SASKATCHEWAN
COLLEGE OF PHARMACY
PROFESSIONALS

Opioid Agonist Therapy (OAT) Standards

Revised October 2020

This document replaces the Methadone Guidelines

Contents

Definitions

"Opioid agonist therapy (OAT)"

Opioid agonist medications, including but not limited to methadone and buprenorphine-naloxone are prescribed for the treatment of opioid use disorder. OAT is typically provided in conjunction with provider-led counselling; long-term substance-use monitoring (e.g. regular assessment, follow-up, and urine screens) comprehensive preventive and primary care; and referrals to psychosocial treatment interventions, psychosocial supports, and specialist care as required.

Opioid agonist therapy (OAT) is the preferred terminology, representing an intentional shift from the use of opioid substitution treatment (OST), opioid maintenance treatment (OMT), and opioid replacement therapy (ORT).[4]

Purpose

Standards are minimum mandatory requirements.[4] The OAT standards define the minimum acceptable level of care to ensure patient safety. The standards include requirements for the dispensing of opioid agonist therapies including, but not limited to, methadone and buprenorphine-naloxone for the treatment of substance use disorders involving opioids. Currently the standards only discuss buprenorphine-naloxone and methadone.

All health professionals are expected to comply with the legal framework of their practice. Pharmacists and pharmacy technicians are expected to be competent to deliver the care and services within the scope of their individual practices.[1]

In Saskatchewan, dispensing of OAT medication is regulated by the following:

- The *Controlled Drugs and Substances Act* and *Narcotic Control Regulations*
- The *Pharmacy and Pharmacy Disciplines Act* and the Saskatchewan College of Pharmacy Professionals Bylaws, Standards, Guidelines and Policies.

Acknowledgement

The information contained in this document was adapted from:

1. Alberta College of Pharmacy
   ODT Guidelines: Medication- Assisted Treatment for Opioid Dependence: Guidelines for Pharmacists and Technicians (Updated Feb 1, 2014)
2. College of Pharmacists of British Columbia
   Professional Practice Policy #66: Policy Guide- Methadone Maintenance Treatment (2013)
3. Saskatchewan College of Pharmacy Professionals
   Reference Manual: Guidelines for Participation in the Methadone Program for Saskatchewan Pharmacists (September 2010)
4. College of Physicians and Surgeons of Saskatchewan

Opioid Agonist Therapy Program - Standards and Guidelines for the Treatment of Opioid Use Disorder (December 2018)
(Further referred to as "CPSS OATP Standards and Guidelines" within this document)

General Information Regarding OAT in Saskatchewan

Pharmacists must have the required skills, knowledge and competencies to provide OAT and the onus is on the pharmacy professionals to obtain evidenced based resources and training to enhance their knowledge. It is strongly recommended that pharmacy professionals new to the practice connect with an experienced pharmacy professional/mentor.

Available resources for patients and pharmacists:

- Find Mental Health and Addictions Services in my Community
- Take home naloxone provider link
- Patients also have access to the HealthLine 811 if needed, addiction support and counselling are within the purview of this service.[4]
- CPDPP online training – LINK to FOLLOW

Products Currently Available in Canada

Health Canada Product Database Accessed Jan 2020

Methadone Hydrochloride (generic, METADOL, METADOL-D, METHADOSE) Oral Concentrate 10 mg/mL[April 2020]
Buprenorphine-Naloxone (generic, SUBOXONE) Sublingual Tablet 2 mg /0.5 mg
Buprenorphine-Naloxone (generic, SUBOXONE) Sublingual Tablet 8 mg/ 2 mg
Buprenorphine (PROBUPHINE) Subcutaneous Implant 80 mg

Methadone Hydrochloride (generic, METADOL, METADOL-D) tablets 1 mg
Methadone Hydrochloride (generic, METADOL, METADOL-D) tablets 5 mg
Methadone Hydrochloride (generic, METADOL, METADOL-D) tablets 10 mg
Methadone Hydrochloride (generic, METADOL, METADOL-D) tablets 25 mg
Methadone Hydrochloride (METADOL, METADOL-D, METHADOSE) Oral Solution
Buprenorphine (SUBLOCADE) Extended Release Subcutaneous Injection 100 mg/ 0.5 mL
Buprenorphine (SUBLOCADE) Extended Release Subcutaneous Injection 300 mg/ 1.5 mL
Buprenorphine (SUBUTEX) Sublingual Tablet

See Appendix 1: General Properties of OAT

Standards of Practice

1. PHARMACY PREMISES

1.1. Operating Hours

Pharmacy operating hours must accommodate the needs of those requiring witnessed ingestion of medication without compromising patient safety or causing undue hardship to the patient.[1]

1.1.1. When a pharmacist accepts a patient, who requires daily witness ingestion of OAT medication (i.e., 7 days per week) the pharmacy hours of service must accommodate this requirement. A pharmacist does not have the independent authority to adapt a prescription for OAT maintenance treatment from 'daily witness' to a 'take-home' (carry) dose.[2]

1.1.2. The pharmacy must ensure that there is no gap in therapy on days the store is closed. While pharmacies are not required to be open seven days a week, the pharmacy is required to ensure that patients are able to receive their dose on the days the pharmacy is closed. This may include (but is not limited to) collaboration with another pharmacy, opening for a short period of time, or weekend take-home doses authorized by the prescriber.[1]

1.2. Privacy and Confidentiality

There must be an area within the pharmacy where the pharmacist can ensure privacy and confidentiality is maintained for the patient during witnessed ingestion and for pharmacy professionals to provide appropriate pharmaceutical care and other pharmacy services to the patient.[1]

1.2.1. Appointments and staggered schedules for regular patients requiring witnessed ingestion may be required to ensure that there is adequate space within the pharmacy to accommodate patients who are waiting and protect the privacy of consultation.[2]

1.3. Security

OAT, including methadone and buprenorphine-naloxone, are regulated under *The Controlled Drugs and Substances Act* and corresponding regulations and as such requires the same security measures as other controlled substances. Pharmacists must also be aware of any further direction provided by the Saskatchewan College of Pharmacy Professionals (SCPP).

1.3.1. Security of the premises must take into consideration the risks of theft of controlled substances. Controlled substances should be stored in a locked and secure location.[1]

1.3.1.1. This applies to prepared dosages (both witnessed and take home) as well as manufactured products and compounded stock solutions.

1.3.1.2. The *Narcotic Control Regulations* require that pharmacists report the loss or theft of controlled drugs and substances to the Office of Controlled Substances, Health Canada within 10 days of the discovery of the loss or theft.[2]

1.3.1.3. For public safety, all losses must also be reported to SCPP and local law enforcement as soon as they are discovered.

1.4. Incentives

Includes, but is not limited to, loyalty points, gift cards, etc.

1.4.1. SCPP strongly discourages the use of incentives for any reason in patients receiving OAT, especially to retain or obtain new patients.

1.4.2. The use of incentives can interfere with the treatment goals of Substance Use Disorder and is not recommended.

2. PHARMACY PROCEDURE TO PROVIDE OAT

See Appendix 2: Pharmacy Staff Roles for Providing OAT

2.1. New Patient on OAT

2.1.1. Upon receiving a new patient on OAT, pharmacists must confirm that the prescription is written by an authorized prescriber who meets the legislative requirements to prescribe OAT (see Appendix 3: Requirements for Prescribing for Opioid Agonist Therapy in Saskatchewan).[1]

2.1.2. Pharmacists are permitted to dispense OAT prescriptions from authorized prescribers in provinces other than Saskatchewan (see Appendix 3.1: Additional Prescribing Circumstances for OAT in Saskatchewan).

2.1.3. The pharmacist must screen and assess the appropriateness of the treatment, including the dose prescribed and view necessary Pharmaceutical Information Program (PIP) and eHealth Viewer information.

2.2. Patient Information and Patient-Pharmacist Agreements

2.2.1. Pharmacists should review the following with the patient to ensure the patient is aware of the: store hours, dispensing process, obligations of the pharmacist(s) and pharmacy staff, the role of the patient in their care, mutual expectations including expectations for trauma-informed, stigma-free patient care, patient conduct and behaviour within the pharmacy, procedure for handling missed, spoiled, lost/stolen, or emesis (vomiting) of doses, and education regarding opioid agonist therapy, including pertinent clinical details related to efficacy, storage and safety.[1]

2.2.1.1. Patient-pharmacist discussions are best documented by signing a Pharmacy- Patient Two-way Agreement for OAT Services (see Appendix 4: Pharmacy-Patient Two-Way Agreement for OAT Services) between pharmacist/pharmacy and the patient to acknowledge the mutual agreement and understanding of key elements involved in the provision of the OAT medication and patient care.[1]

2.2.1.2. Pharmacies with collaborative practices with a prescriber(s) may also consider a three-way agreement between the prescriber, pharmacist/pharmacy, and patient. See “Three-Way Agreement” in Appendix J: Treatment Agreement Sample of the CPSS OATP Standards and Guidelines.[1]

3. MONITORING

3.1. Pharmacist(s) must monitor ongoing patient response and progress with OAT while the client is under the pharmacist care.[4] Monitoring should be completed with regular assessment, follow-up and review of urine screens.

3.2. All concurrent medications used by a patient should be monitored. Saskatchewan electronic Health Record (eHR) Viewer and PIP should be accessed for potential drug interactions, and laboratory results should be regularly assessed.[4]

3.3. Polysubstance use with alcohol, sedative-hypnotics, and cannabis should be addressed at regular intervals and any concerns communicated to the prescriber as benefits of OAT can be reduced if there is continued psychoactive substance use.[4]

3.4. Pharmacists should monitor for risk of misuse and diversion and communicate concerns to the prescriber as misuse could lead to overdose, respiratory depression, and hepatic injury.

3.5. Patients should be regularly assessed for signs of withdrawal and sub-optimal dosing and any concerns communicated to the prescriber.

See Appendix 18: Monitoring Recommendations for Buprenorphine-Naloxone and Appendix 19: Monitoring Recommendations for Methadone for more information.

4. COUNSELLING AND PATIENT EDUCATION FOR OAT

See Appendix 21.1: Methadone Patient Information Handout and Appendix 21.2: Buprenorphine/Naloxone (Suboxone) Patient Information Handout for more information.

5. OAT PRESCRIPTION REQUIREMENTS

5.1. CPSS OATP Standards and Guidelines

CPSS OATP Standards and Guidelines state that OAT prescriptions must be written in accordance with the Prescription Review Program (PRP) bylaws and on the prescriber's personalized prescription pad OR generated through an electronic medication record (EMR) program (e.g., Accuro, MedAccess), unless dispensed from a hospital pharmacy for inpatient use.[4]

5.1.1. CPSS OATP Standards and Guidelines state that all OAT prescriptions must be faxed or sent through an alternative approved electronic means, such as prescriptions generated through the Pharmaceutical Information Program (PIP), to the pharmacy (i.e., never provided directly to the patient).[4]

5.2. Prescription Information

The prescription must contain the following information:

- Patient's name (include all given names, if possible);
- Health Services Number;
- Patient's date of birth;
- Patient's address;
- Name of the medication;
- Dosage and quantity of the medication;

    - For buprenorphine-naloxone, if written as “Suboxone™ 4 mg” this refers to 4 mg of the buprenorphine component (and does not factor in the naloxone component)
- The date range of the prescription (start and end dates)
    - Evaluate the end date of the prescription to ensure that the authorization for dispensing does not end when the patient will not be able to see a prescriber for a new prescription (i.e. on a weekend or when the prescriber is unavailable). [2]
    - Review the prescription directions to determine the dosing schedule (daily witnessed ingestion (DWI), divided dose, take-home doses), including the specific days of the week for each witnessed dose ingestion and take-home doses, to confirm that the pharmacy operating hours accommodate the dosing schedule.[2]
- Any special instructions on dispensing of other medications concurrent to OAT;
- Prescriber’s name and phone number; and,
- Signature of the prescriber.

5.3. Ambiguous or Conflicting Information

Any ambiguous or conflicting information identified must be clarified with the prescriber.[3]

5.4. Final Prescription Record to be Retained by the Pharmacy

After dispensing, the final prescription must include all the above, in a suitable written or electronic format and:

- The pharmacy assigned prescription number;
- Quantity dispensed;
- Initials of pharmacist who authorized the release of the medication;
- The date dispensed.
    - NOTE: Prescriptions to be held for dispensing at a later date must have documentation indicating that the dispensing was “deferred;”
- The signature of the patient who received the dispensed medication.

