

Guidelines
for Participation
in the
Methadone
Program
for
Saskatchewan Pharmacists

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Table of Contents

Executive Summary	Page 1
General Guidelines	Page 2
A) Prescriber Authority	Page 2
B) Preparing Oral Dosages of Methadone	Page 4
C) Administration	Page 5
D) Hospitals.....	Page 6
E) Cost and Payments	Page 6
F) Carry Medications or Take-Homes.....	Page 7
G) Criteria for Carries	Page 7
H) Refusal to Fill a Prescription.....	Page 9
I) Inappropriate Behaviour	Page 9
J) Patient’s Choice to Move to Another Pharmacy.....	Page 9
Pharmacists Role in Pharmaceutical Care	Page 10
A) Care of the Methadone Patient.....	Page 10
B) Pharmacology and Drug Interactions.....	Page 10
C) Side Effects and Adverse Events	Page 11
D) Overdose Information	Page 11
E) Missed Doses	Page 12
F) Use in Pregnancy	Page 12
G) Split Dosing.....	Page 12
Appendix A Part Fill Documentation.....	Page I
Appendix B HPB Psychoactive Drug Forgery Report.....	Page IV
Appendix B HPB Loss/Theft Report	Page V
Appendix C Stability of Methadone ... Conditions of Storage	Page VI
Appendix D Daily Dosages Chart.....	Page VII
Appendix E Methadone Billing Procedure – Bulletin No 257, Oct. 23/97	Page VIII
Appendix F Take Home/Carry Dosage Chart – Sample 1.....	Page IX
Appendix F Take Home/Carry Dosage Chart – Sample 2.....	Page X
Appendix G Incident Report Form.....	Page XI
Appendix H Background Information.....	Page XII
Introduction	Page XII
About the Drug Methadone	Page XII
Treatment Options	Page XIII
About Substance Use and Harm Reduction	Page XIII
High Threshold (“abstinence-based”) Programs	Page XIV
Low Threshold (“harm reduction”) Programs	Page XIV
Diversion Concerns and Public Attitudes.....	Page XV
Use in Pain Management.....	Page XV
Information on the Benefits of Methadone from.....	Page XVI
References.....	Page XVIII

Guidelines for Participation in the Methadone Program for Saskatchewan Pharmacists

Executive Summary

Over the past number of years there has been a dramatic increase in the number of pharmacies providing pharmacy services to patients participating in various Methadone Maintenance Programs. The philosophy of these Methadone programs is based on harm reduction; thereby attempting to nurture an attitude of tolerance and understanding towards injection drug users in our community. Methadone maintenance is considered one component of a harm reduction approach to the health care of opiate drug users.

The purpose of these guidelines is to provide information and guidance to assist pharmacists involved in the dispensing of Methadone for opioid dependence.

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

1. reduce illicit opiate use
2. reduce needle sharing
3. reduce criminal activity associated with addiction

It has been noted that there appears to be a lack of consistent standards with both the prescribing and dispensing of Methadone. In January 2001, the College of Physicians and Surgeons of Saskatchewan approved guidelines for their members. "*Saskatchewan Methadone Guidelines for the Treatment of Opioid Dependence/Addiction*" provides a standard framework for the assessment of potential candidates, dosing guidelines, screening criteria and prescribing issues.

This document for pharmacists is intended to provide Saskatchewan pharmacists some consistency with, not only the proper dispensing practise of Methadone, but also other important patient-pharmacist issues. Officials from federal and provincial jurisdictions and practising pharmacists have reviewed these Guidelines.

Key points of the program include:

1. Understanding the pharmacology of Methadone
2. Patients must understand and adhere to their responsibilities
3. Positive ID is required for all your patients
4. Physicians must be authorized to prescribe Methadone
5. Prescriptions must be written appropriately and meet all the legal requirements

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

These guidelines will be reviewed as treatment protocols are revised. Comments and suggestions should be forwarded to SPhA in Regina.

General Guidelines

In Saskatchewan dispensing of Methadone is regulated by the following legislation:

- the *Controlled Drugs and Substances Act and Narcotic Control Regulations*
- the Saskatchewan Pharmaceutical Association Bylaws
- the Saskatchewan Triplicate Prescription Program

Patient Orientation

The patient should receive an orientation to the pharmacy, including information about Methadone. The patient should be given an opportunity to ask questions about Methadone or any other currently prescribed drug. Relevant written information about the pharmacy, hours of operation, and any treatment agreements you may wish the patient to sign should be made available.

A) Prescriber Authority

A physician who wishes to prescribe or administer Methadone must first obtain an authorization from the Federal Minister of Health. An authorization is issued for a specific time period.

As per the *Controlled Drugs and Substances Act and Narcotic Control Regulations*, **Methadone may ONLY be supplied to certain health professionals or DISPENSED to a person from whom the pharmacist has received a WRITTEN order or prescription, signed and dated by a practitioner of medicine who is authorized to prescribe Methadone.** The pharmacist is responsible for ensuring that the practitioner is authorized to prescribe Methadone prior to dispensing it to the patient.

