

STANDARDS OF PRACTICE

Provision of Opioid Agonist Therapy Medications

March 2024

(for implementation by July 2024)

TABLE OF CONTENTS

1. INTRODUCTION.....	2
2. ETHICAL CONSIDERATIONS	3
3. TREATMENT CHOICES.....	5
4. EXPECTATIONS FOR PHARMACY PROFESSIONALS	6
5. OPERATIONAL STANDARDS	6
6. PRACTICE STANDARDS	8
7. RESPONDING TO SPECIAL CIRCUMSTANCES	20
8. ENSURING CONTINUITY OF CARE	24
9. ACKNOWLEDGEMENTS	29
APPENDIX A	A-1
Recommended Resources and Sources of Education and Training	A-1
APPENDIX B.....	B-1
Methadone Perpetual Inventory Record and Dose Preparation Log.....	B-1
APPENDIX C	C-1
Methadone 10 mg/ml Stock Solution Compounding Log.....	C-1
APPENDIX D	D-1
Opioid Agonist Therapy Medication Administration Log.....	D-1

1. INTRODUCTION

Opioid use disorder (OUD) is a chronic, relapsing condition that has significant personal, public health and economic consequences.¹ Individuals living with OUD may experience many negative effects such as permanent injury following an opioid poisoning event, disease transmission of blood-borne pathogens, social isolation, structural stigmatization (including from the healthcare system), financial hardship, and impacts on mental well-being. Many of the fatal and non-fatal overdoses in Canada's epidemic over recent years have occurred in people with OUD.¹ The Public Health Agency of Canada reports a total of 36,442 apparent opioid toxicity deaths and 36,233 opioid-related poisoning hospitalizations between January 2016 and December 2022.²

The first-line treatment for moderate to severe OUD is opioid agonist therapy (OAT), ideally combined with behavioural and social supports to optimize the determinants of health and address other psychosocial factors that influence substance use and quality of life. OAT can stabilize the cycle of intoxication and withdrawal, reduce opioid cravings, and block the intoxicating effects of other opioids. People who are maintained on OAT typically experience significantly improved health and social functioning and a considerable reduction in the risk of overdose and all-cause mortality.¹

To successfully assist patients in the management of OUD, all members of the care team, including pharmacy professionals, need to understand both the condition as well as the stigmatization and marginalization that people living with OUD face. Treatment for this multi-dimensional condition is optimized through the concerted efforts and collaboration of a multidisciplinary team, all working together to provide the medical, psychological, behavioural, and social interventions that may be required.

Pharmacy professionals who participate in treating OUD must contemplate and understand the complex treatments, ethical considerations, logistical requirements, and the competencies needed to deliver care safely and effectively.

Standards of Practice are minimum standards that all registered pharmacy professionals are expected to meet. Regardless of position or practice environment, when a pharmacy professional performs a specific activity, they must perform it to the level specified in the Standards of Practice and meet all of the standards associated with that activity.

These Standards describe the minimum expectations involved in the provision of OAT medications to treat opioid use disorder and are intended to promote consistency in the provision of this service to the people of this province.

¹ "Opioid Agonist Therapy: A Synthesis of Canadian Guidelines for Treating Opioid Use Disorder", Centre for Addiction and Mental Health, 2021, <https://www.camh.ca/en/professionals/treating-conditions-and-disorders/canadian-opioid-use-disorder-guideline>

² "Opioid- and Stimulant-related Harms in Canada", Public Health Agency of Canada, 2023, <https://health-infobase.canada.ca/substance-related-harms/opioids-stimulants/>

These Standards of Practice are not clinical guidelines and are not to be considered in isolation. They are intended to be used in conjunction with current and evolving best practices and evidence-informed clinical resources from reputable sources (see Appendix A).

2. ETHICAL CONSIDERATIONS

Pharmacy professionals are expected to reflect on the principles of CPNL's *Code of Ethics*³ when providing OAT medications. In particular, understanding the concepts of stigma, trauma-informed care, and harm reduction are fundamental to providing quality and safe care, and meeting the needs of individuals with opioid use disorder.

2.1. Stigma

Stigma is negative attitudes and beliefs about a group of people due to their circumstances in life. It includes discrimination, prejudice, judging, labelling, isolating, and stereotyping. Stigma matters because it can prevent people from getting help and creates barriers to accessing important health and social services.⁴

While stigma can certainly take the form of active negative treatment of individuals by healthcare providers, it can also be more insidious and unintentional. Pharmacy professionals need to understand that patient perceptions of stigma can lead to feelings of shame, guilt, and mistrust by the patient. This may contribute to reduced engagement that may lead to premature discontinuation of treatment and poorer health outcomes.

Pharmacy professionals are responsible to take steps to reduce stigma within their practice environment, and hold themselves and other staff members accountable to:

- identify and recognize their own biases;
- remember that substance use disorders are medical conditions deserving of care and treatment; and
- use respectful, person-centred language when talking about substance use.

The Centre for Addiction and Mental Health (CAMH) toolkit, *Addressing Opioid Stigma in Pharmacies: Strategies for Pharmacy Professionals*⁵ provides a number of strategies and resources to assist pharmacy professionals with reducing stigma in the pharmacy environment.

³ Available on the [Code of Ethics](#) page of the CPNL website.

⁴ "Stigma around drug use", Health Canada, 2023, <https://www.canada.ca/en/health-canada/services/opioids/stigma.html>

⁵ "Addressing Opioid Stigma in Pharmacies", Centre for Addiction and Mental Health, 2024, <https://kmb.camh.ca/eenet/resources/addressing-opioid-stigma-in-pharmacies>

2.2. Trauma-Informed Care

Trauma is defined as experience that overwhelms an individual's capacity to cope. Whether it is experienced early or later in life, trauma can be devastating. Trauma can interfere with a person's sense of safety, self, and self-efficacy, as well as the ability to regulate emotions and navigate relationships. Traumatized people commonly feel terror, shame, helplessness, and powerlessness.

Trauma-informed care integrates an understanding of trauma into all aspects of service delivery and creates a culture of nonviolence, learning and collaboration. Working in a trauma-informed way does not necessarily require disclosure of trauma. Rather, the intention is that services are provided in ways that recognize a patient's potential need for physical and emotional safety, as well as choice and control in decisions affecting their treatment. When providing trauma-informed care, attention is paid to patient safety and empowerment, and this is reflected in the pharmacy's policies and procedures, as well as in how staff interact with patients. Safety is created in every interaction and confrontational approaches are avoided.⁶

2.3. Harm Reduction

Broadly defined, harm reduction refers to policies, programs, and practices that aim to reduce the adverse health, social and economic consequences of licit and illicit substance use without necessarily reducing or ceasing consumption.⁷ It is about meeting people where they are and identifying the goals they wish to achieve based on their individual needs and circumstances at a particular moment in time.

Pharmacy professionals are expected to respect the autonomy, values, and dignity of each patient and accept the patient's personal choices without applying moral judgements.

