

Newfoundland and Labrador Pharmacy Board Standards of Practice



**Standards for the Safe and Effective Provision of
Opioid Agonist Maintenance Treatment**

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1) Introduction

Opioid use disorder is a chronic and relapsing illness that is associated with elevated levels of morbidity and mortality (BCCSU, 2017). The Government of Canada has indicated that the growing number of overdoses and deaths caused by opioids is a public health emergency. The cost of this illness to the individual and to society is significant; opioid use disorder is often associated with a severe decline in the individual's physical and psychological health, unemployment, family disruption, and participation in criminal activities. Opioid use disorder is a complex health and social issue that requires a comprehensive, collaborative, compassionate and evidence-based treatment approach (Government of Canada, 2018).

Although opioid use disorder is associated with higher rates of morbidity and mortality, individuals can achieve sustained long-term remission with appropriate treatments (BCCSU, 2017). The goal of a treatment program for opioid use disorder should be to provide broad access to effective treatments. Clinical practice guidelines strongly recommend against a treatment strategy involving withdrawal management alone (without plans for transition to long-term evidence-based medication-assisted treatment) because this approach has been associated with nearly universal relapse and, subsequently, elevated risk of unsafe drug use and/or overdose in comparison to no treatment provision (CRISM, 2018). However, treatment approaches should be continually evaluated over time, and treatment choice and intensity continually adjusted to match individual patient circumstances and preferences (CRISM, 2018).

OAMT is based on harm reduction and serves to bring normal functioning back to an individual. According to the Centre for Addiction and Mental Health (CAMH):

Harm reduction refers to policies, programs and practices that aim to reduce drug-related harm without requiring the person to stop using the substance. Harm reduction strategies aim to reduce drug related harms not just for the user, but also for families, friends, and communities. The approach is based on the belief that it is in both the user's and society's best interest to minimize the adverse consequences of drug use when the person is unable or unwilling to discontinue using.

The benefits of OAMT can be physiological, psychological, and social. Treatment success is not contingent on an individual being able to eventually stop OAMT and remain abstinent from opioids. According to CAMH, when the goals of treatment retention and abstinence appear to be in conflict, it is more beneficial to prioritize treatment retention and withdrawal management. When used as part of a maintenance program, methadone and buprenorphine/naloxone cause little to no euphoric effect but enable suppression of the withdrawal symptoms and cravings experienced in opioid addiction that often contribute to relapse.

Pharmacy professionals are key to OAMT access. A pharmacy team's decision to provide OAMT services requires thoughtful consideration of professional ethics as well as the capacity of the pharmacy to undertake the associated activities safely and effectively.

Collaboration between health professionals is also critical to the success of OAMT. Many problems in patient care have been found to be a direct result of lack of communication between the prescriber and the pharmacist. Effective collaboration and communication between prescribers, pharmacists, and other members of the health care team is essential and can have a positive impact on patient care and safety.

2) Purpose

Standards of Practice are minimum standards that all registrants are expected to meet. Regardless of position or practice environment, when a registrant performs a specific role, they must perform it to the level specified in the Standards of Practice and meet all of the standards associated with that role. These Standards describe the minimum expectations for pharmacists involved in the provision of OAMT and are intended to promote consistency in the provision of this service to the people of this province.

The Controlled Drugs and Substances Act and its regulations do not permit pharmacy technicians to perform certain activities related to provision of OAMT. For this reason, these Standards explicitly state the activities a pharmacy technician¹ is permitted to undertake.

While methadone, buprenorphine, and slow-release oral morphine are also used in the treatment of chronic pain, these Standards do not address the provision of these medications to treat chronic pain when there is no concern of concomitant opioid use disorder.

3) Ethical Considerations

Persons with opioid use disorder are often stigmatized or blamed for their condition by the wider society, which can make a person's recovery more challenging. Unfortunately, sometimes health care providers can perpetuate stigma. Therefore, pharmacists, pharmacy technicians, and pharmacy support staff should reflect on their own biases and consider how they may affect a patient's recovery.

Pharmacists should reflect on the NLPB Code of Ethics² when deciding whether to offer OAMT services and when evaluating their provision of OAMT services. The sections of the NLPB Code of Ethics that may be considered include, but are not limited to, the following:

Registrants hold the health and safety of each patient to be of primary consideration

- Registrants use their specialized knowledge and skills to make informed decisions that are in the best interest of their patients and the public.
- Registrants place the health and well-being of their patients at the centre of their professional practice.
- Registrants advocate for and protect the well-being of each patient, especially those who are vulnerable or disenfranchised.

Registrants maintain a professional relationship with each patient.

- Registrants treat all those they serve with courtesy and respect.
- Registrants listen to patients to seek understanding of the patient's needs, values and desired health goals.
- Registrants engage in patient-centred care and encourage patients to participate in decisions regarding their health.

Registrants respect the autonomy, values and dignity of each patient.

- Registrants recognize and respect that each patient has different needs, beliefs, values, experiences and preferences that will influence their attitudes towards health care and their desired health goals.

Registrants respect the patient's right to receive care.

- Registrants provide appropriate medications and services to their patients.
- Registrants who are unable to provide appropriate medications or services to their patients take reasonable steps to ensure patient care is not jeopardized.

¹ Throughout this document, "pharmacy technician" refers to a person registered with the NLPB under section 17. of the *Pharmacy Act, 2012*

² Newfoundland and Labrador Pharmacy Board Code of Ethics: http://www.nlpb.ca/media/NLPB_Code_of_Ethics-Sept2014.pdf

- Registrants play a role in assisting patients to navigate the health care system, including referring them to other appropriate health care providers, services and community resources.

Registrants cooperate with colleagues and other health care professionals to ensure optimal patient-centred care.

- Registrants consult with colleagues or other health care professionals, when appropriate, to benefit the patient.
- Registrants seek opportunities to work collaboratively with other health care professionals to foster a collaborative approach to health care and professional development.

Registrants contribute to the health care system and to societal health needs.

- Registrants promote health, wellness and disease prevention.
- Registrants promote fair and equitable access to health care resources and services.
- Registrants support the appropriate use, and the reduction of abuse and misuse, of drugs.

4) Treatment Choices

Treatment choices for OAMT include options such as buprenorphine/naloxone, methadone and slow-release oral morphine. The choice between these options will depend on a number of 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 noncompliance;
- the patient's allergies, concomitant health conditions and comorbidities;
- 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.

Buprenorphine is a partial opioid agonist at the μ (mu) receptor. It is associated with a reduced risk of death in overdose compared to full opioid agonists (e.g. methadone) because it has a ceiling effect to adverse effects such as respiratory depression. This is why many clinicians consider buprenorphine to be a safer drug than methadone. However, buprenorphine's ceiling effect may also result in limitations since its effectiveness may plateau once a certain serum level is reached. Buprenorphine products indicated for OAMT (Suboxone® and generics) also include naloxone which is included to deter against diversion and injection abuse.