A prescription for any narcotic, including Methadone, must have a specified total quantity stated on the prescription for it to be valid and legally filled by a pharmacist. **A physician must state a specific total quantity to be dispensed.** In the *Narcotic Control Regulations* the definition of a prescription is as follows:

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

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

- “(1) No pharmacist shall supply narcotics except in accordance with subsections (2) and (3) and sections 34 to 36.*
- (2) A pharmacist may supply a narcotic other than Methadone to a person*
- (a) if the person is exempted under section 56 of the Act with respect to the possession of that narcotic; or*
 - (b) if the pharmacist has first received a written order or prescription therefor signed and dated by the practitioner and the signature of the practitioner, where not known to the pharmacist, has been verified by him.*
- (3) A pharmacist may supply Methadone to:*
- (a) a licensed dealer*
 - (b) another pharmacist*
 - (c) a hospital employee or a practitioner in a hospital*
 - (d) a person exempted under section 56 of the Act with respect to Methadone; or*
 - (e) a person from whom the pharmacist has received a written order or prescription therefor signed and dated by a practitioner of medicine who is exempted under section 56 of the Act with respect to Methadone.”*

The written prescription must be in the pharmacist’s possession BEFORE the Methadone is given to the patient. In Saskatchewan, Methadone is part of the College of Physicians and Surgeons’ triplicate prescription program. A new prescription is required for any changes in dosage, except when the dosage is being tapered up or down by the physician. A tapered dosage regimen may be written on one prescription. (ie. patients will be started on 30mg for two days, 40mg for two days and 50mg for three days on the first prescription)

Part-fills must not be confused with refills. Refills are not permitted for narcotics.

Part-fills for Methadone are permitted if the total quantity dispensed does not exceed that originally authorized. The principal requirement is that the physician MUST authorize the total quantity as a single figure and not as a smaller figure multiplied by the number of times the medication is to be dispensed. The physician must be conscious of the total, which he is prescribing. (Please see attached example of appropriate part fill documentation – Appendix A)

Faxed prescriptions for Methadone are acceptable as long as the prescriber used a triplicate prescription form and follows SPhA’s *“Operational Guidelines: Facsimile Transmission of Prescriptions”*.

If the pharmacist suspects that the prescription has been tampered with in any way, the prescribing physician must be consulted prior to filling. **If altering is confirmed, the College of Physicians and Surgeons must be notified immediately and an HPB Forgery Report form completed and mailed to the Winnipeg Regional office of Health Canada.** (Appendix B)

B) Preparing Oral Dosages of Methadone

- A stock solution of Methadone is prepared by dissolving the Methadone crystals in distilled water at the strength of 10mg per ml.
- Stock solution should be stored in a glass, light resistant container, in the refrigerator. The major issue of concern with Methadone solutions is bacterial growth, not stability. Check stock solutions regularly for signs of bacterial growth. Orange drinks or other juices used for dilution are also susceptible to bacterial growth and some go rancid in just a few days. A stability chart is provided for your information. (Appendix C)
- 100mls must be dispensed for on site consumption and take home carries.
- Individual dosages are prepared by measuring the required amount of the stock solution (example - a dosage of 90mg requires 9ml of stock solution) then qs to 100ml with liquid Tang*. For lower doses a more dilute stock solution may be prepared. You may wish to adjust the amount of water when preparing Tang to allow for the water in the stock solution.

*Tang is suggested as Methadone should be dispensed in a vehicle which does not lend itself to injection (can't be boiled down). Patients have been known to "cheek" or "emesis" their dose and then inject it. For those unable to tolerate Tang or for a better "mask" of the bitterness, the Methadone may also be dispensed in high quality lemonade.

- To ensure that the patients consume their dosages on site and to prevent diversion to the street:
 1. Q.S. to 100ml of Tang and water as a large volume is harder to divert.
 2. Get the patient to say something once finished and provide more water to rinse.
 - This is an ideal time to do patient counselling and follow up.
 3. Ask the patient to return the bottle or cup they have used.
- Dosages should be bottled and sealed on an individual basis (one bottle per dose) and labelled accordingly for take-home dosages (known as carries). The use of childproof safety caps is strongly encouraged for all take-home dosages.
- A prescription for Kadian® (long acting morphine) may be written until the patient's Methadone dose reaches a level which controls withdrawal symptoms and cravings. The Kadian® is administered daily along with the Methadone in a manner which does not allow for diversion, such as splitting the capsules and placing the granules on a teaspoon or in the Methadone solution. (Note: Kadian® is not soluble in solution and will clump at the bottom of the bottle requiring several rinses of the bottle with water to obtain the total dose.)

