

Professional Practice Policy #66

Policy Guide Methadone Maintenance Treatment (2013)

Forward

Opioid dependence is a health concern with implications for the individual patient as well as the public. Methadone maintenance treatment is recognized internationally as among the most effective treatments for opioid use disorder (OUD). Addiction treatment experts recommend that methadone treatment for OUD be delivered with a maintenance-oriented, rather than abstinence-oriented, philosophy. This approach acknowledges OUD as a chronic disease.

Many studies, conducted over several decades in different countries, have clearly demonstrated that the effective delivery of methadone maintenance treatment reduces non-medical opioid use, other problematic substance use, criminal activity, mortality, injection-related risks and transmission of blood-borne disease. Additional positive results are improvement in physical and mental health, social functioning, quality of living and pregnancy outcomes.

Methadone, a long-acting, orally effective opioid, is used as a substitute for heroin or other narcotics when treating opioid dependence. Methadone eliminates withdrawal from and reduces cravings for, opioids. Methadone does not produce euphoria, and it blocks the euphoric effects of other opioids. When used in the treatment of opioid dependence, a single oral dose of methadone is effective for at least 24 hours. Eventual withdrawal from methadone is not necessarily the goal of the program, although some individuals may work with their physician and pharmacist to decrease their dose and eventually stop using methadone.

Methadone prescribing is controlled by both federal and provincial legislation, as well as administrative procedures and guidelines.

Registered pharmacists are permitted to purchase and dispense methadone without federal exemption. However, the College of Pharmacists of BC (CPBC) *Professional Practice Policy (PPP-66) – Opioid Agonist Treatment* requires that the pharmacy manager and all staff pharmacists employed in a community pharmacy that provides services related to methadone maintenance treatment complete the *CPBC Methadone Maintenance* Treatment (MMT) or the British Columbia Pharmacy Association's (BCPhA) *Opioid Agonist Treatment Compliance and Management Program for Pharmacy* (OAT-CAMPP) training program, and any subsequent updates. You must log into eServices to complete the "*Declaration of Completion and Understanding*" prior to providing methadone maintenance treatment services.

How to Use This Guide

This Policy Guide (the Guide) is a companion to *Professional Practice Policy* (*PPP-66*) –*Opioid Agonist Treatment* (Appendix 1). The intention of the *Guide* is to provide pharmacists with further detail and clarity (including practical examples) to assist in the implementation of the policy into practice to ensure consistency in the safe and effective delivery of methadone maintenance treatment services.

As always the expectation is that pharmacists will practice in compliance with their legislative requirements, including the principles outlined in this *Guide*. It is understood however that pharmacy practice is not always 'black and white' and when navigating the 'grey' pharmacists must use sound professional judgment, ensuring that their decisions are made in the best interest of the patient and with appropriate collaboration, notification and most importantly, documentation.

The *Guide* is to be read in conjunction with completion of the mandatory training session. Information regarding the mandatory sessions can be found on the CPBC website at **www.bcpharmacists.org.**

Note:

This document is not intended to cover all possible practice scenarios.

Declaration

After completing the mandatory training program, and subsequently reading this *Guide*, pharmacists must log into eServices to complete the 'Declaration of Completion and Understanding'.

Acknowledgement

The development of this *Guide* involved a collaborative and consultative process with input and feedback gathered from a volunteer group of dedicated community pharmacists currently engaged, in varying capacities, in the delivery of methadone maintenance treatment services.

The group was comprised of both frontline pharmacists and pharmacy managers and represented a cross-section of practice types (independent to large chain retailers) and practice settings including pharmacies located in Vancouver's Downtown Eastside whose primary focus is on the provision of methadone maintenance treatment.

Feedback was also solicited from other stakeholder groups including; the Ministry of Health Services, the College of Physicians and Surgeons of BC, the BCPhA, the City of Vancouver, patient advocacy groups Vancouver Area Network of Drug Users (VANDU), and the BC Association for People on Methadone (BCAPOM).

The College of Pharmacists of BC would like to sincerely thank each of these individuals and organizations for their invaluable feedback in the creation of this significant resource for pharmacists.

Feedback

Questions and comments about this *Guide* are welcome and can be sent to: College of Pharmacists of British Columbia Telephone: 604-733-2440 or 800-663-1940

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Methadone Maintenance Treatment Policy Guide

In accordance with *Professional Practice Policy (PPP-66) – Opioid Agonist Treatment* (Appendix 1), all pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to methadone maintenance treatment must know and apply the principles and guidelines outlined here in the CPBC *Methadone Maintenance Treatment Policy Guide (2013)* and all subsequent revisions. The responsibility of pharmacy technicians in the dispensing of MMT is consistent with their scope of practice outlined in the *Health Professions Act* (HPA) Bylaws Schedule F Part 1 section 4.

1.0 Administration

1.1 Pharmacy Operating Hours

Principle 1.1.1 The pharmacy hours of service must be consistent with the supervised dosing requirements of your patient.

Guideline: When a pharmacy accepts a patient who requires daily witness ingestion (i.e., 7 days per week) the pharmacy hours of service must accommodate this dosing requirement. A pharmacist does not have the independent authority to adapt a prescription for methadone maintenance treatment from 'daily witness' to a 'take-home' dose.