Beyond the provision of OAT medications, other ways that pharmacy professionals can practice harm reduction include:

- screening and offering immunizations for preventable illness (hepatitis A & B, influenza, etc.);
- educating on overdose prevention and treatment, including the emergency use of naloxone;
- educating on and assisting with the safe use of substances, including providing appropriate supplies;
- referral to an opioid/substance use disorder treatment or counselling program;
- referral to community harm reduction services, including needle distribution programs and supervised consumption services; or

⁶ "The Essentials of Trauma-Informed Care", Canadian Centre on Substance Abuse, 2014, <https://www.ccsa.ca/trauma-informed-care-essentials-series>

⁷ "What is harm reduction?" Harm Reduction International, 2023, <https://hri.global/what-is-harm-reduction/>

- referral to other community agencies that can provide food, shelter, clothing, and other necessities of life.

NALOXONE FOR EMERGENCY USE

Naloxone is an opioid antagonist which acts as an antidote to opioid poisoning. All patients who have been prescribed OAT medications should be offered a naloxone kit for possible emergency use and provided with relevant education on its use at regular intervals. Naloxone kits may also be offered to family members, patient agents, caregivers, and other individuals who may be in position to respond to an opioid poisoning.

More information on the use of naloxone can be found in CPNL's Guidance for the Provision of Emergency-Use Naloxone.⁸

3. TREATMENT CHOICES

Several options are currently used in Canada for the treatment of OUD, including methadone, sublingual buprenorphine-naloxone, extended-release buprenorphine injection, and slow-release oral morphine. The choice between these options will depend on several factors including (but not limited to):

- the degree of opioid dependence and tolerance experienced by the patient;
- an evaluation of the patient's risk of harm from the chosen therapy, including the risk of non-adherence;
- the patient's allergies, concomitant health conditions and comorbidities;
- patient preference, including past experiences with treatments;
- the potential for significant drug interactions with other concomitant therapies;
- the patient's ability to access the specialized services and expertise of an opioid dependence program;
- the patient's response to therapy;
- the patient's ability to afford the chosen therapy; and
- the patient's lifestyle and social history.

⁸ Available on the [Guidelines](#) page of the CPNL website.

4. EXPECTATIONS FOR PHARMACY PROFESSIONALS

Pharmacy professionals must have and maintain the necessary competency to participate in OUD treatment. This includes knowledge of:

- opioid use disorder;
- opioid toxicity;
- opioid withdrawal and its management;
- harm reduction treatment strategies;
- OAT medication options, including pharmacology, therapeutics, dosing, and overdose management;
- culturally competent care related to socioeconomic status, ethnicity, race, language;
- approaches for patient communication and support;
- the importance of inter-professional collaboration in treatment of OUD;
- community support and referral resources for OUD; and
- legislation, standards, and policies related to the provision of OUD treatment and OAT medications.

To meet this competency requirement, pharmacists and pharmacy technicians should complete education and training on OUD and its treatment that is appropriate to their scope of practice and practice site prior to participating in the provision of medications to treat OUD, and on an ongoing basis as their participation continues. See Appendix A for a selection of appropriate sources.

CONSIDERATIONS SPECIFIC TO EXTENDED-RELEASE BUPRENORPHINE INJECTION

Pharmacy professionals participating in the administration of extended-release buprenorphine injection must be authorized to administer injections in accordance with the Standards of Practice - Administration of Drug Therapy by Inhalation or Injection.⁹

5. OPERATIONAL STANDARDS

Pharmacists-in-charge of community pharmacies, or hospital pharmacies providing ambulatory OUD treatment services, must ensure that the following operational requirements are met:

⁹ Available on the [Standards](#) page of the CPNL website.

- a) *Pharmacy Layout and Design.* The pharmacy must be designed and laid out to allow for all patient discussions, witnessed doses and the provision of take-home doses to take place in a patient care environment that ensures visual and acoustical privacy and confidentiality and that is clean, safe, and comfortably furnished for the patient.

CONSIDERATIONS SPECIFIC TO EXTENDED-RELEASE BUPRENORPHINE INJECTION

If a pharmacy intends to offer extended-release buprenorphine injection services, they must also meet the operational requirements outlined in the Standards of Practice - Administration of Drug Therapy by Inhalation or Injection¹⁰ and ensure that the pharmacy's private consultation room is appropriately equipped with an examination table as this medication is to be administered to patients while in the supine position.

- b) *Hours of Operation.* When providing service to a patient who requires daily witnessed ingestion of OAT medications, the pharmacy's operating hours must accommodate these needs without compromising patient safety or causing undue hardship to the patient.

Pharmacists-in-charge at pharmacies that do not typically operate seven days a week must ensure that arrangements are made to enable the patient to access their medication on days the pharmacy is closed. This may include:

- opening at selected pre-scheduled times on the day(s) the pharmacy is closed to provide service to patients who require witnessed daily doses,
- discussing with the patient and prescribers the option of take-home doses (if appropriate for the patient) on days the pharmacy is closed, or
- collaborating with the patient, prescribers, and another pharmacy to arrange witnessed dosing at a secondary pharmacy on days that the primary pharmacy is closed (see section 8.1 for more information).

These limitations should be made clear to both the patient and prescribers prior to the start of OUD treatment so that discussions can be had, and an informed care plan established. Considering the challenges associated with some of these options, it may be in the patient's best interests to use another pharmacy which is able to accommodate the patient seven days per week.

- c) *Staff.* It is the responsibility of the pharmacist-in-charge to ensure that all pharmacists, pharmacy technicians and other support staff are appropriately educated and trained in

¹⁰ Available on the [Standards](#) page of the CPNL website.

the treatment of OUD and understand the scope of their role in the provision of OAT medications.

- d) *Policies and Procedures.* The pharmacy must develop, maintain, and regularly review policies and procedures related to the provision of OAT medications.
- e) *References and Resources.* The pharmacy must have an appropriate selection of clinical references to support the safe provision of OAT medications that are readily available to all dispensary staff. See Appendix A for a selection of sources.
- f) *Secure Storage of OAT Medications.* In accordance with section 1.8 b) of the *Standards of Pharmacy Operation - Community Pharmacy*¹¹ (SOPO-Community) or section 1.8 a) of the *Standards of Pharmacy Operation - Hospital Pharmacy (SOPO-Hospital)*, all narcotics and controlled drugs, including OAT stock medications and prepared doses must be stored securely.
- g) *Inventory Management.* In accordance with section 1.8 c) of the *SOPO-Community* or section 1.8 b) of the *SOPO-Hospital*, pharmacies must maintain a perpetual inventory - a continuous rolling count - of all narcotics, controlled drugs, benzodiazepines, and other targeted substances, including OAT medications. If it is not possible to maintain a computerized perpetual inventory record, a manual record must be maintained for each drug (see the sample templates attached in Appendix B).
- h) *Documentation and Retention Requirements.* All patient records required by these Standards, including prescriptions, compounding records, pick-up and release documentation, and documentation of consultations and communications, must be retained in the pharmacy in a secure, but readily accessible format for a minimum of ten years, in accordance with section 1.6 of the *SOPO-Community* or section 1.7 of the *SOPO-Hospital*. Additionally, section 3.4 b) of the *SOPO-Community* and section 3.1 c) i) of the *SOPO-Hospital* require that the patient record includes the identity of all staff members involved in prescription dispensing and checking processes.
- i) *Other.* The pharmacy must have a naloxone kit on-hand for emergency use and should also have additional kits available for patients who are taking OAT medications.

