empty bottles to us.
- You may also be asked to appear in the pharmacy and bring any remainder carry medication to ensure drug diversion is avoided.

Pharmacists Signature

Patient's Signature

Date

Appendix C: Stability of Methadone

Stability of Methadone According to the Diluent used and Conditions of Storage

(Aug. 1994 *Dispensing of Methadone for the Treatment of Opioid Dependence, Health Canada*)

Diluent	Stability at Room Temp (20-25⁰ C)	Stability Refrigerated (5⁰ C)
Grape flavoured Kool-Aid	17 days	55 days
Orange flavoured Tang	11 days	49 days
Allen's Apple Juice	9 days	47 days
Grape flavoured Crystal Light	8 days	34 days
Grape flavoured Crystal Light with 0.1% Sodium Benzoate	29 days	

Appendix D: Take Home/Carry Dosage Log

ABC Pharmacy

102 – 111 Dependency Street, Our Town, Prince Edward Island H0H 0H0

Phone: 902-555-2111 Fax: 902-555-2112

Patient's Name: _____ Doctor's Name: _____

Month: _____

Day	Dose	Carry Bottles Taken	Carry Bottles Returned	Pharmacist Signature	Patient Signature
1					
2					
3					
4					
5					
6					
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8					
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