Methadone is a full opioid agonist and, as such, has no ceiling effect. The lack of a ceiling effect can pose an increased risk of harm from overdose, due to drug interactions or other circumstances which can lead to increased methadone serum levels.

Slow-release oral morphine in the once daily 24-hour formulation (e.g. Kadian®) is considered as a third-line treatment option for opioid use disorder, according to the BCCSU *Guideline for the Clinical Management of Opioid Use Disorder*³ Though this is an off-label use this option may be prescribed for patients who have been

³ A Guideline for the Clinical Management of Opioid Use Disorder, British Columbia Centre on Substance Use (http://www.bccsu.ca/wp-content/uploads/2017/06/BC-OUD-Guidelines_June2017.pdf)

unsuccessful with, or have contraindications to first- and second- line treatment options. It is important to note that other formulations of oral morphine, such as twice-daily, 12-hour, or extended-release formulations (e.g. M-Eslon®) have not been empirically studied for OAMT and are therefore not recommended for this indication.

See sections 8, 9 and 10 for a more specific description of the practice standards for the provision of each of these options.

5) Registrant Requirements

5.1 Pharmacist Requirements

- a) *Authorization Process.* In order to receive authorization from the Board to participate in opioid agonist maintenance treatment services, pharmacists must first:
- i) apply to the Newfoundland and Labrador Pharmacy Board for authorization; and
 - ii) demonstrate completion of the required orientation program, as approved by the Board.

Applications will be reviewed and, if approved, authorization will be issued to the pharmacist. Once authorized, the pharmacist must:

- i) maintain competence in OAMT. Continuing professional development should be undertaken, as necessary, to maintain knowledge and skills; and
 - ii) agree to provide OAMT in accordance with legislation, the standards established by the Newfoundland and Labrador Pharmacy Board, and within the limits of their own competence.
- b) *Education and Continuing Competency.* Prior to participating in OAMT, pharmacists must declare that they have the necessary competency to provide this service. This includes having knowledge of:
- i) opioid use disorder;
 - ii) opioid toxicity;
 - iii) opioid withdrawal and its management;
 - iv) harm reduction treatment strategies;
 - v) OAMT treatment options, including pharmacology, therapeutics, dosing and overdose management;
 - vi) culturally competent care related to socioeconomic status, ethnicity, race, language;
 - vii) approaches for patient communication and support;
 - viii) inter-professional collaboration in OAMT;
 - ix) community support and referral resources for opioid use disorder and treatment; and
 - x) legislation, standards and policies related to pharmacists providing OAMT.

To meet this competency requirement, pharmacists should complete education on opioid use disorder and treatment. Examples of programs include the following:

- Buprenorphine-Assisted Treatment of Opioid Dependence for Frontline Clinicians, CAMH (<https://www.camh.ca/en/education/continuing-education/continuing-education-programs-and-courses/buprenorphineassisted-treatment-of-opioid-dependence-an-online-course-for-frontline-clinici>)
- Online Addiction Medicine Diploma Program, British Columbia Centre on Substance Use (<http://www.bccsu.ca/courses/online-addiction-medicine-diploma-program/>)

- Opioid Dependence Treatment Core Course, CAMH (<https://www.camh.ca/en/education/continuing-education/continuing-education-programs-and-courses/opioid-dependence-treatment-odt-core-course>)
- Suboxone Training Program (<http://www.suboxonecme.ca/>)

5.2 Pharmacy Technician Requirements

Pharmacy technicians who wish to participate in the provision of OAMT are expected to complete an orientation program approved by the Board, and any additional education and training that is necessary to understand the scope of their role in the provision of OAMT.

To meet competency requirements pharmacy technicians may wish to complete any of the noted education programs under Section 5.1. In addition, CAMH has developed an education program specifically for pharmacy technicians.

- The Opioid Dependence Treatment: Essential Knowledge for Pharmacy Technicians course (<https://www.camh.ca/en/education/continuing-education/continuing-education-programs-and-courses/opioid-dependence-treatment-essential-knowledge-for-pharmacy-technicians>)

6) **Operational Standards**

Before initiating OAMT services at the pharmacy under their supervision, the pharmacist-in-charge must first notify the Newfoundland and Labrador Pharmacy Board that the pharmacy will be offering this service and ensure that the following operational requirements are or will be met:

- Pharmacy Layout and Design.* The pharmacy must be designed and laid out to allow for all pharmacist-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.
- Hours of Operation.* When a pharmacy accepts a patient who requires daily witnessed ingestion of medication, the pharmacy should be prepared to accommodate this dosing requirement and maintain hours of operation necessary to do so. Pharmacies that do not operate seven days a week are expected to facilitate arrangements to enable the patient to acquire their doses on the days the pharmacy is closed. This may include: opening at selected times on the day(s) the pharmacy is closed to service pre-scheduled patients who require witnessed daily doses, collaboration with prescribers for authorization of take-home doses for the selected days the pharmacy is closed (if deemed safe for the patient), or collaboration with prescribers and another pharmacy to arrange dosing at a secondary pharmacy (see section 13) for more information on this practice).

Pharmacists in charge of pharmacies that are not able to open 7 days per week, but who wish to alleviate access issues to OAMT in their communities, may participate to the extent that is possible, but they must make the limitations of their practice clear to patients and prescribers at the outset so that an informed care plan can be established.

- Staff.* It is the responsibility of the pharmacist-in-charge to ensure that all pharmacists, pharmacy technicians and other support staff are appropriately trained and understand the scope of their role in the provision of OAMT.
- Security.* Security of the premises should address the potential risks associated with the provision of OAMT and the risks to the community that can result from theft of these medications. As with other narcotics, OAMT medications should be stored in a secure location at all times (i.e., during hours of operation and when the premises are closed for business).

- e) *Inventory Control.* In accordance with section 1.6 b) of the Standards of Pharmacy Operation-Community Pharmacy (SOPO-Community) or section 1.8 b) of the Standards of Pharmacy Operation-Hospital Pharmacy (SOPO-Hospital), a computerized or manual perpetual inventory must be maintained for all narcotics and controlled drugs, including buprenorphine/naloxone, methadone and slow release oral morphine dispensed for OAMT. If the pharmacy's practice management system is unable to maintain an accurate perpetual inventory for methadone, a manual perpetual inventory must be maintained (see the sample templates attached in Appendix II or III).
- f) *Policy and Procedure Manual.* The pharmacy must develop, maintain and regularly review a policy and procedure manual related to the provision of OAMT.
- g) *Documentation and Retention Requirements.* All documentation related to these Standards, including prescriptions, forms and communications must be retained in the pharmacy in a readily retrievable format in accordance with section 1.5 of the SOPO-Community or section 1.7 of the SOPO-Hospital.

Additionally, section 3.5 c) ii) of the SOPO-Community and section 3.1 c) i) of the SOPO-Hospital require that the identity of all staff members involved in the order entry, preparation, checking, and counselling processes is auditable and traceable.

