

Standards & Guidelines for Methadone Maintenance Treatment in Alberta



College of
Physicians
& Surgeons
of A l b e r t a

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2. Preface

2.1 Introduction

In September 2004, the College of Physicians and Surgeons of Alberta (CPSA) established an expert group of physicians to develop consensus guidelines for Methadone Maintenance Treatment (MMT) in Alberta. The Terms of Reference and the Guidelines Development Committee Membership List are *outlined in Appendix 14.1 and 14.2*.

The Standards and Guidelines for Methadone Maintenance Treatment in Alberta has been produced to guide prescribers using methadone in the treatment of patients diagnosed with an Opioid Dependence Disorder.

NB: Infants born to opioid dependant mothers including those on MMT do not meet the criteria for an Opioid Dependence Disorder or “addiction”. Management of these situations requires the specialized knowledge of a paediatrician or a physician experienced in the management of Neonatal Abstinence Syndrome.

One of the goals of this document is to raise awareness of opioid dependence and to encourage physicians to address this issue in general practice. Standards and guidelines for methadone treatment will improve patient care by increasing the consistency and access to safe clinical methadone maintenance treatment management and contribute to the improvement of patient health and social outcomes. This document will form the foundation for practice reviews of methadone maintenance treatment in programs and individual physician practices in the future.

The standards and guidelines resource is based on a number of sources of evidence for safe and accessible management of opioid dependency. It is primarily based on data obtained from best practices in the field of methadone maintenance and addictions medicine, clinical experience from respected authorities and individual professionals in the field. A high degree of feedback from stakeholders and community partners was received and incorporated. Certain guidelines have been pre-tested by members of the development committee in their clinical practice.

Although it is recognized that other substitution therapies for opioid dependency will be available in the future, only the use of methadone is addressed in this document.

It is acknowledged that other health care professionals are involved in the care of opioid dependent patients. However, the intended audience for this document is physicians. It is not intended as a comprehensive manual or to replace sound clinical judgement. Physicians are encouraged to seek assistance and consultation with a specialist in addiction medicine for any difficult or complex cases. Departure from the identified standards requires clear documentation in the patient’s record with the rationale for the variation.

The governance of the Standards and Guidelines for Methadone Maintenance in Alberta is the responsibility of the CPSA and will be reviewed every 5 years or as necessary.

Support for this project has been made possible through a financial contribution from Health Canada. The views expressed herein do not necessarily represent the views of Health Canada.

2.2 Methadone Maintenance Treatment in Alberta

The goal of Methadone Maintenance Treatment in Alberta is to provide safe, accessible, effective and consistent treatment for opioid dependent individuals.

MMT is a recognized therapy for an Opioid Dependence Disorder. It is not replacing one addiction with another. “Addiction” is a psychiatric and thus medical diagnosis, the criteria of which are not met by the patient who conscientiously adheres to a medication protocol and treatment plan. *See DSM-IV-TR Criteria for Substance Dependence in Appendix 14.4.*

Methadone causes physiological dependence and will result in physical and psychological withdrawal symptoms if discontinued abruptly. This in itself does not constitute “addiction”. The treatment of patients with addictions can be complicated by confusion between physiological dependence and addiction. This misunderstanding can result in reluctance to embark on an appropriate and compassionate treatment plan.

MMT is a substitution therapy that allows return to normal physiological, psychological and societal functioning. It is one of many possible treatments for an Opioid Dependence Disorder. MMT may continue for life for some people, while others may be able to eventually cease all opioid use and remain abstinent while preserving the normal level of function they have attained while on treatment. Each person must be assessed, treated and monitored on an individual basis. Successful outcomes through MMT require knowledge, experience, vigilance and diligence on the part of the prescriber, the patient and all of those involved in treatment.

Opioid dependence is a medical disease and access to treatment services for this disease should be available in a manner congruent with the Canada Health Act. As such, there should be no cost to Albertans to access this treatment.

2.3 Standards and Guidelines

Standards, *which must be followed*, define a minimum acceptable level of care to ensure patient safety.

Guidelines provide direction that *may be useful* in dealing with specific issues.

For MMT, standards address safety and consistency. Guidelines address these issues as well as providing direction and recommendations for optimizing effectiveness.

Accessibility is dependent on resources and is difficult to define as a standard or guideline.

2.4 Staged Care Model of Delivery

The Standards and Guidelines for Methadone Maintenance Treatment in Alberta has been developed based on the assumption that in the future, methadone maintenance treatment will be delivered using a staged care model. The model is based on a stepped care approach where patients are initiated on methadone at an established Methadone Maintenance Treatment Program (MMTP).

The MMTP is a formal program involving collaborative practices among a variety of professionals using methadone maintenance treatment as a core treatment for opioid dependence.

Along with the medical management, enhanced psychosocial interventions are emphasized in the Initiation Phase of treatment provided at the MMTP. The MMTP is commonly comprised of a close network of collaborating disciplines with knowledge and access to ancillary service providers such as Primary Health Care Physicians, Human Resources and Employment, Mental Health Services, and Community Based HIV/AIDS/Hepatitis Organizations.

The multidisciplinary MMTP team roles and core services include:

MMTP Physicians

- Medical and psychosocial assessment
- Disease diagnosis
- Initiation of methadone and ongoing medication management
- Examination of urine toxicology testing
- Referral or medical management of concurrent disorders
- Resource to allied professionals

Nurses

- Screening applicants
- Assess progress and presenting medical issues
- Implementation and evaluation of care plans
- Administering medication and response evaluation
- Case management
- Urine toxicology testing process and follow up
- Patient education
- Resource to public and allied professionals

Pharmacists

- Methadone dispensing
- Methadone administering under direct observation
- Patient monitoring and supportive assessment
- Record keeping and reporting
- Patient education
- Communication with physician and team members
- Input on treatment planning

Laboratory Professionals

- Collection of urine samples for toxicology testing
- Reporting and assisting in the interpretation of toxicology testing results

- Communication with physician or MMTP team members

Addictions Counsellors

- Substance abuse and addiction assessment
- Facilitate individual, group counselling to address addiction issues
- Treatment planning and monitoring
- Case management and referral to ancillary services
- Advocacy

Support Staff

- Administrative duties
- Operational management
- Telephone and scheduling management
- First contact with patient
- Collection and administering urine toxicology testing processes

Once stabilized, the patient is referred to a primary care physician for continued methadone maintenance treatment.

The stabilized individual may demonstrate:

- Reduced or discontinued use of opioids and other mood altering drugs
- Reduced involvement with the criminal justice system
- Improved and safe living environment
- Improved social and personal relationships
- Improved vocational and employment opportunities
- Stable medical and psychiatric issues

See additional Stability Indicators in Appendix 14.3

The Primary care physician will provide care and medication management for those patients who continue through the Maintenance Phase of treatment. The role of the physician will include:

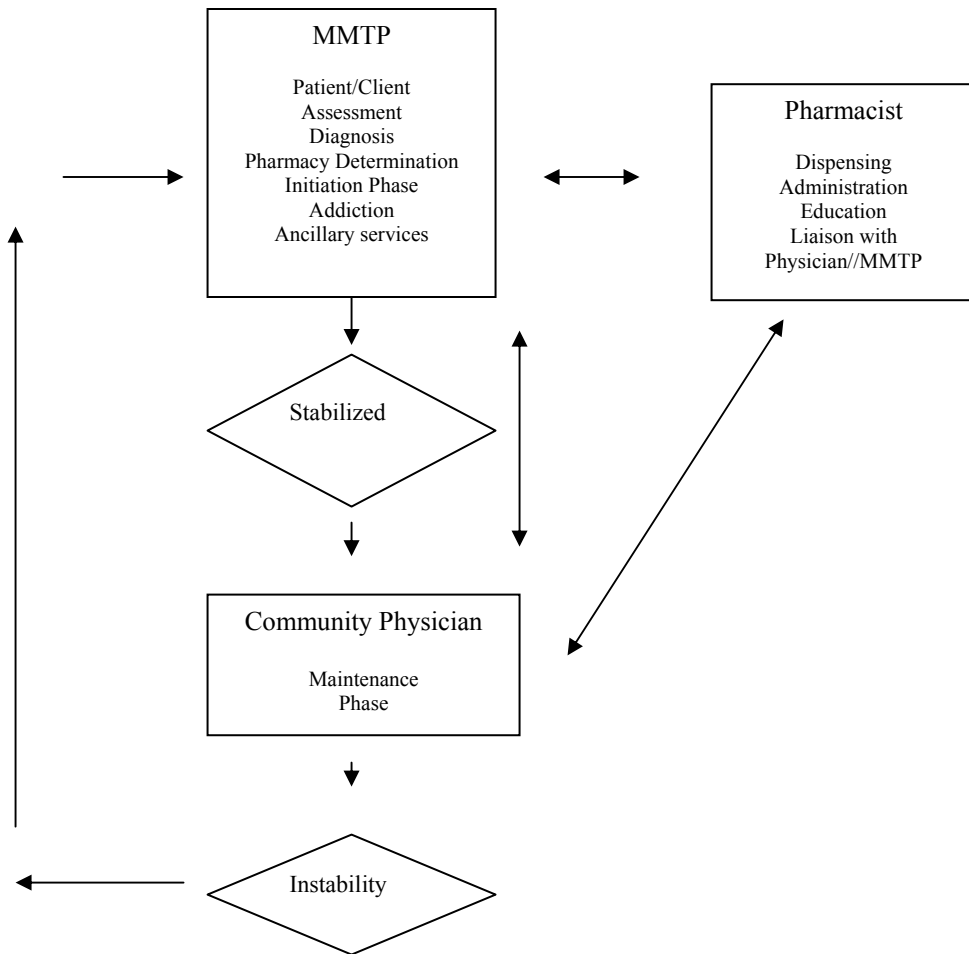
- Maintaining methadone prescriptions
- Treatment of any concurrent medical conditions
- Ongoing monitoring
- Evaluating benefits versus risks, including assessment of stability
- Resource to colleagues
- Active liaison with pharmacist

There will be an ongoing flexible relationship among the MMTP, primary care physician and patient. Furthermore, the program will reassess and resume management of the patient for a period of re-stabilization if needed.

Where changes in stability are occurring, consultation with an MMTP would be recommended. Some examples may include:

- Chronic positive urine toxicology tests for proscribed substances
- Numerous personal crises
- Unexpected and frequent dose increase requests
- Patterns of missed, lost or vomited doses
- Non attendance for required medical or urine toxicology testing appointments

The diagram below describes the relationship, process and decision points of the staged care model of delivery.



2.5 Chronic Pain

MMT is for the treatment of opioid dependence and not for the treatment of pain. The protocol for methadone used for treating chronic pain will almost always be different than the protocol used for treating opioid dependence. If a patient appears to have chronic pain issues, then consultation should be sought ideally with a physician with skills and experience in managing these dual diagnosis patients, that is, those patients with both addiction and chronic pain, or by a physician who deals specifically with chronic pain.

Methadone use in chronic pain is an evolving area. Methadone is a medication being used more frequently in individuals with chronic pain. It is important to understand that it may be impossible to determine the difference between addiction and chronic pain. In such cases consultation should be sought with an addiction medicine specialist, and in any case of doubt the patient should be managed with controls appropriate for the most problematic diagnosis; usually, this is the addiction.

For people with chronic pain who also have lost control of the use of opioid medication, and where other methods fail to result in a return to stability, MMT can be helpful in allowing them to regain control and address their pain issues in a healthier, manageable way.