6. PRACTICE STANDARDS

This section applies to pharmacy professionals practicing in community pharmacies and in hospital pharmacies providing ambulatory OUD treatment services.

¹¹ Both Standards of Pharmacy Operation are available on the [Standards](#) page of the CPNL website.

6.1. Collaboration Between the Pharmacist and Other Members of the Care Team

Pharmacy professionals are expected to work collaboratively and effectively in the patient's best interest with members of the patient's care team. At the start of OUD treatment, a pharmacist should discuss the patient's current health status and treatment plan with the prescriber or another member of the OUD care team, as appropriate. Additionally, it is important to agree on how information about the patient's progress will be shared (including with regard to the management of lost or missed doses) and the best method for urgent and/or after-hours communication. If extended-release buprenorphine injection is being prescribed, the plan for administration of the injection should be confirmed with the prescriber in advance.

6.2. Collaboration Between the Pharmacist and the Patient

Pharmacy professionals are also expected to work collaboratively and effectively in the patient's best interest with the patient themselves. At the start of OUD treatment, a pharmacist should discuss the patient's treatment goals and care plan with them as well as ensuring that the patient understands the services that the pharmacy will provide, along with the obligations and expectations of both the pharmacy staff and the patient within this relationship.

The patient should be given the opportunity to ask questions, and relevant written information should be made available to supplement the discussion. Written documentation of this discussion may be helpful to clarify the roles, expectations and obligations of both parties and can prevent and/or address any misunderstandings that may occur in the future.

6.3. Assessing Prescriptions for OAT Medications

- a) *Prescription Requirements.*¹² In NL, prescriptions for OAT medications must be written on the required tamper-resistant form, in accordance with the Government of NL's Tamper Resistant Prescription Drug Pad Program.¹³ This is the case, regardless of whether the prescription is written by an in-province or out-of-province prescriber, except in

¹² While the College of Physicians and Surgeons of Newfoundland and Labrador has no specific criteria regarding a physician's eligibility to prescribe OAT medications, the College of Registered Nurses of Newfoundland and Labrador (CRNNL) has established specific criteria that nurse practitioners must meet before prescribing these medications. Pharmacy professionals wishing to confirm a nurse practitioner's eligibility to prescribe for OUD can do so using CRNNL's [Member Search](#)

¹³ "Tamper Resistant Prescription Drug Pad Program", Government of Newfoundland and Labrador, 2023, <https://www.gov.nl.ca/hcs/prescription/hcp-tamperresistantdrugpad/>

accordance with the subsection 56(1) class exemption issued by Health Canada in November 2021.¹⁴

In addition to the usual prescription requirements set out in section 3.3 a) of the *SOPO-Community*¹⁵ and section 3.2 a) of the *SOPO-Hospital*, prescriptions for OAT medications must also include the following information:

- i) the start date and end date of the prescription;
- ii) the medication dose, written in milligrams;
- iii) the induction schedule (if applicable);
- iv) the dosing regimen, including:
 - the days of the week that require witnessed ingestion (if applicable); and
 - the number of take-home doses authorized per week, and the take-home dose schedule, if applicable; and
- v) any special instructions or information pertaining to extraordinary situations.

If any of the above information is missing or unclear (e.g., the take-home dose schedule, the indication for OUD, etc.) the pharmacist must consult with the prescriber and appropriately document the discussion on the prescription and in the patient's health record.

- b) *Clinical Assessment.* Pharmacists are responsible for individually assessing patients and ensuring that the choice of medication, formulation, dosage, and dosage regimen prescribed is appropriate based on patient-specific factors such as concomitant medications or medical conditions, allergies, pregnancy status, or the risk of adverse effects. This includes assessing the provision of take-home doses, the scheduling of these doses and whether a witnessed dose is required when take-home doses are picked up.

Pharmacists are expected to refer to reputable sources of clinical information (see Appendix A) when performing this assessment.

If a pharmacist determines that the OAT medication as prescribed is inconsistent with these sources, or if they have concerns or information that they feel would affect the prescriber's decisions, they should consult with the prescriber and appropriately

¹⁴ "Subsection 56(1) class exemption for patients, practitioners and pharmacists prescribing and providing controlled substances in Canada", Health Canada, 2021, <https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/section-56-1-class-exemption-patients-pharmacists-practitioners-controlled-substances-covid-19-pandemic.html>

¹⁵ Both Standards of Pharmacy Operation are available on the [Standards](#) page of the CPNL website.

document the discussion in the patient's health record. This would apply to both the provision of witnessed and/or take-home doses.

6.4. Preparing and Labelling Buprenorphine Doses

- a) *Formulations.* Sublingual dosage forms of buprenorphine/naloxone are generally considered first-line treatment for OUD. Extended-release buprenorphine injection may be appropriate to enhance medication adherence and convenience for patients who are clinically stable.
- b) *Witnessed Doses of Buprenorphine/Naloxone.* Witnessed doses of sublingual buprenorphine/naloxone should be prepared in advance of administration and stored appropriately in a light-resistant vial labelled with:
 - i) patient's first and last name;
 - ii) prescriber's full name or first initial and last name;
 - iii) drug name and formulation;
 - iv) directions for use including the amount of drug to be consumed in a single dose;
 - v) total quantity contained in the bottle;
 - vi) prescription number;
 - vii) date of dispense; and
 - viii) quantity of medication (part-fills) remaining, if applicable.
- c) *Take Home Doses of Buprenorphine/Naloxone.* Generally, take-home doses of sublingual buprenorphine/naloxone should be dispensed in a light-resistant vial with a child-resistant cap and labelled in accordance with section 3.6 c) of the *SOPO-Community*¹⁶, including, at a minimum, the following cautionary/auxiliary labels:
 - i) "Keep out of reach of children"
 - ii) Special label such as: "*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.*"

The decision to dispense sublingual buprenorphine/naloxone in a single vial versus individual doses in multiple vials is dependent upon prescriber instruction and patient specific factors such as understanding of how to take the medication, ability to safely store multiple vials, patient preference, and demonstrated adherence. A pharmacist must confirm the patient's understanding of the dosing instructions prior to releasing take-home doses.

If sublingual buprenorphine/naloxone is being provided in compliance packaging, a pharmacist must ensure that the medication is handled appropriately and that the

¹⁶ Available on the [Standards](#) page of the CPNL website.

requirements of the Standards for the Provision of Compliance Packages¹⁵ are met in addition to the requirements of these Standards. In particular, patients must be cautioned that the packages are not child-safe and must be stored securely.

- d) *Doses of Extended-Release Buprenorphine Injection.* Doses of extended-release buprenorphine injection should be prepared in advance of administration, stored appropriately, and labelled in accordance with section 3.6 c) of the *SOPO-Community*¹⁴.

6.5. Preparing and Labelling Methadone Doses

- a) *Formulations.* Commercially available methadone liquids have been approved by Health Canada for the treatment of OUD. In NL, pharmacists are required to dispense a commercially available 10 mg/mL solution.