- Cases of accidental poisoning have occurred in a pharmacy when a stock solution of Methadone was mistaken for distilled water. All Methadone solutions should be labelled clearly and stored separately from the distilled water in a distinctive container. Colouring the stock solution is an acceptable option.
- Although it may not always be possible or practical for security reasons it is recommended that the Methadone be stored in a separate refrigerator away from the high traffic area in the dispensary.
- The pharmacist is responsible to ensure that the patients receive their Methadone in person. The dosages are not to be released to spouses, relatives or friends. Spilled, damaged, lost or stolen dosages are not replaced without a new prescription from the physician. The patients are responsible for protecting their dosages.
- Records are kept for each daily dose administered to the patient and the patient must sign for each dosage administered including carries authorized by the physician. (Appendix D)
- Do not replace the dosage if the patient claims to have had an emesis (vomiting). You may replace dosages if the emesis happens in front of you and you know beyond a reasonable doubt that it is legitimate. Further discussions regarding lost or emesed dosages should take place with the physician and addictions counsellor. Perhaps the dosage should be replaced initially. It should be documented and not allowed to continue.

C) Administration

Dispensing and administration of Methadone to patients must be done on a daily basis until carry privileges have been granted. For those patients receiving their dose of Methadone on a daily basis, the medication must be consumed under the direct supervision of a health professional. The health professional must ensure that the Methadone has been swallowed, for example by talking to the patient after they drink or having them drink water after their dose. Because a single dose of Methadone is effective for 24 hours, Methadone patients should be counselled to attend the pharmacy at the same time every day to receive their Methadone. This will result in more consistent blood levels and fewer adverse effects.

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

D) Hospitals

Methadone patients admitted to hospitals as in-patients, whether for addiction-related reasons or for unrelated medical and surgical reasons, often are mistreated and mismanaged by hospital staff. This issue could be appropriately addressed by guidelines for hospital staff, which should reflect the following general principles:

- on admission of a Methadone maintenance patient as a hospital inpatient, hospital staff should notify the patient's treatment pharmacy and physician and confirm:
 - the individual's participation in therapy
 - Methadone dose
 - time and date of last dose
- during an inpatient stay, the hospital staff should ensure the continuity of Methadone pharmacotherapy through its own pharmacy or by arrangement with the patient's community pharmacy
- before discharge, hospital staff should notify the patient's community pharmacy of the time of discharge and the time and amount of last dose of Methadone to ensure resumption of outpatient pharmacotherapy without interruption
- if the patient is discharged to continuing care facilities, arrangements for continued provision of Methadone should be part of the discharge plan.

E) Costs and Payments

The patient is responsible for payments as with any other prescription. The patient may be eligible for Special Support Assessment and Emergency Assistance through Saskatchewan Health, Drug Plan and Extended Benefits Branch.

Please review Pharmacy Information Bulletin #257 from Saskatchewan Health in which it discusses the Saskatchewan Minister of Health's authorization of the payment of a "managed care" fee. Pharmacies are to bill the compounding of Methadone on a weekly basis. (Appendix E)

The First Nations and Inuit Health Program (formerly Medical Services Branch, Indian Affairs) has been negotiated. Please contact them for current status.

F) Carry Medication or Take-Homes

Take home medication or “carries” are given to stable patients to reduce disruption in and improve the quality of the patient’s daily life. The patient will usually drink the first dose at the pharmacy under observation and then take home the carry medication in properly labelled, childproof, unit dose containers for the determined number of days. Carries should always be diluted to 100ml with Tang or another suitable vehicle. Patients must be advised to keep all carries out of the reach of children as well as other family members. A dose of as little as 10mg can be fatal to a child. Carries should be refrigerated and taken on the day of the week indicated on the label.

All empty carry bottles are to be returned to the pharmacy by the patient at the time of the next visit.

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

Carries must be labelled according to federal and provincial requirements and must include a warning that the amount of drug contained could cause serious harm or toxicity if taken by someone other than for whom it was prescribed. Records similar to the daily administration records should be kept for carries (Appendix F)

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

G) Criteria for Carries

- Carries are a progression of treatment. Once a patient has been stabilized on Methadone not all doses may have to be witnessed by a pharmacist, carries may be granted by the physician. A decision to grant carries by the physician should ideally be made in consultation with other professionals involved, such as counsellors and pharmacists.
- Carries are issued to patients who are considered to be functionally stable and are assessed by the care team and physician for the following:
 1. Program participation, which includes:
 - attends as required for their Methadone dose;
 - attends scheduled appointments with the physician, nurse or counsellor; and
 - complies with the treatment agreement
 2. Demonstrates cognitive stability to assume responsibility for the care and use of the medication