- h) *References and Resources.* The pharmacy must have appropriate selection of references to support safe OAMT practice.

- i) The following are considered **REQUIRED REFERENCES** and must be accessible and available to the pharmacy staff:

- CAMH Buprenorphine/Naloxone for Opioid Dependence: Clinical Practice Guideline (<https://www.porticonetwork.ca/documents/507864/0/buprenophin+guideline+2012/ef7d9c7a-d1b4-46b7-b566-7207c31ac1b7>)
- Canadian Research Initiative in Substance Misuse (CRISM) National Guidelines for the Clinical Management of Opioid Use Disorder (<https://crism.ca/projects/opioid-guideline/>)
- College of Physicians of Newfoundland and Labrador (CPSNL) Methadone Maintenance Treatment Standards and Guidelines (http://www.cpsnl.ca/WEB/CPSNL/Policies/MMT_Standards_and_Guidelines.aspx)
- CPSNL Practice Guideline: Suboxone® for Opioid Dependence ([https://www.cpsnl.ca/web/files/2017-06-21%20-%20Suboxone%20\(Practice%20Guideline\).pdf](https://www.cpsnl.ca/web/files/2017-06-21%20-%20Suboxone%20(Practice%20Guideline).pdf))
- A Guideline for the Clinical Management of Opioid Use Disorder, British Columbia Centre on Substance Use (http://www.bccsu.ca/wp-content/uploads/2017/06/BC-OUD-Guidelines_June2017.pdf)
- Opioid Agonist Maintenance Treatment, 3rd edition (<http://store-camh.myshopify.com/collections/english-anglais/products/p6500>)

- ii) The following are additional recommended references that may be useful in specific situations:

- Addiction Treatment Forum website (www.atforum.com)
- Combined List of Drugs That Prolong QT and/or Cause Torsades de Pointes (TDP), Crediblemeds.org (<http://www.crediblemeds.org/pdftemp/pdf/CombinedList.pdf>)
- Mental Health and Addiction 101 Series, CAMH (<https://www.camh.ca/en/health-info/mental-health-101>)

- i) *Other.* The pharmacy must have a naloxone kit available for opioid overdose emergencies, and should also have additional kits available for provision to OAMT patients.

7) General Practice Standards

7.1 Collaboration Between the Pharmacist and the Prescriber

- a) *Verbal Discussion.* Prescribers should have a verbal discussion with a pharmacist at the patient's pharmacy to confirm that the pharmacy is able to accept new OAMT patients, and to outline the details of the prescriber's treatment agreement with the patient along with his or her expectations regarding communication methods, among other things, prior to initiating OAMT.
- b) *Written Agreement.* When prescribing methadone, prescribers should send a written Prescriber-Pharmacist Treatment Agreement to the patient's pharmacy that puts in writing the information identified in a) above. This document should also include the prescriber's contact information for use by the pharmacist in situations where the pharmacist needs to contact the prescriber or in the case of an emergency.

Pharmacists who have not had the verbal discussion with the prescriber described in a), or are not in receipt of a Prescriber-Pharmacist Treatment Agreement, may wish to contact the prescriber to discuss the patient's care plan and expectations regarding the provision of pharmacy services prior to initiating therapy. At the very least, the pharmacist must confirm an emergency contact number for the prescriber.

7.2 Establishing the Pharmacist – Patient Relationship

- a) *Verbal Discussion.* Prior to providing OAMT services to a patient, pharmacists should discuss the services that they 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.
- b) *Written Agreement.* 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. (See Appendix I for a Pharmacy-Patient Service Agreement Template).

<p>NOTE: Since some patients may not be receptive to information during this initial discussion or during periods of clinical instability or relapse, it is advisable to revisit this agreement periodically.</p>
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8) Practice Standards Specific for the Provision of Methadone

8.1 Assessing the Prescription

- a) *Prescriber Eligibility.* The CPSNL requirements for physicians who prescribe methadone are available on the Standards of Practice and Practice Guidelines page of the CPSNL website (https://www.cpsnl.ca/WEB/CPSNL/Policies/Policies_Guidelines_and_Advisories.aspx?hkey=3333f997-9f9a-48f7-85e0-64cf0d0f5e68). As of May 2018, pharmacists are **no longer** required to confirm a physician's eligibility to prescribe methadone with CPSNL or Health Canada.

The Association of Registered Nurses of Newfoundland and Labrador (ARNNL) has established specific requirements that nurse practitioners must meet in order to prescribe methadone for OAMT. These requirements are available on the Scope of Practice for NPs page of the ARNNL website (<https://www.arnnl.ca/scope-practice-nps>). Pharmacists can confirm a nurse practitioner's eligibility to prescribe methadone for OAMT on the member search page of the ARNNL website: <https://www.arnnl.ca/member-search>.

- b) *Tamper Resistant Prescription Drug Pad Program Form.* In NL, all prescriptions for methadone must be written on the TRPP form, as required by the Tamper Resistant Prescription Drug Pad Program. This form is required regardless of whether the prescription is written by an in-province or out-of-province prescriber.

For more information on this program and its requirements, visit the Department of Health and Community Services website (http://www.health.gov.nl.ca/health/prescription/hcp_tamperresistantdrugpad.html).

- c) *Required Information.* The prescription must be appropriately signed and dated and also specify:
- i) the daily dose of methadone in milligrams, written in both numbers and words;
 - ii) the start date and end date of the prescription;
 - iii) the total number of witnessed doses of methadone, written in both numbers and words, or the days of the week that doses are to be witnessed (if applicable); and
 - iv) if take-home doses are authorized, the number of take-home doses per week, written in both numbers and words, or the days of the week that the take-home doses are to be given (if applicable).
- d) *Methadone Dosing.* Pharmacists should assess each methadone prescription to determine whether or not the dose, dosing schedule, and duration of prescription falls within recommendations outlined in the product monograph, clinical practice guidelines and standards of practice. If pharmacists receive prescriptions for methadone that are inconsistent with these references, they should consult with the prescriber, and document the conversation and the rationale for their decisions in the patient record.
- e) *Take-Home Doses.* Take-home doses of OAMT may be beneficial as they can motivate patients to participate in OAMT programs, improve treatment retention, increase patient autonomy, positively reinforce abstinence, decrease treatment burden, and decrease program costs associated with daily witnessed ingestion. However, the benefits of take-home doses to the patient must be weighed against the potential risks to patients and the public that can be associated with take-home dosing.

Due to its inferior safety profile in circumstances of diversion, co-ingestion or overdose, methadone should generally be prescribed as a daily dose with ingestion witnessed by a pharmacist until patients demonstrate a high degree of stability including a stable dose, which usually takes months. Take-home doses should be initiated starting with one take-home dose per week, slowly progressing to additional take-home doses per week based on routine assessments of patient stability.