For more information refer to the CPSA resources in the management of chronic non-malignant pain located at

http://www.cpsa.ab.ca/publicationsresources/attachments_policies/management%20of%20chronic%20non-malignant.asp

3. Glossary of Terms

Addiction - A primary, chronic disease, characterized by impaired control over the use of a psychoactive substance and/or behaviour. Clinically, the manifestations occur along biological, psychological, sociological and spiritual dimensions. Common features are change in mood, relief from negative emotions, provision of pleasure, pre-occupation with the use of substance(s) or ritualistic behaviour(s); and continued use of the substance(s) and/or engagement in behaviour(s) despite adverse physical, psychological and/or social consequences. Like other chronic diseases, it can be progressive, relapsing and fatal. (Canadian Society of Addiction Medicine)

Carries - Provision of a dose (or multiple doses) of methadone by the dispensing pharmacist or designated staff, that may be ingested by the patient without supervision.

Chronic Pain - Pain persisting for more than 6 months.

Excessive Methadone Dose - A dosage of methadone, that exceeds that necessary for therapeutic effect. A therapeutic dosage of methadone provides relief from withdrawal symptoms and cravings, without psychomotor retardation or signs or symptoms of more advanced opioid toxicity. See also “Toxicity”.

Guidelines - Serve to encourage maximum benefit from MMT, by providing advice on specific issues. Guidelines focus on safety, effectiveness and consistency of treatment.

HIV - Human Immunodeficiency Virus.

Inappropriately Used Dosages – Dosages that are not taken as prescribed.

Initiation Phase - That individually-variable period beginning with the first dose of methadone, through increasing control of symptoms of withdrawal and craving and continuing until the addictive behaviours are managed and stability is achieved. Stability is determined by the positive changes in patient’s actions, disposition, and physical well-being.

Instability - A clinical situation of increased risk of overdose from abuse of proscribed substances or diversion of methadone by a patient. Signs of instability can include one or more of the following: missed, lost or vomited doses of methadone, unanticipated requests for increased dosage of methadone, presence of proscribed substances in urine, unusual or disruptive behaviour, suicidal ideation or other unstable psychiatric disorders, onset of significant clinical illness.

Maintenance Phase - An indefinite period characterized by a stable methadone dosage, relative improvement of social function and relative control of addictive behaviour(s) (bio-psycho-social-spiritual spheres).

MMT - Methadone Maintenance Treatment – The prolonged use of oral methadone as a substitute for other opioids to reduce or eliminate the negative physical, psychological and social effects of an Opioid Dependence Disorder.

MMTP - Methadone Maintenance Treatment Program- A formal program using MMT as a core approach to treat opioid dependence, combined with ancillary services.

Opiate - A naturally-occurring or semi-synthetic compound derived from the opium poppy (*papaver somnifer*).

Opioid - A compound having actions or properties similar to opiates. A broader term encompassing all opiates (such as heroin, morphine and codeine), as well as synthetic opiate-like compounds (such as methadone and fentanyl).

Opioid Dependence Disorder - DSM-IV-TR term for physical and psychological dependence on opioids, or "opioid addiction". Note: physical dependence on opioids due to long-term, appropriate use for pain management does not constitute a disorder or addiction. *See Appendix 14.4 DSM-IV-TR Criteria for Substance Dependence.*

Overdose - See "Toxicity".

Pain - An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (International Association for the Study of Pain).

Proscribed Substances - Substances which are considered contraindicated by the treating physician during MMT and may include all illicit drugs, ethanol and any psychoactive medication which are not prescribed by a treating physician and reviewed by the methadone prescriber.

Serum Methadone Level - A blood test that measures the methadone plasma concentration. The test may be ordered as Peak and Trough levels. The Peak level of methadone is the concentration expected at 3-4 hours post ingestion and the Trough level or lowest concentration of methadone expected before the next dose ingestion. Quantitative analysis of serum methadone levels is not a routinely available test and thus consultation with the laboratory is strongly recommended as to availability, protocol, costs and turnaround time.

Split Dosages - The splitting of a daily dosage of methadone so that it is not ingested all at one time.

Stability - Subjective and objective measures that correspond to the patient's level of functioning. This takes into consideration all the patient's major life areas such as medical/physical, employment/support, legal, family/social, and leisure.

Standards - A minimum level of care which ensures patient safety, and below which adequate care is not being provided. Any departure from the standard must be fully documented.

Toxicity - Methadone toxicity presents with signs and symptoms identical to those of any other opioid. Besides psychomotor retardation (confusion, slowed mental and physical response), more advanced signs include respiratory suppression (bradypnea, hypopnoea and hypoxia), peripheral vasodilatation (clammy skin and orthostatic hypotension), and miosis (pinpoint pupils). Ventricular arrhythmias are not uncommon. This is a medical emergency and requires immediate treatment in a hospital setting. All treatment of opioid toxicity in this population must include a careful screening for other drugs of abuse, particularly CNS depressants.

Treatment Plan - Treatment planning is an active and progressive process throughout the patient's admission in MMT. It serves as a reference point for the physician and is a collaborative agreement between patient and provider. It is built on the patient's strengths and the application of an appropriate mix of available programs or external resources. The key components include identifying the primary concern, the immediate goal, the actions

required to attain the goal with target dates, and evaluation. As it evolves, it should come to include both short-term as well as long-term objectives.

Urine Toxicology Testing (UTT) - A laboratory analysis that detects specific drugs, medications or substances. The scope of clinical toxicology services offered is influenced by several factors, including equipment availability, analyst expertise, and proximity to specialized toxicology facilities. UTT may involve the use of simple detection kits to a complex drug panel requiring several technologies.

4. Prescribers

4.1 Primary Care Prescribers

The primary care prescriber is in an ideal position to detect patients with opioid abuse problems and who may need referral for comprehensive treatment. The physician's role does not end upon referral; but is seen as an extension of the treatment team and involved in all facets of the recovery process.

The following section is intended for physicians who provide MMT to a limited number of stabilized patients as part of general primary care. Such physicians shall have the following:

Standards

1. A license to practice medicine in the province of Alberta.
2. An exemption granted by the Office of Controlled Substances, Health Canada, to prescribe methadone for the treatment of opioid dependence, endorsed by the Council of The College of Physicians & Surgeons, of Alberta (CPSA). *See Appendix 14.5 Health Canada Exemption*
3. Awareness of and access to ancillary services, including but not limited to counselling, a methadone dispensing pharmacist, and other methadone prescribers from whom advice may be sought.
4. Agree to abide by the standards and participate in periodic review of MMT practice.
5. Training and experience:
 - a. Successful completion of a MMT workshop/course recognized by the CPSA.
6. An interview with the registrar of the CPSA or his/her designate may be required or requested.
 - a. An ongoing association with an experienced MMT prescriber as a resource to the physician.
7. Ongoing education relevant to MMT:
 - a. Completion of a recognised course on the fundamentals of addiction medicine within two years of acquiring a methadone exemption and;
 - b. Re-attendance of a MMT workshop/course within 5 years of acquiring a methadone exemption and;
 - c. A minimum 20 hours of formal Continuing Medical Education (CME) in some aspect of addiction medicine every five years. (Time spent at a recognized MMT workshop/course qualifies);
 - d. *Or equivalent acceptable to the Council of the CPSA.*

Guidelines

Desirable attributes of such physicians also include the following:

1. Training experience with a MMT physician for a period of time or amount of experience to be determined by the preceptor.
2. In addition to the CME requirements defined by the Standards, twenty hours every five years of self-directed CME in the areas of MMT and addictions treatment, formal or informal.
3. Makes arrangements for patients and their other medical care providers to have access to a prescriber knowledgeable in MMT.
4. Provides support and advice to other prescribers and MMT providers.
5. Has a patient-centred, teamwork approach to MMT.

4.2 Methadone Maintenance Treatment Program Prescribers

The following section is intended for the physician who participates in a full-service MMTP. The MMTP program prescriber works closely within an interdisciplinary team, offering core methadone maintenance treatment services to the patient.

Such physicians shall have the following:

Standards

1. Adhere to all Standards listed in *Section 4.1 Primary Care Prescribers*.
2. Participate within a MMTP.
3. Complete training experience with a MMT physician for a period of time or amount of experience to be determined by the preceptor, or equivalent experience or credentials deemed suitable by the CPSA.
4. Re-attend a MMT workshop/course at least once every 5 years.
5. Complete a recognized course on the fundamentals of addiction medicine within 1 year of acquiring a methadone exemption.
6. Have equivalent experience acceptable to the Council.

Guidelines

Desirable attributes of such physicians also include the following:

1. Adherence to all Guidelines listed in *Section 4.1 Primary Care Prescribers*.
2. Collaboration with other members of the MMTP team in clinical decisions.
3. Enlisting patients in the design of their own treatment planning.
4. Consistent treatment decisions within the MMTP.
5. Treatment consistent with other MMTPs in Alberta
6. Commitment to evidence-based care and best practice.

4.3 Hospital-Based Prescribers

This section is intended for physicians who do not normally engage in MMT as part of their practice, but may require brief, patient-specific exemptions to prescribe methadone for the treatment of opioid dependence while attending admitted patients who have been on MMT prior to hospitalization

For more information regarding the hospitalized MMT patient, see Section 13.3 Hospitalization.

Standards

1. Such physicians shall have the following:
 - a. A license to practice medicine in the province of Alberta.
 - b. An exemption specific to in-patient treatment, granted by the Office of Controlled Substances, Health Canada, to prescribe methadone for the treatment of opioid dependence, endorsed by the Council of The College of Physicians & Surgeons, of Alberta (CPSA). *See Appendix 14.5 Health Canada Exemption.*
2. Particularly in urgent or emergent situations where a methadone prescribing physician is not available, physicians should consult their hospital policy.
3. Prescribing of MMT is for the term of patient's admission only.
4. Carried doses are not permitted, except in consultation with the community MMT prescriber.
5. The physician providing MMT during hospitalization will inform the community MMT provider of any changes in dosage or other relevant information such as short-term opioid analgesics, psychoactive or potentially interacting medications prior to discharge from hospital.

Guidelines

Desirable attributes of such physicians also include the following:

1. Familiarity with the basics of MMT through an introductory workshop/course.
2. Collaboration with a prescriber experienced in MMT is recommended if changes are required to methadone dosage, frequency, route, or substitution or supplementation with other opioids.
3. Any physician or surgeon who manages patients on MMT on a routine basis should apply for a general exemption to prescribe methadone for the treatment of opioid dependence. In this case, the Standards and Guidelines under the *Section 4.1 Primary Care Prescribers* apply.

5. Methadone Prescriptions

Standards

1. Methadone prescriptions must be written on a triplicate prescription unless dispensed from a hospital pharmacy for in-patient use.
2. The prescription must be legible and thoroughly understandable to the pharmacist.
3. The prescription is clear as to the daily dose, beginning and end dates for dispensing so that it is apparent that no doses are to be given beyond the end date without explicit instruction from the prescribing physician.
4. With the rare exception of the long term stable patients, who have been specially evaluated, the methadone must be dispensed in a diluted crystalline juice (by the pharmacist) to reduce the likelihood of diversion.
5. Carried doses must be clearly described (examples: “carries q Sunday,” “carries for Sundays and statutory holidays,” “carries for Sundays and closed days”). *See Section 9 Carries.*
6. The prescribing physician must provide clear instructions to the pharmacist with regard to spoiled, lost and missed doses, either with each prescription or as general instructions for all methadone prescriptions. *See Section 8.4 Spoiled, Lost and Missed Doses.*
7. Extraordinary situations and special instructions, such as twice-daily observed, or first-observed/second-carry must be clearly communicated.
8. A new prescription must be written for any change from a previously stable dosage amount or for the provision of a replacement dose.