1.2 Privacy and Confidentiality – Premise

Principle 1.2.1 All pharmacies offering methadone maintenance treatment must be in compliance with all relevant legislation pertaining to the structure of the licensed premise with particular attention given to ensuring there is sufficient space to accommodate patients waiting for witnessed ingestion and/or take home methadone doses while simultaneously maintaining privacy for pharmacist-patient consultation.

Guideline: It may be appropriate to establish a staggered schedule for regular patients requiring witnessed ingestion to ensure that there is adequate space within the pharmacy to accommodate patients who are waiting and ensure privacy of pharmacist-patient consultation.

1.3 Security - Premise

Principle 1.3.1 All pharmacies offering methadone maintenance treatment must ensure that their pharmacy is in compliance with all relevant legislation pertaining to pharmacy security requirements including those outlined in *Professional Practice Policy (PPP-74) – Community Pharmacy and Telepharmacy Security*.

2.0 Receiving Methadone Prescriptions

2.1 Controlled Prescription Program Forms – Overview

Principle 2.1.1 Methadone maintenance prescriptions can only be accepted when written using an original approved Controlled Prescription Program form. Verbal prescriptions for methadone maintenance treatment may be accepted where permitted under a section 56 exemption to the Controlled Drugs and Substances Act in accordance with section 19(6.1) of the bylaws to the Pharmacy Operations and Drug Scheduling Act.

Guideline: When accepting a methadone maintenance prescription written on the Methadone Maintenance Controlled Prescription form, a pharmacist must ensure that the form is completed by the prescriber as outlined in the *Methadone Maintenance Controlled Prescription Form Guidelines* (Appendix 3).

Principle 2.1.2 The pharmacist must ensure that the patient, as well as themselves, sign the form, in the space indicated on the bottom of the form.

Principle 2.1.3 Faxed Controlled Prescription Program forms are not acceptable unless under extenuating circumstances where the prescriber has determined, following consultation with the pharmacist, that the urgency of the situation warrants it, or in accordance with section 7(3) of the Health Professions Act Bylaws Schedule F, Part 1 - Community Pharmacy Standards of Practice.

Guideline: In such cases the pharmacy, prior to dispensing the medication, must receive, in addition to a fax of an approved Controlled Prescription

Program form, written confirmation (fax acceptable) signed by the prescriber that briefly describes the emergency situation and guarantees the delivery of the original approved Controlled Prescription Program form to the pharmacy the next business day or as soon as possible when the prescriber is not available.

The faxed approved Controlled Prescription Program form and related documentation, as described in Appendix 4, must be attached to the original Controlled Prescription Program form once received.

Note: The *Emergency Fax Controlled Prescription Program Form Documentation* (Appendix 4) can be used for this purpose.

Principle 2.1.4

In an effort to maximize the effectiveness of the methadone maintenance treatment program, the pharmacist may find it beneficial to engage in a specific dialogue with the patient, either when they initiate treatment or at various times throughout treatment, that clearly outlines the expectations of both the patient and the pharmacist.

Guideline: The *Methadone Maintenance Treatment Expectation Form* (Appendix 5) can be used for this purpose.

Principle 2.1.5

In the rare circumstance (disruptive or threatening behavior or verbal or physical abuse) where a pharmacist finds that they must terminate the pharmacist-patient relationship, reasonable notice must be provided to the patient to ensure their continuity of care.

Guideline: It is important to remember that the decision to terminate a pharmacist-patient relationship is a serious one and must be made with due consideration and based on appropriate rationale. It is unethical for a pharmacist to terminate the pharmacist-patient relationship or refuse to treat a patient on morally irrelevant grounds. The pharmacist's decision should be documented and retained in the patient record.

2.2 Controlled Prescription Program Forms – Alterations

Principle 2.2.1 Alterations to the approved Controlled Prescription Program form are the exception to the rule and should not be normal practice as they increase the likelihood of errors and drug diversion and put the public at risk. In the rare circumstance when an alteration is necessary to ensure the continuity of care pharmacists must always use due diligence to ensure authenticity and accuracy of the prescription.

Guideline:

Alterations completed at the prescriber's office: Alterations are only permitted on the sections of the form that the prescriber completes provided that the prescriber has initialed the alteration. Alterations are not permitted to the pre-printed sections of the form.

Alterations completed at the pharmacy: Pharmacists do not have independent authority to make any alterations or changes to the approved Controlled Prescription Program form. Any required or requested change(s) must be patient-specific and authorized by the patient's prescriber through direct consultation with the pharmacist. Any prescriber-authorized changes must be confirmed in writing, signed by the prescriber, received by the pharmacy (fax is acceptable) prior to dispensing the medication whenever possible and attached and filed with the original prescription.

Note: The *Pharmacist-Prescriber Communication Form* (Appendix 4) can be used for this purpose.

2.3 Out-of-Province Prescriptions

Principle 2.3.1 Pharmacists are permitted to dispense methadone prescriptions from prescribers in provinces other than BC.

