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PREFACE

The College of Physicians and Surgeons of British Columbia, with the clinical advice of the College’s Methadone Panel of the Quality Assurance Committee, administers the Methadone Maintenance Program in British Columbia under the authority of the Health Professions Act (HPA) and the Bylaws under the HPA, and in accordance with Health Canada’s Drug Strategy and Controlled Substances Programme.

Methadone Maintenance Program (MMP)

The objective of the Methadone Maintenance Program (MMP) is to assist physicians in safely and effectively prescribing methadone for opioid dependence.

The MMP assists physicians in the following ways:

- developing guidelines for safe and effective prescribing of methadone for opioid dependence
- providing education including workshops on prescribing methadone for opioid dependence
- facilitating preceptorships for physicians who wish to prescribe methadone for opioid dependence
- conducting peer practice assessments (PPAs) of the physicians who are authorized to prescribe methadone
- maintaining a central registry of methadone prescribers and registered patients
- making recommendations to the federal Ministry of Health regarding physicians’ authorizations

Methadone Maintenance Program: Clinical Practice Guideline

This guideline addresses the prescribing of methadone for the treatment for opioid dependence—physicians prescribing methadone for analgesia (both for palliative and chronic non-cancer pain) should refer to the handbook Recommendations for the Use of Methadone for Pain.

These clinical guidelines are evidence-based, represent the expert opinion of the Methadone Panel, and are intended for physicians in British Columbia who are prescribing methadone for opioid dependence.

Physicians should exercise careful clinical judgment when considering whether it is appropriate to deviate from these guidelines. Any deviations should be documented in patients’ medical records, together with the rationale for those decisions.
INTRODUCTION

1. The History of Methadone

Methadone was discovered in 1938 by two German scientists, Max Bockmühl and Gustav Ehrhart, and was patented in September 1941. Bockmühl and Ehrhart were attempting to find a gastrointestinal tract antispasmodic and analgesic which would be structurally dissimilar to morphine, non-addictive, and would escape the strict legal controls placed on opioids at that time. In 1947, Harris Isbell and his colleagues, who had been experimenting extensively with methadone, discovered that methadone was beneficial in the treatment of opiate-dependent patients.¹

Several studies from the United Kingdom in the 1940s described methadone’s efficacy in reducing heroin withdrawal symptoms. Ingeborg Paulus and Dr. Robert Halliday, working with the Narcotic Addiction Foundation in Vancouver, established the first methadone maintenance treatment program in the world and published their findings in the Canadian Medical Association Journal in 1967.² In the United States, Dr. Vincent Dole and Dr. Marie Nyswander confirmed the feasibility of using methadone as a maintenance medication for heroin dependence.³ Since then, many other studies have shown the effectiveness of using methadone as a maintenance medication for opioid dependence. These studies demonstrate a three- to four-fold increase in death rates in patients discontinuing methadone maintenance treatment.⁴ ⁵ In addition to physical, mental and social health benefits, studies have consistently shown that risk of blood-borne pathogen transmission is significantly reduced by participation in methadone maintenance treatment, even in patients failing total abstinence from illicit substances.⁶

2. Authorization to Prescribe Methadone

Methadone is a controlled drug and physicians who wish to prescribe methadone in Canada require authorization in the form of an exemption from the federal minister of health, in accordance with section 56 of the Controlled Drugs and Substances Act. Physicians must apply to the Methadone Maintenance Program at the College of Physicians and Surgeons of British Columbia for this exemption.

The College then recommends and forwards physicians’ names to Health Canada to be considered for approval.

The words “exemption” and “authorization” both refer to the exemption which is granted under section 56 of the *Controlled Drugs and Substances Act* and which authorizes a physician to prescribe methadone.

Physicians can apply for one of three types of authorizations to prescribe methadone for opioid dependence: full, temporary or hospitalist.

### 2.1 Full Authorization

The College will recommend a full authorization to Health Canada only after the following requirements have been satisfactorily fulfilled:

- attendance at the [Methadone 101 Workshop](#) sponsored by the College
- a completed [Application for Authorization to Prescribe Methadone in the Treatment of Opioid Dependence](#)
- familiarization with the *Methadone Maintenance Program: Clinical Practice Guideline*
- a [preceptorship](#) satisfactory to the MMP
- an acceptable review of your prescription profile from the PharmaNet database
- an interview with a member of the registrar staff
- an agreement to undertake a minimum of 12 hours of continuing medical education (CME) in addiction medicine each year
- an agreement to provide after-hours contact information regarding your methadone maintenance patients
- an agreement to undergo a practice assessment of your methadone maintenance practice within the first year

The initial authorization is provisional and granted for one year. Continued support for this authorization is contingent upon satisfactory peer practice assessments and acceptable reviews of the prescriber’s PharmaNet practitioner prescription profile. (The Renewal/Cancellation of Methadone Authorization form and the Physician’s Contact Information form are available on the College website under the [BC Methadone Program](#) page.)
2.2 Temporary Authorization

A temporary authorization to prescribe methadone for up to 60 days can be obtained in the following circumstances:

- locum replacement of another authorized physician (advance notice required)
- continuation of methadone prescribing for patients in hospital when no other authorized physician is available

A completed application for either a **Temporary Authorization to Prescribe Methadone as a Locum in a Clinic or Correctional Centre** or a **Temporary Authorization to Prescribe Methadone in a Hospital** is required.

Physicians with temporary authorizations may not initiate patients on methadone treatment for opioid dependence and should exercise caution and consider consulting more experienced prescribers if increasing doses.

2.3 Hospitalist Authorization

Physicians caring for methadone patients in a hospital setting may apply for a hospitalist methadone authorization after satisfactorily fulfilling the following requirements:

- attendance at the **Methadone 101/Hospitalist Workshop** sponsored by the College
- a completed **Application for Authorization to Prescribe Methadone as a Hospitalist**
- familiarization with the **Methadone Maintenance Program: Clinical Practice Guideline**
- familiarization with the recommended **key articles** on methadone for analgesia
- familiarization with the **Recommendations for the Use of Methadone for Pain**
- an interview with a member of the registrar staff
- an acceptable review of your prescription profile from the PharmaNet database

This authorization includes a full authorization to prescribe methadone for analgesia and a limited authorization to prescribe methadone for opioid dependence, which does not include registering patients in the Methadone Maintenance Program unless their continuity of care with a community methadone prescriber is arranged prior to their discharge. Please also refer to **Hospitalized Patients**.

3. Pharmacology of Methadone

Methadone is a long-acting synthetic opioid which as an oral formulation is effective in treating opioid dependence. It is primarily a mu (μ) opioid receptor agonist and when administered in an adequate dose, it will prevent opioid withdrawal, reduce opioid craving and block the euphoric effects of opioids such as heroin.
3.1 Absorption

- Oral methadone is 80–95% bioavailable compared to only 30% for oral morphine.
- Methadone is rapidly absorbed following oral administration and serum levels are detectable 30 minutes post dose.

3.2 Duration of Action/Metabolism

- The time to peak plasma concentration and peak clinical effect is four hours (range of two to six hours).
- The plasma half-life averages 24 to 36 hours at steady state, but ranges from four to 90 hours.
- As a result of its long half-life, methadone may accumulate, leading to sedation and respiratory depression.
- It takes four to five days for methadone plasma levels to reach steady state after each dose change.
- Methadone metabolism is primarily a function of liver enzyme activity involving cytochrome P450 isoforms. There are many substances that interact by inducing, inhibiting or acting as a substrate for these enzymes. This can result in clinically significant drug interactions. Genetic, physiologic and environmental factors can also act on these enzymes, leading to a high degree of variation of individual methadone responsiveness.
- Methadone is primarily excreted as an inactive metabolite (10% as unchanged methadone) primarily in urine and feces. Compromised renal function does not preclude the use of methadone, and the dosage does not need to be adjusted for patients on dialysis.
- Elimination half-life is approximately 22 hours, but ranges from five hours to 130 hours.

3.3 Tolerance

- Cross-tolerance between methadone and other opioids is unpredictable.
- Tolerance to the various effects of methadone develops at different rates. Tolerance to the euphoric effects of methadone develops quickly and may be interpreted by patients as being due to an inadequate dose. Tolerance to respiratory depression is less rapid in onset and tolerance to the autonomic side effects is the slowest.
- Tolerance is lost in as little as three days.
- Methadone is potentially lethal and the risk of toxicity is increased by concomitant ingestion of alcohol and sedative-hypnotics such as benzodiazepines and Z drugs.
ADMISSION TO THE METHADONE MAINTENANCE PROGRAM

1. Criteria for Admission to the Methadone Maintenance Program

All patients being prescribed methadone for maintenance (opioid dependence) must be registered in the Methadone Maintenance Program (MMP) which is administered by the College of Physicians and Surgeons of British Columbia by agreement with the British Columbia provincial government. After an authorized methadone prescriber has assessed a patient as an appropriate candidate for methadone maintenance treatment (MMT) and has formulated a treatment plan with that patient, the patient should be registered with the Methadone Maintenance Program before MMT is initiated (unless the MMT is initiated in hospital, when the registration may be deferred until their discharge to the community).