Guidelines

1. A dispensing schedule is recommended, which lists each day’s dosage, including which are observed and which are carried doses.
2. The last dose day should occur on a regular working day to avoid undue patient hardship.
3. The duration of a methadone prescription should not exceed the interval between clinical visits.
4. In the rare instance where a patient is prescribed methadone in a tablet or capsule form, the rationale must be documented.

See Appendix 14.6 Sample - Initiation Triplicate Prescription and Dispensing Schedule.

See Appendix 14.7 Sample - Maintenance Triplicate Prescription and Dispensing Schedule.

See Appendix 14.8 Sample- MMT Medication Record.

6. Patient Assessment for Admission to a MMT Program

Standards

1. The patient must have a diagnosis of an Opioid Dependence Disorder and be assessed by the physician as likely to benefit from MMT. *See Appendix 14.4 DSM-IV-TR Criteria for Substance Dependence.*
2. The patient must provide informed consent to MMT that is comprehensive and outlines rights, responsibilities, risks and the day-to-day nature of the treatment.
3. The patient must be informed about and understand the risks of certain side effects such as sedation and slowed reaction time. This may limit or preclude their ability to engage in normal work- related or day-to-day activities such as driving or operating machinery particularly during the initiation phase or with increases in doses.
4. The patient must be seen and appropriately assessed including a focused physical exam by the prescribing physician or a qualified designate such as an MMTP nurse prior to any initiation. *Refer to Appendix 14.10 for Sample-Assessment and Medical Examination form.*
5. The patient should sign an MMT agreement that will be kept on file with the prescribing physician/MMTP and a copy will be provided to the patient. *Refer to Appendix 14.9 for Sample- Agreement to Methadone Maintenance Treatment Form.*
6. The prescribing physician or MMTP clinic staff must notify the CPSA within 2 business days of any patient's admission to and or discharge from MMT. The CPSA maintains a registry of MMT patients. *See Appendix 14.11 for The College of Physicians & Surgeons of Alberta, Admission and Discharge form.*
7. The patient requires access to addiction assessment and counselling.
8. A treatment plan must be in place.

Guidelines

1. The patient should have a thorough history and physical examination and other investigations done within seven (7) days of MMT initiation.
2. All women of child-bearing potential should have a pregnancy test.
3. The patient should be initiated at, have access to, and be associated with a recognized MMTP.
4. For recommendations on the management of patients under the age of 18 please reference *Health Canada, Best Practices Methadone Maintenance Treatment, Section 7.5 MMT and Youth.*
http://www.hc-sc.gc.ca/dhp-mps/substancontrol/exemptions/methadone/index_e.html
Telephone (613) 954-5995

For quick tips on Admission Assessment Process see Appendix 14.12

7. Clinical Visits

Standards

1. Patients in the first two weeks of the initiation phase will be seen daily by the prescriber or MMTP clinical staff member that includes the community pharmacist.
2. Thereafter, patients will be seen weekly by the prescriber or his/her explicit designate until stable.
3. With few exceptions, the patients will have contact with the prescribing physician or MMTP clinical staff member at least every three months.
4. Urine toxicology results reported positive for proscribed substances after a period of stability necessitate clinical contact. *See Section 10 that explains urine toxicology testing and rules regarding proscribed substances.*
5. Indications of new instability necessitate clinical contact.

Guidelines

1. Less frequent physician visits may be appropriate for the very stable patient with regular attendance for urine toxicology testing, counselling and pharmacy visits.
2. The frequency of face-to-face interactions should be guided by the clinical situation. However, a typical follow-up plan could be:

Length of Time Patient Stable on Methadone	Frequency of Clinic Visits
Less than 3 months	At least every two weeks
Less than 6 months	At least monthly
Less than 12 months	At least every 2 months
Greater than 12 months	At least every 3 months

3. The patient should be afforded sufficient time at each clinical visit to discuss concerns related to his/her MMT treatment.
4. Any unanticipated requests for a change in dosage, necessitates clinical contact.

8. Dosages

8.1 Initiation Phase

Standards

1. The initial methadone dosage is a clinical decision based on history or current use of opioids.
2. The maximum initial methadone dosage is 40 mg daily.
3. The maximum dosage increment is 10 mg.
4. The minimum interval for a dosage increment is every four days. That is, the dose remains the same for four days and then an increase may occur on the fifth day.
5. Once daily witnessed ingestion with no carries during the initiation phase and until clinically stabilized. Carried doses are not permitted until clinical stability is determined by the prescribing physician or the treatment program staff.

Guidelines

1. If there is uncertainty regarding the patient's tolerance to opioids, the initial dosage may be significantly less than 40 mg.
2. Variations from the standards (i.e. higher dosages) should be supported by documentation of patient requirement and safety.
3. There is insufficient evidence to support the supplementation of methadone with other opioids during initiation.
4. The prescribing physician must be very cautious in approaching frequent requests for dosage increases. When patients continue to request frequent dosage increases after the period of time in which most patients achieve clinical stability, it is important to evaluate the patient for the usual signs and symptoms of opioid withdrawal such as; uneasiness, cravings, diaphoresis, abdominal cramps, diarrhoea, piloerection, lacrimation, and rhinorrhea. Also pay particular attention to the ongoing use of any proscribed substances. However, experience has demonstrated that increasing methadone doses to effective levels can increase retention rates in treatment programs and decrease the use of proscribed substances.

For quick tips on Initiation Phase Process see Appendix 14.13.

8.2 Maintenance Phase

Standards

1. There is no defined minimum or maximum effective daily dosage of methadone.
2. Dosage increases must be supported by documented clinical indications.
3. The maximum dosage increment is 10 mg.
4. The minimum interval for dosage increment is every four days. That is, the dose remains the same for four days and then an increase may occur on the fifth day.

Guidelines

1. Experience has demonstrated the usual range of effective dosage to be between 60 mg and 120 mg per day. Dosages above this range may require specific monitoring, including serum methadone levels.
2. Patients should be encouraged to seek a dosage that eliminates withdrawal symptoms and cravings for opioids.
3. Changes to any concurrent medication should prompt a review of the current methadone dosage. Consultation with a knowledgeable pharmacist is advised.
4. Higher doses of methadone may be implicated in cardiac arrhythmias, a baseline ECG is recommended.
5. If the patient has concerns or there are changes in menstrual patterns, a pregnancy test is advisable.

See Appendix 14.14 Medication/Substances affecting Serum Methadone Levels.

For quick tips on Dosage Increase Process see Appendix 14.15

8.3 Split Dosages

Standards

1. The prescribing and dispensing of split dosages of methadone must be supported by documented withdrawal signs and symptoms after 24 hours of the daily dose, and signs and symptoms of excessive methadone dose in the four hours following a single daily dosage.

Guidelines

1. Split dosages may be required under certain clinical conditions.
2. Rapid metabolizers of methadone are rare; confirmation with peak and trough SML is recommended.
3. Twice-daily observed ingestion may be necessary.
4. Split doses do not necessarily have to be equal. A lower dose of $\frac{1}{4}$ to $\frac{1}{3}$ the total daily dose, provided as a carry, may be satisfactory to the patient, and reduce the amount of methadone prone to diversion or misuse.
5. It is important to recognize that these guidelines are intended for the treatment of the opioid-dependent patient. Patients with concurrent chronic pain may require special consideration, and consultation is advised to ensure optimal care.
6. Split dosages are common for pregnant patients in the third trimester.

8.4 Spoiled, Lost and Missed Doses

When the prescriber is uncertain whether a dosage has been “spoiled, lost, vomited or missed,” it should be recalled that the risk of death from overdose is much greater than the risk of harm from mild withdrawal symptoms. On-going communication between the prescriber and the pharmacist is essential.

The prescribing physician may find it useful to supply this section and related Appendices 14.16 & 14.17, to the patient and the pharmacist.

Standards

1. Unwitnessed vomited doses must not be replaced without documentation of withdrawal signs and symptoms.
2. All reports of vomited, lost or missed doses must be documented on the patient’s medical file.
3. More than 3 consecutive missed doses require that dispensing stop until the prescribing physician has been consulted.
4. More than 2 missed doses in a 7 day period, requires a consultation with the prescribing physician or MMTP team.
5. Repeated vomited or missed doses indicate a significant problem and necessitate clinical contact.
6. All missed doses must be reported, by the pharmacist, to the prescribing physician or MMTP team.
7. Replacement doses for vomited or lost doses require a new prescription. The rationale is that it will usually require a visit to the prescribing physician, and thus opportunity for evaluation.

Guidelines

1. Replacement doses should be given only as witnessed ingestion.
2. Doses vomited and witnessed are replaced at the full dosage if vomiting occurs within 15 minutes.
3. Doses vomited and witnessed are replaced at 50% of the full dosage if vomiting occurs 15 to 30 minutes after ingestion.
4. Doses vomited 30 minutes or more after ingestion are not replaced.
5. Missed Dose Guideline:
 - a. One missed dose permits continuation at the original dose.
 - b. Two consecutive missed doses require resumption at 75% of original dose.
 - c. Three consecutive missed doses require resumption at 50% of original dose.
 - d. Four missed doses necessitate re-initiation according to the protocol outlined in *Section 8.1 Dosages-Initiation Phase*.
6. Consultation with the prescriber or program should be considered for all missed doses regardless of cause, duration or number.

9. Carries

Decision by the physician and programs to permit carried doses must consider first the safety of the patient and the community. Deviation from the Standards and Guidelines, in particular, requires clear documentation of the rationale.

Serious harm to the patient and to others can result from inappropriately used, lost, stolen or spoiled carries. Requests for replacement may indicate clinical instability, and necessitates a thorough clinical evaluation. Decisions to replace doses should be made only after diligent consideration and evaluation of the risks and benefits.

Standards

1. Daily Witnessed Ingestion (DWI) is the accepted standard of care during the initiation phase.
2. Carries must not be granted as a matter of routine; clinical and social stability is required and must be documented.
3. Patients on MMT who continue to use proscribed drugs and other potentially harmful interacting substances such as alcohol and other CNS depressants should be considered unstable and treated accordingly. This usually means no carry doses.
4. Patients on MMT who are prescribed potentially harmful interacting substances such as benzodiazepines or other CNS depressants must be monitored closely. These patients must be clearly warned about the potentially adverse effects if such substances are used to excess, used indiscriminately, including if taken in excess of what has been prescribed. It may be beneficial or even necessary for some patients in these situations to have limited carries or to remain on daily witnessed ingestion.
5. Prescriptions must clearly define ingestion days and carry intervals.
6. With rare exceptions, all carries must include a witnessed ingestion.
7. The prescribing physician must be satisfied that carried doses will be securely transported and stored by the patient. A locked box or secured storage container for 3 or more carried doses is an example of enhanced security.
8. Inappropriately used, lost, stolen or spoiled carried doses require complete withdrawal of carry privileges until clinical and social stability is established.
9. Replacement dosing, when considered appropriate by the prescribing physician, is provided only upon documentation of physiological signs of withdrawal, and only as a daily witnessed ingestion.