Compounded methadone solution may only be dispensed in cases of drug shortage where no Health Canada-approved product is available, or where a clinical reason, such as an allergy to a component of the commercially available product, exists. In these cases, a stock solution may be prepared and clearly labelled with the drug name, strength, use-by date and appropriate warning labels and a compounding log must be used to record the date the methadone stock solution was prepared, how much was prepared, and who prepared the product (see sample Compounding Log in Appendix C).

- b) *Preparing Doses of Methadone.* Equipment and devices used to measure methadone should have an accuracy of at least +/- 0.1 mL and be distinctively labelled and used exclusively for this purpose.

The manufacturer's instructions for the use of measuring devices must be followed, including proper use, cleaning, maintenance, and storage of the device and associated equipment or software. Any required device calibration or quality control processes used to monitor the integrity of the device must be documented in a readily retrievable manner.

To prepare the dose:

- i) measure the amount of 10 mg/mL methadone solution required for the individual dose;
- ii) transfer the measured solution to an amber, calibrated bottle;
- iii) add a sufficient quantity of an appropriate crystalline liquid (e.g., Tang) to bring the final volume of the dose to 100 mL to facilitate oral consumption and deter injection; and
- iv) document the preparation of the dose, including who performed the calculations, the preparation of the dose, and the final product check, in accordance with section 5. h).

In accordance with best practices, **methadone dose calculations and measurements should be independently double-checked** whenever possible.

SAFETY TIPS

- To prevent inefficiency, wasted doses, and errors associated with picking the wrong person's dose for administration, only the minimum number of doses necessary should be prepared for the next dispensing cycle.
- To avoid the potential for error, to optimize stability and sterility, and to avoid dose wastage, doses should only be prepared in advance for the next administration, whenever possible.
- Effectively performing an independent double-check requires two people to separately check each component of the work process and the person asking for the double-check must not influence the individual performing the double-check in any way. Two people are less likely to make the same mistake if they work independently and people are generally better at detecting the errors of others than their own errors. Ideally, both people performing the checks are regulated pharmacy professionals, but, if not possible, a pharmacy assistant may participate in this task.
- If an independent double-check is not possible, separating the dose measurement and final check by time (prior to diluting the dose) may be helpful in preventing errors from reaching patients.

- c) *Witnessed Doses.* Witnessed doses of methadone must be prepared in a light-resistant bottle and be individually labelled with:
- i) patient's first and last name;
 - ii) prescriber's full name or first initial and last name;
 - iii) drug name and formulation;
 - iv) directions for use including the amount of drug to be consumed in a single dose;
 - v) total quantity contained in the bottle;
 - vi) prescription number;
 - vii) date of dispense; and
 - viii) quantity of medication (part-fills) remaining, if applicable.
- d) *Take Home Doses.* Take-home doses of methadone must be prepared in a light-resistant bottle with a child- and tamper-resistant cap and be individually labelled with:
- i) pharmacy name, phone number and street address (if available, or, if not, a way of uniquely identifying the pharmacy location);
 - ii) patient's first and last name;

- iii) prescriber's full name or first initial and last name;
- iv) drug name and formulation;
- v) directions for use including:
 - the amount of drug to be consumed in a single dose;
 - specific instructions such as "Consume the entire contents of this bottle on (insert date).";
- vi) total quantity contained in the bottle;
- vii) prescription number;
- viii) date of dispense;
- ix) quantity of medication (part-fills) remaining, if applicable; and
- x) at a minimum, the following cautionary/auxiliary labels:
 - "Keep out of reach of children"
 - "Keep Refrigerated"
 - "Do Not Consume After ___"
 - Special label such as: *"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."*

DILUTION, REFRIGERATION AND BEYOND-USE DATES

- Once doses are diluted, they must be refrigerated.
 - When assigning beyond-use dates (BUD) for diluted methadone doses, best practices and reputable sources must be utilized to assign a BUD that take storage conditions, stability, and sterility into consideration.
 - The BUD should be based on the earliest expiry of the ingredients used or 14 days refrigerated, whichever comes first. Dilution with fruit juices may require a shorter dating as an opened juice bottle may have a best before date that is earlier than 14 days.
- e) *Documentation.* All methadone doses must be individually recorded in the patient's medication profile. By processing each dose as an individual transaction, each dose label will accurately indicate the amount of methadone contained in each bottle and the patient's medication record will be clear with regard to the prescribed methadone dose, dispense dates, and number of take-home doses provided.

6.6. Preparing and Labelling Slow-Release Oral Morphine Doses

- a) *Formulations.* Once-daily (24-hour), slow-release formulations of oral morphine are a third-line option for OUD when buprenorphine and methadone are ineffective, contraindicated, or refused by the patient. Other formulations of oral morphine, including twice-daily, 12-hour, or other extended-release formulations, have not been empirically studied for OUD and are therefore **not** recommended for this indication.
- b) *Witnessed Doses.* Witnessed doses of slow-release oral morphine should be prepared in advance of administration and stored appropriately in a light-resistant vial labelled with:
 - i) patient's first and last name;
 - ii) prescriber's full name or first initial and last name;
 - iii) drug name and formulation;
 - iv) directions for use including the amount of drug to be consumed in a single dose and the indication for OUD;
 - v) total quantity contained in the bottle;
 - vi) prescription number;
 - vii) date of dispense; and
 - viii) quantity of medication (part-fills) remaining, if applicable.
- c) *Take Home Doses.* Generally, take-home doses of slow-release oral morphine should be dispensed in a light-resistant vial with a child-resistant cap and labelled in accordance with section 3.6 c) of the *SOPO-Community*¹⁷, including, at a minimum, the following cautionary/auxiliary labels:
 - i) "Keep out of reach of children"
 - ii) Special label such as: "*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.*"

The decision to dispense slow-release oral morphine in a single vial versus individual doses in multiple vials is dependent upon prescriber instruction and patient specific factors such as understanding of how to take the medication, ability to safely store multiple vials, patient preference, and demonstrated adherence. A pharmacist must confirm the patient's understanding of the dosing instructions prior to releasing take-home doses.

If slow-release oral morphine is being provided in compliance packaging, a pharmacist must ensure that tablets are handled safely and that the requirements of the Standards for the Provision of Compliance Packages are met in addition to the requirements of

¹⁷ Available on the [Standards](#) page of the CPNL website.

these Standards. In particular, patients must be cautioned that the packages are not child-safe and must be stored securely.

6.7. Releasing Witnessed Doses of OAT Medications

a) *Clinical Assessment and Consultation.* Prior to releasing each witnessed dose of OAT medication to the patient, a pharmacist must first:

- i) Determine that it is safe and appropriate to provide the prescribed medication and dose. This can be accomplished using a combination of:
 - information obtained from the patient;
 - review of the patient's local and provincial electronic health record profiles;
 - review of the patient's Medication Administration Log (see sample in Appendix D); and
 - any other applicable information.

If a drug therapy problem (e.g., unexplained dosage change, drug interaction or contraindication) is detected, the pharmacist is expected to consult with the prescriber prior to releasing the medication and appropriately document the discussion in the patient's health record.