6. METHADONE PREPARATION REQUIREMENTS

Available Products* (Jan 2020)	**Properties**	**Dilution Requirements**	**Notes**
METHADOSE (SUGAR-FREE) 10 mg/ mL	Dye-Free Sugar-Free Unflavoured Oral Concentrate	Requires dilution to avoid diversion and mask the bitter taste of methadone. Dilute the dose to 100 mL in a suitable diluent.*	Has been recommended in other provinces using commercially available products

METADOL-D 10 mg/ mL	Oral Concentrate	Requires dilution to avoid diversion and mask the bitter taste of methadone. Dilute the dose to 100 mL in a suitable diluent.*	Same as METADOL (1 mg/mL) but ONLY 10 mg/mL is indicated for detoxification of opioid addictions as well as the maintenance treatment of opioid addiction. *Also available as 1 mg /mL solution; not approved for use for OAT in Saskatchewan.*
METHADOSE 10 mg/mL	Cherry Oral Concentrate	Dilution is not required as it is a hypertonic sucrose solution for which injection misuse is minimal. May be further diluted if deemed necessary at the discretion of the pharmacist or prescriber.	Use of these formulations should be limited to patient request as there is a risk of destabilizing the patient's OAT due to the small volume required to achieve the dose (destabilization is attributed to the psychological perception of a smaller volume of medication, despite dose being the same)
SANDOZ-METHADONE 10 mg/mL	Sugar-Free Cherry Flavoured Oral Concentrate	Sweetened with xylitol and does not require dilution. May be further diluted if deemed necessary at the discretion of the pharmacist or prescriber.	

*See Appendix 1: Table 2: General Properties of Methadone for a full list of commercially available methadone.

* Coloured, flavoured crystalline drink mix, such orange Tang™. See Appendix 12: Methadone Stability in Various Diluents for a full list of diluents available for use. Plain water is not acceptable.

See Appendix 20: Compounding Methadone Standards for Pharmacists and Technicians for compounding methadone stock solution with methadone powder.

Note: In Saskatchewan, methadone must be dispensed in Tang™ or its equivalent, unless otherwise authorized by the prescriber. The term "Tang™ or its equivalent" will be used throughout the document to identify a crystalline, coloured, flavored drink mix. The use of fruit juices is not recommended without authorization from the prescriber.

The commercially available tablet formulations or compounded capsules or tablets should not be dispensed for OAT as they can be easily misused or diverted. If a patient requests methadone in a form that can be more easily misused/diverted only the prescriber can change a prescription and must document the reason.[4]

6.1. Calculation for Commercially Available Methadone

To calculate the amount of commercially available methadone to dispense in milliliters that will contain the prescribed dose, divide the prescribed dose in milligrams by the concentration of the product.

$$\frac{\text{Prescribed dose (mg)}}{\text{10 mg/mL}} = \text{Measured volume (mL)}$$

Example: 80 mg of methadone is prescribed.

$$\frac{\text{80 mg}}{\text{10 mg/mL}} = \text{x mL}$$

x = 8 mL of commercially available methadone 10 mg/mL

6.2. Refrigeration

There must be a working refrigerator on the pharmacy premises to store prepared (diluted) methadone and diluents such as Tang™ or its equivalent. Pharmacy staff must routinely monitor and record the refrigerator temperature to ensure the appropriate temperature is maintained for refrigerated products. Pharmacy staff must take appropriate action if temperatures fall outside acceptable limits.

6.2.1. All containers used for the storage of Tang™ or its equivalent within the refrigerator and the refrigerator itself must be cleaned on a regular basis to prevent the growth of bacteria and/or mold.

6.3. Shelf-Life/Storage of Commercially Available Methadone

6.3.1. Pharmacy professionals must ensure they are knowledgeable as to the expiry dates and 'shelf-life upon opening' of all commercially available products and document accordingly. Storage must be in accordance with manufacturer requirements.

6.4. Diluting Commercially Available Methadone Products

6.4.1. Dilution of commercially available methadone products must be performed by staff who are competent in the processes to prepare the diluted solution. Staff must be knowledgeable in the use of the appropriate equipment required for dilution.[1]

6.4.1.1. Diluted methadone must be dispensed in a volume of no less than 100 mls.

6.4.2. Although dilution is not required for the cherry-flavoured formulation, there may be situations where dilution should be considered. E.g. when dispensing small volumes where surface adhesion of the concentrated formulation to the dispensing device or bottle may result in inaccurate or variable dose delivery, where risk of potential misuse and/or diversion is suspected, or when dispensing take-home doses.[1]

6.4.3. Pharmacists must ensure that equipment used for dispensing and dilution meet standards for accuracy of measuring.[1]

6.4.3.1. Measuring devices used in the dispensing of methadone must accurately measure the amount of commercially available product (or compounded product) to be dispensed using a calibrated device that will minimize the

error rate to no greater than +/- 0.1 mL (typically oral calibrated device or manual/ electronic pumps meet this accuracy requirement).[1]

6.4.3.2. Graduated cylinders and uncalibrated syringes are not acceptable devices for measuring the amount of commercially available product to be dispensed.[1]

6.4.4. Due to the potential toxicity of methadone if given to opioid naïve individuals, equipment should be distinctly labelled, and devices used to measure commercially available methadone products kept for exclusive use to dispense methadone where possible. Such equipment is to be kept in a designated area.[1]

6.4.5. Devices should be labelled as "ONLY USE FOR METHADONE" and should have a poison auxiliary label on the surface for clear identification by pharmacy staff.[1,2]

6.5. Stability and Sterility of Diluted Commercially Available Methadone

See Appendix 12: Methadone Stability in Various Diluents

6.5.1. Pharmacists are required to use best judgment to assign the beyond-use date (BUD) for diluted products. Guidance is available in the NAPRA compounding standards.

6.5.2. BUD date is based upon the expiry date (and opening date if applicable) of the commercially available methadone product and the BUD of the Tang™ or its equivalent diluent whichever is sooner.

6.5.3. Diluted, commercially available methadone products must be refrigerated.

6.5.4. Take-home doses are permitted a maximum BUD of 14 days from the date of dilution. The pharmacy staff, under the supervision of a pharmacist, must assign BUD based on the earliest of either the BUD of all ingredients used, or 14 days refrigerated, whichever comes first.[1]

To avoid the potential for mix-ups during dosing, and to optimize the stability and sterility of dispensed take home doses, do not dilute commercially available methadone products far in advance.[1]

6.6. Dilution Tracking Record

6.6.1. When diluting commercially available methadone products for witnessed and take-home doses, pharmacist, pharmacy technicians and/or assistants or interns under direct supervision of a pharmacist or pharmacy technician must record the date of dilution, the lot number and the BUD.

6.6.1.1. This information should be documented on the dilution record, see sample Appendix 13: Dilution Record, or the patient's electronic profile, whichever is most feasible, and must be available for review and audit.

7. RELEASING OAT MEDICATIONS

Patient assessment must be done by the pharmacist prior to the release/witnessing of OAT. The witnessing of the OAT medication dose may be done by a pharmacist or pharmacy technician.

7.1. Patient Assessment

Prior to releasing OAT medication, the pharmacist must assess the patient to ensure that the patient is not at risk of harm through the concurrent ingestion of alcohol, cannabis, or other substances, including centrally-acting sedatives and/or stimulants or due to an acute clinical condition that would increase the risk of an adverse event.[2]

7.1.1. If the pharmacist believes that it is not safe for the patient to receive their OAT medication, the pharmacist must inform the patient and consult with the prescriber as soon as possible and document the outcome of the dialogue and include it within the patient profile or patient record. The patient is to be notified as to when they can return for their OAT medication.

7.2. Pharmacist Responsibilities

The pharmacist is responsible for patient safety and clinical outcomes, and must[1]:

- Confirm the patient's identity. Government issued photo identification is recommended, see the Patient Identification Verification policy for other acceptable forms of identification, and additional requirements.
  - The dosages may not be released to spouses, relatives or friends unless an arrangement has been confirmed between the prescriber and the patient and communicated to the pharmacist by the prescriber in writing (e.g. infirmed patient).
  - Delivery of methadone directly to a patient's residence is not permitted unless under exceptional circumstance and as confirmed in writing by the prescriber.
- Review the patient's profile for medication therapy or health related patient care concerns,
- Assess the patient for potential harm (See 7.1. Patient Assessment),
- Document the assessment of the patient and if provided the observation of dose ingestion and, if provided, receipt of take-home doses (See 8.1.1. Documentation). If witness ingestion is performed by the pharmacy technician, they must document accordingly.
- Monitor the patient post-ingestion for adverse events for a duration based on individual patient circumstances, and as recommended by evidenced-based information
- Provide education and medication information to the patient, and
- Not deliver OAT medications to a patient without the authorization of the prescriber and in accordance with the *Narcotic Control Regulations,* SCPP guidelines and policies, CPSS OATP Standards and Guidelines and any future directives of the SRNA as may apply to RN(NP)s.

7.3. Releasing OAT Medications

A pharmacist or pharmacy technician who is registered and licensed by SCPP must be present to release an OAT medication to a patient. Currently, this function cannot be delegated to any other pharmacy support staff.[1,2]

7.3.1. Pharmacists involved in the administration of OAT through witnessed/supervised dosing are expected to maintain the competency, skill and knowledge to ensure optimal patient care.[1]

8. REQUIREMENTS FOR WITNESSED INGESTION OF OAT

The requirements around witnessed ingestion must be part of the patient discussion or agreement and explained at the outset of the initial pharmacist-patient relationship.[1,2]

8.1. Documentation

8.1.1. Documentation of witnessed dose ingestion involves recording the following[1] (See Appendix 14: Patient Record of Witnessed OAT Medication Ingestion and Appendix 15: Patient Record of Witness Ingestion and Take Home Doses)

- Date of the witnessed ingestion,
- Dose administered,
- Signature of the pharmacist or pharmacy technician witnessing the ingestion, confirming the dose and ingestion,
- Signature of the patient confirming the dosage (strength) provided and ingestion of the medications. See the Patient Identification Verification policy for further details.

8.1.2. Documentation on the patient profile

- Pertinent clinical information and observations in the patient's profile as necessary, and
- Information regarding any decision to delay the provision of the dose of OAT, including the rational based upon evidence-based and/or best-practice information.

8.2. Witness Ingestion of Buprenorphine-Naloxone

Patients must be given instructions on how to properly ingest a sublingual tablet including instructions to place and hold the buprenorphine-naloxone tablet(s) under their tongue until fully dissolved. The patient should avoid swallowing the tablet(s), or talking, eating, drinking, and/or smoking while the tablet(s) dissolve.[2]

8.2.1. If the prescriber's intentions regarding witnessed ingestion are unclear, the pharmacist must consult with the prescriber to clarify, and the outcome of this consultation must be documented and included with the original prescription.[2]

8.2.2. If concerned about diversion or misuse of the medication, the prescriber may indicate that the tablet(s) be crushed before sublingual administration. To ensure adequate therapy it is necessary that the patient is able to hold the crushed tablet under their tongue and for it to fully dissolve.

8.2.3. Buprenorphine-naloxone sublingual tablets must be provided to the patient for dissolution under the tongue in a manner which maintains the integrity of the tablet(s) such as a medication cup or other vessel in which the medication can be provided to the patient for ingestion. Care must be taken to ensure the tablet(s) do not come into contact with moisture, including contact with the pharmacist/pharmacy technicians' hands/skin.

8.2.4. Where necessary, pharmacists should use their discretion to determine if the patient is able to comply with the simultaneous administration of two tablets.[1] For example, If the patient is on more than 2 tablets, it may be necessary for them to take 2 tablets, allow them to dissolve, and then take an additional 1-2 tablets. Pharmacists and pharmacy technicians are advised to review the product monograph for more information.

8.2.5. After the tablets are dissolved, ask the patient to lift up their tongue for observed confirmation that the tablets are no longer present.[1]

8.2.5.1. CPSS OATP Standards and Guidelines suggest that the patient may need to be monitored following dose administration to assess for withdrawal symptoms either from inadequate dosing or precipitated withdrawal.

8.2.5.2. When beginning buprenorphine-naloxone induction consideration should be given to the type of opioid dependence (long or short acting) and the time since last opioid use as well as the degree of dependence when determining the period of time observing the patient.

8.2.5.3. Induction of buprenorphine-naloxone when the patient still has an opioid in their system may cause precipitated withdrawal. Patients should be informed of this possibility.