Guideline: If there are any doubts regarding the authenticity of the out-of-province prescription, the pharmacist must contact the out-of-province prescriber to confirm the legitimacy of the prescription. When satisfied that the prescription is authentic, the pharmacist can dispense and process the prescription in the same manner as other prescriptions from out-of-province prescribers.

Note: It's important to realize that not all provinces are required to use Controlled Prescription Program forms.

3.0 Processing (Dispensing) Methadone Prescriptions

3.1 Accepting a Prescription

Principle 3.1.1 Methadone for maintenance must be dispensed to patients in a concentration of 10 mg/ ml.

Guideline: Only commercially available 10 mg/ml oral preparations are permitted for use.

Principle 3.1.2 Positive identification is required for all patients presenting a prescription for the first time, and reasonable steps to positively identify the patient must be taken prior to dispensing any subsequent prescriptions.

Guideline: The CPBC *Professional Practice Policy (PPP-54) – Identifying Patients and Patient Representatives in Community Pharmacy and Telepharmacy Settings* provides guidance for registrants on taking reasonable steps to confirm the identity of patient. The prescriber may be contacted to assist with verifying the patient's identity, if necessary.

Principle 3.1.3 Pharmacists and pharmacy technicians must review the prescription to ensure that it is completed by the prescriber as outlined in the Controlled Prescription Program, and that the directions for use appropriately meet the specific needs of the patient and can be accommodated by the pharmacy. If the prescription is written using the Methadone Maintenance Controlled Prescription Form, it should be completed by the prescriber as outlined in the Methadone Maintenance Controlled Prescription Form Guidelines (Appendix 3).

Guideline: Each prescription must be reviewed in detail in consultation with, and consideration given to the specific needs of, the patient. The following list is a sample only:

- Evaluate the end date of the prescription to ensure that the authorization for dispensing does not end on a weekend when the patient will not be able to see a prescriber for a new prescription.
- Review the prescription directions to determine the dosing schedule (daily witnessed ingestion, divided dose, take-home doses), including the specific days of the week for each witnessed dose or take-home doses, to confirm that the pharmacy operating hours match the dosing schedule.
- Confirm that stamped or preprinted sticker directions do not conflict with written directions.

Any ambiguous or conflicting information identified must be clarified with the prescriber. Should an alteration or change to the prescription be required, it must be done in compliance with the Principles and Guidelines outlined in section 2.2.

3.2 Assessment of a Prescription

Principle 3.2.1 Pharmacists and pharmacy technicians must correctly identify the product as prescribed 'for pain' or 'for opioid use disorder' by using the appropriate Drug Identification Number (DIN) or Product Identification Number (PIN) to ensure patient safety and accurate PharmaNet patient records.

Principle 3.2.2 As with all medications a pharmacist must review each individual PharmaNet patient record, as stated in HPA Bylaws (Schedule F Part 1), and resolve any drug-related problems prior to dispensing any methadone prescription. This step is particularly critical for methadone prescriptions as the automated drug usage evaluation (DUE) built into the PharmaNet system does not include methadone. Pharmacists providing methadone maintenance treatment must therefore ensure they maintain their knowledge with respect to potential drug interactions related to methadone. General information in this regard can be found in Appendix 7.

Guideline: A PharmaNet patient record review must be completed for all prescriptions, including those patients obtaining their prescription on a daily basis or those long-term patients whom the pharmacist may know well.

Principle 3.2.3

Mood altering drugs, including benzodiazepines and narcotics, are not generally prescribed to patients on the methadone maintenance program. Should a patient present a prescription for a mood altering drug or if the pharmacist discovers that a mood altering drug is also being prescribed to the patient in their review of the PharmaNet patient record, they must contact both the prescriber of methadone and, if different, the prescriber of the mood altering drug, prior to dispensing the medication. The purpose of the consultation is to ensure the prescriber(s) are aware that the patient is currently on the methadone maintenance program.

Guideline: The pharmacist should document the outcome of the consultation(s) with the prescriber(s) and attach it to the original prescription.

Principle 3.2.4

The 'sig field' on the prescription label must include the start and end dates of the original current prescription.

Principle 3.2.5 As required by *HPA Bylaws* Schedule F Part 1 the 'dispensing date' on the prescription label must accurately reflect the actual date dispensed on the PharmaNet system.

3.3 Preparing Methadone Prescriptions

Principle 3.3.1

Methadone doses must be accurately measured in a calibrated device that minimizes the error rate to no greater than 0.1 ml.

Guideline: All devices used to measure the methadone 10 mg/ml solutions should be distinctive and recognizable and must be used only to measure methadone solutions. Devices must be labeled with a 'methadone only' label and a 'poison' auxiliary label with the international symbol of the skull and cross bones.

Principle 3.3.2 Reconciliation procedures must be conducted in accordance with *Professional Practice Policy (PPP-65) – Narcotic Counts and Reconciliations.*

Guideline: Reconciliation means the quantity of methadone on hand must equal the quantity received minus the quantity dispensed over a specific period of time.

3.4 Loss or Theft and Disposal of Methadone

Principle 3.4.1 The Narcotic Control Regulations require that pharmacists report the loss or theft of controlled drugs and substances to the Office of Controlled Substances, Health Canada within 10 days of the discovery of the loss or theft. In the event of a loss or theft the pharmacy should also notify the CPBC within 24 hours.