3. Improvement in drug use (as evidenced by acceptable urines for 3 months), either abstinence or non-harmful use of drugs (harm can be seen as a continuum and can result from a single use or from long term use of drugs).
 4. Social integration such as employment, school attendance, child-care responsibilities, volunteer work.
- Patients with carries must be able to accept responsibility for the carried doses, which includes proper security and use of the Methadone.
 - A pharmacist may refuse to fill a prescription for a carry if there is concern for the safety of the patient or the safety of others is at risk. This decision must be communicated to the physician and addictions counsellor. Please see attached incident report (Appendix G).
 - Carries may be discontinued by the physician for any of the following reasons:
 1. Evidence the patient has failed to meet the terms of the treatment agreement;
 2. Sustained use of unauthorized drugs;
 3. The patient has produced an unacceptable urine sample or has tampered with the collection of the urine sample;
 4. The patient has approached another Methadone treated patient suggesting or proposing to sell, buy or share any urine sample or tamper with any urine sample;
 5. The patient has diverted, or permitted to be diverted any part of the Methadone; or
 6. The patient has approached another Methadone treated patient suggesting or proposing to sell, buy or share Methadone.
 - Carries must not exceed 6 doses unless for the following reasons:
 1. Client goes on a vacation to areas where Methadone is not readily available
 2. Compassionate reasons
 3. Out of town employment opportunities to an area when Methadone is not readily available.

H) Refusal to Fill a Prescription

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

1. **Threats** – the patient has threatened the safety or well being of any staff member or another patient or pharmacy customer by oral or written action
2. **Disruptive Behaviour** – the patient has engaged in disruptive behaviour on the premises
3. **Violent Behaviour** – the patient has engaged in violent behaviour towards a staff member, a patient or another person
4. **Illegal Activity** – the patient has engaged in an illegal act on the premises
5. **Diversion of Methadone** – the patient has diverted, or allowed to be diverted, any part of their Methadone
6. **Contraindication of Methadone** – In the opinion of the prescriber, Methadone has become contraindicated for the patient
7. **Missed Doses** – The patient has failed to pick up doses of Methadone for 3 consecutive days (unless alternative arrangements for pick-up has been made or there are convincing evidence that the failure to pick-up was beyond their control). Please see **Missed Doses** – Section E, page 12.

I) Inappropriate Behaviour

Physicians and pharmacists need to come to an agreement and have a good plan of action on how to manage problematic situations which may arise, such as missed/lost/stolen doses, impairment with alcohol and other drugs, violence, selling or diversion of carries, shoplifting, and other inappropriate behaviour **before** the behaviour occurs.

If the patient appears to be intoxicated with alcohol or other drugs they should not receive their dose of Methadone as the use of Methadone in combination with alcohol may lead to serious adverse events. The physician should be contacted and the patient advised that he would be reassessed and asked to come back later.

J) Patient's Choice to Move to Another Pharmacy

If a Methadone patient has come to you from another pharmacy or institution, before administering their first dose you should check with their former pharmacy to make sure when they had their last dose administered and to determine the reason for the patient's choice to move to another pharmacy. Narcotic prescriptions may not be transferred. A new prescription is required.

Pharmacist's Role in Pharmaceutical Care

A) Care of the Methadone Patient

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

Ethics of confidentiality must be maintained. However, to ensure patient's safety, and with the patient's confirmed written consent, the professionals involved with treatment may exchange information regarding:

- prescriptions for mood altering drugs obtained from other doctors
- use of other drugs, whether pharmaceutical, street drugs or alcohol, especially if they appear to be under the influence.
- urine testing results or other information relevant to the patient's medical well being.

The pharmacist should be aware that many patients receiving Methadone have other co-morbid conditions such as HIV, Hepatitis C, endocarditis, depression and other mental illnesses.

As patients often have engaged in criminal activities, they have more involvement with the justice system than the health care system. Continuity of care between correctional services and community pharmacies is required. It is advisable to maintain contacts within the correction, probation and justice services systems.

B) Pharmacology and Drug Interactions

Methadone is extensively metabolized by cytochrome CYP3A4 in human liver microsomes (Chem Res Toxicology 1996;9:365-73). Patients may experience withdrawal symptoms when started on other medications that are known inducers of the cytochrome P450 enzymes, including CYP3A4 and CYP2B6. A "Dear Doctor" letter was issued by the fabricators of the antiretroviral therapy, VIRAMUNE (nevirapine), Boehringer Ingelheim on July 30, 1999 discussing this interaction.

Drugs that are contraindicated and may precipitate a withdrawal syndrome include preparations with opioid antagonist's activity such as pentazocine, butorphanol, nalbuphine and naltrexone.

Drugs, which may lower the plasma level and effectiveness of Methadone, include rifampin, barbiturates, phenytoin, carbamazepine and urinary acidifiers. Chronic alcohol use may also lower plasma levels.

Drugs, which may increase plasma levels and increase the effect of Methadone, include disulfiram, cimetidine, fluvoxamine, diazepam, amitriptyline and urinary alkalinizers. The acute use of alcohol may also increase plasma levels.

The pharmacokinetics of desipramine and zidovudine (AZT) may be altered by Methadone.

C) Side Effects and Adverse Events

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

The most serious adverse effect is the potential for apnea, respiratory failure and hypoxia, leading to coma or death.

Other adverse effects associated with long-term use of Methadone can include increased sweating, constipation, appetite disturbance, sexual dysfunction, abnormal menses, urinary retention, blurred vision, biliary pain, insomnia, gynecomastia and hepatotoxicity.