Pharmacists must be familiar with up-to-date clinical practice guidelines and standards of practice for the provision of take-home doses in order to assess the appropriateness of prescriptions. When assessing prescriptions for methadone take-home doses, pharmacists should consider patients':

- length of time in treatment;
- attendance at the pharmacy for their medication dose on schedule;
- cognitive impairment or unstable mental health;
- ongoing substance use, including benzodiazepines, alcohol, and other sedatives;
- concomitant medications (assess drug interactions that may increase risk of overdose);
- ability to safely store take-home doses (e.g. stable housing); and
- evidence of social integration (e.g. employment, school attendance, child-care responsibilities, volunteer work).

Key questions to reflect upon include:

- Are take-home doses safe for the patient?

- Are take-home doses safe for the public?
- Is there risk of diversion?

If pharmacists see take-home doses being prescribed outside of usual recommendations, they should consult with the prescriber, re-assess the appropriateness of take-home doses based on the additional information obtained, and document the rationale for providing take-home doses in the patient record.

A pharmacist may refuse to fill a prescription for take-home doses if there is concern for the safety of the patient, or the safety of others (e.g. risk of diversion, missed doses, not returning bottles, high risk of misuse). This decision must be documented and communicated to the prescriber.

8.2 Dispensing the Prescription

- a) *Formulations.* With the availability of commercially-prepared, concentrated methadone solution products (e.g. Methadose™), dispensing compounded methadone is no longer permitted, except in exceptional circumstances, as it would be considered manufacturing in accordance with Health Canada's Policy on Manufacturing and Compounding Drug Products in Canada (http://www.hc-sc.gc.ca/dhp-mpps/compli-conform/gmp-bpf/docs/pol_0051-eng.php).

While there are a variety of these products on the market, in Newfoundland and Labrador, **pharmacists must dispense methadone using an unflavoured, commercially-prepared 10 mg/ml methadone solution.**

To determine the amount of concentrated solution to use, simply divide the methadone dose in milligrams by 10. For example, 80 mg methadone would require 8 mL of concentrated solution.

NOTE: In a situation where a commercial product is not available, a 10 mg/mL methadone stock solution may be compounded. In such cases, the stock solution must be clearly labelled with the drug name, strength, use-by date and appropriate warning labels. Additionally, 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 IV).

- b) *Storage.* Commercially-prepared methadone solutions are shelf-stable and, once opened, can generally be stored at room temperature for six months (pharmacists should refer to appropriate product monographs for product-specific storage information). Diluted preparations must be stored in an appropriate secure location (e.g. lockable fridge) until they are released to the patient.
- c) *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.
- d) *Preparing Doses.* Pharmacists should ensure that measuring devices used to measure the concentrated stock solution have an accuracy of at least +/- 0.1 mL. Equipment and devices used to measure methadone should be distinctively labelled and used exclusively for this purpose.

Pharmacists and pharmacy technicians must ensure that the manufacturer's instructions for the use of measuring devices are followed. This includes 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, the pharmacist or pharmacy technician must:

- measure the amount of 10 mg/mL methadone stock solution required for the individual dose;
- transfer the measured stock solution to an amber, calibrated bottle;
- add a sufficient quantity of crystalline liquid (e.g., Kool-Aid or Tang) to bring the final volume of the dose to 100 mL; and
- document the preparation of the dose, in accordance with section 6. g).

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, methadone dose calculations and measurements are to be independently double-checked.

NOTE: According to the Institute for Safe Medication Practices (ISMP), an independent double-check of high-alert medications, such as methadone, should be utilized to help detect potentially harmful errors before they reach patients.

To be most effective, the double-check should be conducted by a second person to reduce the risk of confirmation bias where the individual checking sees what they expect to see, even if an error has occurred. Pharmacists should ask another member of the pharmacy team (preferably another pharmacist or pharmacy technician, but an assistant may perform this task in the event another pharmacist or pharmacy technician is not available) to double-check dose measurements against the prescription order.

In the event that 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.

- e) *Labelling.* Each witnessed dose must 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 (i.e. methadone or Methadose™);
 - iv) amount of drug (in mg) contained in the bottle to be consumed in a single dose;
 - v) volume (in mL) of 10 mg/mL concentrated solution contained in the bottle;
 - vi) local prescription number and DIS prescription number (if applicable);
 - vii) date of dispense;
 - viii) quantity of medication (part-fills) remaining (if applicable); and
 - ix) dispensing pharmacist's initials

Each take-home dose bottle must have a child- and tamper-resistant cap and must 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 (i.e. methadone or Methadose™);
- v) directions for use including the amount of drug (in mg) contained in the bottle to be consumed in a single dose;
- vi) specific directions for use (such as "Consume the entire contents of this bottle on (insert date).");
- vii) volume (in mL) of 10 mg/mL concentrated solution contained in the bottle;
- viii) local prescription number and DIS prescription number (if applicable);
- ix) date of dispense;
- x) quantity of medication (part-fills) remaining (if applicable);
- xi) dispensing pharmacist's initials; and
- xii) required cautionary labels:
 - Keep out of reach of children
 - Keep refrigerated
 - Do not consume alcohol
 - Special cautionary label for methadone such as:

"Methadone 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."

NOTE: In the case of take-home doses, pharmacists should use best judgment to assign beyond-use dates for diluted products. Both stability and sterility should be taken into account. Some literature indicates the stability of methadone in various diluents; however, it does not address sterility (the likelihood of bacterial growth in prepared doses under refrigerated and unrefrigerated conditions). Therefore, beyond-use-dates must be assigned based on the earliest expiry of the ingredients used or 14 days, 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.

8.3 Releasing the Prescription

- a) *Providing Witnessed and Take-Home Doses.* The pharmacist is required to witness the ingestion of the dose. In accordance with section 31.(c) of the Narcotic Control Regulations, **a pharmacist may not delegate the administration of methadone to a pharmacy technician or other member of the pharmacy team.**

In keeping with best practice, a patient should have a witnessed dose prior to releasing any take-home doses. Pharmacists are required to consult with the prescriber regarding directions that deviate from this practice. The practice of dispensing continuous take-home doses without a witnessed ingestion is strongly discouraged since it is inconsistent with best practice, it places the patient at risk of overdose or toxicity, and it places the public at risk of diversion. **Pharmacists must dispense take-home doses directly to the patient.**

Prior to releasing methadone doses to the patient, the pharmacist must:

- i) Review the patient's local profile, the Pharmacy Network profile, and Administration Log, and any other applicable information to determine that it is safe and appropriate to provide the patient with the prescribed methadone dose.