8.2.5.3.1. Withdrawal usually requires ≥6-12 hours since last short acting opioid (e.g. heroin, morphine, hydromorphone), ≥ 18 hours if SR opioid (e.g. Contins) and ≥24-36 hours after methadone. https://www.rxfiles.ca/RxFiles/uploads/documents/members/CHT-Opioid-Use-Disorder-OUD.pdf

8.2.5.4. See Appendix 6: Sample Buprenorphine-Naloxone Induction Prescription.

8.2.5.5. Microdosing: Microdosing is not a labelled indication of buprenorphine/naloxone and information is emerging on best practices. Please see appendix 9.1 for information from RxFiles and 9.2 for current (Sept. 2020) information from the College of Physician and Surgeons of Saskatchewan (Sept. 2020).

8.3. Witnessed Ingestion of Methadone

8.3.1. The pharmacist or pharmacy technician must directly observe the patient ingesting the medication. To confirm the medication has been consumed after ingestion, the pharmacist or pharmacy technician can engage the patient in conversation and/or provide the patient with at least an equivalent amount (100 mL) of water to consume.

8.3.1.1. Patients on OAT should be educated to attend the pharmacy at the same time every day to receive their methadone, as this will result in more consistent blood levels and fewer adverse effects.[3]

8.3.1.2. After ingestion of the methadone dose, encourage the patient to rinse with a glass of water to rinse the sugar contained in the Tang™ or equivalent from their mouth.

9. REQUIREMENTS FOR DISPENSING OAT TAKE HOME DOSES

Pharmacists must confirm that the prescriber has prescribed the take home doses in accordance to his/her standards and guidelines, and must collaborate with the prescriber to discuss concerns regarding prescriptions and decisions that may endanger the safety of the patient or the community.[1] (Page 52, CPSS OATP Standards and Guidelines)

9.1. Buprenorphine – Naloxone Take Home Doses

9.1.1. Take home doses for buprenorphine-naloxone may be initiated once the patient has sufficient clinical stability

9.1.1.1. Patients must be reminded to safely store all take home doses of buprenorphine-naloxone.[1,2]

9.1.2. It is strongly recommended that the patient pick up their take home doses using a lock box.

9.1.3. Dispense buprenorphine-naloxone take home doses in the original foil wrap.[1]

9.1.3.1. It is recommended that take home doses are dispensed in a light-resistant prescription vial or container.[1]

9.1.3.2. Dispense all take home doses in a child-resistant container.

9.1.3.2.1. Deviations from dispensing in a child resistant container (see 9.1.3.2 above) are only permitted at the patient's request for valid medical reasons (e.g. arthritis), and the documented rationale within the patient's records should include the patient's acknowledgement and acceptance of this deviation.[1]

9.1.3.2.2. Adequate counselling must be provided on the potential dangers and toxicity to children and other individuals from inadvertent ingestion of doses intended for the patient.[1]

9.1.3.3. Compliance packaging (e.g. blister packaging, pouch packs) may be ordered by the prescriber to encourage adherence to treatment and allow for better monitoring during medication call-backs. If compliance packaging, the pharmacist must still ensure that the medications are packaged in the original foil package to maintain the integrity of the product.[2]

9.1.3.4. Patients are to be cautioned that the compliance package(s) must be stored in a secure container/cupboard/other area to prevent ingestion by children. (See 9.1.2 above)

9.2. Methadone Take Home Doses

9.2.1. The usual duration of methadone take home doses should be limited to 6 days in succession unless in exceptional circumstances when up to 13 days (or more) may be considered with prescriber authorization.[1,2]

9.2.2. Each dose must be dispensed in an individual, 100 mL (total volume), child-resistant bottle with a tamper proof seal

9.2.2.1. Affix all labelled instructions and auxiliary labels directly on each bottle.

9.2.2.2. If a pharmacist determines that due to a specific patient circumstance a non-child-resistant container (cap) will be used for take-home doses it must be documented on the patient record.[2] A tamper proof seal should still be applied.

9.2.3. With respect to take-home doses, the first dose, whether it is stated on the prescription or not, must be a witnessed ingestion.[2]

9.2.4. The sugar-free, dye-free commercially available methadone must be diluted to 100 mL with Tang™ or its equivalent [1]

9.2.5. The cherry flavoured Methadose™ or the generic equivalent formulation can be dispensed as a take home dose without further dilution, though, dilution is acceptable if deemed necessary by the pharmacist, prescriber or requested by the patient.

9.2.6. Instruct patients to return empty take home dose bottles to the pharmacy for inspection and proper destruction. Do not reuse take home dose bottles for the same or for another patient as they cannot be properly sterilized or cleaned for re-use.[1]

9.2.7. All empty, returned, take home dose bottles must be properly disposed of in a manner that prevents the diversion of any liquid left in the bottle. The patient's identity is to be removed/extracted from the bottle prior to disposal. Empty bottles must be disposed of via authorized pharmaceutical waste processes, following all applicable environmental procedures. No empty, returned, take home bottles are to be placed into municipal waste disposal containers (garbage) or recycling containers.

9.2.8. Any doses which are not consumed by the patient (i.e. missed dose, contaminated, etc.) must be destroyed as per authorized pharmaceutical waste processes and Health Canada guidelines with the appropriate records maintained. A record of all destroyed doses must also be maintained on the patient profile and or dosage administration record(s). See Appendix 14: Patient Record of Witnessed OAT Medication Ingestion and Appendix 15: Patient Record of Witness Ingestion and Take Home Doses

9.2.9. The patient must pick up take-home doses using a lock box.

9.2.9.1. Patients must be reminded that methadone should be stored out of the reach of children, preferably in a locked cupboard or lock box.[2]

10. LABELLING REQUIREMENTS FOR OAT TAKE HOME DOSES

Labelling requirements for take home doses:

- Patient's name;
- Pharmacy name, address and telephone number;
- Prescriber's name;
- The prescription number;
- The date dispensed;
- The name of the active drug (i.e., methadone, buprenorphine-naloxone) and the total mg of drug in a single dose (i.e. The total content of methadone in bottle is 80 mg); and
- Cautionary warning label:
  - "This drug may cause serious harm to someone other than the intended patient. Not to be used by anyone other than the patient for whom it was intended. May be fatal to a child or adult." OR
  - "May be toxic or lethal if ingested by a child or adult other than the intended patient. Accidental ingestion is considered a medical emergency and requires immediate medical attention."

See Appendix 16: Sample Methadone Take Home Dose Labels and Opioid Warning Sticker and Patient Information Handout Required to Accompany Dispensed Opioids.

Adherence to medication therapy is important for the success of OAT program. Missed doses will contribute to a loss of tolerance to OAT medication. The table below outline the protocols to manage the care of patients who have missed doses of methadone or buprenorphine-naloxone medication.[4]

11. REQUIREMENTS FOR DISPENSING AND ADMINISTERING BUPRENORPHINE EXTENDED RELEASE INJECTION (SUBLOCADE ®)

Buprenorphine extended release injection is a long acting formulation of buprenorphine (Sublocade®) available for the treatment of substance use disorder. The product is provided to the patient on a monthly basis. Patients must be stabilized on buprenorphine/naloxone sublingual tablets for a minimum of 7 days prior to being switch to the injectable product.

Pharmacists must obtain a valid written prescription from the practitioner prior to dispensing the product and if administering the product have all required training.

Pharmacists are reminded that it is their responsibility to be educated as to the pharmacology and product monograph information before dispensing buprenorphine extended release injection or any other medication and to provide appropriate patient education.

- Pharmacist Education Requirements for Administration
  - Pharmacists who have taken all required training to administer drugs by injection and other routes as prescribed by Continuing Professional Development for Pharmacy Professionals CPDPP, have valid, in date CPR level C and First Aid training, and have declared Advanced Method Certification (AMC) with SCPP (i.e. DO NOT have a condition A on their current practising licence) may administer medications by injection.
  - Prior to injecting buprenorphine extended release injection (Sublocade ®) SCPP strongly recommends pharmacists undertake the 30-minute online course that Health Canada requires of prescribers at www.sublocadecertification.ca, along with the one-hour live Indivior webinar. To register for the live webinar, contact *Debbie Romaniuk* with Indivior.

See Appendix 10: Buprenorphine Extended Release Injection (Sublocade®)

12. TROUBLESHOOTING DOSING ISSUES

12.1. Missed Doses – Notification to the Prescriber

The pharmacist must notify the prescriber of any missed doses, when known, before the next scheduled release of medication.[2]

12.1.1. See Appendix 17: Pharmacist-Prescriber Faxed Communication[1]

12.2. Restarting Treatment

12.2.1. Unless otherwise directed by the prescriber and documented accordingly, a new prescription is required to restart treatment after missed doses when a dosage change (reduction) is required. Do not delay in restarting treatment and attempt to obtain a new prescription as soon as possible.

12.2.2. If the prescriber has in advance indicated such in writing, the pharmacist may adjust the dose of OAT medication provided to the patient as per CPSS OATP Standards and Guidelines.

12.2.3. Replacement doses must be given only as witnessed ingestion.[4]

12.2.4. All reports of missed doses must be documented on the patient's profile and communicated to the prescriber, regardless of cause, duration or number.[4]

12.3. Buprenorphine-Naloxone Missed Doses Protocol

Buprenorphine-Naloxone missed doses protocol (CPSS OATP Standards and Guidelines, p. 46):[4]

Buprenorphine Dose	Number of Consecutive Missed Days	New Starting Dose
>8 mg	> 7 days	4 mg
>8 mg	6 to 7 days	8 mg
6 to 8 mg	6 or more days	4 mg
2 to 4 mg	6 or more days	2 to 4 mg

12.4. Methadone Missed Doses Protocol

12.4.1. Ongoing communication and collaboration between the prescriber, patient, and pharmacist is essential. Rapid decline in tolerance to methadone necessitates careful management of missed doses, as failure to adjust a dose in this context can result in overdose and/or death.[4]

12.4.2. If a patient misses 2 of 7 non-consecutive doses, the patient must be re-assessed by the prescriber.[4]

Methadone missed doses protocol (CPSS OATP Standards and Guidelines, p. 46):[4]

Missed Days (consecutive)	Dose	Suggested Dose Adjustment
1 to 2	Usual dose	Same dose (no change)
3 to 4	30 mg	Same dose (no change)
	31 to 60 mg	Restart at 30 mg (lower dose if safety concerns)
	60+ mg	Restart at 50% of previous dose
5+	Any dose	Restart at 5 to 30 mg (depending on tolerance)

12.5. Divided (Split) Doses

12.5.1. Only the prescriber, by stating on the original prescription, can authorize a divided (split) dose of OAT medication. Unless otherwise specified by the prescriber, the first portion of a daily dose must be witnessed by ingestion, unless the patient has been granted take home doses.[2]

12.6. Emesis of Dose (Vomiting)

12.6.1. If the patient has observed emesis after taking methadone, by the pharmacist or pharmacy staff, and it occurred within 30 minutes after consumption, a replacement dose can be provided as per the current prescription.[4]

12.6.2. A new dose of methadone cannot be provided if the emesis was not witnessed by the pharmacist or pharmacy staff without consultation with the prescriber, and documentation of the consultation. Methadone absorption typically occurs within 30 to 60 minutes of ingestion. No dose replacement is required after 30 minutes.[4]

12.6.3. Buprenorphine is absorbed sublingually within one to ten minutes, bypassing the gastrointestinal tract. Emesis of doses generally does not require replacement.[1]

12.6.4. All reports of emesis and replaced doses must be documented on the patient's profile.[4]

12.7. Lost or Stolen Doses

12.7.1. Report lost/stolen doses to the prescriber; if the prescriber deems a replacement dose necessary, a written authorization is required.[1]

12.7.2. It is the responsibility of the pharmacy professional to report lost or stolen medication to local law enforcement, SCPP, and Health Canada. Subsections 274(a) and 4(h) of the *Health Information Protection Act* describe disclosure of personal health information without patient consent.[1]

12.7.3. Patients should be informed of the public safety circumstances for reporting lost/stolen doses to law enforcement upon commencement of OAT at the pharmacy. This protocol is to be communicated with the patient during discussion of the Pharmacy-Patient Agreement.[4]

12.8. Accidental Overdose

12.8.1. All patients should be encouraged to obtain training and carry a Take Home Naloxone Kit.

12.8.2. Advise patients that overdose is a medical emergency.[1]

12.8.3. If the person contacting the pharmacy observes an individual experiencing shortness of breath, excessive drowsiness, seizures or loss of consciousness, after ingestion of OAT medication, advise the person that naloxone can be administered (IM or intranasally) following Take Home Naloxone Kit procedures and 911 should be called.[1]

12.8.4. Patients and caregivers should be made aware that the Good Samaritan Drug Overdose Act provides legal protection for those who seek emergency help during an overdose.