Guideline: The form for reporting loss or theft of narcotics can be found on the CPBC website www.bcpharmcists.org under *Resources*.

Principle 3.4.2 Methadone, like any other narcotic or controlled drug, can only be disposed of with authorization from Health Canada and after being rendered unusable.

Guideline: To receive authorization to dispose of methadone the pharmacist must submit a written *Authorization to Destroy for Expired Narcotic and Controlled Drugs* to the Office of Controlled Substances, Health Canada.

An acceptable method of rendering methadone unusable is to place the product in a leak-proof container or plastic bag and add kitty litter until the mixture is almost solid.

Once the required authorization is received from Health Canada the pharmacist must record the amount of product to be disposed of, having a second healthcare professional sign for the disposal, and place the now rendered unusable product in the pharmacy's medication return container.

3.5 Methadone in Tablet Form for Air Travel

Principle 3.5.1 Hand luggage restrictions governing the transportation of fluids in air travel may be problematic for patients and in certain circumstances may necessitate the prescription of methadone in tablet form. Only commercially available methadone in tablet form may be dispensed. Pharmacists need to be aware that the prescription of methadone in tablet form may result in increased risk for both patients and the public. Note: Dispensing of methadone powder by way of sachet, capsule, or other format is never acceptable due to the increased potential for diversion and misuse.

Guideline: Long-term methadone maintenance treatment clearly limits patients' ability to travel because of the need for regular follow-up as well as the restrictions associated with the dispensing of methadone. If patients receiving MMT wish to travel for a period of time that exceeds their regular carry period, the usual standard of care should not be compromised, particularly if the patient is not stable and still requires daily supervised ingestion.

Patients are significantly limited in their ability to transport methadone across international borders but it is possible to arrange for methadone dispensing in some jurisdictions. The CPSBC advises physicians to research each case to ensure decisions do not compromise patient safety. In some cases, patients may require documentation for the purpose of crossing international borders or to assist in accessing temporary care from a methadone program at their destination. The physician is responsible to provide the required travel documentation.

4.0 Releasing Methadone Prescriptions

4.1 Releasing a Prescription

Principle 4.1.1 A pharmacist must be present and witness the release of a methadone prescription to a patient. This function cannot be delegated to a pharmacy technician or any other pharmacy support staff.

Principle 4.1.2

Prior to releasing a methadone prescription the pharmacist must assess the competence of the patient (i.e. ensure that the patient is not currently intoxicated or otherwise mentally impaired) to ensure that it is safe to release the medication to them.

Guideline: Pharmacists must assess patients for symptoms such as slurred speech, ataxia, drowsiness, alcohol smell or unusual behaviour. It is important for the pharmacist to be familiar with each patient's 'normal' behaviour in order to be able to detect significant deviations from normal.

If the pharmacist believes that it is not safe for the patient to receive their prescription they must consult with the prescriber and document the outcome of the dialogue and attach it to the original prescription.

Principle 4.1.3

Prior to releasing a methadone prescription the patient and pharmacist must acknowledge receipt by signing a patient/prescription-specific log (the sample *Methadone Part-Fill Accountability Log* (Appendix 9) can be used for this purpose).

Guideline: Every part-fill dispensed must be accounted for. The pharmacist must be able to review every part-fill dispensed as a complete history on one document.

The pharmacist releasing and the patient receiving the part-fill of the prescription must sign for each witnessed ingestion dose and each takehome dose. Neither the pharmacist nor the patient is permitted to pre-sign for future doses or backdate signing.

The patient/prescription specific log (the sample *Methadone Part-Fill Accountability Log* (Appendix 9) can be used for this purpose) must be attached to the original Controlled Prescription Program form and once complete filed sequentially by the first prescription or transaction number assigned to the prescription.

Principle 4.1.4

As with all prescriptions, prior to releasing a methadone prescription, the pharmacist must counsel the patient on the risks (including common side effects) and benefits of taking their medication as per *HPA Bylaws* Schedule F Part 1 section 12.

Guideline: The most common adverse reactions with methadone include; sweating, constipation, sexual dysfunction, change in menstruation, drowsiness, sleep disturbances, muscle and bone aches, weight changes (usually gain), skin rash, gastrointestinal upset, headaches and edema. Patients will benefit from information about the non-drug approaches, non-prescription products and prescription items that can provide relief from these side effects.

Principle 4.1.5

With respect to witnessed ingestion doses, the pharmacist must directly observe the patient ingesting the medication and be assured that the entire dose has been swallowed.

Guideline: Given the concentrated solution of 10mg/ml, it may be helpful to provide a glass of water to the patient to enable rinsing out of the dispensing container to ensure full dose administration.

Immediately following observing the patient's ingestion of the medication the pharmacist should engage the patient in a short conversation to ensure that the entire dose has been swallowed.

Principle 4.1.6

With respect to take-home doses the first dose (whether it is stated on the prescription or not) must be a witnessed ingestion with all subsequent take-home doses dispensed in child-resistant containers with an explicit warning label indicating that the amount of drug in the container could cause serious harm or toxicity if taken by someone other than the patient.