If a drug therapy problem is detected (for example, another mood-altering or sedating drug has been prescribed) the pharmacist must consult with the relevant prescribers prior to dispensing the prescription and document the outcome of the consultation.
 - ii) Positively identify the patient. If uncertain as to the patient's identity, photo identification must be requested.
 - iii) Assess the patient for signs of intoxication or sedation. If it is determined that the patient is intoxicated or sedated, the pharmacist must withhold the dose and consult with the prescriber (see section 11) a) below).
 - iv) If it is safe to provide the witnessed dose, the pharmacist must:
 - Ask the patient to confirm their prescribed dose and their name on the dose bottle;
 - Directly observe the patient ingesting the medication;
 - Engage the patient in brief conversation to ensure the entire dose has been swallowed.
 - v) If the patient is receiving take-home doses, ask the patient to verify the label on each take-home dose bottle and the number of take-home doses provided.
 - vi) Appropriately document the provision of the witnessed and take-home doses on the Administration Log and ask the patient to sign for each dose provided (see sample in Appendix VI).
- b) *Patient Counselling.* The pharmacist is required to:
- i) Counsel the patient about methadone treatment (upon initiation of methadone treatment and when necessary thereafter). For complete patient counselling information, see the relevant product monograph and information in required references. Counselling should include, but is not limited to:
 - side effects and treatment effects of methadone;
 - symptoms of opioid withdrawal and overdose;
 - the importance of arriving at the pharmacy around the same each day and not missing doses to ensure consistent blood levels of methadone;
 - driving an automobile or operating machinery may be dangerous during the stabilization period or periods of instability due to possible sedation and symptoms of withdrawal;
 - the need to contact the pharmacy prior to taking any prescribed or non-prescribed medications in order to prevent potentially harmful drug interactions with methadone;
 - the risk associated with the use of alcohol and other sedating substances in combination with methadone;
 - the recommendation to have a naloxone kit on-hand at all times; and
 - the need for family planning due to improvements in fertility that is associated with stabilization on OAMT.
 - ii) Counsel the patient appropriately regarding the risks of take-home doses (upon initiation of take-home doses and when necessary thereafter). Counselling should include, but is not limited to:
 - take-home doses are for the patient's consumption only;

- methadone take-home doses must be stored securely in a locked box and the locked box stored in the fridge. If the lock box cannot be stored in the refrigerator, a cooler pack may be added to the lock box to keep doses cool;
- ingestion of methadone by anyone other than the patient should be considered a medical emergency and emergency assistance (911) should be called immediately;
- the entire dose should be consumed as prescribed. Tolerance to methadone will be lost if a dose has not been consumed for 3 consecutive days. In this circumstance, resuming the usual prescribed dose would place the patient at risk of overdose, hospitalization or death;
- take-home dose bottles must be returned to the pharmacy; and
- patients may be advised at any time to return to the pharmacy with the balance of their take-home doses.

NOTE: In accordance with the *SOPo-Community* and the *SOPo-Hospital*, all counselling activities must be documented. The pharmacist should use professional judgement when determining the information to be contained in the counselling record, but it should include, at a minimum, the name of the pharmacist who delivered the counselling and the date and time the counselling was given.

- c) *Monitoring Compliance with Take-Home Doses.* There are several ways that pharmacists can monitor a patient's compliance with take-home doses.

Bottle Return: As noted in the previous section, pharmacists must advise patients that they must return their empty bottles with the original labels intact to the pharmacy for inspection and proper destruction at their next visit. Return of take-home dose bottles should be recorded on the patient's Administration Log. Bottles should never be reused, even for the same patient.

NOTE: Pharmacists must ensure that the returned containers are disposed of in a manner that protects the public from diversion of any methadone remaining in the bottle, and that maintains patient confidentiality. Bottles that are being disposed offsite from the pharmacy must be rinsed of any methadone and patient labels removed.

Take-Home Dose Audit: Patients should be advised that they may be asked at any time to return to the pharmacy with the remainder of their take-home doses and empty bottles. This procedure, known as a "take-home dose audit", may be used to deter patients from diverting their take-home doses. This audit may be initiated by either the prescriber or the pharmacist.

If there are issues of concern with the patient's compliance with their take-home doses or evidence of diversion, the pharmacist should notify the prescriber immediately (see sample Prescriber Notification Form in Appendix V).

9) Practice Standards Specific to the Provision of Buprenorphine/Naloxone

9.1 Assessing the Prescription

- a) *Prescriber Eligibility.* The CPSNL requirements for physicians who prescribe buprenorphine/naloxone are available on the Standards of Practice and Practice Guidelines page of the CPSNL website (https://www.cpsnl.ca/WEB/CPSNL/Policies/Policies_Guidelines_and_Advisories.aspx?hkey=3333f997-

[9f9a-48f7-85e0-64cf0d0f5e68](https://www.arnnl.ca/scope-practice-nps)). Pharmacists are **not** required to confirm a physician's eligibility to prescribe buprenorphine/naloxone with CPSNL.

The Association of Registered Nurses of Newfoundland and Labrador (ARNNL) has established specific requirements that nurse practitioners must meet in order to prescribe buprenorphine/naloxone for OAMT. These requirements are available on the Scope of Practice for NPs page of the ARNNL website (<https://www.arnnl.ca/scope-practice-nps>). Pharmacists can confirm a nurse practitioner's eligibility to prescribe buprenorphine/naloxone for OAMT on the member search page of the ARNNL website (<https://www.arnnl.ca/member-search>).

- b) *Tamper Resistant Prescription Drug Pad Program Form.* In NL, all prescriptions for buprenorphine must be written on the TRPP form, as required by the Tamper Resistant Prescription Drug Pad Program. This form is required regardless of whether the prescription is written by an in-province or out-of-province prescriber.

For more information on this program and its requirements, visit the Department of Health and Community Services website (http://www.health.gov.nl.ca/health/prescription/hcp_tamperresistantdrugpad.html).

- c) *Required Information.* The prescription must be appropriately signed and dated and also specify:
- i) the daily dose of buprenorphine/naloxone in milligrams, written in both numbers and words;
 - ii) the start date and end date of the prescription;
 - iii) the total quantity of tablets written in numbers and words;
 - iv) the total number of witnessed doses of buprenorphine/naloxone, written in both numbers and words, or the days of the week those doses are to be witnessed; and
 - v) if take-home doses are authorized, the number of take-home doses per week, written in both numbers and words, or the days of the week for which take-home doses are to be provided.

If the prescriber's intentions regarding witnessing are unclear, the pharmacist must consult with the prescriber to clarify, and the outcome of this clarification must be documented and included with the original prescription and noted in the patient's medication profile.

- d) *Buprenorphine/Naloxone Dosing.* Buprenorphine/naloxone dosing is based on the buprenorphine component. Patients are generally given an induction dose when they are in a period of at least moderate opioid withdrawal and are then steadily increased according to the patient's needs over a period of a few days.

Pharmacists must assess each buprenorphine/naloxone prescription to determine whether or not the dose, dosing schedule, and duration of prescription falls within recommendations outlined in the product monograph, clinical practice guidelines and standards of practice. If pharmacists receive prescriptions for buprenorphine/naloxone that are inconsistent with these references, they must consult with the prescriber, document the conversation and the rationale for their decision to dispense in the patient record.