12.8.5. Caregivers should be advised that inducing vomiting is unreliable and may not be effective even five minutes from the time of medication ingestion.[1]

12.8.6. The pharmacist should alert the patient's prescriber and/or OAT program of the circumstances surrounding the overdose.

13. SPECIAL SITUATIONS

13.1. Hospitalizations

13.1.1. Patients admitted to hospital who are on a stable dose of OAT medication should be maintained on an appropriate dose for the duration of their hospitalization. The dose of OAT medication may need to be adjusted based on the patient's clinical status (e.g. patient admitted with hepatic dysfunction may require reduced dose). The CPSS OATP Standards and Guidelines provides information on *Hospital-Based Temporary Prescribers*. (section 3)

13.1.2. Patients initiated on OAT medication in hospital should be connected with an outpatient prescriber/OAT program and community pharmacy prior to discharge.

13.1.3. Communication and collaboration between the hospital, the community-based prescriber/OAT program, and community pharmacist are important to ensure a smooth transition of care upon admission and discharge of the patient to and from hospital. Hospital staff, including pharmacists where available, should assist in providing communication between the hospital and community pharmacy regarding OAT doses.

13.1.4. A new OAT prescription must be provided for the patient upon discharge from in-patient hospital treatment in collaboration with the community-based prescriber.

13.1.4.1. Under circumstances of short in-patient treatment of 72 hours or less and when the strength of OAT medication has not been altered, the patient may resume receiving OAT at the community pharmacy if a current prescription is available (valid date range) unless otherwise notified by the community-based or hospital prescriber. The appropriate documentation is required in the patient profile.

13.2. Provincial Correctional Centers

13.2.1. Patients entering a provincial correctional center who are on a stable dose of OAT medication should be maintained on an appropriate dose for the duration of their incarceration.[4]

13.2.2. Pharmacies providing OAT medications and care to patients that become aware of the incarceration of the patient must notify the patient's prescriber or OAT program to facilitate a seamless and coordinated transition of care.[1]

13.2.2.1. Pharmacies that have provided care to OAT patients who become incarcerated may be a resource to the correctional facility, especially as it relates to confirming the details of the patient's most recent doses and progress with treatment goals.[1]

13.2.3. Communication and collaboration between the facility, the prescriber/program, and the pharmacy are also important to ensure a smooth transition of care upon the patient's release from incarceration, if ongoing treatment is necessary.[1]

13.2.3.1. In most facilities a new prescription is initiated upon incarceration. Upon release from incarceration the prescriber treating the patient within the facility should provide the patient with a new OAT prescription in collaboration with community-based prescribers.[4]

See CPSS OATP Standards and Guidelines for more details.

13.3. Remand within Provincial Correctional Centers

Patients with outstanding legal issues may be arrested and placed into a provincial correctional facility 'Remand Center'. As described above, the patient's prescriber should be notified that the patient is in a remand center within the correctional facility.

13.3.1. Patients who appear in court for the purposes of determining charges, etc. will not receive their OAT medication on the day of a court appearance. The facility is not informed if the person will be released or will return to the center.

13.3.2. Every attempt is to be made by the community pharmacist to confirm the patient's last dose of OAT medication while they were in the remand center (time and strength) upon the patient's release after a court hearing and to obtain a new prescription as required.

13.3.3. Patients who are released within 72 hours of detention in a remand center will not require a new prescription if no changes have been made to the dosage of OAT medication and the patient has not missed any doses. The community-based practitioner and, if applicable OAT program, are to be notified of the patient's release and continued therapy as soon as possible and this information is to be documented in the patient's profile.

14. PATIENTS DETAINED BY LAW ENFORCEMENT

A patient may be arrested and detained in law enforcement (police/RCMP) holding cells and necessitate the pharmacist and/or pharmacy technician providing OAT medication to law enforcement.

14.1. All dosages provided to law enforcement must be documented and the officer required to sign for receipt of the patient's dose(s).

15. TERMINATING A PATIENT RELATIONSHIP

15.1. In the event a pharmacist determines it is not in the best interest of the patient for the pharmacist to continue to provide OAT, it is critical that the reason is based on clinical and/or best-practice evidence and is well-documented.[3] Reasonable notice must be provided to the patient and prescriber to ensure continuity of care.[2]

15.2. The termination of a relationship may occur provided there are valid reasons; sufficient documentation of the reason(s) and the patient is not in immediate need of pharmaceutical care or at risk of harm.

15.2.1. Examples of valid reasons include, but are not limited to:

- attempts at communicating with the patient regarding their care have been unsuccessful;

- the patient is uncooperative or unable to follow treatment plans or agreements; or
- the patient is acting in a manner which poses a threat to the safety of the pharmacist(s) and/or staff member(s), and/or other patients.

Please review Saskatchewan College of Pharmacy Professionals Reference Manual: Termination of a Pharmacist-Patient Relationship for further information.

16. ACKNOWLEDGMENTS

16.1. Reviewers

Saskatchewan Professional Practice Committee
Saskatchewan College of Pharmacy Professionals
Continuing Development for Pharmacy Professionals
Katelyn Halpape, BSP ACPR PharmD BCPP

Disclaimer – This document is not intended to be an exhaustive review of all requirements of applicable legislation or of all situations pharmacists may encounter.

Pharmacy Process Flow: Dispensing OAT[1]

Receive faxed or elecronic prescription
- Ensure prescription meets standard prescription requirements in Saskatchewan
- Determine if prescription is for OUD, analgesia, or both
- Confirm physician has traning and prescribing requirements to prescribe for the medication requested. To check, contact CPSS at 306-244-7355

Confirm prescription authenticity and prescriber exemptions

Confirm patient identity
- Photo identificaton is advisable

Gather information from the patient and document patient agreement when initiating treatment
- For ongoing treatment, update patient profile as needed
- See Appendix 4 for Pharmacy-Patient Agreements

Check for appropriateness, accuracy and drug therapy problems before releasing dose
- If concerns of opioid withdrawal (e.g. OAT dose too low), use Clinical Opiate Withdrawal Scaled (COWS - See Appendix 8) to assess patient.
- Review CPSS OATP Standards and Guidelines, RxFiles or call MedSask with questions or concerns

Ensure patient does not have signs of intoxication
- Monitor for toxicity from opioids or other substance misuse
- Check for pinpoint pupils, altered speech or gait, and alcohol or marijuana odours

If no impairement, dispense dose
- Administer methadone using sugar free, dye free 10mg/ml concentrate diluted in a suitable crystalline solution (document dilution)
- Cherry flavoured Methadose™ undiluted can be used if appropriate
- Administer buprenorphine-naloxone sublingually. Optimal to take multiple tablets at once. Split and crush tablets to faciilitate dissolution if necessary

Witness the ingestionsand make sure the patient takes the dose properly

Document every witnessed dose or every missed dose and communicate to the prescriber
- See Appendix 17 for Pharmacist-Prescriber Fax Communication

Monitor patient after dose ingestion. Remind patient of next dose. Discard cup or bottle

Document any compounding, dispensing, administering or cognitive services activity

Take Home Doses Requirements:

- Receive prescription instructions from prescriber
- For methadone dispense with appropriate label and directions on each dose, in child-proof, tamper resistant bottle.
- If directed witness first dose and document (as above)
- Ensure patient returns all methadone bottles with original labels intact.
- Record dispensing and have patient acknowledge receipt of carries through signature (see Appendix 15)

Appendices

APPENDIX 1: GENERAL PROPERTIES OF OAT

Table 1: General Properties of Buprenorphine-Naloxone

1, 4, RxFiles

Currently Available Products in Canada (2020)	Saskatchewan Formulary (EDS): Buprenorphine-Naloxone (generic, SUBOXONE) Sublingual Tablet 2 mg/0.5 mg Buprenorphine-Naloxone (generic, SUBOXONE) Sublingual Tablet 8 mg/2 mg Buprenorphine (PROBUPHINE) Subcutaneous Implant 80 mg
	Buprenorphine (SUBLOCADE) Extended Release Subcutaneous Injection 100mg/0.5 mL Buprenorphine (SUBLOCADE) Extended Release Subcutaneous Injection 300mg/1.5 mL Buprenorphine (SUBUTEX) Sublingual Tablet
General Information	Better safety profile than methadone. Has a ceiling effect on respiratory depression so is safer in overdose compared to methadone (can still be implicated in overdose especially when combined with benzodiazepines and/or alcohol).[1] Partial agonist, therefore, lower misuse potential.[1] Buprenorphine binds tightly to the mu opioid receptor rendering other opioids ineffective. Enhanced convenience, as it may allow for an increased number of take-home doses due to reduced overdose risk.[1] Longer half-life means possibly more moderate withdrawal symptoms when weaning someone completely off treatment. May be a choice for those with a good prognosis to be off opioids with time.[1] Lower prevalence of drug interactions than methadone.[1] The naloxone added in the buprenorphine-naloxone product is added to deter injection misuse. Naloxone has a poor sublingual bioavailability, and as such the addition of it in the combination product appears to be harmless as it does not interfere with the pharmacokinetics of buprenorphine.[4]
Sublingual Tablet	
Onset of action	30 – 60 minutes[1]
Peak Action	1 to 4 hours[1]
Duration of Action	Long duration of action (dose-dependent) due to slow dissociation of buprenorphine from the opioid receptor.[2] Low doses (2 – 4 mg): 4 – 12 hours Mod. doses (4 – 8 mg): ~ 24 hours Higher doses (> 8mg): 36 – 72 hours
Half Life	Between 24 to 60 hours (average 32 hours)[2]
Steady State	7 to 10 days[2]

Metabolism	Occurs in the small intestine and liver via N-dealkylation and glucuronidation.[4]
Dispensing	Sublingual tablets containing buprenorphine-naloxone in a 4:1 ratio. Tablets can be quartered, halved and/or combined to achieve target doses
Dosing (RxFiles)	Induction: Patients MUST be in moderate withdrawal (a score of ≥12 COWS, or >17 SOWS). This generally requires ≥12 hrs. since last short-acting opioid (e.g. heroin, morphine IR, hydrocodone), ≥18 hrs. if SR opioid (e.g. Contins), & ≥24-36 hrs. after methadone. Sample Induction - Day 1: Dissolve 4 mg/1 mg sublingual now. Wait 1-2hrs, then if withdrawal symptoms still present, take 2mg/0.5mg or 4mg/1mg. May repeat cycle. (Max 1st day dose = 12mg/3mg) Sample Induction - Day 2: If NO withdrawal symptoms, take total DAY 1 dose. If withdrawal symptoms, present, take DAY 1 dose + an extra 2mg/0.5mg or 4mg/1mg dose. (Max 2nd day dose = 16mg/4mg) Day 3 and beyond: Take total daily dose given on DAY 2 as a single dose. Increase dose similarly to DAY 1-2 if needed. (Max daily dose of 24mg/6mg) Proper maintenance dose is one that averts significant cravings & physical withdrawal (for 24hrs) without causing sedation. (Typically, 12mg/3mg – 24mg/6mg per day) For MICRODOSING alternate, off label initiating method; see RxFiles

Table 2: General Properties of Methadone
1, 4, RxFiles

Currently Available Products (Jan 2020)	Properties	Strength/ Concentration	Indication	Sask Formulary (EDS)	Notes
METADOL	Tablets	1 mg,5 mg,10 mg and 25mg	Analgesic	√	Not indicated for use in opioid dependence. The tablet formulation should not be prescribed for OAT as it can be easily diverted
	Oral Solution	1mg/mL		√	
	Oral Concentrate	10mg/mL		√	
METADOL-D	Tablets	1 mg,5 mg,10 mg and 25mg	Opioid Dependence	√	Same as METADOL but

	Oral Solution	1mg/mL			indicated for detoxification of opioid addictions as well as the maintenance treatment of opioid addiction.
	Oral Concentrate	10mg/mL			
METHADOSE	Cherry Oral Concentrate	10mg/mL	Opioid dependence	√	Dilution is not required as it is a hypertonic sucrose solution for which injection misuse is minimal. May also be further diluted if deemed necessary at the discretion of the pharmacist or prescriber. Use of this formulation should be limited to patient request as there is a risk of destabilizing the patient's OAT due to the small volume required to achieve the dose (destabilization is attributed to the psychological perception of a smaller volume of medication, despite dose being the same)
METHADOSE	Dye-Free Sugar-Free Unflavoured	10mg/mL	Opioid dependence	√	*PREFERRED