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

D) Overdose Information

With typical maintenance dosing, Methadone has a half-life of about 24 hours. As with all opiates, toxicity is thought to be the result of respiratory depression due to decreased sensitivity of the brain's respiratory centre to the stimulatory effect of carbon dioxide. There is, however, no clear definition of what constitutes a toxic or fatal blood Methadone level. One reason for the difficulty of determining a toxic blood Methadone level is drug interaction. A given blood Methadone level may or may not be toxic depending on the presence of other drugs, which may augment or counteract any toxic effects of Methadone.

E) Missed Doses

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

F) Use in Pregnancy

Methadone crosses the placenta and can cause fetal dependence; therefore, its use in pregnant women should be limited to those with opioid dependence. The primary intent of Methadone use is to create a stable environment for the pregnancy and to improve outcomes. Methadone has no teratogenic effects. Detoxification is not recommended during pregnancy because fetal distress can occur. However, women who are dependent on opioids do better with Methadone than with no treatment. The advantages include longer gestational periods and higher birth weights, as well as a more moderate abstinence syndrome in the neonate. Methadone will pass into the breast milk.

G) Split Dosing

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

Part Fill Documentation

Methadone is a narcotic and federal regulations do not permit the repeating of Narcotic Prescriptions. However, part fills may be dispensed. **A part fill is the dispensing of a quantity of medication which is less than the total amount of the drug specified by a practitioner when the prescription was originally issued.** Due to the uniqueness of the drug and the therapy itself, we will accept methods of documentation and accountability which differ from the conventional methods of documenting part fills. Examples of acceptable methods of accountability are attached as Appendix D, “Daily Dosages Chart and Appendix F, “Take Home/Carry Dosage Chart” samples 1 and 2.)

The following points must be considered when documenting part filling narcotics:

- the total quantity dispensed cannot exceed that originally authorized
- **the total quantity must be expressed as a single figure or the directions must be explicit with reference to dose and time frame (NO room for interpretation)**
- the practitioner must be conscious of the total amount, which he is prescribing

The following examples are provided for your information:

1

Mr. John Doe
Address
SHSP
February 3, 2001
Methadone 80mg
To take eighty (80)
milligrams daily to be
dispensed daily until
March 3, 2001

This example prescription **CAN** be part-filled as the pharmacist can reasonably determine that a specific number of doses has been authorized by the prescriber.

2

Mr. John Doe
Address
SHSP
February 3, 2001
Methadone 80mg
To take 80mg daily
80mg x 30 days

This example prescription **CAN** be part-filled as the pharmacist can reasonably determine that a specific number of doses has been authorized by the prescriber.

3

Mr. John Doe
Address
SHSP
February 3, 2001
Methadone 80mg
To take 80mg daily
x 3 weeks

This example prescription **CAN** be part-filled as the pharmacist can reasonably determine that a specific number of doses has been authorized by the prescriber.

4

Mr. John Doe
Address
SHSP
February 3, 2001
Methadone 80mg
To take eighty milligrams
daily, to be dispensed on a
weekly basis until March 3,
2001

This example prescription **CAN** be part-filled as the pharmacist can reasonably determine that a specific number of doses has been authorized by the prescriber.

5



*Mr. John Doe
Address
SHSP
February 3, 2001
Methadone 80mg
2400mg, dispense in lots of
80mg daily for 30 days*

This prescription is correctly written for part-fills. It is valid for a total of 30 fills - the original plus 29 part-fills.

6



*Mr. John Doe
Address
SHSP
February 3, 2001
2400 mg Methadone
Dispense in 80mg lots
Take 80mg daily*

This prescription is correctly written for part-fills. The pharmacist could fill this particular order 30 times, the original plus 29 part-fills.

7



*Mr. John Doe
Address
SHSP
February 3, 2001
Methadone 80mg
To take eighty (80)
milligrams daily
Fill daily from
February 3, 2001 to March
3, 2001*

This example prescription **CAN** be part-filled as the pharmacist can reasonably determine that a specific number of doses has been authorized by the prescriber.

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

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

Diluent	Period of Stability	
	Room Temp 20-25° C	Refrigerated 5° C
Grape Flavoured Kool Aid	17 days	55 days
Orange Flavoured Tang	11 days	49 days
Allen's Apple Juice	9 days	47 days
Grape Flavoured Crystal Light	8 days	34 days
Grape Flavoured Crystal Light with 0.1% sodium benzoate	29 days	

Methadone Billing Procedure

Saskatchewan Health – Bulletin No 257 – October 23, 1997

The new system allows for pharmacies to bill a weekly “managed care” fee for administering the Methadone Program.

The Minister of Health has authorized a payment of \$3.50 per service to a maximum of \$21.00 per seven-day period to pharmacists of community-based pharmacies who provide monitoring, supervision and other required activities related to Methadone prescriptions.

This authorization will continue until such time as the agreement, between community-based pharmacies and the province governing the payments to be made for prescription drug services provided by pharmacies, is renegotiated.