- e) *Take-Home Doses.* Take-home doses of OAMT may be beneficial as they can motivate patients to participate in OAMT programs, improve treatment retention, increase patient autonomy, positively reinforce abstinence, decrease treatment burden, and decrease program costs associated with daily witnessed ingestion. However, the benefits of take-home doses to the patient must be weighed against the potential risks to patients and the public that can be associated with take-home dosing.

Due to its safety profile, take-home doses of buprenorphine/naloxone can be considered a common part of treatment. It is the responsibility of the prescriber to decide when take-home dosing is advisable and whether ongoing witnessed ingestion of buprenorphine/naloxone is optimal from a patient and public safety perspective.

In certain circumstances, consideration may be given to providing take-home doses during induction when multiple daily visits to the prescriber's office and pharmacy may not be possible or practical.

Pharmacists must be familiar with up-to-date clinical practice guidelines for provision of take-home doses in order to assess the appropriateness of prescriptions. When assessing prescriptions for buprenorphine/naloxone take-home doses, pharmacists should consider patients':

- length of time in treatment;
- attendance at the pharmacy for their medication dose on schedule;
- cognitive impairment or unstable mental health;
- ongoing substance use, especially benzodiazepines, alcohol, or other sedatives;
- concomitant medications (assess drug interactions that may increase risk of overdose);
- ability to safely store take-home doses (e.g. stable housing); and
- evidence of social integration (e.g. employment, school attendance, child-care responsibilities, volunteer work).

Key questions to reflect upon include:

- Are take-home doses safe for the patient?
- Are take-home doses safe for the public?
- Is there risk of diversion?

If pharmacists see take-home doses being prescribed outside of usual recommendations, they should consult with the prescriber, re-assess the appropriateness of take-home doses based on the additional information obtained, and document the rationale for providing take-home doses in the patient record.

A pharmacist may refuse to fill a prescription for take-home doses if there is concern for the safety of the patient, or the safety of others (e.g. risk of diversion, missed doses, not returning vials, high risk of misuse). This decision must be documented and communicated to the prescriber.

9.2 Dispensing the Prescription

- a) *Formulations.* Buprenorphine/naloxone (Suboxone® and generics) is available as a sublingual tablet with either 2 mg of buprenorphine and 0.5 mg of naloxone or 8 mg of buprenorphine and 2 mg of naloxone.
- b) *Preparing Daily Doses.* Buprenorphine/naloxone should be prepared in advance of administration and stored 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 (i.e. buprenorphine/naloxone or Suboxone®);
 - iv) directions for use including the amount of drug to be consumed in a single dose;
 - v) local prescription number and DIS prescription number (if applicable);
 - vi) date of dispense;
 - vii) quantity of medication (part-fills) remaining (if applicable); and
 - viii) dispensing pharmacist's initials.

- c) *Preparing Take Home Doses.* Take-home doses of buprenorphine/naloxone should be dispensed in a light-resistant vial with a child-resistant cap and labelled as above, as well as with the following required cautionary labels:
- Keep out of reach of children
 - Do not consume alcohol
 - Special cautionary 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 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. Pharmacists must confirm patients’ understanding of dosing instructions prior to releasing take-home doses.

NOTE: If compliance packaging is ordered by the prescriber to improve adherence, discourage diversion, or to facilitate take-home dose audits, the pharmacist must ensure that tablets are handled safely and that the requirements of the NLPB Standards for the Safe and Effective Provision of Compliance Packages⁴ are met in addition to the requirements of these Standards. Specifically, patients must be counselled that the packages are not child-safe and must be stored securely and this counselling must be documented in the patient’s file

9.3 Releasing the Prescription

- a) *Providing Witnessed and Take-Home Doses.* Prior to releasing buprenorphine/naloxone doses to the patient, a pharmacist must:
- i) Review the patient's local profile, the Pharmacy Network profile, and Administration Log, and any other applicable information to determine that it is safe and appropriate to provide the patient with the prescribed buprenorphine/naloxone dose.

If a drug-related problem is detected (for example, another mood-altering or sedating drug has been prescribed) the pharmacist must consult with the relevant prescribers prior to dispensing the prescription and document the outcome of the consultation.
 - ii) Positively identify the patient. If uncertain as to the patient's identity, photo identification must be requested.
 - iii) Assess the patient for signs of intoxication or sedation. If it is determined that the patient is intoxicated or sedated, the pharmacist must withhold the dose and consult with the prescriber (see section 11) a) below).
 - iv) If it is safe to provide a dose and the dose is to be witnessed:

⁴ NLPB Standards for the Safe and Effective Provision of Compliance Packages: http://www.nlpb.ca/media/SOPP-Compliance_Packaging-Sept2015.pdf

- A pharmacist or pharmacy technician may prepare the buprenorphine/naloxone dose by placing the tablets in a disposable single-use cup, taking care to avoid skin contact (all doses should be independently double-checked prior to administration).
- A pharmacist must instruct the patient to place the tablet(s) under the tongue. After one minute, the pharmacist must discretely and respectfully check under the patient's tongue to confirm that the tablet(s) have started to dissolve. Once it has been confirmed that the tablets have started to dissolve, the patient may leave the pharmacy.

NOTE: While tablets may take up to 10 minutes to completely dissolve, the first few minutes are the most important for avoiding diversion. Once the tablet dissolves into a pulpy mass, while it is still possible to divert, it is more difficult (section 6 of the CAMH *Opioid Agonist Maintenance Treatment*⁵ reference).

- v) If the patient is receiving take-home doses, ask the patient to verify the label on the vial containing take-home doses and the number of take-home doses provided.
 - vi) Appropriately document the provision of each witnessed and take-home dose on the Administration Log and ask the patient to sign for each dose provided (see sample in Appendix VI).
- b) *Patient Counselling.* Pharmacists are required to:
- i) Counsel the patient about buprenorphine/naloxone treatment (upon initiation and when necessary thereafter). For complete patient counselling information, see the relevant product monograph and information in required references. Counselling should include, but is not limited to, the following:
 - Instructions on how to take the dose, for example,
 - Do not chew, suck, or swallow the tablets.
 - Place and hold the tablet(s) under the tongue until fully dissolved (which may take up to 10 minutes).
 - Avoid swallowing (tipping head forward may help), talking, eating, drinking, and smoking while the tablets are dissolving.
 - If the patient has a dry mouth, drink water prior to taking buprenorphine/naloxone to help the tablets dissolve quicker.
 - Avoid eating or drinking for about 5 minutes after the dose has fully dissolved.
 - Side effects and treatment effects of buprenorphine/naloxone;
 - Symptoms of opioid withdrawal and overdose;
 - The need to contact the pharmacy prior to taking any prescribed or non-prescribed medications in order to prevent potentially harmful drug interactions;
 - The risk associated with driving an automobile or operating machinery during the stabilization period or periods of instability due to possible sedation and symptoms of withdrawal;

⁵ Opioid Agonist Maintenance Treatment, 3rd edition (<http://store-camh.myshopify.com/collections/english-anglais/products/p6500>)