For admission to the program the patient must meet the following inclusion criteria:

- meet DSM-IV-TR criteria for opioid dependence (the panel opted to continue using DSM-IV-TR criteria due to the large body of literature supporting clinical outcomes using these criteria)
- have experienced adverse consequences in multiple life realms
- have undergone a documented and comprehensive evaluation to determine the risks and benefits of methadone and other treatment options
- have documented initial goals of treatment
- be informed of all other treatment options for opioid dependence so that their decision to start MMT is based on valid informed consent

These forms are available for your use:

- MMP Patient Assessment Form
- Methadone Maintenance Treatment Agreement and Consent
- Patient Registration
- Patient Transfer
- Family Physician Notification

Methadone prescribers should not hesitate to seek a second opinion when dealing with difficult management problems such as patients with chronic pain, adolescents, pregnant patients and patients with polydrug dependence. See Special Populations for more information.
2. **DSM-IV-TR Diagnostic Definition of Opioid Use Disorder**

Opioid dependence, as a type of substance dependence, is defined as follows:

A *maladaptive pattern of substance use*, leading to clinically significant impairment or distress, **as manifested by** three (or more) of the following, occurring at any time in the same 12-month period:

1. **Tolerance**, as defined by either of the following:
   - A need for markedly increased amounts of the substance to achieve intoxication or desired effect
   - Markedly diminished effect with continued use of the same amount of the substance
2. **Withdrawal**, as manifested by either of the following:
   - The characteristic withdrawal syndrome for the substance (refer to criteria A and B of the criteria sets for withdrawal from the specific substances)
   - The same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms
3. The substance is often taken in larger amounts or over a longer period than was intended
4. There is a persistent desire or unsuccessful efforts to cut down or control substance use
5. A great deal of time is spent in activities necessary to obtain the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g., chain-smoking), or recover from its effects
6. Important social, occupational, or recreational activities are given up or reduced because of substance use
7. The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance (e.g., current cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was made worse by alcohol consumption)

3. Treatment Considerations

It is recommended that MMT be part of a spectrum of treatment focused on improving health and social outcomes. Because the majority of MMT patients are polysubstance dependent, it is important for physicians prescribing methadone to be aware of, and familiar with, a broad range of other treatment resources. The problematic use of one substance places the individual at risk of having problems with others. It is current expert opinion that MMT is compatible with abstinence-based treatment programs. In addition, lifestyle modification is an essential aspect of substance use disorders.

3.1 Detoxification

Detoxification, or withdrawal management, refers to the management of substance withdrawal in order to reduce severity of symptoms. Most MMT patients are also dependent on other substances, and these dependencies must be individually addressed in order to achieve long-term stability. In-patient or outpatient detoxification for other psychoactive substances such as alcohol, sedative-hypnotics or stimulants should be offered concurrently.

3.2 Outpatient and Day Treatment Programs

Most health authorities, community substance use services, employee assistance programs and private service providers offer a range of outpatient and day treatment programs. Physicians prescribing methadone must be familiar with outpatient programs in their community and build relationships with other care providers. Successful treatment for opioid and other addictions is based on counselling and individual or group programs, together with regular brief interventions by physicians.

3.3 Residential and Support Recovery Programs

Residential and support recovery programs vary in structure, length and mandate. Physicians practising addiction medicine must be familiar with the philosophy, entrance criteria and treatment objectives of a variety of residential programs. Many programs accept patients in the MMP and offer patients with addictions a substantial opportunity for behaviour change and long-term abstinence. These programs offer safe, supportive housing as well as aftercare for patients who have completed detoxification or who are on MMT.

3.4 Alternative Pharmacotherapies

Health Canada approved Suboxone for the treatment of opioid dependence in adults in 2008. Suboxone combines buprenorphine, a partial mu-receptor agonist which is an effective therapy for opioid dependence, and naloxone, an opioid antagonist whose inclusion is intended to limit intravenous misuse and the potential for diversion. The naloxone component of Suboxone has limited sublingual and oral bioavailability and is inactive when Suboxone is taken as prescribed.
Suboxone is contraindicated in pregnancy; however, physicians may contact Health Canada’s Special Access Programme to obtain authorization for the buprenorphine-only product.

Suboxone may only be prescribed under the following circumstances:

- the physician must have an authorization to prescribe methadone for opioid dependence (this includes hospitalists)
- physicians must have completed an accredited Suboxone training program, i.e. Schering-Plough Canada’s online education module at www.suboxonecme.ca, or the American Association of Addiction Medicine (ASAM) Buprenorphine and Office Based Treatment of Opioid Dependence program
- Suboxone must be prescribed on a controlled prescription form (also known as a duplicate prescription pad)

**Note:** Patients meeting specific criteria may receive PharmaCare coverage. Physicians may apply for coverage by completing the Collaborative Prescribing Agreement for Suboxone (http://www.health.gov.bc.ca/pharmacare/pdf/cpa-buprenorphine.pdf).

### 3.5 Mutual Support Groups

Mutual Support groups such as Narcotics Anonymous, Methadone Anonymous, Alcoholics Anonymous, SMART and 16-Steps, are generally very accessible and can provide continuing support and promote accountability.

### 3.6 Mental Health Services

The comorbidity of substance dependence and mood, thought and anxiety disorders, such as post-traumatic stress disorder is as high as 50%.

Physicians practising addiction medicine must be familiar with the identification and management of common mental illness and be aware of treatment resources in their community. It is the current standard of care that mental health and addiction be treated concurrently. For more information, see Mental Health – Concurrent Disorders.
ASSESSMENT FOR INITIATION

The methadone treating physician is responsible for patient selection, dose determination, and monitoring and documenting progress.

Newer technologies including telemedicine may reduce the barriers to access to care; however, this technology should not reduce the level of clinical care as outlined in these guidelines. Initial assessments and induction of patients must involve a face-to-face encounter and clinical examination.

The Methadone Maintenance Program provides the following forms for your use:

- MMP Patient Assessment Form
- Methadone Maintenance Treatment Agreement and Consent
- Patient Registration
- Patient Transfer
- Family Physician Notification

1. Assessment Checklist

Assessment of substance-dependent patients must include the following:

1. a complete medical history, including a chronological substance-use history, confirming the diagnosis with documentation of opioid dependence, other substance dependence, and process addictions diagnoses
2. a family history including addictions history
3. a biopsychosocial assessment with relevant information regarding the patient’s current and past social situation, including supports and stressors
4. a complete physical examination with special attention to signs of opioid withdrawal, needle tracks, abscesses, jaundice and hepatosplenomegaly
5. urine drug test (UDT)
6. a laboratory assessment which includes the following:
   - CBC
   - liver function panel
   - HIV, hepatitis A, B and C serology
   - syphilis serology
   - TB testing, when appropriate
   - pregnancy test, on all women of child-bearing age
   - EKG if indicated
7. documented communication with the patient’s prior methadone prescriber and family physician
8. documented review of the PharmaNet prescription profile
9. documented treatment goals and plans, with a signed treatment agreement

2. **Treatment Goals and Plans**

Treatment goals are objective outcomes that the patient and physician expect will result from methadone maintenance treatment. Treatment plans describe the steps required to achieve the goals.

Once a goal has been defined, a brief outline of the plan for achieving that goal should be documented to help direct patient care. The following table represents examples of treatment plans and goals.

**Table 1: Treatment goal and plans example**

<table>
<thead>
<tr>
<th>GOAL</th>
<th>PLAN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stop illicit substance use</strong></td>
<td>• review weekly and adjust methadone dose as necessary</td>
</tr>
<tr>
<td>Barriers are unsafe housing, drug-dealing partner and lack of non-chemical coping skills. (Recognizing 20% of patients will never reach total abstinence from illicit opioids, documented reduction is also a reasonable goal)</td>
<td>• refer patient to counsellor and social worker regarding safe housing and access to a women’s shelter</td>
</tr>
<tr>
<td></td>
<td>• monthly treatment team meeting to review progress</td>
</tr>
<tr>
<td></td>
<td>• document reduction in illicit opioid use</td>
</tr>
<tr>
<td><strong>Address health concerns</strong></td>
<td>• HIV work-up and consider referral to immunodeficiency specialist</td>
</tr>
<tr>
<td>Patient is HIV positive, has multiple skin infections and recurrent cellulitis, as well as untreated mental illness</td>
<td>• contact street nurse re: daily change of dressings and antibiotic administration</td>
</tr>
<tr>
<td></td>
<td>• refer to community mental health service with referral letter</td>
</tr>
</tbody>
</table>

3. **Problematic Alcohol Use**

1. Problematic alcohol use is the most common problematic substance use disorder.
2. Comorbidity – up to 40% of methadone-maintained populations will meet criteria for problematic alcohol use at any one time. It is critical that all patients be screened for problem drinking at initiation and intermittently.
3. There is evidence that between 5% and 50% of patients\textsuperscript{7,8,9} enrolled in MMT will meet criteria for alcohol misuse disorder at any one time. Additionally, alcohol misusing methadone maintained patients demonstrate poor MMT outcomes and experience higher morbidity and mortality rates than non-alcohol abusing methadone maintained patients.

4. Screening, diagnosis and management protocol is available at the following link: http://www.bcguidelines.ca/alphabetical.html#problem_drinking

4. **Process (Behavioural) Addictions**

Process addictions commonly occur with substance use disorders and share the common characteristics:

- cravings
- loss of control
- compulsive use
- use despite consequences

Examples of process addictions include, but are not limited to, the following areas:

- gambling
- sexual behaviours such as use of pornography, Internet or sex trade workers
- compulsive shopping, spending, or shoplifting
- eating disorders
- compulsive exercise or work behaviours

Given the connection between process addictions and substance use disorders, screening of patients for process addictions at the initial evaluation and on an intermittent basis is recommended. Evaluation for process addictions should be incorporated into a yearly review, or used in the evaluation of recurrent relapse or failure to progress through the stages of recovery.