Process:

1. Pharmacies will bill the Methadone compound under a separate **DIN 00990043** on a weekly basis.
 - a. The quantity will be used to indicate the number of times per week that the drug was dispensed (i.e. maximum of 7).
 - b. The acquisition cost will be the cost for ONE dose.
 - c. The compounding fee will be a weekly amount that includes the compounding time only.
 - d. The dispensing fee is your usual and customary fee up to a maximum allowed (i.e. only ONE dispensing fee per week).
 - e. Therefore, the total cost of the drug will be the quantity times the acquisition cost + the appropriate tiered mark-up + the compounding fee + the dispensing fee.
 - f. Payment for the Methadone compound is treated the same as all other Formulary products.

2. Pharmacies will bill the “managed care” fee under a separate **DIN 00990058** on a weekly basis.
 - a. The quantity will be used to indicate the number of times per week that the drug was dispensed (i.e. maximum of 7).
 - b. The acquisition cost will be zero.
 - c. The compounding fee will be zero.
 - d. The dispensing fee will be the cost for one pharmacy visit (maximum is \$3.50).
 - e. Therefore, **the total cost of the managed care will be the quantity times the dispensing fee to a maximum cost of \$21.00.**
 - f. The Drug Plan will pay for the “managed care” fee at 100%.

Methadone compound: DIN 00990043

Methadone “managed care” fee: DIN 00990058

Take Home/Carry Dosage Chart – Sample 1

Our Town Medical Clinic

101 - 111 Dependency Street, Our Town, Saskatchewan S0S 0S0
Phone: 306-555-1111 Fax: 306-555-2222

METHADONE CARRY SHEET – PHARMACY

Circle: ABC Pharmacy White's Black's Brown's
 Green's John's Jane's XYZ Pharmacy

Patient: _____	Chart # _____
Start Methadone _____	Meth mg: _____

Reason: _____	
Employer: _____	
From: Day: _____	Date: _____
To: Day: _____	Date: _____
Recurrent - Drink: _____	Carry: _____
Current Rx – Exp: _____	Carry: As before pending new Rx
Date: _____	Doctor: _____

Comments: _____

<p>METHADONE IS DANGEROUS. PATIENTS ARE RESPONSIBLE FOR THEIR CARRIES. CARRIES WILL NOT BE MODIFIED, SOLD, DONATED – OR REPLACED IF LOST.</p> <p>Patient must sign before medications dispensed: _____</p>

Take Home/Carry Dosage Chart – Sample 2

ABC Pharmacy

102 - 111 Dependency Street, Our Town, Saskatchewan S0S 0S0

Phone: 306-555-2111

Fax: 306-555-2112

CARRY RETURNS	
Day	# Bottles

Patient's Name: _____

Doctor's Name: _____

Month: _____

Drug: Methadone _____ mg

Day	Drinks	Carry Bottles Taken	Carry Bottles Ret'd	Signature
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				

Day	Drinks	Carry Bottles Taken	Carry Bottles Ret'd	Signature
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				

Incident Report Form

ABC Pharmacy

102 - 111 Dependency Street, Our Town, Saskatchewan S0S 0S0

Phone: 306-555-2111

Fax: 306-555-2112

INCIDENT REPORT

To: Dr. _____ Fax # _____

Patient: _____

Today's Date: _____

Date of Occurrence: _____

Pharmacist's Report: _____

Pharmacist's Name: _____

Signature: _____

Background Information

Introduction

According to the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders) addiction involves substance tolerance, symptoms secondary to substance withdrawal, escalating substance use, reduction in social and recreational activities because of substance use and increased expenditure of time to obtain and use the substance.

Opiate addiction has become a serious problem in society causing unemployment and family disruption, leading to criminal activities such as prostitution, vandalism, drug dealing and theft. Most break and enters/robberies of homes and cars are used to finance drug abuse. Addiction may also lead to HIV, Hepatitis B&C, TB, STDs and death. Pharmacotherapy may assist the opioid abuser in re-establishing life along more constructive lines by promoting rehabilitation, reducing health risks and costs to the community. Support services addressing the psychological, social and physical health issues in an abuser's life must be available to support pharmacotherapy.

Opiate addiction is a medical illness, a recognized chronic progressive disease. Long standing opiate addiction can be permanent and require permanent treatment. Withdrawing from opiate addiction is very distressing and painful (dope sickness).

Some pharmacists find it very rewarding to watch patients transform from someone whose language of medical commerce includes lies, deceit, manipulation and mistrust to a person capable of being in the mainstream with responsibilities to themselves and their communities. Not all patients are a success story, but it is well worth participating in the program for those who do succeed.

About the Drug Methadone:

Methadone is a synthetic opioid (mu receptor) agonist with actions similar to morphine, that has good oral bioavailability and three important functions:

- analgesia for about 6 hours,
- suppression of opioid withdrawal and craving for about 24 hours, and
- a mood stabilizing effect for longer periods.