Guidelines

1. Carries are strongly discouraged in the initiation phase.
2. Even in the most stable of clinical and social settings, the number of carries should be no greater than 14 consecutive doses. Longer carry periods require documentation of supporting safety considerations.
3. Evidence of instability, including the use of proscribed substances, should result in the curtailment of carry privileges.
4. Carries should only be provided as individual doses rather than in bulk form requiring the patient to apportion the daily dosage.
5. Carries should only be provided in a stepwise fashion, such as one carry dose per week, two carry doses per week, three carry doses per week per week, twice-weekly visits to the pharmacy, once-weekly visit.
6. Methadone carries should be dispensed in a crystalline liquid juice or similar product not suited to intravenous injection. Prescribing methadone in plain water or in capsule formulation is discouraged. Exceptions necessitate clear documentation of the justification.
7. Resumption of carry privileges after reports of inappropriately used, lost, stolen or spoiled carried doses should take into account the circumstances of the incident, as well as the patient's clinical and social situation. A cautious and conservative approach is recommended.

For quick tips on Carries Process see Appendix 14.18

10. Urine Toxicology Testing (UTT)

Urine Toxicology Testing (UTT) provides objective adjunctive information as part of a global clinical assessment.

UTT for the purposes of these standards and guidelines is for medical use in MMT and is not intended, nor should it be used for, legal or any other purpose.

False positives and false negatives may occur in UTT as in any other medical test. As well, different substances may be detected in the urine for variable periods after their use. Therefore caution should be taken in the interpretation of these results and consultation with a clinical toxicologist may be advisable.

Standards

1. An initial UTT must be performed and should be comprehensive in nature (e.g. Gas Chromatography/Mass Spectrometry).
2. UTT must be random; that is, the patient will have no more than 24 hours notice that a urine collection is required. This will allow that most substances, including alcohol, to be detected if present.
3. Routine UTT can be more focused but will include methadone metabolite, opiates, cocaine metabolite, amphetamines, alcohol, benzodiazepines and barbiturates for reasons of patient safety.
4. UTT must be done no less frequently than every three months. *See Appendix 14.19 Urine Toxicology Test-Scheduling and Coordinating.*
5. Evidence of patient interference with urines (such as presence of methadone but no methadone metabolite, or absence of methadone metabolite) must result in a complete withdrawal of carries until the clinical and social situation is satisfactorily resolved.
6. The UTT results must not be divulged to anyone outside the treatment team without explicit permission from the patient, except to a physician who is actively caring for the patient and the information is beneficial to their treatment.

Guidelines

1. UTT is useful as a tool for monitoring patient stability. *See Appendix 14.20 Sample-MMT Urine Toxicology Testing Results Record.*
2. A complete list of the patient's medications should be provided with every UTT request.
3. UTT should include cannabinoid metabolites or any other psychoactive drug that may indicate patient instability.
4. Presence of proscribed substances in the urine is usually indicative of clinical or social instability and should result in a delay in the granting of carry privileges, or the consideration of curtailment or suspension of existing carry privileges.

5. UTT should be based on clinical parameters; that is, frequency and drugs screened for is based on patient reports, treatment team observations, drug detection time lines and previous drug test results. The less stable the patient, the more frequent the drug screening.
6. UTT which is positive for proscribed substances should be repeated within two weeks, depending on the clinical situation.
7. Testing for substances that will not influence clinical decision making is unnecessary. For instance a patient-reported usage of a substance may obviate the need to test for that substance, depending on the clinical situation.
8. When a patient is prescribed a substance which has potential for interaction with methadone, UTT should include requests for differentiation within the drug class in question if available (particularly opioids and benzodiazepines) to ensure that prescribed medications are not being used to mask the presence of other substances. *See Appendix 14.21 for Urine Toxicology Testing Techniques*
9. Confirmation has an important role to play in drug testing as it rules out false positives. False positives may result from the techniques that all laboratories use in the initial screening. The physician should request confirmation of a positive result if the initial screen is not consistent with patient history.
10. Failure to attend for required urine toxicology testing within a reasonable time (generally 24 hours) should be considered positive for proscribed substances and may result in the suspension of carries. Clinical re-evaluation is required.
11. Where there is concern of the integrity of urine samples, an observed collection may be considered.

For Urine Toxicology Testing Collection Practice see Appendix 14.22

For quick tips on Urine Toxicology Testing Process see Appendix 14.23

11. Methadone and Other Prescribed Medications

Patients receiving MMT frequently have other medical problems including psychiatric conditions for which they receive medication. People with a history of addiction to one substance have a much greater risk of developing other addictions. Some medications may interact with methadone or may themselves have potential for abuse or addiction. Every patient on MMT requires a thorough evaluation of all medications on an on-going basis. Information and communication are imperative for patient safety and wellbeing where there two or more physicians prescribing medications.

Standards

1. The methadone prescribing physician must inform other treating physicians of the patient's MMT status.

Guidelines

1. In the event that the methadone prescriber/treatment team feels that other prescribed substances are interfering with methadone treatment, and a satisfactory resolution cannot be reached after consulting with the prescribing physician or physicians, the methadone prescriber may decide to discontinue methadone treatment.
2. Short-term use (usually less than two weeks) of other opioids for acute pain may be appropriate, but may require more careful monitoring. Advice should be sought from an experienced MMT prescriber.
3. Supplementation of methadone with other opioids for the treatment of chronic pain should be done only under the supervision of or in consultation with a physician knowledgeable in both opioid dependence and chronic pain management.
4. Benzodiazepines are CNS depressants and have a high potential for addiction; therefore they should be prescribed and dispensed with caution for patients on MMT.
5. Daily Witnessed Ingestion should be considered for any patient on MMT who is receiving prescribed benzodiazepines, and where there is reason to believe the patient is at risk.
6. For the majority of patients, the long-term use of benzodiazepines is not recommended. For patients with a concurrent major mental disorder where such treatment is considered, it is recommended that a consultation be obtained from a psychiatric colleague with expertise in the diagnosis and treatment of addictions. Wherever possible, alternative medications should be considered before prescribing benzodiazepines or other CNS depressants.
7. Psycho stimulant medications for the treatment of conditions such as Attention-Deficit/Hyperactivity Disorder (ADHD) or narcolepsy must be used with particular caution in patients on MMT. Prior consultation with a psychiatrist with expertise in the diagnosis and treatment of addictions is recommended.
8. When a patient is prescribed a substance which has potential for interaction with methadone, UTT should include requests for differentiation within the drug class in

question if available (particularly opioids and benzodiazepines) to ensure that prescribed medications are not being used to mask the presence of other substances.

9. The prescriber of psychoactive or other potentially interactive substances should be encouraged to limit amounts and the frequency of dispensing to coincide with methadone dispensing. PRN doses should be limited.

12. Discontinuation

12.1 Involuntary Withdrawal from MMT

Safety of the patients, treatment staff, prescribers and pharmacists, should be the principal consideration for involuntary cessation of MMT. Involuntary cessation of MMT is a last resort after all other avenues of resolution have been exhausted and should be the consensus of the treatment team.

Standards

1. There is no time limit for which a patient may continue MMT.
2. Evidence of failure to ingest prescribed methadone doses constitutes sufficient grounds for immediate cessation of MMT.
3. Physical or verbal threats to anyone involved in the patient's MMT treatment, constitutes sufficient grounds for immediate cessation of MMT.
4. Evidence of diversion of prescribed methadone doses constitutes sufficient grounds for immediate cessation of MMT.
5. All doses during involuntary withdrawal must be Daily Witnessed Ingestion, with no carries except as pharmacy closure requires.
6. The prescribing MD or treatment staff must notify The CPSA within 2 business days of any patients' admission to and or discharge from MMT. *See Appendix 14.11 for The College of Physicians & Surgeons of Alberta, Admission and Discharge Form.*

Guidelines

1. The purpose of involuntary withdrawal from MMT is to discontinue treatment as quickly and as safely as possible.
2. A typical schedule for involuntary withdrawal is as follows: a 10% reduction of the daily dose per day, or 1 mg per day, whichever is greater. This results in complete cessation within 30 days for any dose under 150 mg, and within forty days for any dose less than 500 mg.
3. Continued use of proscribed substances may result in cessation of MMT; a risk-benefit assessment should determine whether methadone should be continued.
4. Patients who are involuntarily withdrawn can be considered for resumption of MMT at a future date or even during the withdrawal process. This is a decision of the prescriber or treatment team, based on the situation at the time of involuntary withdrawal and the situation when the patient reapplies for treatment. Physicians are not obligated to resume treating patients who have been involuntarily withdrawn.

12.2 Voluntary Withdrawal from MMT

Any change in methadone dose, including voluntary tapering, may increase the risk of instability. Therefore, it is prudent to discuss with the patient issues such as preparation for this process including on-going or enhanced counselling or a reduction in the numbers of carried doses.

Standards

1. There is no time limit for which a patient may continue with MMT.
2. The duration and amount of dosage reduction during voluntary withdrawal can be individualized.
3. The prescribing MD or treatment staff must notify The CPSA within 2 business days of any patients' admission to and or discharge from MMT patients. *See Appendix 14.11 for The College of Physicians & Surgeons of Alberta, Admission and Discharge Form.*

Guidelines

1. Experience has shown that a reduction of no greater than 3% per week avoids significant withdrawal symptoms.
2. Voluntary withdrawal can be suspended at any time; however, resumption to higher dosages must follow the standards and guidelines *as outlined in Sections 8.1 and 8.2.*
3. While patient preferences are to be respected, the treatment team will make every effort to assist the patient in making a withdrawal plan which has the greatest likelihood of success.
4. Patients who cease MMT through voluntary withdrawal should be encouraged to use all available community resources that may be helpful to the ongoing treatment of addictions.

For quick tips on Voluntary Withdrawal Process see Appendix 14.24

13. Special Situations

13.1 Transfer of Care

Standards

1. The prescriber/program will continue to provide services until they are no longer required or desired, or until involuntary withdrawal is completed.
2. When a current MMT prescriber initiates a transfer of care, he or she must assist the patient to find alternate MMT services.
3. When a patient on MMT moves to another community or region in Canada, it is the patient's responsibility to arrange ongoing MMT, if needed. However, the current prescriber/program should provide all reasonable assistance to the patient.
4. The current MMT prescriber must provide the receiving physician with sufficient clinical background to permit the safe and effective continuation of MMT.
5. When a patient is undergoing involuntary withdrawal, the MMTP/prescriber is under no obligation to find another MMTP/prescriber. However, the current MMTP/prescriber must provide the receiving MMTP/prescriber with sufficient clinical background to permit the safe and effective continuation of MMT.
6. When an MMTP transfers care to a primary care physician, all assistance will be given to the physician at the time of transfer and at any time thereafter to enhance optimum care of the patient.

Guidelines

1. The physician initiating transfer of care should make all reasonable efforts to ensure access to patient information for the receiving physician at the time of transfer and anytime thereafter.
2. When care is transferred from an MMTP to a primary care physician, arrangements should be in place for rapid resumption of treatment by the referring program if necessary, should the primary care physician be unable to provide safe and effective MMT.
3. The resources of the referring MMTP remain available to the patient and the primary care physician on an ongoing basis.

13.2 Incarceration

Necessary medical treatment, including MMT, should be provided to any individual incarcerated in a provincial correctional centre or remand centre.

Community resources, including MMTPs and primary care physicians knowledgeable in MMT should be readily available resources for methadone prescribers in correctional or remand centres.