Guideline: Each dose must be dispensed in an individual, appropriately sized, child-resistant container.

Each container must be individually labeled.

If a pharmacist determines that due to a specific patient circumstance a non-child-resistant container will be used for take-home doses it must be documented on the patient record.

Patients should be reminded that methadone should be stored out of the reach of children, preferably in a locked cupboard or small lock box if stored in the refrigerator.

Note: The decision to authorize take-home doses can only be made by the prescriber. However, should a pharmacist believe that a patient is or is not

ready to manage take-home doses they should discuss their recommendations or concerns with the prescriber.

Principle 4.1.7

In extraordinary situations, when a patient cannot attend the pharmacy, the patient's representative may pick up and sign for their authorized takehome dose(s) if confirmed in writing by the prescriber.

Guideline: This authorization must be date specific, and the representative and circumstances must be clearly defined. The written and signed authorization from the prescriber (fax acceptable) must be attached to the original approved Controlled Prescription Program form.

Note: Patient representative is defined in *HPA Bylaws*.

5.0 Responding to Methadone Dosing **Issues**

5.1 Divided (Split) Doses

Principle 5.1.1 Only the prescriber, by stating this on the original approved Controlled Prescription Program form, can authorize a divided (split) dose of a prescription. Unless otherwise specified by the prescriber, the first portion of the daily dose must be by witnessed ingestion.

> **Guideline:** The decision to authorize a divided dose can only be made by the prescriber, however, should a pharmacist believe that a patient would benefit from this they should discuss this option with the prescriber.

5.2 Missed Doses

Principle 5.2.1 Any methadone prescription that has been processed and prepared but is not consumed or picked up by the patient on the prescribed day is considered cancelled and must be reversed on PharmaNet before the end of the business day.

> **Guideline:** It is imperative that the PharmaNet patient record reflects accurate and current information in terms of consumed and picked-up

methadone doses as other healthcare practitioners rely on this information in making treatment decisions.

Principle 5.2.2 If a patient misses a dose, they cannot receive the missed dose at a later date.

Principle 5.2.3 The pharmacist must notify the prescriber of any missed doses (unless a specified number of missed doses has been indicated by the prescriber) before the next scheduled release of medication.

Guideline: The notification document must be retained and filed with the prescription consistent with filing retention requirements. The *Pharmacist-Prescriber Communication Form* (Appendix 6) can be used for this purpose.

5.3 Partial Consumption of Doses

Principle 5.3.1 If a patient refuses to consume their full dose, the pharmacist must not insist that they ingest the total amount. The unconsumed portion however cannot be given as a take-home dose.

Guideline: The patient's partial consumption of a dose and their reason(s) for it must be documented and reported to the prescriber. *The Pharmacist-Prescriber Communication Form* (Appendix 6) can be used for this purpose.

All patient documentation including the *Methadone Part-Fill Accountability Log* (Appendix 9) and PharmaNet record must accurately reflect the actual dose consumed by the patient.

5.4 Vomited Doses

Principle 5.4.1 If a patient reports that they vomited their dose, a replacement dose cannot be provided without authorization from the patient's prescriber.

Guideline: The pharmacist must contact the prescriber and provide them with information about the incident (time the dose was taken, time of vomiting, and other relevant points). Should the prescriber authorize a replacement dose, it must be confirmed in writing, signed by the prescriber,

received by the pharmacy (fax is acceptable) prior to dispensing the medication and attached and filed with the original prescription.

5.5 Lost or Stolen Doses

Principle 5.5.1 If a patient reports that their take-home dose(s) have been lost, stolen or misplaced, a replacement dose(s) cannot be provided without authorization from the patient's prescriber.

Guideline: The pharmacist must contact the prescriber and discuss the situation with them. Should the prescriber determine that the situation warrants it they may authorize the acceptance of a new approved Controlled Prescription Program form by fax (refer to Principle 2.1.3) or the prescriber may advise the pharmacy that they must wait until the patient presents a new original approved Controlled Prescription Program form.

5.6 Tapering

Principle 5.6.1 If a patient has decided to initiate a self-tapering regimen by decreasing

their daily dose consumption, the pharmacist must record the dose consumed on the patient/ prescription specific log (refer to Principle 4.1.3), record the actual dose consumed on the patient's PharmaNet record and notify the prescriber.

Guideline: The *Pharmacist-Prescriber Communication Form* (Appendix 6) can be used for the purpose of notifying the prescriber.

5.7 Emergency Dosing

Principle 5.7.1

Emergency dosing is not recommended. If however a pharmacist feels in their professional judgement that an emergency dose is required to ensure continuity of patient treatment the pharmacist may provide an emergency dose. The pharmacist must counsel the patient to obtain a new prescription as soon as possible. This practice is the exception to the rule and not the normal practice, refer to *Professional Practice Policy (PPP-31) – Emergency Supply for Continuity of Care*.

Guideline: Pharmacists need to document, as per *PPP-31*, the attempt to reach the prescriber with information about the situation. The prolonged

half-life of methadone ensures that a patient maintains a single dose for at least 36 hours. Although the patient may feel uncomfortable an emergency dose may not be necessary. Emergency doses may hinder treatment success and health outcomes. It is a patient's responsibility to make sure they have a valid prescription.