The following clinical screening tools are useful in assessing process addictions:

1. **Gambling**
   - South Oaks Gambling Screen
   - Canadian Problem Gambling Index

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• Gamblers Anonymous 20 Questions

2. Sexual addiction
   • Sexual Addiction Screening Test (SAST)
MAINTENANCE AND MONITORING

### 1. Methadone Dosing

As of February 2014, methadone for opioid dependence will be dispensed in a new formulation called Methadose, with a strength of 10 mg/ml.

#### 1.1 Initiation (Induction)

Methadone for opioid dependence should initially be prescribed for ingestion under supervision (“daily witnessed ingestion” or “DWI”) at the pharmacy. There is no clear relationship between the amount of opioid used and the dose of methadone that will be required for initiation.

The following factors will affect the amount of the initial dose required:

- amount, concentration and purity of opioid used
- accuracy of the medical and drug use history
- variation in rates of methadone metabolism
- variation in opioid cross-tolerance to methadone

Equi-analgesic tables for converting opioid-using patients to methadone are unreliable. Such tables are not recommended for initiating patients onto methadone maintenance. Methadone blood levels will continue to rise for up to four to five days after starting or increasing a dose due to its long half-life. At day three (48 hours after the first dose), an individual’s methadone blood level will be 87.5% of steady-state dose.

**Table 2: Initiation doses**

<table>
<thead>
<tr>
<th>Level of tolerance</th>
<th>Recommended daily starting dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-tolerant or opioid-naive</strong></td>
<td>5–10 mg/day</td>
</tr>
<tr>
<td>This category includes patients not currently using opioids but who are at risk of relapse.</td>
<td></td>
</tr>
<tr>
<td><strong>Unknown tolerance</strong></td>
<td>10–20 mg/day</td>
</tr>
<tr>
<td>This category includes patients known to be using other sedative drugs or alcohol.</td>
<td></td>
</tr>
</tbody>
</table>
## Level of tolerance

<table>
<thead>
<tr>
<th>Known tolerance</th>
<th>Recommended daily starting dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20–30 mg/day</td>
</tr>
</tbody>
</table>

During initiation, patients should be seen frequently (at least weekly) and doses should not be adjusted if patients have not been seen. It is important to start with a safe initial dose which does not exceed the maximum recommended starting dose of 30 mg/day.

Most deaths occur during initiation due to too rapid dose escalation. Initiation outside of the above recommended ranges may result in patient deaths which have been associated with starting doses as low as 30 mg.

### 1.2 Titration

Methadone can cause fatal respiratory depression because of its long half-life and the consequent risk of drug accumulation. The dosage must therefore be titrated carefully.

Risk factors for methadone toxicity include the following:

- use of other central nervous system (CNS) depressants, e.g. benzodiazepines and alcohol
- lack of tolerance, i.e. recent detox, discharge from jail or treatment centre
- use of medications that affect methadone metabolism
- respiratory illness
- decompensated liver disease
- advanced biological age

Note the following:

- dose increases should be no more than 5–10 mg at a time
- the interval between dose adjustments should never be less than five days, but may need to be longer due to the above risk factors
- patients should be seen frequently (at least weekly) during titration phase

If physicians wish to accelerate treatment, a daily clinical reassessment of the patient at three to four hours post-ingestion (peak methadone blood level) for the first three to five days after initiation or dose adjustment is required. Prescribers should not allow weekends to interrupt this process and should select a start date accordingly.
1.3 Stabilization

An effective maintenance dose:

- eliminates withdrawal symptoms for more than 24 hours
- blocks the euphoric effects of opioids
- reduces or eliminates drug craving
- does not induce excess sedation

An adequate dose should be prescribed. Those who receive a dose of 40 mg a day or less are five times more likely to drop out of treatment prematurely than patients who receive a dose of 60 mg or more.10

Once a daily dose of 80 mg is reached further dose increases should be made with caution, not exceeding 10 mg every five to seven days but more slowly in the presence of the risk factors noted above.

Most patients will achieve stability on maintenance doses of 60 to 120 mg daily.

Methadone doses must always be individualized and based on clinical response.

1.4 Split Doses

Split doses may be used in symptomatic patients who are pregnant or who demonstrate rapid metabolism. Less than 5% of patients are rapid metabolisers and this should be documented with peak and trough methadone levels. Another common cause of rapid metabolism is use of concurrent medications which induce cytochrome P450 3A4 enzymes.

- Rapid metabolizers generally experience symptoms of opioid withdrawal within 12 hours even with dose escalation; methadone dose increases result in sedation with no alleviation of withdrawal symptoms.
- Split doses should not be provided in the absence of laboratory evidence of rapid metabolism because of the difficulty of ensuring twice daily witnessed ingestion and the risk of diversion of the second dose.

A list of medications metabolized by cytochrome P450 3A4 is available here.

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• Rapid metabolism is confirmed by measuring serum trough (prior to ingestion) and peak (four hours post-ingestion) methadone levels. A peak to trough ratio greater than 2:1 is consistent with rapid metabolism.
• Split dose transition: day 1 = 100% of original daily dose and 50% of the original daily dose to take in 12 hours; day 2 = 50% of original daily dose every 12 hours.

Figure 1: Split dose simulation

1.5 Missed Doses

Tolerance is rapidly lost when methadone ingestion is interrupted or discontinued. Pharmacists are required to notify physicians of missed doses but physicians must document review of PharmaNet profiles.

Suggested Protocol for Managing Missed Doses

a. One or two days missed
   No change in dose is required as long as there is no other reason to withhold methadone. The reasons for the missed doses should be discussed and documented at the next visit
b. **Three or four consecutive days missed**

Methadone should be held until the patient has been reassessed by a physician. The remainder of the prescriptions should be cancelled. Loss of tolerance may occur in as little as three days, and the usual dose may be excessive.

- dose of 30 mg or less – continue same dose
- dose greater than 30 mg – restart at 50% of the usual dose, but the reduced dose should be no less than the initial dose of 30 mg unless there is sedative-hypnotic or alcohol use
- after tolerance to the reduced dose is demonstrated, the dose can be rapidly increased (a maximum of 10 mg per day). A slower dose escalation is suggested for patients with an unstable clinical picture or with concurrent sedative or hypnotics use. During this rapid re-titration, the patient should be reassessed at least every two days until a stable dose has been re-established.

c. **Five or more consecutive days missed**

Restart at a maximum of 30 mg of methadone, then titrate with frequent re-evaluation until stable.

The reasons for the missed doses should be discussed and documented in the clinical records. The treatment plan may need to be updated.

### 1.6 Dosing Precautions

#### 1.6.1 Side Effects of Methadone

In addition to profound sedation, respiratory depression and coma other side effects are:

- bradycardia and hypotension
- constipation
- perspiration
- endocrine effects/depressed libido
- xerostomia (dry mouth)
- sleep disturbance
- dysphoria
- dyspepsia
- opioid-induced edema
- pruritus

Any of these side effects may occur during chronic opioid therapy but often diminish with time. Prescription medications may be required to treat these symptoms.
### 1.6.2 Toxicity

Patients at risk for methadone toxicity include those who concurrently use alcohol, sedative-hypnotics (including benzodiazepines), stimulants, or medications that interfere with methadone metabolism. An overdose can result from sudden cessation of a drug that induces methadone metabolism. There have been reports of torsades de pointes cardiac arrhythmia in patients taking high dose methadone. It is recommended that patients who have cardiac disease, who are taking medications that prolong the QT interval or have metabolic concerns known to cause QT interval prolongation, should have an electrocardiogram (ECG) reviewed prior to starting methadone. The ECG should be repeated as clinically indicated. In patients with no other risk factors for cardiac arrhythmia, an ECG should be done if the dose of methadone exceeds 150 mg and repeated when the patients’ clinical status changes.

QTc intervals greater than 450 msecs should prompt review of methadone doses for other potential causes including medications which prolong QTc. Physicians should discuss the clinical implications with their patient and consider dose reduction and/or cardiology consultation.

### 1.6.3 Fatal Overdoses

Fatal overdoses most often occur during initiation or dose escalation or resulting from changes in prescribed medications or illicit substance use. It is essential that constant communication occurs between treating physicians to ensure that prescribed medication changes are made safely.

Fatal overdoses of methadone often occur in individuals who have acquired methadone from other individuals for whom it was prescribed. Therefore, it is important for the physician to be aware of the risk of diversion of prescribed methadone and to take responsibility for ensuring that the methadone they prescribe as carries is actually being taken by the patient.

Fatal overdoses are also often associated with concurrent use of:

- sedative-hypnotics such as benzodiazepines
- alcohol
- cocaine

Prescribing physicians should be aware of factors such as the long half-life of methadone, variable rates of methadone metabolism and variation in patients’ tolerance levels that can potentially lead to overdose. During the induction phase, patients are likely to continue to use illicit drugs. Physicians should closely monitor patients during induction and caution patients about the risk of overdose if certain illicit drugs are continued.
Physicians must document review of PharmaNet profiles on a regular basis.