- ii) Positively identify the patient, including using at least two patient identifiers and/or an independent double check, where possible. If uncertain as to the patient's identity, the pharmacist should request photo identification or collaborate with other members of the patient's care team to validate their identity.
- iii) Screen the patient for signs of intoxication or sedation (see section 7.2). If it is determined that the patient is intoxicated or sedated, the pharmacist must withhold the dose and consult with the prescriber.
- iv) Provide the patient with appropriate consultation regarding the use of the OAT medication (upon initiation of treatment and as necessary, thereafter). The information provided should be appropriate to the medication and the specific patient circumstances and include, but not be limited to:
 - side effects and treatment expectations, including the potential risks associated with sedation;
 - symptoms of opioid withdrawal and overdose including the importance of having a naloxone kit on-hand at all times;
 - if receiving witnessed doses or administered doses, the importance of arriving at the pharmacy around the same each day and not missing doses; and

- the risk for potential interactions with prescribed or non-prescribed medications, alcohol or other sedating substances when used in combination with the medication.

CONSIDERATIONS SPECIFIC TO EXTENDED-RELEASE BUPRENORPHINE INJECTION

- Doses of extended-release buprenorphine injection must either be administered in the pharmacy or released to the prescriber or other authorized administering health professional. Doses may not be released to a patient or a patient's agent.
- If the injection is being administered in the pharmacy, pharmacy professionals participating in the administration must do so in accordance with the Standards of Practice - Administration of Drug Therapy by Inhalation or Injection.¹⁸

- b) *Witnessing Patient Self-Administration.* Once a pharmacist has completed the assessment and consultation described in section 6.7 a), and has determined that it is appropriate for a patient to receive the witnessed dose,;
- i) the pharmacist may witness the patient self-administering the dose of medication themselves; or
 - ii) a pharmacy technician may witness the patient self-administering the dose.

Prior to self-administering the medication, the patient should be asked to review the medication label and confirm that their name and dose is correct.

Once the dose has been self-administered, appropriate documentation on the patient's Medication Administration Log should be completed, including obtaining the patient's signature (see sample in Appendix D).

CONSIDERATIONS SPECIFIC TO BUPRENORPHINE/NALOXONE

Clinical judgement applies with respect to monitoring the degree of dissolution of the dosage form. The need to ensure a fully dissolved dosage form may not be required for all patients. Semi-dissolved dosage forms are more difficult, although not impossible, to divert.

¹⁸ Available on the [Standards](#) page of the CPNL website.

CONSIDERATIONS SPECIFIC TO METHADONE

When observing the ingestion of methadone, the pharmacy professional must ensure that the liquid dose has been swallowed and the patient must speak to ensure swallowing has occurred.

CONSIDERATIONS SPECIFIC TO SLOW-RELEASE ORAL MORPHINE

Crushing, chewing, or dissolving slow-release oral morphine capsules or pellets can cause rapid release and absorption of a potentially fatal dose of morphine, therefore the pharmacy professional must observe the patient swallowing the intact pellets, whether sprinkled on applesauce, pudding or similar. Drinking water after the pellets helps to ensure all pellets are ingested.

6.8. Releasing Take-Home Doses of OAT Medications

- a) *Clinical Assessment and Consultation.* Prior to releasing take-home doses of OAT medication to the patient, a pharmacist must first:
- i) Determine that it is safe and appropriate to provide the prescribed medication and doses. This can be accomplished using a combination of:
 - information obtained from the patient;
 - review of the patient's local and provincial electronic health record profiles;
 - review of the patient's Medication Administration Log (see sample in Appendix D); and
 - any other applicable information.

If a drug therapy problem (e.g., unexplained dosage change, drug interaction or contraindication) is detected, the pharmacist is expected to consult with the prescriber prior to releasing the medication and appropriately document the discussion in the patient's health record.

- ii) Positively identify the patient, including using at least two patient identifiers and/or an independent double check, where possible. If uncertain as to the patient's identity, the pharmacist should request photo identification or collaborate with other members of the patient's care team to validate their identity.
- iii) Screen the patient for signs of intoxication or sedation (see section 7.2). If it is determined that the patient is intoxicated or sedated, the pharmacist must consider whether they should withhold the dose and consult with the prescriber.

- iv) Provide the patient with appropriate consultation regarding the use of the OAT medication (upon initiation of treatment and as necessary, thereafter) and, specifically, the appropriate use and storage of take-home doses. The information provided should be appropriate to the medication and the specific patient circumstances and include, at a minimum:
- side effects and treatment expectations, including the potential risks associated with sedation;
 - symptoms of opioid withdrawal and overdose and the importance of having a naloxone kit on-hand at all times;
 - the risk for potential interactions with prescribed or non-prescribed medications, alcohol or other sedating substances when used in combination with the medication;
 - the proper storage of the doses at home, including the use of a locked box, locked cupboard, etc. and the need for refrigeration, if applicable;
 - how and when to take their doses, including instructions to consume the entire dose, as prescribed and dispensed;
 - instructions to call for emergency assistance immediately if their medication is ingested by another person;
 - the expectation for take-home dose bottles to be returned to the pharmacy (see below); and
 - advising the patient of any audit expectations including that they may be asked at any time to return to the pharmacy with their remaining take-home doses.

BOTTLE RETURN

- Patients must be advised ahead of time of the expectation to return their empty bottles with the original labels intact to the pharmacy at their next visit. Return of take-home dose bottles should be recorded on the patient's Medication Administration Log (see sample in Appendix D).
- Returned bottles must never be reused, even for the same patient.
- Returned bottles must be disposed of in a manner that protects the public from diversion of any medication remaining in the bottle and maintains patient confidentiality. If bottles are disposed of offsite from the pharmacy, they must be rinsed of any medication and have patient labels removed.

- b) *Providing the Take-Home Doses.* Once a pharmacist has completed the assessment and consultation described in section 6.8 a), and has determined that it is appropriate for a patient to receive the take-home doses:

- i) the pharmacist may provide the patient with the take-home doses themselves; or
- ii) a pharmacy technician may provide the patient with the take-home doses.

Prior to the release of the doses, the patient should be asked to review the medication labels and confirm that their name, dose, and the number of take-home doses is correct.

Finally, appropriate documentation on the patient's Medication Administration Log should be completed, including obtaining the patient's signature (see sample in Appendix D).

PICKING UP TAKE-HOME DOSES

Usual practice would be for take-home doses to be picked up by the patient personally and not by an agent on their behalf. In extenuating circumstances, where it is not possible or practical for the patient to attend the pharmacy in person, and the pharmacist, in collaboration with the patient's OUD care team, determines that the benefits of providing the take-home doses to the patient's agent outweigh the risks to the patient and the public, the take-home dose may be released to the patient's agent.

- c) *Monitoring Compliance with Take-Home Doses.* A patient's compliance with take-home doses may be monitored in several ways including by conducting a take-home dose audit. If take-home dose audits are utilized, patients must be advised ahead of time that they may be asked at any time to return to the pharmacy with the remainder of their take-home doses and empty bottles. If such audits are conducted, appropriate documentation should be retained.