Standards

1. MMT prescribers practicing within provincial correctional or remand institutions must adhere to these Standards and Guidelines.
2. MMT prescribers practicing within federal correctional institutions must adhere to these Standards and Guidelines. If a prescriber feels that a conflict might exist between the Alberta Standards and Guidelines and the CSC Methadone Guidelines, it is recommended that the prescriber contact the Director General of Health Services for CSC at National Headquarters in Ottawa for clarification, at which point follow-up with the CPSA may occur, if required.
3. The prescriber/program providing MMT to the patient at the time of incarceration must provide all information necessary for safe and effective MMT upon the request of the correctional or remand centre.
4. The prescriber/program providing MMT to the patient at the time of incarceration and the prescriber during incarceration will collaborate to ensure continuity of care prior to and at the time of release.
5. Prior to release, the methadone prescriber or designate within the correctional or remand centre will assist the patient in making arrangements for continuation of MMT upon release.
6. The prescriber/program providing MMT to the patient at the time of incarceration will resume MMT at the time of release unless other arrangements have been made. Under extraordinary circumstances the prescriber may continue to prescribe during the incarceration.

Guidelines

1. Patients entering a provincial correctional or remand centre who are on a stable dose of methadone should be maintained on an appropriate dose for the duration of their incarceration, except where patient behaviour incurs involuntary withdrawal as outlined in *Section 12.1 Discontinuation: Involuntary Withdrawal* or where clinical assessment determines the need for a dosage change.

13.3 Hospitalization

Hospital-based attending physicians and surgeons are encouraged to acquire limited, patient-specific exemptions for the occasional hospitalized patient on MMT. Particularly in urgent or emergent situations where a methadone prescribing physician is not available, physicians should consult their hospital policy.

Standards

1. MMT should continue during hospitalization unless contraindicated by clear medical reasons.
2. The physician prescribing MMT prior to hospitalization must make available all information necessary for continuation of safe and effective medical care, prior to elective hospitalization and as soon as possible after an emergency admission.
3. The MMT prescriber or qualified designate must be available 7 days of the week to assist with ongoing MMT for a patient registered with that program.
4. Prior to a MMT patient's discharge, a hospital physician providing MMT during hospitalization must inform community MMT providers of any changes in dosage of methadone and information relevant to MMT—such as short-term opioid analgesic prescriptions, or the addition of potentially-interacting or psychoactive medications.

Guidelines

1. Changes to methadone dosages, or substitution or supplementation with other opioids, should be made only after consultation with a physician knowledgeable in MMT and opioids.
2. The prescriber of MMT prior to hospitalization should be contacted by a hospital staff member to facilitate proper arrangements for the resumption of MMT upon discharge.
3. Hospitals should have a structured means of communication with the community MMT prescriber or treatment staff.

13.4 Pregnancy

Split doses for pregnant patients are common. The benefits of MMT outweigh the risks of untreated opioid addiction in pregnancy. There is no evidence of permanent harmful effects to the fetus or child or of added risks during pregnancy, parturition or in the postnatal period from maternal MMT. There is ample evidence of increased frequency and severity of adverse outcomes during pregnancy among opioid dependent women who are not receiving supervised opioid replacement therapy.

Infants born to opioid dependant mothers including women on MMT do not meet the criteria for an opioid dependence disorder or “addiction”. Management of these situations requires the specialised knowledge of a paediatrician or a physician experienced in the management of Neonatal Abstinence Syndrome.

Standards

1. All women of child bearing age on MMT are to be given appropriate advice about contraception and the risks and benefits of becoming pregnant while on MMT.
2. MMT is the accepted standard of care for pregnant women with an Opioid Dependence Disorder. Cessation of or withdrawal from MMT during pregnancy is neither indicated nor recommended.
3. Pregnant women requesting MMT are to be given priority over other applicants to a MMTP.
4. Currently, a pregnant woman with opioid dependence, whether on MMT or not, is considered to be “high risk”. Medical care for this patient includes immediate consultation with an experienced methadone prescriber and ideally with an obstetrician knowledgeable in MMT.
5. The prescriber/program providing MMT prior to pregnancy must remain available to the admitting physician and hospital staff for consultation on MMT.
6. Where a MMT prescriber is not available in the hospital, the community prescriber/program must assist in ensuring MMT continues.
7. Appropriate pain management must be provided during labour and delivery, and in the post-partum period.

Guidelines

1. A pregnancy test should be considered on women of child bearing potential.
2. Pregnancy can reduce serum methadone levels, particularly in the third trimester. Changes in dosage should follow the protocols found in *Sections 8.1 & 8.2*
3. Post-partum methadone requirements may change rapidly. Careful and frequent monitoring is necessary.
4. Physician providing obstetrical care should be encouraged to obtain temporary, patient-specific exemptions to prescribe methadone well in advance of patient admission.

5. Plans should be made well in advance for continuation of MMT during in-hospital perinatal care.
6. Pregnancy while on MMT is regarded as a high-risk pregnancy, so that births at home under the sole direction of a midwife are not recommended.
7. MMT is not a contraindication to breastfeeding.

13.5 Concurrent Diseases

In general, priority should be given to patients where MMT will have a significant, positive effect on their treatment for concurrent medical diseases such as HIV, Hepatitis C or severe psychiatric illnesses.

Additionally, it is recognized that MMT reduces the risk both to patients and others of the transmission of blood-borne communicable infections. Priority may be given to these patients.

The role of MMT in preventing infection with HIV is well-documented. HIV positive patients with an Opioid Dependence Disorder benefit from enhanced social, psychological and physiological stability during MMT. Their overall MMT and HIV treatment and compliance is enhanced.

Standards

1. People with HIV/AIDS presenting for MMT will be given priority over those without.

Guidelines

1. Some medications used for the treatment of HIV/AIDS can affect serum methadone levels. Consultation with a knowledgeable physician or pharmacist is recommended. Adjustments to methadone dosage should follow the standards and guidelines in *Sections 8.1 and 8.2*.
2. A more liberal approach to monitoring and treatment is often advocated for this population due to a greater importance of preventing needle sharing and other high-risk behaviours in this population. However, the Standards and Guidelines still apply, and any deviation from them should be supported by clear documentation of reasons and projected benefit.
3. Daily observed anti-retroviral treatment can be linked to daily witnessed ingestion of methadone and can assist in the compliance with both treatments.

14 Appendices

The College of Physicians & Surgeons of Alberta acknowledges the contributions from the Colleges of Physicians and Surgeons of BC and Ontario, as well as the Alberta Alcohol and Drug Abuse Commission Opioid Dependency Program for permission to adapt certain written materials.

1. Methadone Guidelines Development Committee Terms of Reference
2. Methadone Guidelines Development Committee Membership List
3. Indicators of Stability
4. DSM-IV-TR Criteria for Substance Abuse
5. Health Canada Exemption
6. Sample Initiation Triplicate Prescription and Dispensing Schedule
7. Sample Maintenance Triplicate Prescription and Dispensing Schedule
8. Sample-MMT Medication Record
9. Sample-Agreement to Methadone Maintenance Treatment
10. Sample-Assessment and Medical Examination form
11. Admission and Discharge form
12. Admission Assessment Process
13. Initiation Phase Process
14. Medications and Substances affecting Serum Methadone Levels
15. Dosage Increase Process
16. Missed or Lost Doses Process
17. Emesis of Doses Process
18. Carries Process
19. Urine Toxicology Test- Scheduling and Coordinating
20. Sample- Methadone Maintenance Treatment Urine Toxicology Testing Results Record
21. Urine Toxicology Testing Techniques
22. Urine Toxicology Testing Collection Practice
23. Urine Toxicology Testing Process
24. Voluntary Withdrawal Process

14.1 Methadone Guidelines Development Committee Terms of Reference

Purpose:

The Committee shall develop provincial methadone maintenance guidelines for opioid dependency.

Membership:

The Committee shall consist of a minimum of three (3) physicians who have expertise and experience in the provision of methadone maintenance for opioid dependency. The Committee shall exist until such time as a provincial guideline is developed and approved by Council. The Committee shall elect a chair from among the members.

Activities

- Review of appropriate literature and other background material.
- Review and development of consensus on various issues in the provision of methadone treatment.
- Advice to Council on issues pertinent to the dissemination and use of the guidelines.
- Other activities.

Meetings

- At least 4 – 6 meetings will be held for the development of the guidelines.
- A quorum will consist of two members.

14.2 Methadone Guidelines Development Committee Membership List

Chair

Dr. Mat Rose
General Practitioner
Boyle McCauley Health Centre
Edmonton, AB

Members

Dr. Bill Campbell
Addiction Medicine
Calgary, AB

Dr. Bryan Ward
Assistant Registrar
College of Physicians and Surgeons of
Alberta

Dr. Ian Forster
Medical Director
Life Mark Health Institute
Edmonton, AB

Dr. Ian Postnikoff
Psychiatrist
Central Alberta Methadone Program
(CAMP) Red Deer
First Street Methadone Program,
Calgary, AB

Dr. Dan Ryan
Family Physician
Addiction Medicine
Edmonton, AB

Dr. Nick Wong
Family Physician
Alberta Alcohol and Drug Abuse
Commission (AADAC)
Edmonton Opioid Dependency Program

Ms. Catherine McCann
Manager, Physician Prescribing Practices
College of Physicians and Surgeons of
Alberta

Ms. Chris Mayberry
Opioid Dependency Treatment
Coordinator
College of Physicians and Surgeons of
Alberta

Ms. Kimberley Murphy
Administrative Assistant
College of Physicians and Surgeons of
Alberta

Dr. Janet Wright
Assistant Registrar
College of Physicians & Surgeons of
Alberta

14.3 Indicators of Stability

The patient's level of stability and evaluating the benefits of MMT are based on the improvement in all the major life areas of the patient.

The following are some illustrations of outcomes that define patient stability and should be considered when planning a transfer of care from the Methadone Maintenance Treatment Program to the primary care physician.