2. Urine Drug Testing (UDT)

Urine drug testing is the standard of care in methadone programs, because it provides an essential tool for the interpretation of clinical status. UDT answers three questions:

- Is the patient taking the prescribed medications?
- Is the patient taking other drugs/substances?
- Is the patient taking steps to conceal use?

2.1 When and Why to Order UDT

UDT must be obtained at the initial assessment as it provides information about current drug use, which is essential in the treatment planning process. The absence of opioids in the urine does not preclude admission to the MMP. For example, an opioid-dependent patient who is currently abstinent but assessed to be at high risk of relapse and having a negative UDT, may be a good candidate for the MMP. UDT should be performed at least monthly until the patient is stable.

Patients who take methadone as DWI may be monitored with UDT as clinically indicated.

Patients receiving carries should have random UDT on a regular basis and refusal to comply with UDT should result in reassessment and possible return to DWI as a safety precaution.

2.2 Method of Collection

The BC Methadone Program provides guidelines for urine collection.

2.3 Urine Toxicology

Either point of care (POC) or laboratory testing is appropriate and the decision on which to use would be an assessment of advantages and disadvantages of your practice. It may be helpful to discuss with your local laboratory service. Point of care UDT for methadone maintenance can be billed to Medical Services Plan (MSP) under fee code P15039 and covers seven substances:

- amphetamines
- benzodiazepines
- cocaine metabolites
- opiates
- oxycodone
- buprenorphine
- methadone metabolites

Laboratory UDT will typically detect the following substances, but you should check with your local laboratory service:

- amphetamines (e.g. amphetamine, dextro and methamphetamine, MDMA (Ecstasy))
- benzodiazepines (e.g. diazepam, oxazepam, temazepam, triazolam)
- cocaine metabolite (e.g. benzoylecgonine)
- methadone metabolite (e.g. EDDP)
- opiates (e.g. heroin metabolite, morphine, codeine)

Common options include:

- “confirm – if positive”
- oxycodone
- buprenorphine
- cannabinoids
- fentanyl

The standard amphetamine screen does not detect methylphenidate (Ritalin).

The standard benzodiazepine screen does not reliably detect clonazepam or lorazepam and will not detect the Z drugs (zopiclone, zolpidem, zaleplon).

The standard opiate screen does not detect synthetic opioids such as oxycodone, hydrocodone, meperidine fentanyl—these tests must be ordered individually. Avoid ordering “opioids” or using trade names.

Hydromorphone may produce positive opiate screen in high doses and it is currently not available as a POC test.

Buprenorphine needs to be specifically requested.

Urine toxicology for alcohol is unreliable due to the rapid rate of metabolism, but ethyl glucuronide (EtG) can detect alcohol use for one to two days.

Confirmatory testing (GC/MS) is expensive and should only be ordered if the result will alter management. It is also expensive to order uncommon substances and before doing so consider consultation with a laboratory physician.
Testing for adulterants and sample dilution is not routinely performed: most laboratories will automatically test for creatinine, but only if a specimen appears clear and colourless. Creatinine levels between 0.18 and 1.8 mmol/L suggest dilution, and levels less than 0.18 mmol/L suggest substitution.

Relevant information is available in the Ministry of Health Guidelines and Protocols Advisory Committee document titled *Methadone Maintenance Therapy (MMT) Program: Urine Drug Testing of Patients.*

### 3. Carry Privileges

Patients starting MMT must ingest methadone in the pharmacy under the supervision of a pharmacist (i.e. DWI). Patients who are biopsychosocially stable and who demonstrate appropriate UDT may be granted carries.

A “carry” refers to patients receiving doses of methadone to be taken home for self-administration. The initial dose of a carry prescription is always witnessed.

The decision to initiate carries can only be made by the physician. The reasons for granting carry privileges must be documented. Physicians must ensure that carries are safe for both patients and the public. A discussion around safe storage of methadone must occur. Unsafe storage and diversion may result in lethal consequences.

#### 3.1 Criteria for Initiating Methadone Carries

##### 3.1.1 Biopsychosocial Stability

- Patients should be established on a stable methadone dose for at least four weeks.
- Patients should have demonstrated social, cognitive and emotional stability as confirmed by attending all scheduled appointments, no missed doses, improved social relationships or returning to work or school.
- Patients medical records should document the interpretation of appropriate UDTs for a minimum of 12 weeks.

##### 3.1.2 Safe Methadone Storage

- Physicians who prescribe methadone as carries are responsible to make patients aware that this medication can be very dangerous especially to opioid-naive people and children.
- Methadone should be stored in locked containers or cabinets.
- Carries should not be provided if safe storage cannot be ensured.
3.2 Carry Schedule

There is evidence that the effectiveness of MMT can be enhanced by allowing carry privileges. Progressive carry privileges should be dependent on the patient’s increasing stability; reduction or discontinuation of carry privileges should occur with evidence of instability. Criteria for assessing stability should be transparent and consistent.

Carry schedules should start with a one-day carry, progressing to additional carry days every month or two months. The first dose should always be witnessed in the pharmacy on the day the prescription is picked up. Most stable patients are established on a twice-weekly witnessed ingestion. This is a reasonable balance between safety and patient inconvenience.

Patients receiving carries must be seen at least monthly and provide unscheduled (random) UDTs.

3.3 Exceptions to Carry Guidelines

Exceptions may be granted at the discretion of the prescribing physician. Exceptions should only be initiated as a trial and be reviewed to ensure benefits outweigh risks to the patient and to the public. The reason for any exception to the carry guidelines must be documented.

3.4 Prescriptions for Carries

Methadone prescriptions must include the total methadone dose, the daily methadone dose, the first and last dates of the prescription, and, if carries are allowed, the number of days the patient is required to attend the pharmacy each week for witnessed ingestions.

3.5 Reassessment of Carry Privileges

Patients who demonstrate instability must be reassessed. Signs of instability include:

- evidence of non-prescribed psychoactive substance use
- missed appointments with physicians, counsellors or support groups
- missed methadone doses
- requests for increasing a previously stable methadone dose
- reports of lost, spilled, stolen or vomited methadone
- non-attendance for random UDT

These last two points may indicate diversion. Physicians are responsible to their patient and the public to take appropriate steps to minimize the possibility of diversion of all prescription opioids including methadone.
When there is evidence of instability the physician may reduce the number of carries per week or return
to daily witnessed ingestion depending on the extent and duration of instability. Carry privileges may
gradually be reinstated once patients demonstrate evidence of stability.

4. Counselling

Many methadone patients struggle with a number of challenges, such as poverty, lack of education,
exposure to violence, poor nutrition, serious physical or mental health problems and involvement with
the criminal justice system. These problems are not addressed with the provision of methadone alone.

Methadone programs that do little more than provide a methadone prescription are inadequate;
methadone programs are expected to incorporate a comprehensive biopsychosocial and spiritual
approach to treatment.

When counselling is integrated into methadone maintenance programs, there are significant reductions
in drug use. It is important for methadone prescribers not to adopt the perception that counselling is a
task to be taken on exclusively by other staff or caregivers. All MMT physicians share this significant
responsibility as part of their overall mission to facilitate treatment and, ultimately, recovery.

4.1 The Methadone Prescriber’s Role

In order to assist the patient in meeting treatment goals, methadone prescribers must establish trusting,
therapeutic relationships with their patients. Physicians need to create non-judgmental, collaborative
environments in which patients feel safe to discuss their concerns. If positive relationships do not
develop, the methadone maintenance program will have minimal benefit.

Once constructive relationships have been established, physicians must work with patients to identify
aspects of each patient’s life that could be changed or modified to benefit the patient. These treatment
goals should be identified collaboratively between the patient and the physician. Many appropriate
treatment goals are not necessarily focused on drug-using behaviour. For example, patients may wish to
move to better or safer housing, improve their general health, enrol in training programs, learn better
communication skills, learn relaxation techniques or improve the quality of their personal relationships.

Newer technologies including telemedicine may reduce the barriers to access to care; however, this
technology should not reduce the level of clinical care as outlined in these guidelines. Initial assessments
and induction of patients must involve a face-to-face encounter and clinical examination.

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11 McLellan AT, Arndt IO, Metzger DS, Woody GE, O’Brien CP. The effects of psychosocial services in substance
After goals have been identified, methadone prescribers should work with patients to develop treatment plans to meet these goals. This progress should be monitored and outcomes documented.

Depending on each patient’s circumstances, physicians may opt to work in collaboration with counsellors, or may refer patients to independent counselling agencies or self-help groups such as Alcoholics Anonymous (AA) or Narcotics Anonymous (NA) and Self-Management and Recovery Training (SMART). Many other specialized resources may be available to aid methadone patients. Physicians are expected to familiarize themselves with the full spectrum of services available to their patient population through their local health authorities, and are encouraged to refer their MMT patients to appropriate community treatment programs, support groups and counsellors (see also Community Substance Use Services). Whatever resources are chosen, physicians should be aware of the issues each patient is attempting to address and what progress has been made. This information should be incorporated into the patient’s treatment plan.

Regardless of where the patient is engaged in counselling, the physician should communicate with the counsellor (with the patient’s consent), document and play an active role in the process.

The most important element of treatment is ensuring that the patient is engaged in the treatment, rather than the particular therapeutic model employed or the details of the treatment.

### 4.2 Brief Interventions

Methadone prescribers can effectively use frequent brief interventions to instill motivation in patients who lack self-motivation. Substance-dependent patients are often described as lacking motivation to change, especially if that change requires some self-organization.