If there are issues of concern with the patient's compliance with their take-home doses or evidence of diversion, the pharmacist should consult with the prescriber as soon as possible.

7. RESPONDING TO SPECIAL CIRCUMSTANCES

7.1. Delivery of OAT Medications

- a) *Appropriateness.* If a patient is unable to attend the pharmacy due to extenuating circumstances (such as short-term illness, public health emergency, or transportation issues), OAT medications may be delivered to the patient in accordance with section 2.2

of the *SOPO-Community*¹⁹, the *Controlled Drugs and Substances Act*, and related guidance from Health Canada²⁰.

The prescriber must be consulted to determine if an assessment and witnessed ingestion is required and the consultation must be appropriately documented in the patient's health record.

PLEASE NOTE

If a patient requires assessment and witnessed ingestion, a pharmacist or other appropriate health professional (e.g., nurse with appropriate training, nurse practitioner or physician with this scope of practice) must deliver the dose.

For patients who do not require assessment and witnessed dosing, the qualifications of the person carrying out the delivery must be determined by the pharmacist-in-charge of the pharmacy.

- b) *Procedures*. For all deliveries of OAT medications, the pharmacist-in-charge must ensure that procedures are in place to ensure that:
- i) pharmacists understand the expectations on them both if they are making the delivery themselves and if they are delegating the delivery to another individual;
 - ii) the delivery process is explained to the patient ahead of time with consent being obtained verbally;
 - iii) the packaging and labelling of the OAT medication is consistent with that used for take-home doses;

¹⁹ Available on the [Standards](#) page of the CPNL website.

²⁰ Guidance includes:

"Transportation of Controlled Substances in Canada", Health Canada, 2022, <https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/transportation-of-controlled-substances-in-canada.html>

"Subsection 56(1) class exemption for patients, practitioners and pharmacists prescribing and providing controlled substances in Canada", Health Canada, 2021, <https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/section-56-1-class-exemption-patients-pharmacists-practitioners-controlled-substances-covid-19-pandemic.html>

"Subsection 56(1) Class Exemption for the Person in Charge of a Hospital and/or a Pharmacist who Supplies Controlled Substances to a Community Health Facility", Health Canada, 2019, <https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/subsection-56-class-exemption-person-in-charge-hospital-pharmacist-controlled-substances-community-health-facility.html>

- iv) the delivery is appropriately documented; and
 - v) the administration is appropriately documented, or, in the event a person other than a pharmacist or health professional delivers the dose, there is documentation that a pharmacy staff member followed-up with the patient to confirm that the dose was delivered untampered, and that the patient has consumed and/or safely stored their dose(s).
- c) *Delegation*. If a pharmacist delegates delivery to another individual, they must provide the person carrying out the delivery with:
- i) written authorization to deliver the medications that includes the names of people to whom they are delivering and the pharmacy contact information;
 - ii) a copy of the Health Canada Subsection 56(1) Class Exemption; and
 - iii) clear instructions so that:
 - they know who they are authorized to release the medication to and the process for identifying the individual (i.e., checking photo identification);
 - the dose is returned to the pharmacy as soon as possible if release to the patient or authorized person is not possible (doses cannot be left at the door); and
 - medication deliveries are never left unattended.

7.2. Intoxication or Sedation

When assessing a patient for intoxication or sedation, pharmacists should:

- consider the patient's general demeanor and behaviour in comparison to what they know as their usual behaviour;
- ask the patient to remove sunglasses and observe their eyes for pin-point pupils, alertness, or sedation;
- talk to the patient, asking questions to determine if they are slurring or incoherent;
- ask the patient to walk to the counter and observe their gait; and
- assess for the smell of alcohol.

If there is evidence of intoxication or sedation, the pharmacist must withhold the patient's dose, the prescriber should be consulted, and the consultation appropriately documented in the patient's health record. If the pharmacist cannot reach the prescriber, they may use their professional judgement to determine whether it is appropriate to have the patient come back later in the day to reassess for intoxication and safety of providing the medication, and document and notify the prescriber accordingly. It is generally safer to refuse to dispense a dose of OAT medication, than to medicate an intoxicated patient.

7.3. Partial Consumption of Witnessed Doses

If a patient declines or is unable to consume their full witnessed dose, the patient's choice must be respected. The unconsumed portion cannot be given as a take-home dose. The partial consumption of the dose and the reasons for it must be documented, and, depending on the medication and the potential need to reassess the patient's dosage, a pharmacist should consult with the prescriber or another member of the OUD care team in a timely manner.

7.4. Missed Doses

Pharmacists must be familiar with clinical practice guidelines regarding how to handle missed doses of OAT medications and when prescriber consultation, dosage adjustment and a new prescription is necessary.

If a patient misses a dose of OAT medication, a pharmacist must use their professional judgement to determine when it is necessary to consult with the prescriber or another appropriate member of the OUD care team to assess whether the current prescription should be held or cancelled and the appropriateness of prescribed doses upon re-initiation.

PLEASE NOTE

Any dose of OAT medication that has been processed and prepared but is not consumed or picked-up by the patient on the prescribed day must be cancelled and reversed on the Pharmacy Network before the end of the business day. It is imperative that the patient's provincial electronic health record reflects accurate and current information in terms of consumed and picked-up doses as other health care providers should be able to rely on this information when making treatment decisions.

7.5. Vomited Doses

Pharmacists must be familiar with clinical practice guidelines regarding how to handle vomited doses.

If a patient vomits a sublingual **buprenorphine/naloxone** dose, no replacement dose is needed because vomiting has no impact on the effectiveness of the medication as it is absorbed from under the tongue.

If a patient vomits a **methadone** or **slow-release oral morphine** dose, a pharmacist would not be able to prescribe a replacement dose in this situation as replacement of vomited doses of these medications often require a dose adjustment (i.e. a lesser dose) and a clinical consultation with the OAT prescriber. The pharmacist must provide the prescriber with information about the incident (time the dose was taken, time of vomiting, and other relevant points) to aid in decision-making regarding dose replacement.

7.6. Lost or Stolen Doses

If a patient reports that their take-home doses have been lost, stolen, or misplaced, replacement doses must not be provided. A pharmacist must notify and consult with the prescriber. If the prescriber chooses to authorize a replacement dose, a new prescription must be received by the pharmacy.

7.7. Administration or Dosing Errors

In the event of a confirmed or suspected medication, administration, or dosing error, a pharmacist must take appropriate and necessary action to minimize harm to the patient, including prompt consultation with the patient's other health care providers to determine appropriate actions to be taken. The error should also be appropriately reported in accordance with established policies and procedures.

7.8. Discontinuation of OUD Treatment

Even though the efficacy of long-term OUD treatment is well recognized, a patient may eventually decide to discontinue therapy. In general, the decision to discontinue and the medication taper should be guided by the patient. When assessing tapering doses of OAT medications, pharmacists are expected to refer to reputable sources of clinical information (see Appendix A) and consider patient-specific factors. If doses are inconsistent with these sources, the pharmacist should consult with the prescriber and appropriately document the discussion in the patient's health record.