	Oral Concentrate				Requires dilution to avoid diversion. Dilute the dose in approximately 100 mL of a suitable diluent.
SANDOZ-METHADONE	Sugar-Free Cherry Flavoured Oral Concentrate	10 mg/mL	Opioid dependence	√	Sweetened with xylitol and does not require dilution.
PMS-METHADONE	Tablets	1 mg,5 mg,10 mg and 25mg	Analgesic		The tablet formulation should not be prescribed for OAT as it can be easily diverted
General Information		No ceiling effects. Better efficacy profile in those addicted to higher doses of opioid.[1] Flexible dosing.[1] Long history of use and clinical experience. Many resources for guidance on proper use.[1] Considered a safer option to buprenorphine-naloxone in pregnancy (although there is a body of evidence growing that buprenorphine-naloxone is an acceptable option) .[1] It prevents withdrawal, decreases craving, and blocks euphoria produced by short-acting opioids.[4]			
Onset of Action		3 hours[1]			
Peak Action		4 hours (ranges from 2 to 6)[4]			
Duration of Action		Duration of analgesia: Oral: 4 to 8 hours (single-dose studies), increases to 22 to 48 hours with repeated doses.			
Half Life		Averages 24 to 36 hours at steady state but ranges from 4 to 90 hours.[4] As a result of its long half-life, methadone may accumulate, leading to sedation and respiratory depression.[4]			
Steady State		It takes 4 to 5 days (if using t ½ of 24 hours) for methadone plasma levels to reach steady state after each dose change.[4]			
Metabolism		Primarily a function of liver enzyme activity involving cytochrome P450 isoforms. Genetic, physiologic and environmental factors can also act on these enzymes, leading to a high degree of variation of individual methadone responsiveness.[4]			

Tolerance	Tolerance to the euphoric effects of methadone develops quickly and may be interpreted by patients as being due to an inadequate dose.[4] Tolerance to respiratory depression occurs slower and tolerance to the autonomic side effects is further delayed.[4] Tolerance is lost in as little as 3 days from last dose of methadone.[4]
Dosing (RxFiles)	Initial: 5-30mg po once daily, depending on tolerance. Maintenance: 60-120mg po once daily No “maximum” dose. Can increase dose by 5-10mg every 5 days. Must re-titrate if 3-4 consecutive doses missed. Oral suspension preferred over tablets due to lower diversion risk.

See RxFiles - Opioid Use Disorder (OUD) Opioid Agonist Therapy (OAT) Chart

APPENDIX 2: PHARMACY STAFF ROLES IN PROVIDING OAT

	Pharmacist	Pharmacy Technician	Assistant Technician
Intake new prescription from OAT Patient	√	√	X
Review 2-way agreement with patient; including store policies	√	√	X
Clarify ambiguous or conflicting information with the prescriber	√	X	X
Complete calculation for amount of commercially available methadone to dispense in millilitres that will contain the prescribed dose	√	√	√
Verify calculation for amount of commercially available methadone to dispense in millilitres that will contain the prescribed dose	√	√	X
Input the prescription into the patient profile	√	√	√
Prepare label for OAT	√	√	√
Verify label for OAT	√	√	X
Prepare buprenorphine-naloxone for witness dose ingestion	√	√	√
Document for buprenorphine-naloxone for witness dose ingestion	√	√	X
Prepare buprenorphine-naloxone for take home doses	√	√	√
Verify prepared buprenorphine-naloxone for take home doses	√	√	X
Prepare buprenorphine-naloxone in blister packs	√	√	√
Verify prepared buprenorphine-naloxone in blister packs	√	X	X
Measure commercially prepared methadone dose using a calibrated device into labelled single use child resistant bottles	√	√	√
Verify measurement of commercially prepared methadone in labelled single use child resistant bottles	√	√	X
Dilute commercially prepared methadone in labelled single use child-resistant bottles	√	√	√
Assign beyond-use dates for diluted products	√	√	X
Clean containers in which crystalline drink for dilution is mixed with suitable cleaning agent	√	√	√
Ensure cold-chain maintenance of refrigerated diluted commercially prepared methadone	√	√	√
Record methadone take home doses dilution in Dispensing Record	√	√	√
Provide education and medication information to the patient	√	X	X
Assess patient for intoxication	√	X	X
Witness and document OAT dose ingestion	√	√	X

	Pharmacist	Pharmacy Technician	Assistant Technician
Destroy remaining portions of tablet from buprenorphine-naloxone microedose with co-signature of staff member witnessing destruction	√	X	X
Monitor patient post-ingestion for adverse effects for an appropriate duration	√	√	X
Handle and document empty OAT packaging returns	√	To be determined	X
Releasing OAT medication to patient	√	√	X
Notify prescriber of missed doses	√	√	X
Termination of Pharmacist- Patient Relationships	√	X	X
Complete and record routine OAT inventory check and back-counts	√	√	X
Destruction of OAT in the pharmacy must follow all applicable environmental guidelines, ensure the confidentiality and privacy of the patient is maintained and follow Health Canada guidelines	√	X	X

APPENDIX 3: REQUIREMENTS FOR PRESCRIBING FOR OPIOID AGONIST THERAPY IN SASKATCHEWAN[4]

In order to prescribe OAT (including methadone and/or buprenorphine-naloxone) in Saskatchewan, a physician must:

1. Have a license to practice medicine in Saskatchewan.
2. Have received CPSS Registrar approval (or approval from his/her designate) to prescribe OAT for the treatment of opioid dependence. See the CPSS OATP Standards and Guidelines.
   Note: an exception applies to Hospital-Based Temporary Prescribers and Corrections-Based Temporary Prescribers.
3. Meet the educational requirements outlined in the CPSS OATP Standards and Guidelines.

Appendix 3.1: Additional Prescribing Circumstances for OAT in Saskatchewan
Pharmacists are permitted to dispense methadone and buprenorphine-naloxone prescriptions from prescribers in provinces other than Saskatchewan.

If there are any doubts regarding the authenticity of the prescription, the pharmacist must contact the out-of-province prescriber or their regulatory body to confirm the legitimacy of the prescription. When satisfied that the prescription is authentic, the pharmacist can dispense and process the prescription in the same manner as other prescriptions from out-of-province prescribers.[2]

APPENDIX 4: PHARMACY-PATIENT TWO-WAY AGREEMENT FOR OAT SERVICES[4]

Your prescriber prescribed Opioid Agonist Therapy (OAT) (methadone or buprenorphine-naloxone) for your opioid use disorder. Our pharmacy will provide the pharmacy services for treatment. OAT is generally taken long-term and will require your commitment to take the medication as prescribed. If prescribed methadone, a pharmacist will observe you as you ingest the dose. Your practitioner will determine if you require observed doses of buprenorphine-naloxone (Suboxone™). Observation of daily doses will continue until your prescriber considers that you may be ready to receive take-home doses. Your pharmacist may ask you questions about ingestion of other substances which may impact your health and safety and may determine it is not in your best interest to received your dose and ask you to return after they have consulted with your prescriber.

Your prescriber or/and other treatment team members and pharmacist will work together to support you. While following all applicable privacy legislation, they may consult each other, your family doctor (as applicable), or other members of your treatment team if health care concerns arise as you progress with your treatment. You are also encouraged to consult your prescriber, doctor or pharmacist as needed if you have concerns about your health or your treatment.

This agreement is between:

- You, our patient
- Your pharmacy and its staff

This agreement outlines responsibilities and obligations of each party to ensure a mutual understanding and awareness of the expectations involved in our collaboration. You may ask to review this agreement at any time during your OAT treatment.

Your pharmacy agrees to provide you with:

- Professional services that recognize your rights to respect and personal dignity.
- Access to trained professionals who are competent in OAT to answer your questions and concerns about your treatment(s).
- Professional expertise, skills, and knowledge about your treatment that will always have your best health interests in mind for decisions that are made.
- Privacy and confidentiality with your private and health information. Your private information will only be shared with your consent and on a need to know basis or if required by law.
- Ongoing monitoring and support of your progress with OAT while you remain under the pharmacy team's care.

As the patient receiving OAT medication, I agree to:

- Take my OAT medications as prescribed for my opioid use disorder. I will let my prescriber and/or pharmacist know if I am experiencing any unexpected or unpleasant effects of treatment.
- Keep my regular daily meeting with the pharmacy team to receive my dose and/or follow the plan for my take home doses. I will make every effort to come to the pharmacy when I am to receive my OAT medication and I will call the pharmacy if I am going to be late. If I am not compliant with my dosing regimen, (missed/lost doses) I am aware that my treatment may

have to adjusted or discontinued as inconsistent dosing of OAT medication can pose a danger to me.

- Bring and show my photo ID to the pharmacy team as requested when I visit my pharmacy for my OAT medication dose.
- The pharmacy team calling my prescriber if they have any concerns about my safety on OAT treatment(s).
- The pharmacy team calling my prescriber if a dose is missed, lost, stolen, and/or partially administered.
- Call the local law enforcement, as well as my pharmacist and my prescriber, if I lose a dose or if a dose in my possession is stolen, as the drug may be dangerous to the community. Alternatively, I agree to allow the pharmacist to call local law enforcement and my prescriber.
- I will also inform my pharmacy team and prescriber of any other medication that I am prescribed or taking, including natural health products and vitamins as I realize that some treatments may interact with OAT medications and cause harm to me.
- Provide urine screens and take other tests required to monitor progress and safety of treatment as directed by my prescriber or pharmacist.
- Be polite and respectful of other patients and the pharmacy staff while on the premises of the pharmacy. I acknowledge that poor behaviour, such as verbal or physical harm to others, crimes committed within the pharmacy, uttering profanities, threats, etc. may result in a restriction or termination of my services from the pharmacy.

As the patient on OAT, I am aware that:

- I agree not to drive or operate machinery that requires my alertness when I am being initiated on therapy (typically the first two weeks) or when I am having doses adjusted or if I am having treatment effects that are making me sleepy or not alert.
- Taking narcotics, sleeping pills, alcohol, or other sedating substances may interact with OAT to cause overdose, coma, or even death. I will not take other medications unless prescribed by either my methadone prescriber or another prescriber (if different).
- The pharmacy will not provide me with my OAT dose if I arrive impaired by a medical condition or drugs or alcohol or with other symptoms where taking the dose may be harmful to me.
- Through this agreement, I have been made aware that in Saskatchewan, the laws that govern physicians and pharmacists require that prescription information will be recorded. This may involve occasional review of my file by an external reviewer working within the regulatory colleges of physicians or pharmacists to view my health files or the pharmacy's prescription files. I am aware this is a legal requirement and that my prescriber and pharmacist do not control and that the review is part of the regular auditing and inspection process of their respective governing bodies. I understand that my personal health information may be shared in such circumstances as required by law.

Patient Signature	Date
Pharmacy Representative Signature	Date

APPENDIX 5: EXAMPLE PATIENT BILL OF RIGHTS

EXAMPLE PATIENT BILL OF RIGHTS

Respectful Care

You have the right to be treated with compassion and respect and to receive care provided in a manner that respects your dignity, independence, and self-determination.
You have the right to have your identity (for example, gender identity, culture) respected.

Information

You have the right to be informed about the risks, benefits, and side effects of injectable opioid agonist treatment (iOAT) and other treatment options before you agree to receive iOAT.

Privacy

You have the right to privacy. Case discussion, consultation, examination, and treatment should be conducted in a way that protects your and every patient's privacy.

You have the right to expect confidentiality. Your care providers will maintain confidentiality of your care and medical records except in cases required by law (for example, suspected abuse of a minor).

Quality of Care

You have the right to receive high quality, evidence-based medical care.

You have the right to continuity of care. If you are incarcerated, you have the right to receive opioid agonist treatment in a timely manner, although you may not receive injectable opioid agonist treatment due to limitations on availability.

You have the right to be informed by your prescriber of available and realistic care options if your prescriber can no longer provider care (for example, due to relocation or retirement).

Involvement in Care

You have the right to work with your health care team to create treatment and wellness goals for yourself and to receive care or referrals to meet those goals.

You have the right to involve your family and social circle (e.g., romantic partners, close friends, and other people of significance) in your care when appropriate. You also have the right to exclude your family and social circle from your care.