Its major short-term effect is to prevent withdrawal symptoms and help reduce drug and needle cravings in opiate-dependent/addicted individuals. It slowly accumulates in the liver giving it a long duration of action (24 to 36 hours). It is available in Canada as a white, odourless, crystalline powder. The correct dose in a stabilized patient should prevent cravings for about 24 hours without causing euphoria or sedation. It is chemically unrelated to opiates, therefore, when required, other opiates may also be prescribed (i.e. post-op pain, chronic pain).

Methadone is commonly prescribed as maintenance therapy for opiate addicts because its long half-life delays the withdrawal syndrome, making its effects less severe. Over time, Methadone eventually replaces and blocks all other opiates at the mu receptor site. In sufficient doses, cross-tolerance to other opioids develops (i.e. Methadone "blocks" the euphoric effects of self-administered opioids).

Initially, Methadone and morphine may both be prescribed. The morphine (or other opiate) is prescribed orally for detoxification purposes. Over the stabilization or transition period Methadone is increased and opiates are decreased to zero. During this transition, no other doctor should prescribe drugs of dependency. For patients with a dual diagnosis the use of other medications to treat their psychiatric conditions is appropriate.

The dose of Methadone is adjusted depending on the withdrawal and craving symptoms. This must be done gradually as Methadone can be fatal for anyone not used to it (even for heavy opiate addicts). There is no simple mg for mg dose and the adjusted dose usually ends up in the range of 60 to 100 mg administered orally once daily. Increase in dosing may cause drowsiness; therefore patients should be cautioned about driving. They should also be counselled regarding nausea.

Treatment Options

In Saskatchewan, treatment of opiate dependence with Methadone has evolved from the use of only more traditional clinic type programs to outpatient/community based care for opiate addicts wishing to reduce or eliminate their use of drugs. The latter option allows the treatment to function at the community level and promotes the normalization of patients' lifestyles and behaviour patterns.

About Substance Use and Harm Reduction

Substance use involves three elements – the properties of the substance, the characteristics of the user and the environment in which the use occurs. Although a drug produces a psychoactive effect on the body, the harm varies according to the user. Patterns of use, perceptions of pleasure and risk, demographics, socio-economic and culture characteristics of the user are all important.

Currently there is no international or nationally recognized definition of harm reduction. The World Health Organization has stressed that any country's attempts to reduce drug use should not compromise the measure to stop the spread of AIDS. Harm reduction focuses on public health principles not moral concerns. It strives to reduce the immediate harmful consequences of drug use and acknowledges the role of the user in harm reduction without insisting on abstinence. Policies and programs such as Methadone maintenance needle exchange and outreach projects are all part of harm reduction.

Many substance users lack the capacity to understand the consequences of their actions. These individuals often exist on society's periphery because of such factors as mental illness, lack of safe affordable housing and societal judgement. A team approach is required, including physicians, pharmacists, nurses and other health care professionals, addiction and mental health workers, lawmakers, law enforcement agencies, community representatives, advocates, social services, justice and parole services and various outreach agencies as well as native elders and spiritual advisors. A professional response that demonstrates respect for individual differences is essential.

Most programs offer three options:

1. Withdrawal from morphine or heroin without Methadone
2. Methadone maintenance for as long as needed
3. Methadone withdrawal over a period of time.

In Saskatchewan, in various locations, two different types of treatment programs are utilized. They are commonly referred to as either High Threshold or Low Threshold Programs and are described as follows:

High Threshold ("abstinence-based") Programs:

Most traditional Methadone maintenance therapy programs have "high thresholds" for admissions and continuation in treatment. An opioid user who has been accepted for the program must have clear abstinence goals, be willing to attend compulsory counselling, and provide supervised urine samples on an ongoing basis throughout the therapy. Should the user fail to comply with these conditions, s/he will be automatically discharged from the program.

Low Threshold ("harm reduction") Programs:

"Low threshold" programs respond to the situation of those that are discharged from or not admitted to "high threshold" approaches. This is a more "patient-centred" model of treatment, focusing on reducing harm from drug use rather than requiring abstinence. A low-threshold program offers elective rather than mandatory counselling and case management services, allows functionally stable patients more take-away doses of medication (or "carries"), and fewer urine tests.

Further information regarding treatment is available in the College of Physicians and Surgeons of Saskatchewan and Saskatchewan Health document "*Saskatchewan Methadone Guidelines for the Treatment of Opioid Dependence/Addiction*".

Diversion Concerns and Public Attitudes

No other medication is so highly regulated. Methadone is the only opiate authorized to be used to treat opiate addicts. Therefore, its intended use creates a potential for abuse different from that of other controlled substances insofar as providing Methadone to patients on a regular basis creates special opportunities for diversion. Previous guidelines were written in part, to respond to real abuses and to the perceived threat of diversion of Methadone into illicit channels. It is now perceived that the benefits both to the individual patient and to society at large from authorizing greater clinical discretion in Methadone treatment far outweigh the risks from diversion, with recognition of the existence of both a real threat and considerable public fear of diversion.