Clinical Issues	Indicators
<p>Methadone dosage and use of other substances</p>	<ul style="list-style-type: none"> • Reported suppression or elimination of opioid withdrawal symptoms • Reported reduction or elimination of craving for opioids • Reported and documented absence of over-sedation or euphoria on current dosage • Reported and evidence of reduction or elimination in the number of injection drug-use events • Demonstrated awareness of resources to obtain clean injection apparatus and knowledgeable in proper cleaning and non-sharing of equipment • Demonstrated knowledge of the serious health consequences of CNS depressant use, combined with methadone • Reported management of methadone related side effects • Evidence of unadulterated urine samples that are absent of proscribed substances • Demonstrated personal and social stability • Reported sense of well-being • Reported active avoidance of situations that are recognized triggers for relapse • Abstinent social support systems identified and in place • Demonstrated efforts to achieve positive lifestyle changes • Positive supportive information from treatment team members • Demonstrated mechanisms in place for the safety and storage of carries
	<ul style="list-style-type: none"> • Documented attendance at counselling to reduce high risk practices and increase coping skills

<p>Medical and Psychiatric Issues</p>	<ul style="list-style-type: none"> • Documented stabilization of acute medical conditions • Established attendance for ongoing health care for chronic conditions. • Demonstrated improvement in overall health status • Noted improved dental health and hygiene • Stable medical and mental health status • No reports of accidental overdose • The patient has an ongoing relationship with a primary care provider who has knowledge of or is the prescriber of the methadone
<p>Basic Necessities</p>	<ul style="list-style-type: none"> • Provisions made for food, clothing, housing, and safety needs and financial assistance if necessary. • Demonstrated management of basic personal care activities • Relatively stable and secure living conditions • Receipt of prenatal care • Documented established childcare resources • Transportation resources available • Documented stable source of income • Demonstrated involvement in productive activity: school, employment, volunteer, work • Reported involvement in healthy and safe leisure activities
<p>Relationships</p>	<ul style="list-style-type: none"> • Documented regular attendance for medication, UTT, counselling and medical appointments • Documented follow up with appropriate resources as per patient assessment and agreed upon treatment goals • Reported positive interactions with treatment team members • Reported maintenance of positive support systems • Reported absence of major conflict within family support system • Reported resolution of, or ongoing efforts to resolve, legal problems • Evidence of no illegal activities

14.4 DSM-IV-TR Criteria for Substance Dependence

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) a need for markedly increased amounts of the substance to achieve intoxication or desired effect
 - (b) markedly diminished effect with continued use of the same amount of the substance
2. withdrawal, as manifested by either of the following:
 - (a) the characteristic withdrawal syndrome for the substance (refer to Criteria A and B of the criteria sets for Withdrawal from the specific substances)
 - (b) 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)

Specify if:

With Physiological Dependence: evidence of tolerance or withdrawal
(i.e., either item 1 or 2 is present)

Without Physiological Dependence: no evidence of tolerance or withdrawal
(i.e., neither item 1 nor 2 is present)

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14.5 Health Canada Exemption



Health Sante
Canada Canada

Healthy Environments and Consumer Safety
Sante environnementale et securite des consommateurs



HC PROTECTED WHEN COMPLETED/ PROTÉGÉ SC LORSQUE REMPLI

Methadone

Exemption Application/Application pour une exemption

1. IDENTIFICATION

Please Print / s.v.p. en lettres moulées

Applicant: Physician/ Médecin <input type="checkbox"/> Veterinarian/Vétérinaire <input type="checkbox"/> Dentist/Dentiste <input type="checkbox"/>	
Surname/ Nom: _____ Given Name/ Prénom: _____	
Licence(s)/ License(s):	
Specialty/Spécialité:	
Post Graduate Training/Formation Professionnelle:	
Primary Practice Address/ Adresse du lieu d'exercice:	Institution:
	Street/Rue:
	Room/Piece:
	City/Ville:
	Province:
	Postal Code/Code Postal:
	Telephone/Telephone:
	Fax/Télécopieur:
E-mail Address/Courriel:	
Mailing Address (if different from above)/Adresse de correspondance (si différente)	
Language / Langue	English <input type="checkbox"/> Français <input type="checkbox"/>

Office of Controlled Substances June 2003



2. EXEMPTION

Please print/s.v.p. lettres moulées

Indication:	Dependency / Dépendance <input type="checkbox"/> Analgesia / Analgésie <input type="checkbox"/>
Type:	New/ Nouvelle <input type="checkbox"/> Renewal/ Renouvellement <input type="checkbox"/> Cancellation / Annulation <input type="checkbox"/>
Other/ Autre:	For one patient only/ pour un(e) patient(e) seulement <input type="checkbox"/>
	name of patient/ nom du/de la patient(e):
	Correctional Services/ Service Correctionnel <input type="checkbox"/>

3. QUALIFICATIONS & EXPERIENCE

Please print/s.v.p. lettres moulées

Describe qualifications and experience with methadone (courses, seminars, conferences, etc)/Décrire qualifications et expérience avec la méthadone (cours, séminars, conférences, etc.):	
Type of practice (solo or group)/Type de pratique (seul/en groupe):	



6. DECLARATION

By, this and under the condition that the released information is treated confidentially, I consent to the release from the licensing authority of the province or provinces in which I am registered and entitled to practice, to the Office of Controlled Substances of information from my personal file pertaining to the review of my application to prescribe methadone or to any other action related to this request for an exemption

Par la présente, et sous réserve que soit respecté leur caractère confidentiel, j'autorise le Collège des médecins de la / des provinces où je suis enregistré à dévoiler au Bureau des substances contrôlées toute recommandation ou tout renseignement contenu dans mon dossier personnel susceptible d'être utile à l'étude de ma demande d'exemption à prescrire la méthadone ou toute autre action pouvant être prise en rapport avec cette demande d'exemption.

Signature:	Date:
-------------------	--------------

Please send the application to the address below:

**Evaluation and Research Coordination Division
Office of Controlled Substances
Health Canada
3rd Floor
123 Slater St
AL 3503B
Ottawa ON K1A 1B9**

A copy of the application may be faxed to (613) 952-2196, however, the original must be sent by mail. For further information, you may contact Kim Barber at (613) 946-5139, by fax at (613) 952-2196 or by e-mail at exemption@hc-sc.gc.ca

Veillez faire parvenir la demande à l'adresse ci-dessous :

**Division de l'Évaluation et coordination de la recherche
Bureau des substances contrôlées
Santé Canada
3ième étage
123 rue Slater
IA 3503B
Ottawa ON K1A 1B9**

Il est à noter qu'une copie de la demande peut être envoyée par télécopieur au (613) 952-2196; l'original doit cependant être envoyé par la poste. Pour plus d'information, vous pouvez joindre par téléphone Kim Barber au (613) 946-5139, par télécopieur au (613) 952-2196 ou par courriel à exemption@hc-sc.gc.ca

14.6 Sample –Initiation Triplicate Prescription and Dispensing Schedule

The dispensing pharmacy should be indicated on the Rx or the schedule.

Triplicate Prescription number is found next to prescriber's name.

This Methadone Dispensing Schedule forms part of Triplicate Prescription No: **6824083** which replaces all previous methadone prescriptions.

Patient name: Joseph Blow
Pharmacy: Community Drug Store **Phone no:** 780-555-1212 **Fax no:** 780-555-1213

It is necessary to specify "for Methadone Maintenance". Other indications for methadone utilize liquid formulations

Rx: Methadone solution mixed with a crystalline juice such as Tang®. For methadone maintenance.

Pharmacist please note: this prescription is limited by the dispensing dates, for which first and last dates are clearly indicated. The total amount prescribed is provided to allow timely reporting to the CPSA TPP. The actual amount dispensed may be less due to, for example, missed doses. Report all missed or vomited doses, or any concerns, to the prescribing physician/Methadone Maintenance Treatment Program.

Under no circumstances should a dose be provided beyond the last date for which a "daily dose" is indicated.

The prescription is limited not by the total amount, but by the first and last dates of dispensing.

daily dose in mg methadone	First date of this dose	Last date of this dose	total amount in mg
40	4-Jan-05	7-Jan-05	160
50	8-Jan-05	11-Jan-05	200
60	12-Jan-05	15-Jan-05	240
70	16-Jan-05	23-Apr-05	6860
total amount prescribed (mg):			7460

Carried doses—including "no carries"—must be clearly indicated, with care taken to prevent alteration.

All doses are daily witnessed ingestion except the following Carried Doses:
*** no carries***

The total amount of methadone prescribed is required for the pharmacist to forward the triplicate prescription to the CPSA in a timely manner.

Prescriber

VOID
[Signature]

signature:

In order for the dispensing schedule to be a valid part of the triplicate prescription,

All the normal patient information, drug name and total amount prescribed appear on the triplicate. This example indicates "In juice per schedule. For methadone maintenance"

ALBERTA TRIPPLICATE PRESCRIPTION FORM

Take by patient or pharmacy of choice.

HEALTH CARE NUMBER: 123456789

PATIENT NAME: Joseph Blow

DATE ISSUED: 05 01 05

INITIAL: JB

LAST NAME: BLOW

DATE OF BIRTH: 67 03 15

PROVINCE: AB

ADDRESS: 101, 10101 - 1st

CITY: Edmonton

NO REFILLS PERMITTED

DRUG NAME & DOSAGE: - No the dose in juice

QUANTITY: NUMERIC: 1

DIRECTIONS FOR USE: - 7460 - seven thousand four hundred and sixty mg in juice per schedule for methadone maintenance

PHARMACY USE: DR. MATTHEW D B ROSE, BOYLE MCCRAUKEY HEALTH CT, 18628 96 ST, EDMONTON AB T5H 2J2, 780-422-7333

TRIPPLICATE PRESCRIPTION NUMBER: 6824083

DATE DISPENSED: YY | MM | DD

QUANTITY

PHARMACIST'S SIGN. & CERT. #

RECEIVED BY

918987

The pharmacy does not require the original triplicate when a fax is provided. Faxing ensures that the prescribing physician is aware at all times where the prescription is being dispensed.

14.7 Sample-Maintenance Triplicate Prescription and Dispensing Schedule

Please refer to the example of the *initiation/changing dose* dispensing schedule and prescription for the particulars to consider when writing MMT prescriptions.

This Methadone Dispensing Schedule forms part of Triplicate Prescription No: 6824084 that replaces all previous methadone prescriptions.

Patient name: Joseph Blow

Pharmacy: Community Drug Store Phone no: 780-555-1212 Fax no: 780-555-1213

Rx: Methadone solution mixed with a crystalline juice such as Tang®. For methadone maintenance.

Pharmacist please note: this prescription is limited by the dispensing dates, for which first and last dates are clearly indicated. The total amount prescribed is provided to allow timely reporting to the CPSA TPP. The actual amount dispensed may be less due to, for example, missed doses. Report all missed or vomited doses, or any concerns, to the prescribing physician/Methadone Maintenance Treatment Program.

Under no circumstances should a dose be provided beyond the last date for which a “daily dose” is indicated.

daily dose in mg methadone	First date of this dose	Last date of this dose	total amount in mg
115	24-Feb-05	25-May-05	10465

All doses are daily witnessed ingestion except the following Carried Doses:

*** Saturdays, Sundays, Tuesdays, Thursdays, Holidays***

VOID

Carried doses—including “no carries”—must be clearly indicated, with care taken to prevent alteration.