Complaints

You have the right to make a complaint to the appropriate authority about any violation of your rights. [contact information for regulatory bodies and any other complaint mechanisms]

THIS EXAMPLE PATIENT BILL OF RIGHTS MAY BE ADAPTED FOR USE
THIS FORM IS NOT MEANT FOR CLINICAL USE

CIHR IRSC Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

CRISM-ICRAS Canadian Research Initiative in Substance Misuse / Initiative Canadienne de Recherche en Abus de Substance

1

APPENDIX 6: SAMPLE BUPRENORPHINE-NALOXONE INDUCTION PRESCRIPTION

J Myers, Opioid Stewardship Program; Department of Stewardship and Clinical Appropriateness, Saskatchewan Health Authority. November 2019

Example home/community pharmacy induction with prescriber follow up on Day 4 (WITH take home doses/PRN doses):

Day 1 (November 4):	Suboxone® 4 mg sublingual x 1 dose witnessed in pharmacy. Suboxone® 2 mg sublingual q2h PRN x 2 doses to be given as take-home doses.* Please ensure COWS is equal or greater than 12 or SOWS is greater than 17 before administering Suboxone® to patient. Mitte: 4 (four) x 2 mg tablets
Day 2 (November 5):	Suboxone® 4 – 8 mg sublingual x 1 dose witnessed in pharmacy (give Day 1 total dose). Suboxone® 2 mg sublingual q2h PRN x 2 doses to be given as take-home doses.* Mitte: 6 (six) x 2 mg tablets
Day 3 (November 6):	Suboxone® 8 – 12 mg sublingual x 1 dose witnessed in pharmacy (give Day 2 total dose). Mitte: 1.5 (one and one-half) x 8 mg tablets OR 6 (six) x 2 mg tablets

*If uncomfortable providing patient with take home doses, patient may present back to pharmacy to receive PRN doses.

Example of home/community pharmacy induction with prescriber follow up on Day 8 (NO take home doses/PRN doses):

Example of in office induction:

Day 1 (November 4):	Suboxone® for in office induction.
	Please dispense tablets to patient with instructions to bring to physician's office for appointment.
	Mitte: 6 (six) x 2 mg tablets
Day 2 prescription will be variable based on patient's response on Day 1.	
Example of maintenance dose prescription:	
	Suboxone® 16 mg sublingual daily (Nov 4 to Dec 1 inclusive)
	Witness dose once weekly (Mondays) in pharmacy. Take home doses Tuesdays-Sundays.
	Mitte: 56 (fifty-six) x 8 mg tablets

Day 1 (November 12):	Suboxone® 4 mg sublingual x 1 dose witnessed in pharmacy.
	Please ensure COWS is equal or greater than 12 or SOWS is greater than 17 before administering Suboxone® to patient.
	Mitte: 2 (two) x 2 mg tablets
Day 2 (November 13):	Suboxone® 8 mg sublingual x 1 dose witnessed in pharmacy
	Mitte: 1 (one) x 8 mg tablet
Day 3-8:	Suboxone® 12 mg sublingual daily.
(November 14-18)	Witness doses daily in pharmacy.
	Mitte: 9 (nine) x 8 mg tablets

APPENDIX 7: DAY 1 STARTING SUBOXONE

Day 1 Starting Suboxone® (buprenorphine/naloxone)

Page 1

Are you in withdrawal? Before starting Suboxone® (buprenorphine/naloxone) you need to be in withdrawal (dope-sick). Use the 'SOWS' withdrawal scale on the back page to determine how bad your withdrawal is. Wait until your withdrawal score is 17 or more to begin.

- **Do not take with alcohol or sedatives.**
- **Do not take more than 12 mg total on Day 1.**
- **Do not inject. You will be dope-sick if you inject.**

☐ My doctor/nurse practitioner and I agree on this treatment plan.

Contact Information

Patient Name _____

Provider Name _____

Provider Number _____

1st Dose — Take your 1st dose

- **Keep medication under your tongue until fully dissolved** (this can take up to 10 min) **or it will not work.** Do not chew or swallow.
- Do not eat, drink, or swallow while it is dissolving.
- Contact your provider to let them know you took your 1st dose.

My dose:
_____ mg
= _____ tablets
Time: _____

It usually takes 20-45 min for the medication to start to work. Wait 1-3 hours before your 2nd dose.

If you feel a lot worse → Contact your provider if your symptoms feel a LOT WORSE. This happens when you start before you are in enough withdrawal and is called "precipitated" withdrawal. Talk to your provider about managing symptoms and next steps.

Notes

2nd Dose — 1-3 hours after 1st dose

How do you feel?

- Still feeling withdrawal (dope-sick) symptoms → Take a 2nd dose (keep under tongue until fully dissolved).
- Better → Check in with yourself later.

My dose:
_____ mg
= _____ tablets
Time: _____

3rd Dose — 1-3 hours after 2nd dose or later in evening

How do you feel?

- Still feeling withdrawal (dope-sick) symptoms → Take a 3rd dose (keep under tongue until fully dissolved).
- Better → Check in with yourself later, you may not need another dose.

My dose:
_____ mg
= _____ tablets
Time: _____

Most people feel much better by the end of the first day. Contact your provider if you are still feeling bad withdrawal or feel like using and have taken the daily max of 12 mg.

How many doses did you take today?

	1st Dose	2nd Dose	3rd Dose	Total
Amount	mg	mg	mg	mg

The total for Day 1 is your starting dose for Day 2. Whether you started treatment at home or in the clinic, most providers will ask you to start Day 2 with a clinic visit. Take this sheet with you to your next appointment.

Next appointment info: Date: _____ Time: _____ Location: _____

Additional Information for Starting Suboxone® (buprenorphine/naloxone)

Knowing when to start

Suboxone® (also known by generic name buprenorphine/naloxone) helps you manage opioid withdrawal symptoms and cravings.

You need to be in withdrawal (dope-sick) to start or your symptoms will get a lot worse – the more in withdrawal you are the better.

You know your symptoms. Wait until you are in moderate to severe withdrawal (dope-sick) before you begin. You can use the SOWS scale (below) to help you see if you are in enough withdrawal to start. You can also check your SOWS score throughout the day. You should feel better and see your SOWS withdrawal scores decrease throughout the day. If your SOWS withdrawal score increases and your symptoms get worse, contact your provider.

Subjective Opiate Withdrawal Scale (SOWS)[1]

Please score each of the statements according to how you feel right now on a scale of 1 to 4. Add up all your scores to get your total SOWS withdrawal score.

Scale: 0= Not at all 1= A little 2= Moderately 3= Quite a bit 4= Extremely

	Time:					
	Symptoms:	**Score**	**Score**	**Score**	**Score**	**Score**
	I feel anxious					
	I feel like yawning					
	I am perspiring					
	My eyes are teary					
	My nose is running					
	I have goosebumps					
	I am shaking					
	I have hot flushes					
	I have cold flushes					
	My bones and muscles ache					
	I feel restless					
	I feel nauseous					
	I feel like vomiting					
	My muscles twitch					
	I have stomach cramps					
	I feel like using now					
	My SOWS score (total score):					

If your SOWS withdrawal score is **17 or more** → You are ready to start, follow the instructions on page 1.
If your SOWS withdrawal score is **less than 17** → Check your score again in 1-3 hours.

[1] Handelsman L et al. Am J Drug Alcohol Abuse.1987.

Notes:

This handout is based on the *BC Guideline Opioid Use Disorder - Diagnosis and Management in Primary Care* available at BCGuidelines.ca

British Columbia | Ministry of Health

doctors of bc

British Columbia Centre on Substance Use

APPENDIX 8: CLINICAL OPIATE WITHDRAWAL SCALE

BRITISH COLUMBIA CENTRE ON **SUBSTANCE USE**
Networking researchers, educators & care providers

CLINICAL OPIATE WITHDRAWAL SCALE[1]

For each item, circle the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.

Patient's name: _____ Date and Time: _____/_____/____:____

Reason for assessment: _____

Resting Pulse Rate _____ beats/minute *Measured after patient is sitting or lying for one minute* 0 pulse rate 80 or below 1 pulse rate 81–100 2 pulse rate 101–120 4 pulse rate greater than 120	**GI Upset** *over last ½ hour* 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting
Sweating *over past ½ hour not accounted for by room temperature or patient activity* 0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face	**Tremor** *observation of outstretched hands* 0 no tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching
Restlessness *observation during assessment* 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 unable to sit still for more than a few seconds	**Yawning** *observation during assessment* 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute
Pupil Size 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible	**Anxiety or Irritability** 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable anxious 4 patient so irritable or anxious that participation in the assessment is difficult
Bone or Joint Aches *If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored* 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	**Gooseflesh Skin** 0 skin is smooth 3 piloerrection of skin can be felt or hairs standing up on arms 5 prominent piloerrection
Runny Nose or Tearing *Not accounted for by cold symptoms or allergies* 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks	**Total Score** _____ *The total score is the sum of all 11 items.* Initials of person completing assessment: _____

Score: 5–12 = mild; 13–24: moderate; 25–36 = moderately severe; more than 36 = severe withdrawal

Reference:

1. Wesson DR, Ling W. The Clinical Opiate Withdrawal Scale (COWS). J Psychoactive Drugs. 2003;35(2):253–259.

More information:
www.bccsu.ca

BRITISH COLUMBIA CENTRE *for* EXCELLENCE *in* HIV/AIDS · Providence HEALTH CARE · UBC · St Paul's FOUNDATION

BRITISH COLUMBIA CENTRE ON SUBSTANCE USE
Networking researchers, educators & care providers

SUBJECTIVE OPIATE WITHDRAWAL SCALE (SOWS)[1]

The SOWS is a self-administered scale for grading opioid withdrawal symptoms. It contains 16 symptoms whose intensity the patient rates on a scale of 0 (not at all) to 4 (extremely), and takes less than 10 minutes to complete.

Patient Instructions: please score each of the 16 items below according to how you feel right now. Circle one number only.

Item	Symptom	Not at all	A little	Moderately	Quite a bit	Extremely
1	I feel anxious	0	1	2	3	4
2	I feel like yawning	0	1	2	3	4
3	I am perspiring	0	1	2	3	4
4	My eyes are teary	0	1	2	3	4
5	My nose is running	0	1	2	3	4
6	I have goosebumps	0	1	2	3	4
7	I am shaking	0	1	2	3	4
8	I have hot flushes	0	1	2	3	4
9	I have cold flushes	0	1	2	3	4
10	My bones and muscles ache	0	1	2	3	4
11	I feel restless	0	1	2	3	4
12	I feel nauseous	0	1	2	3	4
13	I feel like vomiting	0	1	2	3	4
14	My muscles twitch	0	1	2	3	4
15	I have stomach cramps	0	1	2	3	4
16	I feel like using now	0	1	2	3	4

Total Score: _____

Reference:
1. Handelsman L, Cochrane KJ, Aronson MJ, Ness R, Rubinstein KJ, Kanof PD. Two New Rating Scales for Opiate Withdrawal. 1987. American Journal of Alcohol Abuse 13, 293-308.

More information:
www.bccsu.ca

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UBC
ST paul's FOUNDATION

APPENDIX 9: BUPRENORPHINE-NALOXONE MICRODOSING

Appendix 9.1: Microdosing as Initiation

Microdosing is done to initiate a patient on buprenorphine-naloxone while they continue using a full opioid agonist (either methadone or illicit opioid). This off-label approach to buprenorphine-naloxone induction avoids having to experience opioid withdrawal before starting buprenorphine-naloxone and minimizes the risk of precipitated withdrawal if buprenorphine-naloxone were to be started at a full dose while full opioid agonist is still being used.

Appendix 9.2: Buprenorphine/naloxone (bup/nx) Microdosing (from CPSS Standards and Guidelines)

Some patients struggle with bup/nx initiation because of precipitated withdrawal and the need to be opioid free to obtain an appropriate COWS score (>12-24 hours). Although considered off-label, microdosing involves induction of small bup/nx doses which is less likely to precipitate withdrawal.

Switching from methadone to bup/nx

Because of the high affinity for the mμ receptor, bup accumulates at the receptor and bumps off the full mμ opioid agonist (e.g. methadone).

Day	Bup Dosing	Methadone Dosing
1	0.5 mg SL once daily	Full dose
2	0.5 mg SL twice daily	Full dose
3	1 mg SL twice daily	Full dose
4	2 mg SL twice daily	Full dose
5	4 mg SL twice daily	Full dose
6	8 mg SL once daily	Full dose
7	8 mg SL in AM and 4 mg SL in PM	Full dose
8	12 mg SL once daily	Stop

Reference: Terasaki D., et al. Transitioning Hospitalized Patients with Opioid Use Disorder from Methadone to Buprenorphine without a Period of Opioid Abstinence Using a Microdosing Protocol. Pharmacotherapy 2019;39(1): 1023-9.

Appendix 9.3: Microdose Tablet Destruction

If a patient is prescribed buprenorphine-naloxone microdosing (i.e. a dose less than a full tablet), the rest of the sublingual tablet must be destroyed. The destruction must be documented and co-signed by a pharmacy staff member who witnessed the destruction.