Effective therapeutic relationships are best provided where the same clinicians are consistently available to the patient.

The following are examples of positive brief interventions that address different barriers to change in patients’ lives:

1. **Building a therapeutic relationship**
   - Demonstrate sustained interest and concern for patients’ progress.
   - Schedule regular visits and ensure that two-way communication exists.

2. **Education**
   - Provide factual drug information and information on post-acute withdrawal syndrome.
   - Educate patients regarding the symptoms of impending relapse, such as exhaustion, complacency, impatience, dishonesty, self-pity, frustration, and depression.
   - Discuss behaviours such as denying, minimizing, rationalizing, intellectualizing and compartmentalizing.
3. Goal planning
   - Consider all areas of patients’ lives, not just substance use issues.
   - Prepare and document plans on how to avoid drug using situations.
   - Identify and help remove impediments to change, such as the need for childcare or transportation.
   - Remind patients that it is better to reach a modest goal than to aim for, but fail to reach, a more ambitious target. Coach patients to take small steps on the road to recovery.

4. Promoting self-awareness and positive behaviours
   - Identify internal and external triggers for relapse.
   - Avoid dwelling on failures. Help patients take pride in and build on their successes.
   - Encourage harm-reduction behaviour.
   - Encourage the development of self-esteem, which is the primary ingredient necessary for any successful therapy.

4.3 Transtheoretical Model of Change

The process of change has been conceptualized by J.O. Prochaska and C.C. DiClemente as a series of stages through which individuals may move cyclically until permanent change has occurred. These stages are as follows:

- pre-contemplation
- contemplation
- preparation
- action
- maintenance
- relapse

Motivational interventions must match the patient’s stage of change. Patients will quickly become frustrated when the intervention offered is out of step with their own view of the problem. For example, if a patient has only just started to weigh the pros and cons of whether or not a particular issue is a problem (the contemplation stage), recommending a particular solution (action stage) will only elicit resistance and be counterproductive.

The table titled Appropriate Motivational Strategies for Each Stage of Change suggests several interventions for each stage of change.

4.4 Community Substance Use Services

All publicly funded treatment facilities located throughout British Columbia fall under the jurisdiction of the health authorities. The range of options for treatment of substance dependence includes outpatient counselling services, detoxification, intensive residential treatment, support recovery and other forms of
supportive housing. Many of these ancillary treatment options are available to patients on methadone. Methadone treatment is much more successful in preventing drug-related harm, reducing drug use and fostering long-term recovery from substance dependence when counselling is included as part of the treatment. Methadone prescribers and clinics are strongly urged to take advantage of the resources available to their patients and to refer appropriate MMT patients to community treatment facilities, support groups and counsellors for additional support.

5. Documentation of Benefits

Not every opioid-dependent patient will benefit from MMT. Like any other medical treatment, there are risks and benefits associated with this treatment. Methadone prescribers must clearly document the benefits derived from MMT in each patient’s chart, and also develop and record a treatment plan outlining how further benefits (goals) are to be achieved. Documenting the benefits of MMT is the standard of care of MMT. In addition to recording the dose of methadone provided at each visit, reference to parameters of benefit and current treatment plans should be recorded.

5.1 Categories of Benefits

The benefits of methadone maintenance treatment fall into seven categories. Methadone prescribers may find the following list useful for assessing their patients’ progress, and for formulating and monitoring treatment plans:

1. reduction or cessation of opioids use, particularly intravenous
2. reduction or cessation of other psychoactive substance use
3. improved mental and physical health
   • decreased incidence of concomitant infections such as endocarditis, osteomyelitis, and cellulitis, with consequently reduced need for hospitalization
   • decreased emergency room visits for drug-related complications
   • improved mental health outcomes
   • improved hepatitis C (HCV) and HIV clinical parameters
   • improved engagement with primary care
   • improved nutrition and weight gain
   • improved pregnancy outcomes
4. decreased involvement with the criminal justice system
5. improved living situations – end-stage opioid dependence often results in homelessness or unsafe living conditions; methadone maintenance patients should be encouraged to seek drug-free accommodation, as this is essential for successful recovery; improved living situations might include an environment with sober friends, or safe long-term, drug-free housing as well as other forms of supportive housing
6. improved social and personal relationships
7. improved vocational and employment opportunities
8. patients who attain improved medical and social stability are much more likely to connect with social agencies to gain access to financial support; they are also more likely to be considered for educational and training programs which may be necessary for eventual employment.

6. **Prescriptions for Methadone Maintenance**

1. Methadone maintenance prescriptions must be written only on designated methadone maintenance controlled prescription forms (see figure 2). **Note that these prescriptions will be considered void if the preprinted text is altered.** It is permissible to mark an “x” in the home delivery box if you do not want to authorize home delivery.

Figure 2: Methadone maintenance controlled prescription form
2. The regular controlled prescription form is to be used for all prescriptions for methadone for analgesia, as well as prescriptions for formulations of methadone other than Methadose (such as Metadol tablets) being prescribed for MMP patients for reasons such as travel.

3. As of February 2014, the standard concentration of methadone for maintenance purposes is 10 mg/ml.

4. The methadone maintenance controlled prescription form must specify the following:
   a. daily dosage in mg, with inclusive start and stop dates
   b. if the patient is restricted to daily witnessed ingestion (DWI) in pharmacy or if carry privileges are allowed
      i. if carry privileges are allowed, physicians must specify the number of witnessed ingestions
      ii. if specific dates are not indicated by the physician on the methadone maintenance controlled prescription form, the days for witnessed ingestion are set to maximize the number of days between witnessed ingestions by the College of Pharmacists of British Columbia

5. If any change occurs prior to the completion of a current prescription, a new prescription must be issued and include instructions to cancel the previously issued prescription.

6. Physicians’ copies of the controlled prescription forms must be retained by the physician and must be identical to the copies issued to the patients.

7. Prescriptions for methadone may only be faxed under extenuating circumstances and should be communicated to the pharmacist. In these exceptional cases, the original prescription must be sent to the pharmacy by the next business day.

8. The use of previously signed blank prescription forms is unacceptable.

9. Optimal methadone prescribing occurs when good communication exists between physicians other health-care providers and pharmacists. Physicians must provide a contact number for the use of other health-care providers involved in the care of their registered MMP patients.
DISCONTINUATION OF METHADONE MAINTENANCE TREATMENT

There is compelling evidence that patients who remain in long-term MMT continue to derive benefit. There is also evidence that the majority of patients who discontinue MMT relapse to non-medical opioid use within one year.

Methadone maintenance treatment may, however, be discontinued for a variety of reasons:

- treatment goals have been achieved and patient wishes to withdraw
- treatment goals not achieved but patient wishes to withdraw anyway
- involuntary dismissal from care

When MMT is discontinued, please submit a [Patient Cessation of Treatment](#) form providing information, if possible, about the reasons for discontinuation of treatment.

1. **Discontinuation in Stable Patients: Treatment Goals Achieved**

Optimum benefits from MMT are not realized for at least a year. Generally, patients who have been on the Methadone Maintenance Program (MMP) for two or three years will have better outcomes when tapered off methadone than those who start the tapering process before two years of treatment.

In order to reduce the risk of relapse, patients should be encouraged to stay in MMT, although the decision whether or not to discontinue methadone ultimately lies with the patient. The following goals are associated with a reduced risk of relapse while engaged in MMT and following discontinuation:

- long-term abstinence from opioids and other psychoactive drugs
- development of non-chemical coping skills
- stable housing
- stable mental and physical health
- development of supportive relationships with non-drug users
- stable source of income

Patients who continue to benefit from methadone and do not wish to be tapered from methadone should not be pressured to do so.
Literature suggests that the maximum weekly reduction of methadone should be no more than 5% of the total dose in order to minimize withdrawal symptoms and the risk of relapse. Patients frequently request more rapid tapering, and it is important that physicians explain the dangers of rapid tapering. Tapering should be undertaken as a trial. Patients who feel at risk or relapse to opioids or decompensate in other aspects of their lives during or after tapering should be offered re-entry to MMT and re-stabilized. Patients should not be penalized for unsuccessful tapering from MMT.

2. Discontinuation in Unstable Patients: Treatment Goals Not Achieved

Some patients choose to taper methadone despite its benefits even though they are not yet fully stable. In this case, tapering will place patients at high risk for relapse. The physician and counselling team should explore the patient’s motivation for tapering and provide alternative treatment options, including Suboxone. Physicians may recommend continuation in MMT, but if patients still insist on withdrawing from methadone, the patient and physician should prepare a plan for a trial of tapering, taking into consideration the relevant risks. Patients who relapse to non-medical opioids, become unstable, or alter their decision to taper at any time should be encouraged to re-engage MMT and return to a stabilizing dose.

3. Involuntary Dismissal

Patients not demonstrating objective benefits from MMT should have their treatment plans re-evaluated and be offered all reasonable interventions, including transfer to another methadone treatment provider. Should they still continue to fail to demonstrate objective benefits and all interventions have failed, they should be tapered from MMT and offered alternative treatment. Discontinuation of methadone should not result in disruption of patients’ use of available primary care or mental health services.

Patients who are in violation of significant sections of their contracts should be tapered off methadone at a reasonable schedule. However, if patients are verbally abusive or threaten clinic staff with violence, this schedule can be accelerated at the discretion of the prescriber. If a physician feels unsafe while treating a patient, the physician can provide the patient with a two-week DWI prescription and discontinue the physician-patient relationship.