6.0 Continuity of Care

6.1 Transfer of Pharmacy

Principle 6.1.1 When a patient chooses to move from one pharmacy to another to receive their methadone prescription it is the responsibility of the new pharmacy to contact the previous pharmacy and prescriber (if applicable) to discuss the exact transfer date and any other pertinent concerns. The previous pharmacy must cooperate fully with the request from the new pharmacy.

Guideline: Communication between the previous and new pharmacy is critical to ensure the patient's continuity of care and to avoid duplicate or missed methadone doses. A review of the patient's PharmaNet patient record can be of assistance in determining the previous pharmacy and prescriber.

6.2 Hospitalization or Incarceration

Principle 6.2.1 When a patient is discharged or released to the community from a hospital or correctional facility it is the responsibility of the community pharmacist receiving the patient to verify the date and amount of the last dose administered.

Guideline: Effective communication sharing among those who provide the patient's methadone maintenance treatment (hospital or correctional facility and pharmacy) is essential to ensure the patient's continuity of care and to avoid duplicate or missed methadone doses.

6.3 Compounding in Exceptional Circumstances

Principle 6.3.1 The only situation that would constitute consideration of exceptional circumstances is when a commercially available 10 mg/ml oral preparation is not available.

Principle 6.3.2 Methadone for maintenance must be at the strength of 10 mg/ml to ensure minimization of errors.

Principle 6.3.3 A compounding log must be established to record when methadone solutions are prepared, how much was prepared, and who prepared the product. The *Compounding Log* (Appendix 8) can be used for this purpose.

Guideline: The compounding log must incorporate the following elements:

- Preparation date,
- Methadone powder and/or liquid concentrate manufacturer's lot number and expiry date,
- Methadone powder and/or liquid concentrate quantity used and quantity prepared,
- Batch number and use-by date assigned by the pharmacy, and
- Preparer's and pharmacist's identification.

A separate compounding log must be maintained for each strength of stock solution

Principle 6.3.4 All concentrated solution containers must be clearly labeled with the drug name, strength, use-by date and appropriate warning labels.

Guideline: If different concentrations are prepared for pain management, they must be easily identifiable with clear labeling. A best practice would be to use different styles of storage container for each concentration or use food grade dyes to differentiate between the different concentrations prepared.

In order to help ensure liquid methadone preparations remain stable for up to 30 days from the date of pharmacy dispensing and to minimize the

growth of bacteria, mold and fungus the *American Association for the Treatment of Opioid Dependence* recommends that pharmacists should:

- Use distilled water for the dilution of methadone products,
- Use new, clean, light-resistant containers for dispensing,
- Refrigerate take-home containers as soon as possible and keep refrigerated until used.

Principle 6.3.5

Methadone for maintenance solutions must be made with full-strength Tang™ or similar full-strength beverage crystals with daily doses (witnessed ingestion or take-home). Plain water is never an acceptable vehicle for dispensing to patients in the methadone maintenance treatment program.

Guideline: The beverage crystals are full-strength when made according to the manufacturer's directions found on the product's packaging.

Dispensing as a standard volume (e.g., all doses dispensed as a volume of 100 mL) is not acceptable.

CPBC Professional Practice Policy PPP-66 – Opioid Agonist Treatment

See the most up-to-date *Professional Practice Policy – 66 Opioid Agonist Treatment* on the CPBC website: http://library.bcpharmacists.org/6 Resources/6-2 PPP/5003-PGP-PPP66.pdf

CPBC Professional Practice Policy PPP-71 – Delivery of Opioid Agonist Treatment

See the most up-to-date *Professional Practice Policy – 71 Delivery of Opioid Agonist Treatment* on the CPBC website: http://library.bcpharmacists.org/6 Resources/6-2 PPP/5003-PGP-PPP71.pdf

Methadone for Maintenance Controlled Prescription Form Guidelines

When accepting a Methadone Maintenance Controlled Prescription form a pharmacist must ensure that the form is completed by the prescriber as outlined in these guidelines.

Methadone Maintenance Controlled Prescription Form (Example; Figure 1):

These duplicate copy prescriptions are pre-printed with the following information; drug name and strength, prescriber's name, address (optional), College ID number and prescription folio number. These prescription forms are used <u>only</u> for prescribing methadone for maintenance.

Top Section of Form:

The prescriber must complete in full, the patient information including; personal health number (PHN), name, address and date of birth. The 'prescribing date' indicates the date that the prescriber saw the patient. The 'Drug Name and Strength' section is preprinted and the prescriber must complete the 'Quantity' section by stating the total quantity of the prescription in numeric and alpha forms.

Note: If no 'start day' is indicated in the 'Directions for Use' section of the form the 'prescribing date' becomes the 'start day'.