Prescriber signature: _____

ALBERTA TRIPPLICATE PRESCRIPTION FORM
 Void after three days.
 Take both copies to pharmacy of choice.
 E-PRINT

HEALTH CARE # 1233 DATE ISSUED 05.02.24
 PATIENT NAME Joseph Blow LAST NAME BLOW
 ADDRESS #1011 DATE OF BIRTH 07.03.15
 CITY Edmonton SEX M

ONLY ONE DRUG/DOSAGE PER FORM NO REFILLS PERMITTED

DRUG NAME & DOSAGE Methadone juice
 QUANTITY NUMBER 10465
 DIRECTIONS FOR USE In juice for maintenance

No Substitution: _____
 INITIALS _____
 DR. MATTHEW B ROSE 6793
 BOYLE MCCAULEY HE 4084
 18628 96 ST
 EDMONTON AB T5H
 780-422-7333

PHARMACY USE ONLY
 DATE DISPENSED YY | MM | DD
 D.I.N. QUANTITY PHARMIC #
 PHARMACIST'S SIGN. & C. #
 PHARMACY COPY RECEIVED

918989

14.9 Sample-Agreement to Methadone Maintenance Treatment

This is an agreement for methadone maintenance treatment between
_____ and _____

(Patient/Client)

(Physician/Clinic)

1. I understand that the methadone maintenance doctor will perform an assessment and medical examination, will establish the diagnosis of an Opioid Dependence Disorder, and will prescribe methadone, if it is considered appropriate and safe for me.
2. I agree to take methadone under medical direction, to assist me in dealing with my opioid dependence. I have tried or considered other treatment options. I understand that methadone maintenance is generally a long-term treatment.
3. I understand that I will become physically dependent on methadone and will experience withdrawal symptoms if I suddenly stop taking it.
4. I understand that methadone may cause drowsiness especially when starting treatment or when I receive increases in my dose. As a result, this may impair my ability in operating motor vehicles.
5. I am aware that the methadone maintenance treatment team may consist of several professionals including doctors, pharmacists, nurses, counsellors, social workers and support staff, who will be in close communication with each other to assure safety in my care.
6. For safety reasons, the methadone doctor will contact my doctor in order to ensure that each is fully aware of the treatment being provided by the other.
7. I recognize that counselling and other addiction assessments are available to assist me in dealing with the psychological and social difficulties that can accompany problems of opioid dependence.
8. I understand that when on methadone, taking other narcotics (e.g. Tylenol # 1,2,3, or 4, codeine, morphine, oxycodone, hydromorphone, fentanyl) and/or other substances, especially alcohol and benzodiazepines (Ativan, Lectopam, Restoril, Rivotril, Serax, Valium, Xanax) could be dangerous, especially if taken in excess. They may interact with methadone and cause overdose, coma, or even death.
9. I agree that when I see another doctor or dentist I will inform them that I am taking methadone. I agree to provide copies of any prescriptions obtained by me for medical reasons to be reviewed by the methadone maintenance doctor. The treatment team, if necessary, may do follow up with the prescribing doctor. I understand that in certain cases, the methadone prescribing doctor might not feel comfortable in prescribing methadone to me in combination with other medications that I have been prescribed.
10. I understand that initially I will be required to drink my methadone daily under the direct observation of a pharmacist or other qualified health care professional. Even after carry privileges have been granted (see # 11 below), I will still be required intermittently to drink a dose of my methadone under direct pharmacy or health care supervision.

11. I am aware that I may be granted a limited number of take-home carries of methadone once I have demonstrated sufficiently that I am no longer continuing to use illicit and/or other non-prescribed drugs and have made obvious positive and stable life-style changes. Carries may also be considered for specific reasons such as work/school. Carry privileges may not be provided if I miss clinic or medical appointments, not provide urine samples for toxicology testing when requested, misuse or divert my carries, as examples.
12. I realize that methadone can be fatal to others and will keep any methadone in my possession secure.
13. I understand that I must satisfy the doctor prescribing methadone for me that I have made all necessary arrangements to ensure the safety of myself and others, where carries are involved. This may include transporting and storing carries in a locked box or other secure container.
14. I realize that if I use my carries inappropriately, further carries will be suspended.
15. I understand that missed doses will be recorded on my file and will result in actions to ensure my safety. These may include a reduction or suspension of my dosage until I am reassessed.
16. I understand that the College of Physicians and Surgeons of Alberta, Triplicate Prescription Program monitors methadone prescriptions, and as such my prescription information will be recorded. This may involve occasional review of my file by an external reviewer, to ensure that my medical treatment is delivered in a safe fashion. None of the information on my file will be given to anyone outside this review process.
17. I understand that all clinical information on my file is confidential and will not be released to anyone without my written consent, except where staff believes there is a medical emergency and intervention is required by clinic staff and/or other persons.
18. I agree to attend ongoing medical examinations, urine drug testing, other laboratory testing, and counselling appointments when required.
19. A witnessed collection of may be required in the following examples: an invalid sample based on its temperature, results or repeated missed appointments for the required urine drug testing.
20. I agree to behave in a respectful manner towards all treatment team members and other patients/clients.
21. I understand that any violence, threats of violence, verbal abuse or disruptive behaviour, or diversion of my methadone will not be tolerated and could result in my termination from treatment.
22. I understand that my dose may be decreased and then stopped if it is determined that I am not benefiting from methadone maintenance treatment. Involuntary withdrawal from methadone may be more rapid if it is medically indicated for my safety or the safety of others.

**The undersigned fully understands the conditions of the agreement,
agrees to the provisions in full and has received a copy of this document.**

(Patient/client) signature

Date

Witness signature

Date

14.10 Sample-Assessment and Medical Examination

Name: _____ DOB: ____/____/____ Date: _____
DD/MM/YY

PHN: _____ Family MD: _____ File #: _____

Chief Concern:

History of Present Illness and Substance Abuse History:

Substance	Amount Used Day/Week/Month	Route IV/Other	Age First Used	Date Last Used DD/MM/YY

Drug Costs/day: <\$50; \$50-\$100; \$100-\$200; >\$200 Financing drug use: medication coverage plan
(including AHRE/AISH/VA); cash; illegal; sex

Past Treatment Attempts:

(Abstinence
History)

Medications:

Allergies:

Psych Hx:

(overdose, suicide, mini mental exam)

P Med Hx: _____

Social Hx:
 Education: _____
 Living Sit: _____

Surg Hx: _____

Support System: _____

Family Hx:
 (incl chem hx) _____

Employ Hx: _____

Criminal Hx: _____

Domestic/Sexual Abuse: _____

Screening:	Yes	No	Result	Date
HIV	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
Hep C	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
Last Pap	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
Preg Test	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
ECG	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
RPR	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____

Immune Status:	Immune	Not Immune	Immunization Counselling Provided
Hep A	<input type="checkbox"/>	<input type="checkbox"/>	_____
Hep B	<input type="checkbox"/>	<input type="checkbox"/>	_____

Review of Systems:

EENT _____ RESP _____
 CVS _____ GI _____
 CNS _____ ENDO _____
 STD _____ GU _____
 GYNE: G: P: A:

Ht _____ Wt _____ BP/HR _____ T _____

Track
Marks _____

Signs of Recent
Opioid Use_ ie. Injection
site abscess _____

Signs/Sx of
Withdrawal _____

Meets Criteria for:
Substance Dependence
to: _____

Readiness to Change:
Precontemplative

Contemplative

Preparation

Substance Abuse
of: _____

Action

Relapse

Maintenance

Summary/Clinical Impressions:

Treatment Plan:

14.11 Admission and Discharge



Methadone Patients/Clients Admissions and Discharges

To be provided to CPSA within 2 business days of admission/discharge dates

Date _____

Attention: **Janet Wright**
Triplicate Prescription Program
College of Physicians & Surgeons of Alberta
 Phone: (780) 412-2680 or 1-800-320-8624
 Fax: (780) 429-1981 (CPSA confidential fax machine)

From: Contact Name: _____

Contact Ph #: _____

Following is a list of methadone maintenance patients/clients admitted or discharged.

Patient Name	Health Care Number	Date of Birth	Admission Date	Discharge Date (last recorded ingestion date)	Formal Discharge Date	Profile Required

14.12 Admission Assessment Process

<p>Preliminary findings</p>	<ul style="list-style-type: none"> • Consider obtaining a triplicate prescription profile from the College of Physicians & Surgeons of Alberta • Preadmission toxicology testing results as appropriate • When possible, gather supportive documentation from physicians, social services, corrections
<p>Social/ Drug History and Medical Exam</p>	<ul style="list-style-type: none"> • Diagnosis of an Opioid Dependence Disorder supported by history and physical examination, based on DSM-IV-TR • Other treatment options explored such as 12 step program, abstinence based intensive out patient treatment, intensive in patient treatment, and in patient detoxification • Development of a non-judgemental relationship • Focused investigations and assessment to be completed <ul style="list-style-type: none"> ○ CBC ○ ALT, AST, GGT ○ Random blood glucose ○ Creatinine ○ TSH ○ ECG ○ Pregnancy test, if applicable • Additional recommended investigations <ul style="list-style-type: none"> ○ RPR ○ HIV includes pre and post test counselling ○ Hep A,B,C ○ CXR ○ Routine urinalysis- not toxicology testing • Development of a collaborative treatment plan based on realistic patient goals • Determination of a patient's motivation to change
<p>Education</p>	<ul style="list-style-type: none"> • Discussion of opioid dependence, disease process and benefits of substitution therapy • Provision of proper orientation to the program, policies and procedures, rights and responsibilities • Management of other drugs of abuse • Review of safe injection practices
<p>Administration</p>	<ul style="list-style-type: none"> • Signing of agreement for MMT with provision of copy to patient • Fax notification of admission to CPSA • Signing of release of confidentiality for family physician

14.13 Initiation Phase Process

<p>Methadone Dosage Determination</p>	<ul style="list-style-type: none"> • Determine initial dosage on the basis of clinical findings including objective and subjective information • Maximum initial dosage of 40 mg daily • If there is uncertainty regarding patients tolerance to opioids initial dosage may be significantly less than 40 mg • No carries of dosage • There is insufficient evidence to support the supplementation of methadone with other opioids during initiation • Minimum interval for dose increases is every four days • Maximum dosage increases is 10 mg
<p>Education</p>	<ul style="list-style-type: none"> • Expected outcomes during titration of dosage • Daily administered medication, to be witnessed • Half life of methadone and accumulative effects as a result of daily dosing • Health consequences of CNS depressant drug use combined with methadone • Clarification of any methadone myths • Provision of information related to adjunct treatment services such as addiction counselling and 12 step programs • Safe injection practices
<p>Triplicate Prescription</p>	<ul style="list-style-type: none"> • Determine pharmacy • Complete sections of the Triplicate Prescription as required • Fax prescription to pharmacy
<p>Administration</p>	<ul style="list-style-type: none"> • Notification of family physician, preferably with patient's consent • Preparation of supportive correspondence for funding of prescriptions or transportation needs through AHRE or AISH • Scheduling of subsequent appointments • Completion of appropriate documentation in patient's medical file

14.14 Medications and Substances affecting Serum Methadone Levels

Methadone is metabolized by cytochrome P450 (CYP) enzymes, and primarily CYP3A4. Medications and other substances may inhibit the actions of CYP3A4 resulting in an increase in serum methadone level (SML) and methadone's effects. Alternately, enzyme activity may be induced resulting in a decrease in SML and methadone's effects. Changes to methadone dosage should be made only on the basis of clinical signs and symptoms.

The table illustrates some examples of medications and substances that can alter SML. A review of current drug interaction sources is recommended before initiating any new drug therapy.