4. Transfer of Care

The patient or the physician may decide that the responsibility for prescribing methadone should be transferred to another methadone prescriber. The patient must therefore be registered with the new
prescriber, who is responsible for completing the transfer form and submitting it to the Methadone Maintenance Program.

The physician assuming care of the patient is responsible for contacting the previous MMT prescriber in order to obtain appropriate clinical information and verify drug dosage and transfer date. Mutual agreement regarding the transfer date is critically important to ensure that a double dose is not given. It is not sufficient to communicate with the previous prescriber merely by leaving messages or contacting the physician after MMT has begun. The patient’s new physician may not prescribe methadone until the completed form is submitted and approved by the BC Methadone Program at the College.

Patients who have recently been released from correctional facilities will have been transferred to the correctional facility physician and need to be transferred back to their previous community prescribers. If there is any uncertainty about a patient’s registration status, physicians are encouraged to contact the BC Methadone Program so that previous methadone prescribers, if any, can be contacted to facilitate continuity of care. A review of the PharmaNet profile can also provide information on previous methadone prescribers.

In all cases, the new methadone prescriber must perform an updated comprehensive biopsychosocial assessment and physical examination with appropriate laboratory investigations and create a treatment plan that takes into account all the previous MMT physician’s treatment concerns. If, for example, collateral information about a patient’s inappropriate or threatening behaviour as the reason for transfer is not conveyed by the previous physician or included in the new prescriber’s treatment plan, it is likely that the new prescriber will be subjected to the same behaviour pattern.
ADVICE TO PHYSICIANS DOWNSIZING OR LEAVING THEIR METHADONE MAINTENANCE PRACTICES

- When planning to discharge or transfer a methadone maintenance patient because you are either downsizing or leaving your methadone maintenance practice, remember that patient safety is the primary concern.

- Appropriate communication with other treating physicians is essential for the safe continuity of care of methadone maintenance patients.

- If you are considering methadone tapering or transferring a patient to Suboxone, remember that this should only be done for reasons of clinical appropriateness.

- If it is necessary to provide bridging methadone prescriptions during patient transfer to another prescribing physician, these prescriptions should be clinically appropriate and should not compromise patient safety.

- If it is not possible to transfer a patient to another treating physician then medical office staff should be able to provide patients with written information about alternative local resources (a list of methadone clinics accepting new patients is available on the College website).

- Any physician who is leaving practice should be aware that the College has a guideline titled *Leaving Practice*, and it is the College’s recommendation that three months’ notice is a reasonable time to allow a patient to find a new treating physician.
SPECIAL POPULATIONS

1. Introduction

All patients, whether from special populations or in non-community based settings, should receive a comprehensive initial assessment.

This section will deal with the following populations:

- adolescent patients
- women of child-bearing potential
- pregnant women
- non-injecting opioid-dependent patients
- patients with comorbid conditions
- hospitalized patients
- provincial and federal corrections patients
- patients who wish to travel

2. Adolescent Patients

Adolescent patients requesting methadone maintenance treatment (MMT) need careful assessment, as they may have had short-term exposure to opioids without sustaining significant adverse consequences. These patients often still have intact support systems and consideration should be given to referral for abstinence-based treatment programs in which detoxification is followed by intensive in-patient or outpatient therapy. Mutual self-help groups provide good support for these patients.

Some adolescent patients do meet criteria for late-stage dependence, are experiencing significant adverse consequences, have inadequate support systems and have relapsed after previous abstinence-based treatments. These patients may benefit from Suboxone or MMT, but they require rigorous assessment and a detailed treatment plan which is frequently reviewed. Supportive counselling must be a condition for continued Suboxone or MMT.

Only physicians who work with counsellors and have some experience in dealing with substance-dependent youth should agree to accept these patients.

Adolescent patients should be maintained on Suboxone or MMT only if the benefits of treatment can be clearly documented.
3. **Women of Child-Bearing Potential**

Women seeking treatment for opioid dependence may have a number of predisposing psychosocial risk factors for drug use and have experienced multiple adverse consequences. Their histories may include disrupted family lives, physical violence, incarceration, sexual assault, sex trade work, child custody issues, unstable housing, mental health issues (such as mood and personality disorders), and physical health issues (such as HIV, hepatitis C virus or STIs). Physicians should be aware that the different causes of addiction, patterns of use and reasons for relapse are often gender-specific. Clinicians can offer more effective treatment by being conversant in the identification and treatment of these issues as they apply to women.

Knowledge of other community resources (for example, PEERS, a rehabilitation program for sex trade workers, based in Vancouver and Victoria) is also essential in treating women with opioid dependence. Many other resources in BC can be found on Red Book Online, an online directory of services for the lower mainland. Treating opioid-dependent women with respect and compassion is fundamental to their recovery.

Opioid dependent women commonly experience menstrual irregularity and amenorrhea. For many women, this will be regulated and ovulation will start once they are stabilized on methadone. All women of child-bearing age should have a pregnancy test at the initial triage visit and periodically thereafter.

Birth control should be offered to all women upon initiation of methadone. When stable non-pregnant women suddenly feel the need to increase their methadone dose, consider the possibility of pregnancy. Depo-Provera and progesterone-impregnated intrauterine devices (IUDs) are the least expensive and the most reliable option in this often unstable population. Oral contraceptives can be taken daily with methadone to reduce missed doses. Pharmacists will sometimes allow patients to store their OCPs at the pharmacy. The availability of free condoms in the office will also encourage women patients to practise safe sex (these are obtainable from health authorities and public health departments).

Methadone-maintained women contemplating pregnancy must be encouraged to remain in MMT.

4. **Pregnant Women**

4.1 **Introduction**

The quality and nature of the initial encounter is crucial when providing prenatal care for pregnant women who use opioids. By providing non-judgmental care, physicians support these women’s self-
determination and increase the chances of engaging in treatment.\textsuperscript{12} The most effective care for pregnant women with substance use problems involves a collaborative approach by physicians, midwives, nurses and social workers, in hospital and the community.\textsuperscript{13}

Opioid use is a powerful self-medication for blocking intrusive thoughts, avoiding feelings and achieving sleep. Many women who use substances have a history of physical, sexual or emotional trauma.\textsuperscript{14} Physicians should be aware of and address issues of power (for example, loss of carries) with this knowledge in mind. Women may present late in pregnancy due to additional barriers such as fear of losing their children. Some women may be uncertain of dates due to their chaotic lifestyle or menstrual irregularities.

MMT is the treatment of choice throughout pregnancy and the postpartum period for opioid-dependent women.\textsuperscript{15,16} Women who are engaged in MMT experience better pregnancy and birth outcomes than those who continue to use non-medical opioids. Pregnancy complications due to illicit opioid use include intrauterine growth restriction (IUGR), low birth weight and premature labour (due to opioid withdrawal), and risk of hepatitis C and HIV with needle use.\textsuperscript{17,18} Methadone has been shown to be beneficial in the reduction of maternal relapse, particularly when a comprehensive system of support is in place.\textsuperscript{19}

Suboxone is contraindicated in pregnancy however, physicians may contact Health Canada’s \textit{Special Access Programme} to obtain authorization for the buprenorphine-only product.

4.2 Guiding Principles

1. **Respect is key**: Guilt and shame about substance use, fear of being judged and of having children removed are major barriers to care. A respectful approach acknowledges that change is a process and meets women at their stages of change.\(^{20,21}\)

2. **Informed choice**: All women who are pregnant and using substances are informed by their health-care providers of their choices and rights at all steps of the care process. Side effects of methadone treatment are described and discussed.

3. **Working from strengths**: Strengths and protective factors of each woman, her family and community are recognized and enhanced.\(^{22}\)

4. **Reducing harms**: Helping women reduce the harms associated with substance use, such as facilitating access to general medical care, addressing homelessness, and providing other supports will improve outcomes for women and children.

5. **Addressing violence**: Understanding the impact of violence against women, including the high incidence of post-traumatic stress disorder (PTSD).

6. **Culturally sensitive care**: Understanding cultural, racial and religious differences in the provision of methadone care.

7. **Respecting all goals for change** in substance use along the continuum from reducing use to abstinence, using early intervention strategies, medical and psychological treatment and follow-up supports.

8. **Teamwork**: All care team members, including the patient, share the decision making, development, implementation and monitoring of a single service plan.

9. **Preserving the mother-infant bond**: Supporting measures such as hospital rooming-in and breastfeeding.

Pregnancy provides a “window of opportunity” to motivate substance-using women to make changes in their lives.

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4.3 Management

Acute withdrawal in pregnancy increases the risk of preterm labour or miscarriage. Rapid uptake into treatment, active ongoing support and practical measures to encourage attendance are all approaches that research suggests improves engagement\(^{23}\) and continued access to care. Methadone initiation is most efficient in an in-patient setting; however, outpatient initiation is practical and appropriate when in-patient treatment is not an option.