Middle Section of Form:

The prescriber must complete the 'Directions for Use' section as follows:

- State the daily dose:
 - the daily dose multiplied by the number of days must equal the total quantity indicated on the prescription, if there is a discrepancy the pharmacist should seek clarification from the prescriber
- Indicate the 'start day' and 'last day':
 - if no 'start day' is indicated, the 'prescribing date' becomes the 'start day'
 - should the 'start day' overlap with, or leave gaps from, an existing prescription the pharmacist should seek clarification from the prescriber
- Indicate any special instructions:

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- may be used to provide special instructions to the pharmacist for example split doses, or special situations for carries.
- Indicate either DWI or CARRIES, if carries are indicated the prescriber must indicate both in numeric and alpha the required number of days per week of witnessed ingestion:
 - if neither of these options are circled the pharmacist is to assume that all doses are DWI
 - if CARRIES has been circled but the specific witnessed ingestion days (ex; Monday and Thursday) have not been noted by the prescriber the pharmacist can determine the days in consultation with the patient. However, the first dose of the prescription and the dose before any carries must be witnessed ingestion. Additionally, the witnessed ingestion doses must be spread evenly throughout the week
 - if CARRIES has been circled but the number of days per week of witnessed ingestion has been left blank the pharmacist must seek clarification from the prescriber

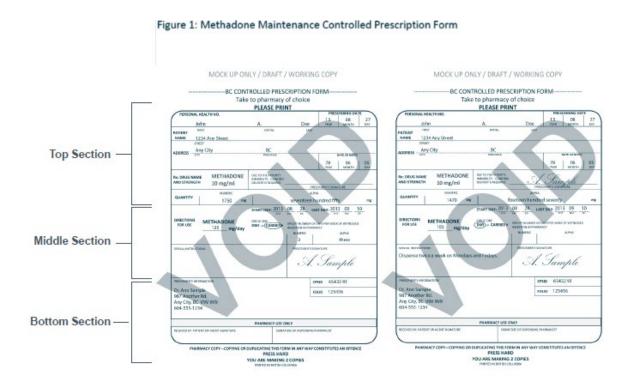
Note: "DWI except when pharmacy closed" is <u>not</u> an acceptable prescription instruction.

 Authorize the prescription by signing their name in the 'prescriber's signature' box

Bottom Section of Form:

As a minimum the prescriber's name, College ID number and prescription folio number will be pre-printed on the form. If the prescribers address is not pre-printed it must be completed by the pharmacist prior to dispensing the prescription. Both the patient and the pharmacist must sign the prescription in the appropriate box.

Note: A patient's representative signature is only acceptable with prior written authorization from the prescriber.



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Emergency Fax Controlled Prescription Program Form Documentation

This form is for the use only in the event of an emergency that requires a faxed Controlled Prescription Program form which has been initiated following direct consultation between the patient's pharmacist and prescriber.

It is understood that the pharmacist must obtain written documentation from the prescriber prior to dispensing any medication and as such is requesting that the prescriber complete this form and fax back to the pharmacy along with a fax of the Controlled Prescription Program form as soon as possible.

Prescriber:	Patient Name:					
	Fax Number:					
Pharmacist:						
As the prescriber, I request that the above-named						
pharmacy accept a faxed transmission of the Controlled Prescription Program form for the above-named patient. I understand that the Controlled Prescription Program form must be faxed to and received by the pharmacy prior to the pharmacy dispensing methadone. I guarantee that the original Controlled Prescription Program form will be sent to the pharmacy by the next business day. Brief description of the emergency situation:	Affix Controlled Prescription Program form here					
Prescriber's Name: Prescriber ID: Prescriber's Signature: Signature Date:						

Methadone Maintenance Treatment Expectation Form

As your pharmacists, we believe in the principles of the methadone maintenance treatment program, and the valuable role it can play in improving people's lives and their health. We are committed to being an active member of your healthcare team and understand that the success of the program is dependent on ongoing collaboration and communication between yourself, ourselves and your prescriber.

To help you succeed in the program it is important that we both clearly understand the commitment and expectations of each other.

As your pharmacists, you can expect that we will:

- Treat you professionally and respectfully at all times.
- Make ourselves available to discuss any questions or concerns that you
 may have regarding the program.
- Provide methadone to you exactly as your prescriber has prescribed it and will ensure that they are made aware of any of the following:
 - Missed dose(s) for any reason (ie; failure to pick up, vomited, lost or stolen)
 - Less than full dose consumed (ie; tolerance, self-initiated tapering)
 - Presenting at the pharmacy while intoxicated
 - Prescribing of contraindicated medications (ie; mood-altering drugs)
- Not dispense your methadone (unless directed by your prescriber) to anyone other than you.
- Respect your choice (unless directed by your prescriber) of the pharmacy you wish to have dispense your medication.

As our patient, we can expect that you will:

- Treat all pharmacy staff and other patients respectfully at all times.
- Do your utmost to adhere to the methadone maintenance treatment program as prescribed to you.
- Discuss any concerns you may have regarding your methadone maintenance treatment with us or your prescriber prior to making any adjustments to treatment independently.
- Ensure that any take-home doses of methadone are stored safely and securely.
- Respect the pharmacy's greater community by refraining from loitering or littering.