See RxFiles Opioid Use Disorder: Opioid Agonist Therapy (Nov 2019) for an example microdosing regimen.

APPENDIX 10: BUPRENORPHINE EXTENDED RELEASE INJECTION (SUBLOCADE ®)

Appendix 10.1: Dosing Information

- Prior to starting buprenorphine extended release injection patients should first undergo induction and stabilization by initiating a transmucosal buprenorphine-containing product, delivering the equivalent of 8-24 mg/day of buprenorphine for a minimum of 7 days.
- Following induction and stabilization, patients can be transitioned to buprenorphine extended release injection starting with 300 mg/month for two months, followed by a maintenance dose of 100 mg/month. The maintenance dose can be increased to 300mg/month if patient does not demonstrate response to and can tolerate the 100mg dose.
- A minimum of 26 days is required between doses.
- A patient who misses a dose should receive the next dose as soon as possible, with the following dose given no less than 26 days later. Occasional delays in dosing up to 2 weeks are not expected to have a clinically significant impact on treatment effect.

Appendix 10.2: Storage and Handling

- Store refrigerated at 2°C - 8°C (35.6°F - 46.4°F)
- Remove buprenorphine extended release injection from the refrigerator prior to administration. The product requires at least 15 minutes to reach room temperature. Do not open the foil pouch until the patient has arrived for his or her injection
- Once outside the refrigerator this product may be stored in its original packaging at room temperature, 15°C - 30°C (59°F - 86°F), for up to 7 days prior to administration
- Discard buprenorphine extended release injection if left at room temperature for longer than 7 days.

Appendix 10.3: Administration

- For abdominal subcutaneous injection only
- Please see section *4.3 Administration* from the Buprenorphine Extended Release Injection (Sublocade ®) Product Monograph
- After injection advise the patient that they may have a lump for several weeks that will decrease in size over time. Instruct the patient not to rub or massage the injection site and to be aware of the placement of any belts or clothing waistbands that could cause irritation of the injection site.

Appendix 10.1: Monitoring

- Buprenorphine extended release formation is injected as a solution and the subsequent precipitation of the polymer creates a buprenorphine containing mass. Clinical monitoring for evidence at the injection site of tampering or attempting to remove the mass should be ongoing throughout treatment.
- Liver function tests, prior to initiation of treatment, are recommended to establish a baseline. Monthly monitoring of liver function during treatment, particularly with 300 mg maintenance dose, is also recommended.

See Buprenorphine Extended Release Injection (Sublocade ®) Product Monograph for more information.

APPENDIX 11: SAMPLE METHADONE PRESCRIPTION[4]

Dr. Jill Testing 4444
111 Saskatoon St
Saskatoon, SK
M1M 1M1
(306) 111-1111

Rx

John Smith-OAT 2020-Mar-16
PHN: 988 888 888 Birthdate: 1990-Oct-10 male
123 Main St
Regina, SK S4R 1Z9
(306) 233-2323

---

1) NEW Rx (Substitutions Allowed) #TBD

methadone HCL 1 mg/ml Oral Solution, Oral

15 mg Once daily X 14 Day(s) starting on 2020-Mar-17

SIG Instructions:
Start: Mar 17 2020 End: Mar 31 2020
Daily Witnessed Ingestion: Monday Tuesday Wednesday Thursday Take Home Carries: Friday Saturday Sunday

Qty:	**210 mL (Two hundred Ten)**
Refills:	**None**
Drug Use:	Continuous
Route:	Oral

Generated By Jill on 2020-Mar-16 9:32 AM

Signature: _____
*** Please take this prescription to your pharmacist. ***

APPENDIX 12: METHADONE STABILITY IN VARIOUS DILUENTS[1,3]

Diluent	Stability at room temperature (20° to 25°C)	Period of stability at refrigerated temperature (5°C)	Period of acceptable sterility for oral consumption under refrigeration (i.e., bacterial or pathogenic growth)
Orange flavoured Tang™	11 days	49 days	• 14 days for diluted Metadol™ and Methadose™ preparations
Grape flavoured Crystal Light ™	8 days	34 days	• Unknown for dilution with Methadose™ • 14 days for diluted Metadol™ preparation
Grape flavoured Crystal Light™ with 0.1% sodium benzoate	29 days	Not available	• Unknown for dilution with Methadose™
Allen's Apple Juice™ not recommended	9 days	47 days	• Unknown for dilution with Methadose™ • 7 days for diluted Metadol™ preparations

The stability and sterility of commercially prepared diluted with Tang™, or its equivalent may be unknown as published studies are not available for all formulations.[1] Dispensing guidelines within many provincial jurisdictions have identified the duration of stability of methadone in various diluents from a collection of past literature; however, available literature does not address the issue of sterility, which includes the likelihood of bacterial or mold growth in the prepared solution stored under refrigerated or unrefrigerated conditions.[1] The information in this table is provided as best existing guidance to allow you to use professional judgment when assigning best-before dates to diluted commercially prepared methadone and is consistent with USP guidelines for aqueous products when no stability data is.[1]

APPENDIX 13: DILUTION RECORD[1]

Special Instructions:	Label Instructions: Label with 14 days expiration from date of dilution. Keep refrigerated.

Staff name (please print)	Staff initials	Staff name (please print)	Staff initials

Date prepared/ Prescription #	Prescribed Methadone Dose	Quantity Used	Ingredient name	Lot #	Expiry Date	Beyond Use Date of Dilution	Prepared By Checked By

APPENDIX 14: PATIENT RECORD OF WITNESSED OAT MEDICATION INGESTION[1,3]

Pharmacy Name:

Patient Name: Health Services Number:

Doctor's Name:

OAT Medication (methadone or buprenorphine-naloxone):

Date of Ingestion	Prescription #	Strength of Dose Ingested	Signature of Patient	Pharmacist/Pharmacy technician Initials

APPENDIX 15: PATIENT RECORD OF WITNESS INGESTION AND TAKE HOME DOSES[1,3]

Pharmacy Name:

Patient Name: Health Services Number:

Doctor's Name:

OAT Medication (methadone or buprenorphine-naloxone):

Date	Prescription #	Strength of Dose	# of Take-home doses	Date take home doses received	# of Bottle Returned/ Notes *	Signature of Patient	Pharmacist/ Pharmacy technician Initials

*at request of the prescriber or pharmacist(s)

APPENDIX 16: SAMPLE METHADONE TAKE HOME DOSE LABELS

(containing information for a diluted methadone take home dose)[1]

Pharmacy name
Pharmacy address
Pharmacy phone number

Patient name Prescription number

Methadone 100 mg diluted to 100 mL with Tang™ orange drink.

Drug is diluted. **Consume the ENTIRE contents of this bottle on** [insert the date of intended ingestion].

KEEP REFRIGERATED IN A LOCKED AND SAFE AREA AWAY FROM THE REACH OF CHILDREN.

May be toxic or lethal if ingested by a child or adult other than the intended patient. Accidental ingestion is considered a medical emergency and requires immediate medical attention.

RETURN ALL USED AND UNUSED CARRY BOTTLES TO THE PHARMACY

Date dispensed Expiry date of bottle Prescriber's name

Appendix 16.1: Sample take home dose label where Methadose™ is dispensed in an undiluted form

(Note that Methadose™ cherry-flavoured concentrate 10 mg/mL does not require further dilution and may be stored at room temperature)[1]:

Pharmacy name
Pharmacy address
Pharmacy phone number

Patient name Prescription number

Methadone 100 mg cherry-flavoured syrup.
(Note that the total 100 mg dose is contained within 10 ml of this syrup)

Consume the ENTIRE contents of this bottle on [insert the date of intended ingestion].

STORE AT ROOM TEMPERATURE IN A LOCKED AND SAFE AREA AWAY FROM THE REACH OF CHILDREN.

May be toxic or lethal if ingested by a child or adult other than the intended patient. Accidental ingestion is considered a medical emergency and requires immediate medical attention.

RETURN ALL USED AND UNUSED CARRY BOTTLES TO THE PHARMACY

Date dispensed Expiry date of bottle Prescriber's name

APPENDIX 17: PHARMACIST-PRESCRIBER FAXED COMMUNICATION[1]

Pharmacy name: _____	Pharmacist: _____
Date: _____	Time: _____
Pharmacy Phone #: _____	Fax #: _____

Dear Dr. and or RN(NP)_____:

For your records, please note that your patient,_____ is taking_____ for substance use disorder.

The following situation has occurred:

- ☐ Missed their dose on (date(s)): _____
- ☐ Vomited their dose on (date): _____
  - ☐ Witnessed by pharmacist or other health care professional
  - ☐ Vomiting but not witnessed
    - ☐ Comments: _____
- ☐ Reported a lost dose(s) on: _____
- ☐ Reported a stolen dose(s) on: _____
- ☐ Was unable to attend the pharmacy due to hospitalization at _____ hospital on: _____ (date range)
- ☐ Was unable to attend the pharmacy due to incarnation at _____ facility/remand center/police holding cells on: _____(date range)

Further explanation is provided as follows:

We require a prescription to clarify the dose of ongoing treatment and to meet legal requirements.

To our knowledge, the last dose of _____ was provided on _____and ingested on the following date: _____.

- ☐ This dose was witnessed by a pharmacist
- ☐ This dose was not witnessed by a pharmacist

Please fax us a prescription indicating the ongoing treatment dosage.

Sincerely,

APPENDIX 18: MONITORING RECOMMENDATIONS FOR BUPRENORPHINE-NALOXONE

(RxTx, e-therapeautic.ca, accessed Nov 15, 2019)

Monitor: liver function tests, regular urine drug screen (at least monthly during induction and titration), random pill counts

- Long-term use of opioids may be associated with decreased sex hormone levels and symptoms such as low libido, erectile dysfunction, or infertility.
- Buprenorphine-naloxone may cause orthostatic hypotension in ambulatory patients. Signs of hypotension should be monitored in patients whose ability to maintain adequate blood pressure is compromised by blood volume or medication.
- Buprenorphine, and other morphine-like opioids have been shown to decrease bowel motility and increase pressure. Bowel habits should be discussed during initiation and monitored during maintenance phase.

Precipitation of opioid withdrawal syndrome of buprenorphine-naloxone:

- Because of the partial agonist properties of buprenorphine, withdrawal symptoms may precipitate in opioid-dependent patients if administered before the agonist effects resulting from recent opioid use or misuse have subsided.
- Naloxone may produce marked and intense withdrawal signs and symptoms if misused intranasally or by injection by individual dependent on full opioid agonists such as heroin, morphine or methadone.
- To avoid precipitating an opioid withdrawal syndrome during induction onto buprenorphine-naloxone from short-acting or long-acting opioids, the patient should show objective signs and symptoms of at least moderate withdrawal prior to induction dosing. For example, a moderate score of withdrawal, equal or greater than 12 on the Clinical Opiate Withdrawal Scale (COWS) (See Appendix 8: Clinical Opiate Withdrawal Scale) may be a useful reference assessment.
- Withdrawal symptoms may also be associated with sub-optimal dosing.

Please see individual drug monographs for more information on monitoring for warnings and precautions, adverse drug reactions, and drug interactions.

See RxFiles

See College of Physicians and Surgeons of Saskatchewan: Opioid Substitution Therapy Program - Guidelines and Standards for the Treatment of Opioid Addiction/Dependence for monitoring during Maintenance Phase in OAT (page 45), information about Random Urine Drug Screening (page 48) and Urine Drug Screening Collecting Practices (page 143).

APPENDIX 19: MONITORING RECOMMENDATIONS FOR METHADONE

(RxTx, e-therapeautic.ca, accessed Nov 15, 2019)

Monitor: regular urine drug screen (monthly during initiation and dose escalation), ECG baseline: 30 days after therapy initiation and dose increase- yearly thereafter.

- Careful monitoring is recommended when using methadone in patients with a history of cardiac conduction abnormalities, those taking medications affecting cardiac conduction, and in other cases where history or physical exam suggest an increased risk of dysrhythmia due to potential risk for development of prolong QT interval.
- Methadone may cause severe hypotension in ambulatory patients. Signs of hypotension should be monitored in patients whose ability to maintain adequate blood pressure is compromised by blood volume or medication.
- Methadone, and other morphine-like opioids have been shown to decrease bowel motility. Bowel habits should be discussed during initiation and monitored during maintenance phase.
- Monitor patients with significant chronic obstructive pulmonary disease, and patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression for respiratory depression, particularly when initiating therapy and titrating with methadone, as in these patients, even usual therapeutic doses of methadone may decrease respiratory drive to the point of apnea.