4.3.1 Initial Assessment

- Complete medical history, including substance use history, obstetric history and assessment of the patient’s risk factors for exposure to infectious diseases
- Assessment for mental health comorbidities
- Assessment of personal safety, nutritional and housing needs
- Complete physical and fetal examination, including measurement of fetal heart rate for baseline (if the patient is more than 14 weeks pregnant)
- Completed Part 1 of the **BCPHP British Columbia Antenatal Record**
- Appropriate laboratory testing, including prenatal blood work, hepatitis C serology and liver function tests
- Ultrasound to estimate gestational age of the fetus
- UDT to confirm opioid use, and to provide information about other drug use which is essential in the treatment planning process—an opioid negative UDT does not preclude admission if the assessment confirms that MMT is appropriate

4.3.2 Prenatal Management

- An effective dose of methadone is one that prevents withdrawal symptoms and reduces cravings for 24 hours.
- An adequate methadone dose will protect the fetus from repeated withdrawal.
- Recent studies have shown that higher doses of methadone do not correlate with the occurrence or severity of neonatal abstinence syndrome (NAS).\(^{24}\)
- Higher doses of methadone are often needed as pregnancy advances due to increased blood volume, especially in the third trimester.\(^{25}\)
- Split methadone doses may be needed to deal with increased hepatic metabolism and to prevent day-to-day withdrawal symptoms.\(^{26}\)

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• Carry doses should only be provided to stable patients. Indicators of stability include negative random UDTs, safe and supportive drug-free housing, safe methadone storage facilities, and appropriate relapse prevention plans.

4.3.3 Third Trimester

• The planning around hospital admissions for birth should be coordinated as early as possible between the maternity care teams, the methadone prescriber and the patient.

• If a dosage increase is needed, it can be done in steps of 5 mg to 10 mg per week as an outpatient. Physicians can consider split doses in pregnant women who experience early withdrawal due to changes in methadone metabolism, to keep the total amount of the dose down and to even out blood levels over a 24-hour period. For example, two-thirds of the dose can be taken as DWI in the morning, with the remaining one-third dispensed as carries for the evening. Note that split dosing can increase the risk of diversion.

4.3.4 Intrapartum

• Methadone is not used as pain control. Regular methadone dosage should be continued and not considered as part of the pain management plan.

• Regular labour and delivery pain medication can be used. Epidural anesthesia is the preferred analgesic method due to altered pain perception in this population. Nitrous oxide may be useful in the second stage. Opioid analgesics may be used but the dose may need to be increased due to tolerance and the patient must be monitored for somnolence and respiratory depression.

• When methadone-maintained women present in labour, methadone can be given in a decreased volume of fluid (by arrangement with the pharmacy).

• If oral fluids are contraindicated, methadone should be replaced with parenteral opioids.

• Mixed agonist/antagonists are contraindicated as they will precipitate acute withdrawal.

• Sensitivity is needed during intrapartum and postpartum pain management. Many women who use substances have experienced sexual trauma and PTSD. Vaginal exams or the pain of childbirth can trigger symptoms which in turn may cause intensification of labour pain.

4.3.5 Postpartum

• Postpartum maternal methadone requirements usually drop due to a decrease in blood volume and changes in metabolism. Consequently, the dose may need to be decreased over a few days or weeks. A split dose will generally no longer be required.

• Daily witnessed ingestion of methadone for unstable patients is recommended. It may be difficult for new mothers to go to the pharmacy daily, therefore the risks versus the benefits of granting carry privileges must be carefully considered.

• Continuation of methadone is a joint decision between the patient and her physician. Stability is the goal, and if patients choose to withdraw from methadone, they should be informed of the risk of relapse and offered relapse prevention strategies.

4.3.6 Breastfeeding and Methadone

• Breastfeeding is compatible with MMT, regardless of the maternal dose.\textsuperscript{27,28}
• Breastfeeding is contraindicated in active substance abuse and in HIV-positive patients.
• Studies to date evaluating the effect of breastfeeding on HCV transmission indicate that breastfeeding does not appreciably increase the risk of transmitting HCV to a neonate.

4.3.7 Urine Drug Testing (UDT)

• UDT is always collected at the initial visit to confirm opioid use. Results also provide information about other drug use. This information is essential in the treatment planning process.
• Pregnant patients should provide UDTs at the same frequency as other MMT patients depending on stability.
• A positive UDT or self-reported drug use is not an indication for an involuntary taper or withdrawal from methadone and should never preclude medical care. Even with continued use of illicit drugs, continued contact with health-care providers improves pregnancy outcomes and builds trust. Unstable patients must remain on daily witnessed ingestion.
• Carries are a privilege and should only be granted to stable patients (e.g. negative UDTs, safe housing, and relapse prevention plans in place). Carry privileges are not recommended for pregnant women who do not provide random UDT.

4.3.8 Prenatal Methadone Withdrawal Management

• The standard of care for pregnant opioid-dependent women is MMT throughout pregnancy and postpartum. However, some patients insist on detoxification from all drugs during pregnancy. Patients insisting on withdrawal or tapering should be informed that the risk of relapse with dose reduction or discontinuation of methadone in pregnancy is high and no less than in other patients.
• The patients who are most likely to be successful in withdrawal during pregnancy and to remain drug free are those who have had prolonged stability on methadone, have had drug treatment including relapse prevention and are socially stable.

4.3.9 Neonatal Abstinence Syndrome (NAS)

- Some infants exposed to opioids during pregnancy undergo withdrawal. If withdrawal occurs, the onset of symptoms depends on the half-life of the substance used and when the last dose was taken.
- The occurrence and severity of NAS does not correlate with higher maternal methadone dose.
- NAS is always a diagnosis of exclusion. When NAS is suspected, other diagnoses such as hypoglycemia, hypocalcemia and sepsis should be ruled out first.
- Infants of mothers who used prescription drugs during pregnancy, especially benzodiazepines, barbiturates and antipsychotics, as well as alcohol and nicotine, may have neonatal withdrawal symptoms for a longer duration.
- Rooming-in with the infant, frequent skin-to-skin contact and cuddling is encouraged. This increased contact results in a demonstrated reduction in the need to treat opioid-exposed infants.29

4.3.10 Child Protection

Pregnancy is an ideal time to assess a mother’s social situation and to engage her in positive planning for a healthy pregnancy and a healthy baby. Planning should be a coordinated effort, involving the healthcare team and patient, as well as supportive family members, community support agencies, and child protection and social workers.

- Once patients have consented to the exchange of information, all necessary health-care providers, including physicians and community-based resources, are encouraged to participate in an integrated process to coordinate care. Advance care planning should result in additional supports for the patient and allow her to play a key role in planning for her and her newborn’s care after birth.
- The provincial Ministry for Children and Family Development (MCFD) can be involved in a supportive role during pregnancy with the patient’s consent, and this partnership leads to the best outcomes for the infant.
- There is no legal obligation to report any concerns regarding a pregnant woman’s care to child protection authorities, including methadone use in pregnancy; however, each patient should be informed that if there are protection concerns, a report will have to be made once the child is born.
- The BC Representative for Children and Youth may also be contacted to support children, youth and families who need help in dealing with the child-serving system. It advocates for vulnerable children and youth up to the age of 18 and is particularly concerned with children in government care.

• The MCFD provides child protection services under provincial child welfare legislation, the *Child, Family and Community Service Act (CFCSA)*.
• Section 13 of the *CFCSA* describes the circumstances when a child needs to be protected.
• Section 14 of the *CFCSA* describes the health-care professional’s duty to report the need for protection. Note that the actual determination of whether an infant is at risk for harm, neglect or abuse can only be done by appropriately authorized individuals.
• Access to medical records for the purpose of assessing the infant’s safety by these persons must be in accordance with statutory and legal authority.

5. Patients with Comorbid Conditions

Opioid dependent patients must be screened for specific comorbidities given the prevalence in this patient population. A *specific treatment plan needs to be documented in the physician’s overall treatment strategy for these conditions.*

5.1 Hepatitis C

Over 80% of people who inject illicit drugs are hepatitis C positive. All patients considered for MMT must be tested for hepatitis A, B and C, and serum transaminase levels. Periodic retesting for hepatitis C is indicated when risk-taking behaviours continue.

Flow sheets such as the *Liver Function Record* should be used to track liver enzymes and help determine when referral for definitive hepatitis C treatment is indicated.

5.1.1 Management issues

Hepatitis C management should focus on the following areas:

1. Lifestyle
   • emphasize abstinence from alcohol
   • discuss appropriate diet
   • advise use of condoms in non-monogamous sexual encounters
2. Immunization
   • vaccinate for hepatitis A and B, and provide other relevant vaccinations
3. Treatment
   • initiate treatment or refer to a physician with expertise in hepatitis C treatment when indicated

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5.2 HIV/AIDS

People who inject illicit drugs are at high risk for contracting HIV and MMT is among the best ways to prevent HIV transmission in this population. Some MMT patients will be HIV positive on entry into treatment or may acquire HIV during treatment, if they continue to engage in other high-risk behaviours.

Among other potential benefits of MMT, stabilization on methadone may make it easier for HIV-positive opioid-dependent patients to comply with HIV treatment regimens. Priority access to MMT should be provided whenever possible for HIV-positive patients because of the individual and public health consequences of untreated HIV infection, especially in the intravenous drug-using population.

5.2.1 Management Issues

HIV management should focus on the following areas:

1. Education
   - provide education on sexual contact precautions and needle sharing
2. Immunization
   - immunize for hepatitis A and B
   - immunize for tetanus toxoid, pneumococcal vaccine and influenza vaccine
3. Testing and monitoring
   - consider testing for tuberculosis and syphilis
   - monitor CD4 counts and viral load
4. Treatment and referral
   - refer to an infectious disease specialist for assessment and treatment plan
   - many HIV medications interact with methadone—dose adjustments may be required

5.3 Mental Health Issues – Concurrent Disorders

Lifetime prevalence for another Axis I co-occurring disorder in substance dependent patients is at least 30%. Depression, anxiety, bipolar disorder, eating disorders and process addictions (compulsive gambling, sexual and internet behaviours, etc.) are common, as are Axis II disorders.