- The risk associated with the use of alcohol and other sedating substances in combination with buprenorphine/naloxone;
 - The recommendation to have a naloxone kit on-hand at all times; and
 - The need for family planning due to improvements in fertility that is associated with stabilization on OAMT.
- ii) Counsel the patient appropriately regarding the risks of take-home doses (upon initiation of take-home doses and when necessary thereafter). This counselling should include, but is not limited to, the following:
- Take-home doses are for the patient's consumption only;
 - Take-home doses must be stored securely, e.g. in a locked cupboard or small locked box, and out of reach of children;
 - Ingestion of buprenorphine/naloxone by anyone other than the patient should be considered a medical emergency and emergency assistance (911) should be called immediately;
 - The entire dose should be consumed as prescribed. Tolerance to buprenorphine/naloxone can be lost with repeated consecutive missed doses, increasing the risk of overdose, hospitalization or death;
 - Take-home dose vials must be returned to the pharmacy; and
 - Patients may be advised at any time to return to the pharmacy with the balance of their take-home doses.

NOTE: In accordance with the *SOPo-Community* and the *SOPo-Hospital*, all counselling activities must be documented. The pharmacist should use professional judgement when determining the information to be contained in the counselling record, but it should include, at a minimum, the name of the pharmacist who delivered the counselling and the date and time the counselling was given.

- c) *Monitoring Compliance with Take-Home Doses.* There are several ways that pharmacists can monitor a patient's compliance with take-home doses.
- i) Vial Return: As noted in the previous section, patients should be advised to return their empty vials with the original labels intact to the pharmacy for inspection and proper destruction at their next visit. Return of take-home dose vials should be recorded on the patient's Administration Log. These vials should not be reused, even for the same patient.
 - ii) Take-Home Dose Audit: Patients should be advised that they may be asked at any time to return to the pharmacy with the remainder of their take-home doses and empty vials. This procedure, known as a "take-home dose audit", may be used to deter patients from diverting their take home doses. This audit may be initiated by either the prescriber or the pharmacist.

If there are issues of concern with the patient's compliance with their take-home doses or evidence of diversion, the pharmacist should notify the prescriber immediately (see sample Prescriber Notification Form in Appendix V).

10) Practice Standards Specific to the Provision of Slow-Release Oral Morphine

10.1 Assessing the Prescription

- a) *Tamper Resistant Prescription Drug Pad Program Form.* In NL, all prescriptions for slow-release oral morphine must be written on the TRPP form, as required by the Tamper Resistant Prescription Drug Pad Program. This form is required regardless of whether the prescription is written by an in-province or out-of-province prescriber.

For more information on this program and its requirements, visit the Department of Health and Community Services website (http://www.health.gov.nl.ca/health/prescription/hcp_tamperresistantdrugpad.html).

- b) *Required Information.* The prescription must be appropriately signed and dated and also specify:
- i) the indication for OAMT;
 - ii) the daily dose of slow-release oral morphine in milligrams, written in both numbers and words;
 - iii) the start date and end date of the prescription;
 - iv) the total quantity of tablets written in numbers and words;
 - v) the total number of witnessed doses of slow-release oral morphine, written in both numbers and words or the days of the week those doses are to be witnessed; and
 - vi) if take-home doses are authorized, the number of take-home doses per week, written in both numbers and words, or the days of the week for which take-home doses are to be provided.

If the prescriber's intentions regarding indication for use or witnessing are unclear, the pharmacist must consult with the prescriber to clarify, and the outcome of this clarification must be documented and included with the original prescription and noted in the patient's medication profile.

- c) *Slow-Release Oral Morphine Dosing.* Pharmacists should assess each slow-release oral morphine prescription to determine if the dose, dosing schedule, and duration of prescription falls within recommendations outlined in the product monograph, clinical practice guidelines and standards of practice. If pharmacists receive prescriptions for slow-release oral morphine that are inconsistent with these references, they should consult with the prescriber, document the conversation and the rationale for their decision to dispense in the patient record.
- d) *Take-Home Doses.* The majority of prescriptions for slow-release oral morphine will be for daily witnessed ingestion. In exceptional cases, patients may be transitioned to take-home dosing schedules. It is recommended that tighter restrictions for daily witnessed ingestion be implemented as there are no established protocols for slow-release oral morphine take-home dosing and monitoring when used as OAMT (BCCSU, 2017).

Pharmacists must be familiar with up-to-date clinical practice guidelines for provision of slow-release oral morphine take-home doses in order to assess the appropriateness of prescriptions. When assessing prescriptions for take-home doses, pharmacists should consider patients':

- Length of time in treatment;
- Attendance at the pharmacy for their medication dose on schedule;
- Cognitive impairment or unstable mental health;
- Ongoing substance use, especially benzodiazepines, alcohol, or other sedatives;
- Concomitant medications (assess drug interactions that may increase risk of overdose);
- Ability to safely store take-home doses (e.g. stable housing); and
- Evidence of social integration (e.g. employment, school attendance, child-care responsibilities, volunteer work).

Key questions to reflect upon include:

- Are take-home doses safe for the patient?
- Are take-home doses safe for the public?
- Is there risk of diversion?

If pharmacists see take-home doses being prescribed outside of usual recommendations, they should consult with the prescriber, re-assess the appropriateness of take-home doses based on the additional information obtained, and document the rationale for providing or not providing take-home doses in the patient record.

A pharmacist may refuse to fill a prescription for take-home doses if there is concern for the safety of the patient, or the safety of others (e.g. risk of diversion, missed doses, not returning vials, high risk of misuse). This decision must be documented and communicated to the prescriber.

10.2 Dispensing the Prescription

- a) *Formulations.* Only the once-daily, 24-hour formulation of slow-release oral morphine (e.g. Kadian) in approved, commercially available strengths may be dispensed for OAMT. Capsule contents cannot be split. It is important to note that other formulations of oral morphine, such as twice-daily, 12-hour, or extended-release formulations (e.g. M-Eslon®) have not been empirically studied for OAMT and are therefore not recommended for this indication.
- b) *Preparing Daily Doses.* Slow-release oral morphine should be prepared in advance of administration and stored 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;
 - iv) directions for use including the indication for OAMT and the amount of drug to be consumed in a single dose;
 - v) local prescription number and DIS prescription number (if applicable);
 - vi) date of dispense;
 - vii) quantity of medication (part-fills) remaining (if applicable); and
 - viii) dispensing pharmacist's initials.
- c) *Preparing Take Home Doses.* Take-home doses of slow-release oral morphine should be dispensed in a light-resistant vial with a child-resistant cap and labelled as above, as well as with the following required cautionary labels:
 - Keep out of reach of children
 - Do not crush, chew or dissolve
 - Do not consume alcohol
 - Special cautionary label such as: "May cause serious harm or toxicity 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. Pharmacists must confirm patients' understanding of dosing instructions prior to releasing take-home doses.