8. ENSURING CONTINUITY OF CARE

8.1. Secondary Pharmacy

If a patient requires daily witnessed ingestion, but the pharmacy is not normally open seven days a week, the pharmacist-in-charge may collaborate with the patient, prescriber, and another pharmacy to arrange witnessed dosing at a secondary pharmacy on days that the primary pharmacy is closed.

These cases require intentional and well-documented communication between the pharmacies, as well as with the patient and the prescriber, to mitigate risk associated with dosing errors or missed doses. Both pharmacies are responsible for confirming the quantity and time of last dose ingested at their location. This information must be documented on administration logs.

8.2. Guest Dosing

Guest dosing refers to situations, such as a vacation or business travel, when a patient taking an OAT medication may ask to temporarily receive their OAT medication at another pharmacy.

Such situations generally arise when it is not advisable or practical for the patient to be provided with take-home doses for the given time period.

Pharmacists at both pharmacies must communicate clearly with one another at the beginning and end of the guest dosing period, so that everyone understands where and when the patient is receiving the medication. This communication is imperative to prevent double-dosing or missed dosing and must be documented in the patient's administration record at both the home pharmacy and the guest pharmacy.

8.3. Providing Care to Residents of Personal Care Homes or Long-Term Care Facilities

Providing OAT to patients residing in personal care homes or long-term care facilities requires special consideration, policies and procedures, and care planning. The requirements of these standards and standards for *The Provision of Pharmaceutical Care to Long-Term Care Facilities* and *The Provision of Pharmaceutical Care to Personal Care Homes*²¹, along with the patient's need for access to necessary medications and continuity of care must be considered.

In addition to their own policies and procedures, pharmacists-in-charge who provide OAT medications to patients residing in personal care homes must support the development of specific policies and procedures for safe storage, handling, and administration of OAT medications within the homes. Processes for providing OAT medications in a PCH or LTC facility should be aligned with these Standards to the extent possible. PCH and LTC facilities should only have a minimum amount of prepared OAT doses on hand, and pharmacies should only provide the minimum number of doses necessary to ensure continuity of care. Delivery of OAT medications to the home must be carried out in accordance with section 7.1.

With respect to witnessed dosing, if a pharmacist is not able to visit a PCH or LTC facility to provide witnessed dosing, they must consult with the patient's OAT prescriber and staff at the PCH or LTC facility to determine whether there is an appropriate person at the home to perform patient assessment and witnessed dosing. Generally, only a health care professional with the scope of practice to support patient assessment (e.g., pharmacist, nurse, nurse practitioner, physician) should provide witnessed doses. If there is not a suitable health care professional on staff and a pharmacist cannot visit the home to provide witnessed doses, then the prescriber should be consulted on a per-patient basis to determine whether it is safe to provide the patient with OAT medication without patient assessment, and the specific plan for administration of doses should be documented in each patient's record.

8.4. Health Canada Subsection 56(1) Class Exemption

- a) *Prescription Transfers*. In accordance with the subsection 56(1) class exemption issued by Health Canada in November 2021²², prescriptions for controlled substances, including

²¹ Available on the [Standards](#) page of the CPNL website.

²² "Subsection 56(1) class exemption for patients, practitioners and pharmacists prescribing and providing controlled substances in Canada", Health Canada, 2021, <https://www.canada.ca/en/health->

methadone, buprenorphine, and SROM, may be transferred to another pharmacy providing that all of the requirements outlined in the exemption are met. Pharmacists must be familiar with the exemption documents and NLPB Standards of Pharmacy Operation and ensure documentation requirements are fully met.

In these situations, it is critical for the pharmacy assuming the patient's care to collect pertinent details about the patient's care plan and dosing history. In addition, the prescriber should be advised of the change in pharmacy and the reason for such.

- b) *Pharmacist Prescribing*. Pharmacists who are authorized by NLPB to prescribe may prescribe interim supplies of, or extend prescriptions for, OAT medications to provide continuity of care to patients in accordance with the subsection 56(1) class exemption issued by Health Canada in November 2021²³, and the *Standards of Practice-Prescribing by Pharmacists*²⁴. In these cases, pharmacists should:
- i) consult with the primary OAT prescriber regarding continuation of therapy, wherever possible;
 - ii) prescribe only for the minimum duration necessary in the circumstance; and
 - iii) if clinical stability is a concern, only continue the original prescription one day at a time, reassessing the risks versus overall benefits to the patient each day, until they can reach the prescriber.

Pharmacists may not initiate take-home doses or change the number of take-home doses; they may only continue OAT prescriptions as originally prescribed.

Pharmacists may not adapt prescriptions for OAT medications as this is, is beyond the scope of the subsection 56(1) class exemption and provincial regulations related to prescribing.

If a pharmacist is providing an interim supply for or extending a prescription for an OAT medication that was originally dispensed at another pharmacy, the pharmacist should speak directly with a pharmacist at the original pharmacy to collect relevant details regarding the patient's care plan and dosing history. If this is not possible (e.g., the pharmacy is closed), the pharmacist must base prescribing and dispensing decisions on

[canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/section-56-1-class-exemption-patients-pharmacists-practitioners-controlled-substances-covid-19-pandemic.html](https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/section-56-1-class-exemption-patients-pharmacists-practitioners-controlled-substances-covid-19-pandemic.html)

²³ "Subsection 56(1) class exemption for patients, practitioners and pharmacists prescribing and providing controlled substances in Canada", Health Canada, 2021, <https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/section-56-1-class-exemption-patients-pharmacists-practitioners-controlled-substances-covid-19-pandemic.html>

²⁴ Available on the [Standards](#) page of the CPNL website.

the best information available (i.e., HEALTHe NL, consultation with the patient and prescriber, if possible) while prioritizing the patient's safety and best interests.

8.5. Continuity of Care During Hospitalization²⁵

- a) *Pre-Admission.* If known ahead of time that a patient who is taking an OAT medication is going to be admitted to hospital (e.g., for a scheduled surgery or procedure), staff at the community pharmacy should attempt to contact staff at the hospital pharmacy to initiate transition of care planning prior to the patient being admitted to the hospital.
- b) *Admission.* When a patient who is taking an OAT medication is admitted to hospital or visits an emergency/outpatient department, pharmacists, and other health care providers at the institution, must coordinate with the patient's prescriber and staff at the community pharmacy to ensure that care is uninterrupted but remains optimal, safe, and effective. This includes ensuring that appropriate information is obtained from both the community pharmacy and also from the patient, as appropriate.
- c) *Assessment of Prescriptions and Preparation of Doses.* Prescriptions for OAT medications should be assessed in accordance with section 6.3. Witnessed doses of OAT medications must be prepared in accordance with sections 6.4, 6.5 and 6.6. The institution should use its own supply of medications, even if a patient has brought in their own take-home doses.
- d) *Distribution of Doses.* Whenever possible, OAT medications should be dispensed to the patient care area as individual patient-specific doses each day.
- e) *Storage.* Prepared doses of OAT medications must be stored in both the pharmacy and patient care areas in a manner that meets the security requirements outlined in section 5) f). Specifically, if they are to be stored in a patient care area, prepared methadone doses must be stored in a locked refrigerator. If the patient care area does not have a locked refrigerator, doses must be stored in another secure location until administration.
- f) *Witnessed Ingestion.* In a hospital setting, witnessing the ingestion of OAT medications may be carried out by pharmacists or other qualified health care providers (e.g., nurses, physicians). The hospital's established policies and procedures for the administration of OAT medications must be aligned with these Standards and recognized clinical practice guidelines.
- g) *Inpatient Leave of Absence (Pass) Medications.* If the patient did not have take-home privileges prior to admission, the patient should not be provided with take-home doses as part of a leave of absence (pass) medications. Alternatives to take-home doses might be:

²⁵ This section is specific to the provision of OAT medications to acute care patients. As per section 2.5 of the Standards of Pharmacy Operation – Hospital Pharmacy, service to ambulatory patients must be performed in accordance with the Standards of Pharmacy Operation – Community Pharmacy.