With respect to public opinion, a substantial segment of public opinion over the years has opposed the use of Methadone for the treatment of opiate addiction, and another segment is ambivalent about its use. Public attitudes toward addiction of any type, but particularly heroin addiction, are overwhelmingly negative. The debate over the extent to which addiction is a disease or a moral failure remains unsettled in the public mind. The stereotypes of addicts are of individuals engaged in criminal activity, predatory toward others, and unable or unwilling to respect the norms of acceptable social behaviour or participate in the work force. The public's fear of opiate addicts creates a reluctance to spend "treatment" dollars on them; it also creates sympathy for a criminal justice response.

In general, members of the medical profession often share many of the negative attitudes of the general public. Many are either indifferent or hostile to its use for the treatment of heroin addiction. Ignorance about its effectiveness may stem from the fact that Methadone maintenance historically has been poorly linked to the provision of primary and specialized medical care and to mental health services, both of which are often needed by patients.

Use in Pain Management

Methadone is a good alternative to morphine sulfate for pain management, particularly parenteral Methadone, which is about twice as potent as oral Methadone. Because analgesia is not related to serum half-life, frequent daily dosing usually is needed for pain management. The normal adult dosage for acute severe pain is 2.5-10mg every three to four hours as needed and 5-20mg every six to eight hours for severe chronic pain. Dosing should be individualized to meet the needs of the patient.

Information on the Benefits of Methadone from the National Institute on Drug Abuse

The use of Methadone has recently been comprehensively re-evaluated by the National Institute on Drug Abuse in the United States and found to be effective for opioid addiction. Researchers found that, in adequate dosage and with supportive therapy, Methadone reduces illicit opioid use and criminal activity, improves social health and productivity, improves physical health, reduces HIV (human immunodeficiency virus) transmission, improves pregnancy outcomes in opioid addicted women, and is safe for long-term use.

Research has also shown that Methadone maintenance treatment pays for itself in basic economic terms. Researchers at the National Institute on Drug Abuse for example, estimated that the yearly cost (figures shown are in US dollars) to maintain an opioid addict in New York in 1991 was: untreated and on the street (\$43,000), in prison (\$34,000), in a residential drug-free program (\$11,000), and in Methadone maintenance treatment (\$2,400).

Opioid Use:

The effects of any drug depend on several factors:

- the amount taken at one time
- the user's past drug experience
- the manner in which the drug is taken
- the circumstances under which the drug is taken (the place, the user's psychological and emotional stability, the presence of other people, simultaneous use of alcohol or other drugs, etc.).

Short-term effects appear soon after a single dose and disappear in a few hours or days. Opioids briefly stimulate the higher centres of the brain but then depress activity of the central nervous system. Immediately after injection of an opioid into a vein, the user feels a surge of pleasure or a "rush." This gives way to a state of gratification; hunger, pain, and sexual urges rarely intrude.

The dose required to produce this effect may at first cause restlessness, nausea, and vomiting. With moderately high doses, however, the body feels warm, the extremities heavy, and the mouth dry. Soon, the user goes "on the nod," an alternately wakeful and drowsy state during which the world is forgotten.

As the dose is increased, breathing becomes gradually slower. With very large doses, the user cannot be roused; the pupils contract to pinpoints; the skin is cold, moist, and bluish; and profound respiratory depression resulting in death may occur.

Overdose is a particular risk on the street, where the amount of drug contained in a "hit" cannot be accurately gauged. In a treatment setting, the effects of a usual dose of morphine last three to four hours. Although pain may still be felt, the reaction to it is reduced, and the patient feels content because of the emotional detachment induced by the drug.

Long-term effects appear after repeated use over a long period. Chronic opiate users may develop endocarditis, an infection of the heart lining and valves as a result of unsterile injection techniques. Drug users who share needles are also at a high risk of acquiring AIDS (acquired immune deficiency syndrome) and HIV infection (human immunodeficiency virus). Unsterile injection techniques can also cause abscesses, cellulitis, liver disease, and even brain damage. Among users with a long history of subcutaneous injection, tetanus is common. Pulmonary complications, including various types of pneumonia, may also result from the unhealthy lifestyle of the user, as well as from the depressant effect of opiates on respiration.

Psychological dependence exists when a drug is so central to a person's thoughts, emotions, and activities that the need to continue its use becomes a craving or compulsion.

With physical dependence, the body has adapted to the presence of the drug, and withdrawal symptoms occur if use of the drug is reduced or stopped abruptly. Some users take heroin on an occasional basis, thus avoiding physical dependence.

Withdrawal from opioids, which in regular users may occur as early as a few hours after the last administration, produces uneasiness, yawning, tears, diarrhea, abdominal cramps, goose bumps, and runny nose. These symptoms are accompanied by a craving for the drug.

Major withdrawal symptoms peak between 48 and 72 hours after the last dose and subside after a week. Some bodily functions, however, do not return to normal levels for as long as six months. Sudden withdrawal by heavily dependent users who are in poor health has occasionally been fatal. Opioid withdrawal, however, is much less dangerous to life than alcohol and barbiturate withdrawal.

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