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Pharmacist – Prescriber Communication

Patient Name:			
Patient PHN:			
escription Form Folio Number:			
Pharmacy Fax:			
Pharmacy Telephone:			
(dates).			
(date) and consumed only			
armacy			
date' and/or 'start day' for the attached e indicate the actual 'prescribing date' (actual nsing 'start date' or range.			
Affix Controlled Prescription Program form here			

Drug Interactions – General Information

Methadone is extensively metabolized by cytochrome CYP3A4 in liver microsomes. Most drug interactions with methadone are associated with drugs that either induce or inhibit these enzymes.

The sequence of administration of the drugs is the key to evaluating the significance of the interaction. When a patient is stabilized on a drug that affects liver metabolism and methadone is introduced, the interaction may not be observed unless the first drug is discontinued. It is only if a patient is stabilized on methadone and an interacting drug is initiated or discontinued that an interaction may occur.

Drugs that may lower plasma levels (ie; increase the metabolism) of methadone include rifampin, barbiturates, phenytoin and carbamazepine. Drugs that may increase plasma levels (ie; decrease the metabolism) of methadone include ciprofloxacin and fluvoxamine.

Medications that might precipitate a withdrawal syndrome for patients on methadone must be avoided. These are mainly opioid antagonists such as pentazocine, butorphanol, nalbuphine, and naltrexone.

Pharmacists should not rely on PharmaNet to warn of a drug interactions for methadone. The use of PharmaNet is not intended as a substitute for professional judgment. Information on PharmaNet is not exhaustive and cannot be relied upon as complete. The absence of a warning about a drug or drug combination is not an indication that the drug or drug combination is safe, appropriate or effective in any given patient. Health care professionals should confirm information obtained from PharmaNet, and ensure no additional relevant information exists, before making patient care decisions.

Compounding Log

g/ml Stock Solution

Preparation Date	Manufac- turer's Lot Number (Powder)	Manufac- turer's Expiry Date (Powder)	Quantity Used (Powder)	Quantity Prepared (Solution)	Use-By Date (Solution)	Batch Number (Assigned by pharmacy)	Preparer's ID (Initials)	Pharmacist's ID (Initials)

Methadone Part-Fill Accountability Log

Pa	tiei	nt	Na	me:
Гα	LICI	IΙι	IVa	IIIC.

	Prescription or Transaction Number	Quantity			Delivery Information (if applicable)			
Date Dispensed		Witnessed	Take Home	Total	Address	Time	Pharmacist's Initials	Patient's signature

*	

Patient Name: _____

	Prescription or Transaction Number	Quantity		Delivery Information (if applicable)				
Date Dispensed		Witnessed	Take Home	Total	Address	Time	Pharmacist's Initials	Patient's signature

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Methadone Information for Patients

What is methadone?

Methadone is a long-acting narcotic medication. Since the mid-1960s methadone has been used as an effective and legal substitute for heroin and other opiates. Methadone maintenance programs help opiate-dependent individuals stabilize their lives and reduce the harm associated with drug use.

How is methadone taken?

Methadone is prepared in a liquid. Doses are usually taken once a day as the effects of a single dose last for about one day. Your physician will write a prescription specifying your dose and how often you need to come to the pharmacy. Initially methadone is prescribed as a daily witnessed dose. As your treatment progresses you may be eligible for take-home doses.

How does methadone work?

Methadone is part of a long-term maintenance program for opiate or heroin dependent people. Drug cravings are reduced without producing a "high." The goal is to find the dose that will prevent physical withdrawal. The right dose will decrease your drug cravings, and help you to reduce or eliminate heroin use.

How long do I have to stay on methadone?

You should stay on methadone for as long as you experience benefits. Everyone responds differently and methadone can safely be taken for years. If you decide you want to stop taking methadone, you should discuss this with your physician.

Does methadone have side effects?

Methadone is usually tolerated well once the dose is stabilized. Most people experience few, if any, side effects. Please let your pharmacist or physician know if any of these symptoms are bothering you:

- Sweating This can be due to the methadone itself, or a dose that is too high or too low.
- Constipation Increasing exercise, fluids and fiber in your diet may decrease this problem.

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- Sexual difficulties This can be either a reduction or an increase in desire.
- Sleepiness or drowsiness This may be caused by too much methadone.
 If this occurs consult your doctor to have your dose adjusted. Do not drive a car or participate in activities that require you to be alert when you are drowsy.
- Weight change An increase in body weight may be due to better health and an improved appetite.

Can methadone interact with other drugs?

Yes. Alcohol and drugs, including prescription, nonprescription, herbal and street drugs, may interfere with the action of methadone in your body. Discuss all medications you are taking with your pharmacist or physician.

Is methadone dangerous?

Methadone is safe to use when it is prescribed and monitored by a physician. It can be very dangerous if used inappropriately. Methadone should never be taken by anybody except the person for whom it is prescribed as overdose and death can occur if the person is not dependent on opiates. Children are especially at risk for overdose and death if they swallow methadone accidentally.

What is my responsibility?

Your responsibility is to drink your methadone dose every day. If you have carries, you must make sure that they are stored safely to prevent possible ingestion by anyone else. If you store your carries in the fridge ensure that they are not accessible. Methadone can be very dangerous if used inappropriately so you must not give or sell your dose to anyone.

Will methadone cure me?

The methadone maintenance program can help you to make positive lifestyle changes. The goal of treatment is to stabilize your body physically and to provide an environment that supports you.