- return to the hospital for daily dosing;
- daily dosing at the usual community pharmacy; or
- daily dosing at another pharmacy close to where the patient will be staying during the pass (see Guest Dosing in section 8.2).

If the patient usually receives take-home doses, it is best to consult with the usual community prescriber regarding the suitability of take-home dose during the leave of absence.

h) *Pre-Discharge.* Before discharge, hospital pharmacy staff are expected to communicate with the patient's usual community prescriber and/or staff at the community pharmacy to ensure that the patient has a valid and appropriate prescription for their OAT medication at a community pharmacy. This discussion should include:

- the date of discharge;
- whether a prescription for OAT medication was given to the patient when discharged;
- whether any changes were made to the patient's OAT medication during the stay in the hospital, and what the current medication and dose is, and;
- when the last dose was given in the hospital, and whether any take-home doses were dispensed, destroyed, or returned.

PLEASE NOTE

Prescriptions being written to be presented to a community pharmacy must be written in accordance with the Provincial Tamper Resistant Drug Pad Program as noted in section 6.3 a).

i) *Post-Discharge.* While it is expected that a hospital pharmacist has communicated pertinent information in advance, if a patient presents to a community pharmacy, and there is no record of information being received from the hospital pharmacy, a pharmacist is responsible for ensuring that they have the appropriate information required prior to re-initiating the provision of OAT medication to the patient, which may include contacting the hospital pharmacy department, to obtain the information detailed in section 8.5 h).

8.6. Continuity of Care During Incarceration

Treatment should not be disrupted if a patient taking an OAT medication is incarcerated. In these situations, the effective sharing of information between members of the patient's care team and correctional facility staff is critically important for patient safety and continuity of care both when the patient enters and leaves the facility.

Pharmacy professionals should be familiar with up-to-date practice guidelines and best practices for the provision of OAT medications in correctional facilities to help inform policies and procedures related to this area of service.

9. ACKNOWLEDGEMENTS

Development of this Standard of Practice involved a review of best practice documents, including:

- "A Guideline for the Clinical Management of Opioid Use Disorder", British Columbia Centre on Substance Use, 2017, http://www.bccsu.ca/wp-content/uploads/2017/06/BC-OUD-Guidelines_June2017.pdf
- "National Guidelines for the Clinical Management of Opioid Use Disorder", Canadian Research Initiative in Substance Misuse, 2018, <https://crism.ca/projects/opioid-guideline/>
- "Nurse Practitioner Authority to Prescribe Buprenorphine-Naloxone and/or Methadone for Opioid Use Disorder", College of Registered Nurses of Newfoundland and Labrador, 2021, <https://crnnl.ca/site/uploads/2021/09/np-authority-to-prescribe-for-opioid-use-disorder.pdf>
- "Opioid Agonist Maintenance Treatment, 3rd edition", Centre for Addiction and Mental Health, 2015, <https://store-camh.myshopify.com/products/p6500>
- "Opioid Agonist Therapy: A Synthesis of Canadian Guidelines for Treating Opioid Use Disorder", Centre for Addiction and Mental Health, 2021, <https://www.camh.ca/-/media/files/professionals/canadian-opioid-use-disorder-guideline2021-pdf.pdf>
- "Opioid Agonist Therapy Guidelines for Manitoba Pharmacists", College of Pharmacists of Manitoba, 2023, <https://cphm.ca/wp-content/uploads/Resource-Library/Opioid-Agonist-Therapy/OAT-Guidelines-May-1-2023-approved.pdf>
- "Opioid Agonist Therapy Guidelines: Medication-Assisted Treatment for Opioid Use Disorder: Guidelines for Pharmacists and Pharmacy Technicians", Alberta College of Pharmacy, 2022, https://abpharmacy.ca/wp-content/uploads/Guidelines_OAT.pdf
- "Opioid Agonist Therapy (OAT) Standards", Saskatchewan College of Pharmacy Professionals, 2020, https://www.saskpharm.ca/document/5871/REF_OAT_Standards.pdf
- "Opioid Prescribing for Opioid Use Disorder", College of Physicians and Surgeons of Newfoundland and Labrador, 2022, <https://cpsnl.ca/wp-content/uploads/2023/03/Opioid-Prescribing-for-Opioid-Use-Disorder-2022.pdf>
- "Opioid Use Disorder: Practice Update", British Columbia Centre on Substance Use, 2022, <https://www.bccsu.ca/wp-content/uploads/2022/02/Opioid-Use-Disorder-Practice-Update-February-2022.pdf>

- "Practice Directive: Opioid Agonist Treatment (OAT)", New Brunswick College of Pharmacists, 2022, <https://nbpharmacists.ca/opioid-agonist-treatment-practice-directive-oat/>
- "Standards of Practice: Opioid Agonist Maintenance Treatment Services", Nova Scotia College of Pharmacists, 2022, https://www.nspharmacists.ca/wp-content/uploads/2017/07/SOP_OpioidAgonistMaintenanceTreatmentServices.pdf

APPENDIX A

Recommended Resources and Sources of Education and Training

[British Columbia Centre on Substance Use \(BCCSU\)](#)

[Canadian Research Initiative in Substance Misuse \(CRISM\)](#)

[The Centre for Addiction and Mental Health \(CAMH\)](#)

[College of Physicians and Surgeons of Newfoundland and Labrador \(CPSNL\)](#)

[College of Registered Nurses of Newfoundland and Labrador \(CRNNL\)](#)

[Mentoring, Education and Clinical Tools for Addiction: Partners in Health Integration \(META:PHI\)](#)

[National Harm Reduction Coalition](#)

[Newfoundland and Labrador Centre on Substance Use](#)

APPENDIX B

Methadone Perpetual Inventory Record and Dose Preparation Log

Staff Name (please print)	Initials (for file)	Staff Name (please print)	Initials (for file)	Notes

Date	Methadone 10 mg/ml Lot & Expiry Date	Patient Name	Amt(mg) of methadone Per bottle	Diluent Used	# of doses	Total QTY Methadone 10 mg/ml used (ml)	Adjustments to inventory (Reasons for any Adjustment must be clearly noted)	QTY of methadone 10 mg/ml remaining in inventory	First Check (Initials)	Final Check (RPh or RPt initials)
							Starting Inventory			