Identifying and providing treatment for patients with mental illness improves MMT outcomes, such as reducing substance use and improving treatment retention.31

5.3.1 Management Issues

The initial assessment should always include screening questions for comorbid mental illnesses. Past psychiatric treatment, a family history of mental illness and drug-free periods are all important considerations when assessing for mental illness independent of substance use.

It may be difficult to determine whether a psychiatric disorder is primary or secondary to substance use. Alcohol, for example, may cause symptoms which present as mental illness (such as bipolar or depression) or may interfere with the management of an underlying mental illness. The distinction may be clearer, as in the case of a rapidly resolving psychotic state, on cessation of cocaine use. In order to differentiate primary from secondary psychiatric disorders, a skilled assessment is required that takes into account symptom progression during substance use and periods of abstinence.

Substance dependent patients also have a significantly higher incidence of mental, physical and sexual abuse. Identifying and providing focused counselling may be beneficial in assisting recovery.

Although referral for further assessment and treatment is still a considerable challenge, concurrent disorder clinics and in-patient treatment options are increasingly available. Health Canada’s Best Practices – Concurrent Mental Health and Substances Use Disorders further outlines guiding principles for the treatment of concurrent disorders.

5.4 Polysubstance Comorbidity

The benefits of MMT are reduced in the setting of continued psychoactive substance use. Polysubstance misuse (both prescription and illicit) is the norm among opioid-dependent patients. All patients require a comprehensive assessment that includes a detailed inventory of drug use and an individualized treatment plan.

5.4.1 Management Issues

Stimulants

Patients may meet criteria for opioid dependence when the drug of choice is a stimulant. Failure to recognize stimulant-use disorders will undermine methadone treatment outcomes. A trial of methadone treatment may be appropriate but a stimulant management plan must be in place from the outset. Methadone treatment should only be continued long-term if objective benefits can be documented.

Alcohol

Alcohol use poses unique concerns in methadone maintenance patients. The risk of overdose is increased, given the synergistic respiratory depressant effect alcohol has with methadone. In addition, alcohol interferes with the metabolism of methadone. In its early stages, problem drinking has the potential to induce hepatic enzymes which can accelerate methadone metabolism. At later stages, liver failure can precipitously reduce a patient’s tolerance to methadone. These complicated interactions
underscore the need for physicians to appropriately screen and monitor for alcohol use disorders and provide intervention and treatment.

**Sedative-Hypnotics Including Benzodiazepines and Z Drugs**

Comorbid sedative-hypnotic use poses another set of unique challenges. Like alcohol, these drugs have a synergistic respiratory depressant effect when used with methadone and may increase the risk of fatal overdose. Multidisciplining for sedative-hypnotics is common. It is the responsibility of the methadone prescriber to review PharmaNet profiles regularly. All psychoactive substances act through a final common end pathway in the brain and therefore sedative-hypnotics are relatively contraindicated in patients with addiction disorders.

**Marijuana**

Continuing use of a psychoactive substance such as marijuana can undermine treatment focused on developing non-chemical coping strategies. While there is controversy as to whether marijuana causes an “amotivational syndrome,” there is evidence that psychosis, anxiety and mood disorders, and permanent cognitive changes can occur secondary to chronic marijuana use.

Physicians considering the provision of support for medical marijuana exemption should review the College’s guideline *Marijuana for Medical Purposes*.

**Tobacco**

Tobacco consumption rates are comparatively high for those with addictions to opioids, which means tobacco-related disease and associated mortality are significant long-term risks to their health. Physicians with MMT patients are encouraged to

- inquire about their tobacco use and advise them to quit
- assist in an attempt to quit (and, if appropriate, offer medication support from the BC Smoking Cessation Program), and
- arrange for follow-up (the QuitNow BC referral program is available to offer behavioural support).

### 6. Hospitalized Patients

Methadone maintenance patients are commonly hospitalized. These patients will have to have their methadone prescribed by a physician who has one of the following:

- a [full authorization](#) to prescribe methadone for opioid dependence
- a [temporary authorization](#) to prescribe methadone
- a [hospitalist authorization](#), which is a hybrid of a full exemption to prescribe methadone for analgesia and a limited authorization to prescribe methadone for opioid dependence, for in-hospital use only
Physicians prescribing methadone for hospitalized patients are expected to adjust the dose as clinically indicated. Physicians with temporary or hospitalist methadone authorizations may write short bridging methadone prescriptions for patients discharged from hospital, after which patients should return to their community prescriber.

Hospital-based physicians are encouraged to obtain hospitalist authorizations to prescribe methadone. These are granted after physicians attend the College-sponsored Hospitalist Workshop (held in conjunction with the Methadone 101 Workshop) and undergo a brief interview with the deputy registrar.

The role of the hospital-based physician is to:

- determine if methadone continuation is appropriate
- determine the dose and frequency of administration
- reassess and adjust the dose as clinically indicated
- facilitate transfer of care to the community physician on discharge

The Hospitalist Workshop is offered once or twice a year to educate physicians on the management of hospitalized patients for both opioid dependence and analgesia.

Management of hospitalized methadone patients should include:

- appropriate patient assessment, including confirmation of current and last dose
- assessment of current substance use, medications and medical conditions affecting methadone pharmacokinetics
- contact with the community methadone prescriber
- pain management
- informing community physicians about discharge information

7. **Provincial and Federal Corrections Facilities**

7.1 **Provincial Corrections Facilities**

There are nine adult correctional and three youth custody centres in British Columbia, with over 25,000 admissions per year. Health-care services are provided in each centre. All centres but one, a remote camp with limited access to health-care services on weekends, provide for continuation of methadone and Suboxone. All medical information is confidential and restricted to health-care providers only.

Transfer forms are completed upon admission. PharmaNet profiles are reviewed and patients sign a standard BC Corrections methadone patient agreement. BC Corrections advises community physicians by fax when their patients are in custody. An admission UDT is provided by all inmates. Frequency of
subsequent testing is individualized and included as part of the treatment plan. Only physicians working within correctional and youth custody facilities are able to prescribe methadone for inmates. All physicians working in BC Corrections have current methadone authorization. Methadone doses are individualized and administered by nurses using daily witnessed ingestion protocol. Drug counselling, education and mutual help meetings are available in most centres and participation is strongly encouraged.

When released, MMP patients are transferred back to a community prescriber. The health-care staff or the inmate makes an appointment with the community prescriber. To facilitate transfer of care a short-term DWI prescription is faxed to a pharmacy chosen by the inmate. Many inmates are released without notice immediately following their court appearances. In these cases, arrangements for methadone prescriptions and follow-up appointments are exclusively the responsibility of the patient.

7.1.1 Initiation of Methadone Maintenance Treatment

Initiation of methadone maintenance in provincial correctional facilities is increasing. High volume and short periods of incarceration (generally under 30 days) preclude initiation of many inmates. Inmates are selected according to criteria outlined in this guideline, but with the additional criteria of being medically stable and being incarcerated for substantial periods of time.

7.1.2 Drug Treatment Court of Vancouver

The Drug Treatment Court of Vancouver is a voluntary alternative to incarceration available to some offenders charged with drug-related offences. Once accepted into the program, patients receive intensive substance dependence treatment as well as medical and mental health care. Both methadone initiation and continuation feature prominently in this program.

7.2 Federal Corrections Facilities

Federal correctional institutions house inmates serving sentences of two years or more, with most sentences exceeding three years. Correctional Service Canada offers a comprehensive methadone maintenance treatment program with extensive mental health, substance dependence, medical and risk-behaviour assessment. Patients are screened regarding need and suitability for this treatment program. Methadone initiation is available whenever appropriate, and all inmates already enrolled in the Methadone Maintenance Program and receiving Suboxone are continued on maintenance. Extensive counselling is available and strongly encouraged.

8. Patients Who Wish to Travel

Long-term MMT limits patients’ ability to travel. If patients receiving MMT wish to travel for a period of time that exceeds their regular carry period, patient and public safety should not be compromised. Physicians should not authorize carries for patients who are unstable even if patients are planning to
travel unless a documented risk-benefit assessment outlines the reasons for granting the carry for travel.

Physicians who are concerned about prescribing carries for travel should confirm travel plans when possible. Physicians may assist with arrangements for DWI at pharmacies in other locations but this is not always possible. Physicians may also assist by faxing prescriptions or liaising with the destination pharmacist although they cannot guarantee the dispensing which will not be covered by PharmaCare.

Physicians who agree to provide methadone carries for travel may offer patients the option of a prescription for Metadol tablets instead of solution. Metadol tablets are not covered by PharmaCare for opioid dependence and should be prescribed on the regular controlled prescription form and not the methadone prescription pad.
METHADONE AND PAIN

The authorization to prescribe methadone for analgesia is separate from the authorization to prescribe methadone for opioid dependence.

Physicians wishing to obtain an exemption under section 56 of the Controlled Drugs and Substances Act for an authorization to prescribe methadone for analgesic purposes must follow the BC Methadone Program application process.

Required readings for physicians who prescribe methadone for pain include the Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain, developed by the National Opioid Use Guideline Group (NOUGG). This guideline has been adopted by the College of Physicians and Surgeons of British Columbia.