Please see individual drug monographs for more information on monitoring for warnings and precautions, adverse drug reactions, and drug interactions.

See RxFiles

See College of Physicians and Surgeons of Saskatchewan: Opioid Substitution Therapy Program- Guidelines and Standards for the Treatment of Opioid Addiction/Dependence for monitoring during Maintenance Phase in OAT (page 45), information about Random Urine Drug Screening (page 48) and Urine Drug Screening Collecting Practices (page 143).

APPENDIX 20: COMPOUNDING METHADONE STANDARDS FOR PHARMACISTS AND TECHNICIANS

Methadone should only be compounded if there is a specific therapeutic need or a shortage of a commercially available product, and if required, upon the prior approval of the Drug Plan or Non-Insured Health Benefits. Compounding of methadone should not be done solely for economic reasons that benefit the involved healthcare professionals.[1]

20.1 Authorization to Compound and Prepare

Pharmacists and pharmacy technicians are both authorized to compound and prepare methadone. Pharmacy staff compounding methadone must be competent in the processes and use of equipment to compound the stock solution.[1]

20.1.1 Pharmacy assistants and interns under the direct supervision of a pharmacist or pharmacy technician may compound Methadone.

20.2 Preparing Methadone Stock Solution

20.2.1 A stock solution of methadone is prepared by dissolving methadone crystals in distilled water at a strength of 10 mg per mL.[3]

20.2.2 Prepare methadone stock solution according to NAPRA Compounding Standards within a clean and organized environment following work processes that minimize the risk of error and mix-ups with other pharmaceuticals.[1]

20.2.3 Ensure that equipment or devices used to prepare the stock solution meet NAPRA and/or USP compounding standards for accuracy of measuring devices (e.g., calibrated device with marked volumes).[1]

20.2.3.1 If possible, pharmacies should label measuring equipment used to prepare methadone compounds and keep this equipment separate for the sole purpose of compounding methadone. If this is not possible, all equipment used must be properly washed and cleaned before reuse to prevent cross-contamination with other preparations.[1]

20.2.4 Ensure that equipment or devices used to prepare the stock solution meet NAPRA and/or USP compounding standards for accuracy of measuring devices (e.g., calibrated device with marked volumes).[1]

20.2.5 Label the stock solution distinctly.[1]

20.2.6 The label should include:[1]

- The ingredients and concentration of the solution (e.g., methadone 10 mg/mL stock solution in distilled water), and
- The best before date of the solution.

20.2.7 To avoid mix-ups, store methadone stock solutions in a separate area away from other solutions.[1]

20.2.7.1 Stock solutions should be stored in a glass, light resistant container, in the refrigerator to avoid bacterial and mold growth.[3]

20.3 Visible Distinction

Label and identify the compounded solution in such a way that it is visibly distinct from other solutions. This may include a distinct bottle with appropriate labeling. [1]

20.4 Bold Labels and Stickers

A boldly marked label and a poison sticker should be included in the labeling of the methadone solution.[1]

20.4.1 The pharmacy must keep a bulk compounding log and record the following information for each prepared solution:[1]

- Date prepared;
- Assigned batch number;
- Names (printed legibly) and signatures of personnel involved in preparing and/or checking the preparation;
- Name, quantity, lot numbers, and expiry dates of ingredients used to prepare the stock solution (e.g., methadone, distilled or bacteriostatic water, preservatives, etc.);
- Concentration of the final solution;
- Volume of the final solution; and
- Beyond-use date.

20.5 Stability of Compounded Methadone Stock Solution

20.5.1 Current recommendation is to discard stock solution prepared without a preservative after 14 days. This includes solutions prepared with distilled water.[1]

20.5.2 Check stock solutions regularly for signs of bacterial and mold growth.[3]

20.6 Diluting Compounded Methadone Stock Solution for Dispensing

20.6.1 Unless otherwise indicated by the prescriber, pharmacists must dispense all compounded methadone in a crystalline drink deemed compatible with the methadone.[1]

20.6.1.1 If the prescriber directs the pharmacist to deviate from this standard, the prescriber must provide and document a clear rationale on the prescription.[1]

20.6.2 Dilute the prescribed dose (for example a dosage of 90 mg requires 9 mls of 10 mg/mL stock solution) to 100 mL of a flavoured crystalline vehicle such as Tang™ crystalline drink. Plain water is not acceptable.[1]

20.6.3 Dilution in no less than 100 mL volume of flavoured drink will[1]:

- Mask the bitter taste of methadone,
- Prevent conversion to a substance which can be injected due to the sugar content and excipients in the crystalline drink or juice and discourage diversion.

20.6.4 If stored under refrigeration, the diluted preparation should be used within 14 days of compounding.

20.6.4.1 Formulations prepared in juices should have a before use date that does not exceed the shelf-life of the juice under the conditions of storage recommended upon opening the bottle. In general, dispensing methadone in fruit juices or diluents not identified in Appendix 12: Methadone Stability in Various Diluents is not recommended.

20.7 Tamper Resistance

Dosages should be sealed with a tamper resistance seal, one bottle per dose and labelled accordingly (see example labels Appendix 12: Methadone Stability in Various Diluents).

20.8 Take Home Doses (Carries)

20.8.1 Take home doses (carries) must be dispensed in child-resistant containers with a tamper resistance seal with an explicit warning label indicating that the amount of drug in the container could cause serious harm or toxicity if taken by someone other than the patient.[2]

20.8.2 Each dose must be dispensed in an individual, 100 mL, child-resistant container/bottle.[2]

20.8.3 Each container/bottle must be individually labeled.[2]

20.8.4 If a pharmacist determines that due to a specific patient circumstance a non-child-resistant container/bottle will be used for take-home doses it must be documented on the patient record.[2]

APPENDIX 21: PATIENT INFORMATION HANDOUTS

Appendix 21.1: Methadone

Methadone for Opioid Use Disorder: Your Questions Answered

METHADONE

Seeking help for your opioid dependence is a wise and important step in your road to recovery. There are people who can help you to develop goals and who can support you along the way. Talk to your healthcare provider about your support options.

Methadone is an opioid used to treat opioid use disorder. Unlike most opioids, methadone lasts a long time in your body to help prevent cravings and feelings of withdrawal. Once you've taken this medication for a while, you should feel more energetic and clear-headed. This will let you focus on things like work, school, and family.

1. Changes?

You've been prescribed methadone for opioid use disorder (opioid dependence). You'll take the first dose of methadone in the presence of a health care provider. The first dose will be small to see how you tolerate it. The dose can be increased based on how you feel. It may take weeks to get to the dose that is right for you.

2. Continue?

You and your health care provider will decide how long you'll take methadone. Usually, long-term treatment is most effective (e.g., months to years). You may decide to try stopping this medication at some point. It's important to do this together with your health care provider so the dose can be lowered very slowly.

3. Proper Use?

Methadone is a liquid medication. It's mixed with juice by a pharmacist and given to you to drink at the pharmacy. When starting methadone, you will have to go to the pharmacy every day to take your dose. Over time many people can take doses at home – these are called "carries". Talk with your healthcare provider about how to manage missed doses, as changes to your medication may be needed. Overdose can happen with methadone when it's not taken properly. Do not take other opioids, alcohol, or sleeping pills (e.g., benzodiazepines like lorazepam [Ativan]) while on this medication, as they increase the risk of an overdose. It may not be safe to drive a car or operate machinery when you first start taking this medication.

4. Monitor?

You may experience side effects, especially when you start methadone or increase the dose. You may feel light-headed, dizzy, drowsy, and sweaty. You may be constipated. You might also feel sick to your stomach and vomit. These side effects may go away as your body gets used to the medication but if they do not, talk with your health care provider. Contact a health care provider right away if you have a hard time breathing or staying awake, are experiencing severe dizziness or chest pain, or if you feel a rapid or irregular heartbeat.

5. Follow-up?

When you start methadone, you'll have extra visits with your health care provider. Your health care provider will want to see how you're feeling and may change your dose if needed. You'll also need to provide urine samples when asked by your health care provider.

It is important to:

Store methadone carries in a locked box in the refrigerator. Keep it out of sight and reach of children and pets. A small amount of this medication can kill a child.

Never share your methadone with anyone. Your dose is tailored to you and can be dangerous or even deadly for someone else.

Take all unused and expired medications back to the pharmacy for safe disposal.

Talk to your health care provider or pharmacist about Take Home Naloxone kits and overdose response training. More information is available at: **www.saskatchewan.ca/opioids**

Did you know?

There are many medications that are not safe to take while on methadone therapy. Tell your health care providers about all street drugs, vitamins, and other medicines that you're taking, and talk with them before starting anything new. This includes natural medicines, herbal products, and supplements.

Questions and Notes:

To find out more visit the Saskatchewan Opioid Agonist Therapy Program website at:
https://bit.ly/2Gm5BMQ

To access a PDF of this handout visit: **www.saskatchewan.ca/opioids**

Appendix 21.2: Buprenorphine/Naloxone (Suboxone)

Buprenorphine/Naloxone (Suboxone) for Opioid Use Disorder: Your Questions Answered

SUBOXONE

Seeking help for your opioid dependence is a wise and important step in your road to recovery. There are people who can help you to develop goals and who can support you along the way. Talk to your healthcare provider about your support options.

Buprenorphine/naloxone (brand name Suboxone) contains an opioid used to treat opioid use disorder. Unlike most opioids, buprenorphine/naloxone lasts a long time in your body to help prevent cravings and feelings of withdrawal. Once you've taken this medication for a while, you should feel more energetic and clear-headed. This will let you focus on things like work, school, and family.

1. Changes?

You've been prescribed buprenorphine/naloxone (brand name Suboxone) for opioid use disorder (opioid dependence). You'll likely take your first dose of buprenorphine/naloxone in the presence of a health care provider when you feel symptoms of withdrawal. 12-36 hours before your first dose, you'll need to stop taking other opioids. Your withdrawal symptoms should get better when you start this medication. They should go away once you get on the dose that is right for you, but it may take a few days to get to the right dose.

2. Continue?

You and your health care provider will decide how long you'll take buprenorphine/naloxone. Usually, long-term treatment is most effective (e.g., months to years). You may decide to try stopping this medication at some point. It's important to do this with your health care provider so the dose can be lowered very slowly.

3. Proper Use?

Buprenorphine/naloxone is a pill that is placed under your tongue and dissolves. This can take up to 10 minutes. Do not swallow, eat, drink, or smoke while the pill dissolves. You may have to go to the pharmacy as often as daily to take your dose. Over time, many people can take doses at home – these are called "carries". Talk with your healthcare provider about how to manage missed doses, as changes to your medication may be needed. The risk of overdose is lower with buprenorphine/naloxone compared to methadone. However, do not take other opioids, alcohol, or sleeping pills (e.g., benzodiazepines like lorazepam [Ativan]) while on buprenorphine/naloxone, as they can increase the risk of an overdose. It may not be safe to drive a car or operate machinery when you first start taking this medication.

4. Monitor?

You may experience side effects, especially when you start buprenorphine/naloxone or increase the dose. You may feel anxious, drowsy, dizzy, or depressed. You may have trouble sleeping and may be constipated. You might have a headache, and you may feel symptoms of withdrawal such as sweating, diarrhea, or feeling sick to your stomach. These side effects may go away once your body gets used to the medication but if they do not, talk with your health care provider. Contact a health care provider right away if you have a hard time breathing, staying awake, or are experiencing severe dizziness.

5. Follow-up?

When you start buprenorphine/naloxone, you'll have extra visits with your health care provider. Your health care provider will want to see how you are feeling and may change your dose if needed. You'll also need to provide urine samples when asked by your health care provider.

It is important to:

Store buprenorphine/naloxone in a locked box in a secure place. Keep it out of sight and reach of children and pets. A small amount of this medication can kill a child.

Never share your buprenorphine/naloxone with anyone. Your dose is tailored to you and can be dangerous or even deadly for someone else.

Take all unused and expired medications back to the pharmacy for safe disposal.

Talk to your health care provider or pharmacist about Take Home Naloxone kits and overdose response training. More information is available at: **www.saskatchewan.ca/opioids**

Did you know?

Naloxone is combined with buprenorphine to stop people from snorting or injecting the medication. If you inject or snort it, the naloxone will send you into withdrawal. When it is dissolved under your tongue, the naloxone does not get absorbed into your body and therefore has no effect.

Questions and Notes:

To find out more visit the Saskatchewan Opioid Agonist Therapy Program website at:
https://bit.ly/2Gm5BMQ

To access a PDF of this handout visit: **www.saskatchewan.ca/opioids**