Websites to reference for additional information www.drug-interactions.com and www.atforum.com/SiteRoot/pages/rxmethadone/methadonedruginteractions.shtml

Inhibitors- May require to decrease methadone	Inducers-May require to increase methadone
<p>HIV Antivirals Delaviridine Indinavir Nelfinavir Ritonavir Saquinavir</p> <p>Amiodarone Aprepitant NOT azithromycin Chloramphenicol Cimetidine Ciprofloxacin Clarithromycin Delaviridine Diazepam Diethyl-dithiocarbamate Dihydroergotamine Diltiazem Disulfiram Erythromycin Ethanol (acute use) Fluconazole Fluoxetine Fluvoxamine Gestodene Grapefruit and/or Juice Itraconazole Ketoconazole Mibefradil Mifepristone Moclobemide Nefazodone Norfloxacin Norfluoxetine Omeprazole Paroxetine Sertraline Star fruit Troleandomycin Urinary alkalinizers (e.g. sodium bicarbonate) Verapamil</p>	<p>HIV Antivirals Abacavir Amprenavir Efavirenz Lopinavir + Ritonavir Nelfinavir Nevirapine</p> <p>Barbiturates Carbamazepine Cocaine Ethanol (chronic use) Fusidic acid Glucocorticoids Heroin Modafinil Phenytoin Pioglitazone Rifabutin Rifampin Spironolactone St. John's wort Troglitazone Urinary acidifiers (e.g. ascorbic acid)</p>

14.15 Dosage Increase Process

<p>Maintenance of Adequate Dosage of Methadone based on individual patient need</p>	<ul style="list-style-type: none"> • Clinical evaluation, signs of withdrawal, self-reported symptoms of withdrawal and craving • Exploration of motivation for the request <ul style="list-style-type: none"> ○ Chronic positive confirmed opioid urine toxicology tests ○ Changes in lifestyle ○ Increased stress ○ Increased physical labour ○ Negative environmental factors ○ Other medications • Attempts made to focus on resolving the offending situation • Consideration of obtaining serum methadone level
<p>Triplicate Prescription</p>	<ul style="list-style-type: none"> • All changes from previously stable dosages require a new Rx • Determine last date of dosage change • Minimum interval for dosage increases is every four days • Maximum dosage increment is 10 mg. • Re-evaluation of carries • Completion of triplicate prescription sections as required
<p>Education</p>	<ul style="list-style-type: none"> • Safe injection practices • Relapse prevention
<p>Administration</p>	<ul style="list-style-type: none"> • Review and update of treatment plan • Scheduling of follow up appointment • Completion of appropriate documentation in patient's medical file

14.16 Missed or Lost Doses Process

<p>One missed dose/lost dose</p>	<ul style="list-style-type: none"> • All reported missed/lost doses must be documented on the patient's medical file • No methadone dosage change is required
<p>More than 2 missed/lost doses in a 7 day period</p>	<ul style="list-style-type: none"> • All reported missed/lost doses must be documented on patient's medical file • Clinical consultation • Prescription duration is NOT EXTENDED due to missed/lost doses • Re evaluation of dosage and carries
<p>Two consecutive missed/lost doses</p>	<ul style="list-style-type: none"> • All reported missed/lost doses must be documented on patient's medical file • Reduction of dosage by 25% • New Rx required • Clinical consultation • Re-evaluation of carries
<p>Three consecutive missed/lost doses</p>	<ul style="list-style-type: none"> • All reported missed/lost doses must be documented on patient's medical file • Reduction of dosage by 50% • New Rx required • Clinical consultation • Re-evaluation of carries
<p>Four missed/lost dosages</p>	<ul style="list-style-type: none"> • All reported missed/lost doses must be documented on patient's file • Cancellation of methadone Rx • Clinical consultation • Re-initiation of MMT according to protocol: <ul style="list-style-type: none"> ○ Maximum initial dosage of 40 mg daily ○ If there is uncertainty regarding the patient's tolerance to opioids, the initial dosage may be significantly less than 40 mg ○ No carries of daily dosages ○ There is insufficient evidence to support the supplementation of methadone with other opioids during initiation ○ Minimum interval for dose increases is every four days ○ Maximum dosage increases is 10 mg.

14.17 Emesis of Doses Process

Witnessed emesis <15minutes after ingestion- replace full dose	<ul style="list-style-type: none">• All reported events of emesis must be documented on patient's medical file• Full dosage replacement• New Triplicate Rx required• Witnessed ingestion required
Witnessed emesis between 15-30 minutes after ingestion- replace 50% of dose	<ul style="list-style-type: none">• All reported events of emesis must be documented on patient's medical file• 50 % of full dosage replaced• New Triplicate Rx required• Witnessed ingestion required
Witnessed emesis >30 minutes after ingestion-no replacement	<ul style="list-style-type: none">• All reported events of emesis must be documented on patient's medical file• Dosage not replaced

14.18 Carries Process

<p>Considerations for Carries</p>	<ul style="list-style-type: none"> • Length of time in treatment • Clinical stability and progress <ul style="list-style-type: none"> ○ Regular attendance for urine toxicology testing, clinical visits ○ Urine specimens free of proscribed substances; evidence of methadone metabolites; no evidence of adulteration • Employment or school commitments • Medical necessity as based on a treating physician’s recommendations • Emergency circumstances • Demonstration of consistent stability in social and personal life e.g. Living arrangements, work, school, etc. • Secure storage of medication
<p>Carry Intervals</p>	<ul style="list-style-type: none"> • All carries must include a witnessed ingestion • Graduated carries • 14 days maximum carries unless documented rationale for variation and safety considerations
<p>Triplicate Prescription</p>	<ul style="list-style-type: none"> • Completion of triplicate prescription sections as required • Clear instructions related to carries including consumption days and pharmacy closure days

14.19 Urine Toxicology Testing- Scheduling and Coordinating

Case management of random UTT can be coordinated through various methods, including calendaring with the use of Personal Digital Assistant, day timer or developing your own system. Typically the most successful method of notifying the patient is through the pharmacist. Alternatively, contacting the patient at their home may be an agreed-upon strategy between the physician and patient.

The pharmacist should be advised two business days in advance and the pharmacist should inform the patient one business day in advance. The following simple chart may assist in the process for a limited caseload of MMT patients.

Month	Notification Pharmacy Date	Random UTT Date	Patients' Names
Week 1			
Week 2			
Week 3			
Week 4			
Week 5			

14.20 Sample-MMT Urine Toxicology Testing Results Record

Name: _____ DOB: _____
 File #: _____ PHN: _____

Collection Site: _____
 Phone: _____ Fax: _____

Date	Methadone	Methadone Metabolite	Opioids	Benzos	Alcohol	Barbiturates	Cocaine	Amphetamines	Cannabinoids	Other	Random (Y,N)	Action

14.21 Urine Toxicology Testing Techniques

Toxicology testing techniques are determined by the laboratory involved in providing this component of services in MMT based on the physician's order. Consultation with the toxicology personnel is important to determine the method and scope of their testing applications and will influence the specific drug testing orders by the physician. E.g. Immunoassay techniques may not screen effectively for synthetic narcotics such as Oxycodone or Meperidine and therefore the orders must specify these drugs.

Typical qualitative screening methods for specific drugs or medications are outlined below:

1. Enzyme Immunoassays
 - Amphetamines
 - Barbiturates
 - Benzodiazepines
 - Cannabinoid metabolites
 - Cocaine metabolite
 - Methadone,
 - Methadone metabolite- on request
 - Opiates- may not detect synthetic opioids

2. Enzyme Oxidation
 - Ethanol

Confirmatory testing involves further testing subsequent of an original positive immunoassay result using another analytical method. This confirmatory testing verifies the immunoassay result and may provide differentiation within a drug class. Some examples of these confirmatory techniques are:

1. Gas Chromatography
e.g. Ethanol

2. Gas Chromatography/Mass Spectrometry or Liquid Chromatography/Mass Spectrometry
e.g. Amphetamine (amphetamine, methamphetamine, MDMA, etc.)
Barbiturates (phenobarbital, secobarbital, amobarbital, etc.)
Benzodiazepines (oxazepam, temazepam, etc.)
Cannabinoid metabolites
Cocaine metabolites
Methadone and Metabolite
Opioids (codeine, morphine, oxycodone, 6-monoacetylmorphine, etc.)

14.22 Urine Toxicology Testing Collection Practice

UTT is more clinically reliable when urine collection is directly observed. However, other measures can be taken to enhance the authenticity of the urine sample and consequently the test results. In most cases directly observing urine collection is not required.

Chain of custody is for legal matters and does not apply to MMT.

The primary care physician may not have direct lab services in concert with the clinical practice and therefore patients will have a choice of labs for this service. This document may be attached to the requisition for collection of urines to ensure the proper protocol is followed.

- Extra clothing such as coats and sweaters should be removed.
- Parcels, bags and purses must not be taken into the collection area.
- Patients should receive a pre-labelled urinalysis container prior to entering the collection area.
- The patient must bring the sample directly to the collector and not place it in a pass-through-window.
- No other urine samples should be accessible to the patient during the provision of the sample. i.e. Specimen pass-through cabinet
- A minimum volume of 30 ml is required.

Considerations:

- Hand washing facilities are made available to patient after provision of the sample
- Provide a dry collection area
- All sources of water should be disabled
- Bluing of toilet water
- Temperature check to be performed immediately after urine sample is obtained- using a temperature sensitive strip
- **Lab staff do not witness urine collection**

If there is concern about the integrity of the sample, please notify the ordering physician's office and indicate concerns on the requisition, providing all relevant details.

14.23 Urine Toxicology Testing Process

<p style="text-align: center;">Scheduling</p>	<ul style="list-style-type: none"> • Random UTT are most relevant clinically • Contact pharmacist to notify patient 24 hours in advance of required sample date • Fax to lab or have patient obtain appropriate requisition from office • Frequency of collection intervals are linked to patient stability • Schedule UTT within 2 weeks following a positive result unless otherwise indicated • Questionable sample integrity may require an observed collection
<p style="text-align: center;">Drugs Tested For</p>	<ul style="list-style-type: none"> • An initial comprehensive urine toxicology test (e.g. GC/MS analysis) must be performed. • Routine testing can be more comprehensive but will include opiates, ethanol, benzodiazepines barbiturates, methadone metabolite, cocaine metabolite, amphetamines • Testing for a substance that will not influence clinical decision making may not be necessary • Include a list of patient’s medications with the UTT request • Request confirmatory testing to obtain differentiation within a drug class subsequent to an initial positive result • Request confirmatory testing in the case of a client appeal • Self-reported use of a substance may not require testing for that substance
<p style="text-align: center;">Actions</p>	<ul style="list-style-type: none"> • Monitoring of results • Non attendance for urine toxicology testing is considered a positive result • Clinical contact to discuss positive results and window of opportunity to educate • Re-evaluate dosage if chronic positive opioids • Consideration of adjunct treatment options such as intensified supports and structures, and/or additional pharmacological interventions • Re- evaluate/suspension/initiation of carries • Education on safe injection practices • Re- evaluate benefits of treatment and patient safety in continuing methadone • Review and update treatment plan
<p style="text-align: center;">Administration</p>	<ul style="list-style-type: none"> • Schedule follow up appointment • Documentation of discussions in patient’s file

14.24 Voluntary Withdrawal Process

<p>Readiness for taper</p>	<ul style="list-style-type: none"> • Explore motivation for the request (finances, family pressures, client’s misconception of needing to withdraw due to pending incarceration) • Review past history attempts at withdrawal
<p>Indicators that may influence positive outcomes</p>	<ul style="list-style-type: none"> • Abstinence from other proscribed substances • Personal, financial and social stability • No inappropriate involvement with other drug users • Developed relapse prevention plan • Stable mental and physical health
<p>Education</p>	<ul style="list-style-type: none"> • Describe process of voluntary withdrawal • Methadone as a medication vs. a drug • Benefits of long-term substitution therapy • Methadone continuance during incarceration • Prepare patient for potential difficulties associated with taper: craving, anxiety, impatience, withdrawal symptoms • Assure patient that return to previous dosage is possible following dosage increment protocols • Offer supportive resources during process including referral to an in-patient detoxification
<p>Triplicate prescription</p>	<ul style="list-style-type: none"> • Tailor withdrawal according to patient’s request; however, no more than 3% of total dosage is recommended weekly • Re-evaluate carries • Completion of triplicate prescription sections as required • Whenever possible, attach detailed withdrawal regimen with triplicate Rx, for the pharmacist. i.e. Excel program
<p>Administration</p>	<ul style="list-style-type: none"> • Schedule follow-up appointment • Review and update treatment plan • Documentation on patient’s file • Fax notification of discharge to CPSA once withdrawal completed

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16. Recommended Resources

Located at www.cpsa.ab.ca Methadone Program