NOTE: If compliance packaging is ordered by the prescriber to improve adherence, discourage diversion, or to facilitate take-home dose audits, the pharmacist must ensure that the capsules are handled safely and that the requirements of the NLPB Standards for the Safe and Effective Provision of Compliance Packages⁶ are met in addition to the requirements of these Standards. Specifically, patients must be counselled that the packages are not child-safe and must be stored securely.

10.3 Releasing the Prescription

- a) *Providing Witnessed and Take-home Doses.* As discussed in section 10.1 d), the majority of prescriptions for slow-release oral morphine will be for daily witnessed ingestion. Take-home doses of slow-release oral morphine are only provided in exceptional circumstances. A patient **MUST** have a witnessed dose prior to releasing any take-home doses of slow-release oral morphine.

Pharmacist must dispense take-home doses directly to the patient.

Prior to releasing slow-release oral morphine doses to the patient, a pharmacist must:

- i) Review the patient's local profile, the Pharmacy Network profile, and Administration Log, and any other applicable information to determine that it is safe and appropriate to provide the patient with the prescribed slow-release oral morphine dose.

If a drug-related problem is detected (for example, another mood-altering or sedating drug has been prescribed) the pharmacist must consult with the relevant prescribers prior to dispensing the prescription and document the outcome of the consultation.

- ii) Positively identify the patient. If uncertain as to the patient's identity, photo identification must be requested.
- iii) Assess the patient for signs of intoxication or sedation. If it is determined that the patient is intoxicated or sedated, the pharmacist must withhold the dose and consult with the prescriber (see section 11) a) below).
- iv) Once it has been determined to be appropriate to release the witnessed dose, the pharmacist must:
- Prepare the dose by opening the capsule(s) and sprinkling the enclosed pellets into a medicine cup for immediate ingestion.
 - Instruct the patient not to chew or crush the pellets (chewing or crushing the pellets can result in rapid release and absorption of a potentially fatal dose of morphine sulfate).
 - Directly observe the patient ingesting the medication (this cannot be delegated to a pharmacy technician or support staff) and instruct the patient to drink a cup of water;

⁶ NLPB Standards for the Safe and Effective Provision of Compliance Packages: http://www.nlpb.ca/media/SOPP-Compliance_Packaging-Sept2015.pdf

- Ensure the entire dose has been swallowed by engaging in conversation, asking the patient if there are pellets remaining in their teeth or gums, offering additional water for rinsing, or inspecting the inside of the patient's mouth
 - v) If the patient is receiving take-home doses, ask the patient to verify the label on the vial containing take-home doses and the number of take-home doses provided.
 - vi) Appropriately document the provision of the witnessed and take-home doses on the Administration Log and ask the patient to sign for each dose provided (see sample in Appendix VI).
- b) *Patient Counselling.* Pharmacists are required to:
 - i) Counsel the patient about slow-release oral morphine for OAMT (upon initiation of treatment and when necessary thereafter). For complete patient counselling information, see the relevant product monograph and information in required references. Counselling should include, but is not limited to:
 - Side effects and treatment effects of slow-release oral morphine;
 - Slow-release oral morphine must be swallowed whole. Crushing, chewing, or dissolving slow-release oral morphine capsules or pellets can cause rapid release and absorption of a potentially fatal dose of morphine sulphate.
 - Symptoms of opioid withdrawal and overdose;
 - The importance of arriving at the pharmacy around the same each day and not missing doses to ensure consistent blood levels of slow-release oral morphine;
 - Driving an automobile or operating machinery may be dangerous, especially during the stabilization period or periods of instability due to possible sedation and symptoms of withdrawal;
 - The need to contact the pharmacy prior to taking any prescribed or non-prescribed medications in order to prevent potentially harmful drug interactions;
 - The risk associated with the use of alcohol and other sedating substances in combination with slow-release oral morphine;
 - The recommendation to have a naloxone kit on-hand at all times; and
 - The need for family planning due to improvements in fertility that is associated with stabilization on OAMT.
 - ii) Counsel the patient appropriately regarding the risks of take-home doses (upon initiation of take-home doses and when necessary thereafter). Counselling should include, but is not limited to:
 - Take-home doses are for the patient's consumption only;
 - Slow-release oral morphine take-home doses must be stored securely, preferably in a locked cupboard or small lock box;
 - Ingestion of slow-release oral morphine by anyone other than the patient should be considered a medical emergency and emergency assistance (911) should be called immediately;
 - The entire dose should be consumed as prescribed, at the same time each day.
 - Slow-release oral morphine must be swallowed whole. Crushing, chewing, or dissolving slow-release oral morphine capsules or pellets can cause rapid release and absorption of a potentially fatal dose of morphine sulphate.
 - Tolerance to slow-release oral morphine may be lost if a dose has not been consumed for two consecutive days. In this circumstance, resuming the usual prescribed dose would place the patient at risk of overdose or toxicity.
 - Take-home dose vials must be returned to the pharmacy; and

- Patients may be advised at any time to return to the pharmacy with the balance of their take-home doses.

NOTE: In accordance with the *SOPO-Community* and the *SOPO-Hospital*, all counselling activities must be documented. The pharmacist should use professional judgement when determining the information to be contained in the counselling record, but it should include, at a minimum, the name of the pharmacist who delivered the counselling and the date and time the counselling was given.

- c) *Monitoring Compliance with Take-Home Doses.* There are several ways that pharmacists can monitor a patient's compliance with take-home doses.
- i) Vial Return: As noted in the previous section, patients should be advised to return their empty vials with the original labels intact to the pharmacy for inspection and proper destruction at their next visit. Return of take-home dose vials should be recorded on the patient's Administration Log. These vials should not be reused, even for the same patient.
 - ii) Take-Home Dose Audit: Patients should be advised that they may be asked at any time to return to the pharmacy with the remainder of their take-home doses and empty vials. This procedure, known as a "take-home dose audit", may be used to deter patients from diverting their take home doses. This audit may be initiated by either the prescriber or the pharmacist.

If there are issues of concern with the patient's compliance with their take-home doses or evidence of diversion, the pharmacist should notify the prescriber immediately (see sample Prescriber Notification Form in Appendix V).

11) Responding to Special Circumstances

- a) *Intoxication or Sedation.* To assess a patient for intoxication or sedation, the pharmacist should:
- Consider their general demeanor and behaviour in comparison to what you 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, consult with the patient's prescriber, and document the outcome of this conversation.

It is safer to refuse to dispense a patient's OAMT dose, than to medicate an intoxicated patient.

- b) *Partial Consumption of Doses.* If a patient declines or is unable to consume their full dose, the pharmacist must respect the patient's choice. The unconsumed portion cannot be given as a take-home dose. The pharmacist must clearly document the patient's partial consumption of the dose and the reasons for it and inform the prescriber of the incident (see sample Prescriber Notification Form in Appendix V).
- c) *Missed Doses.* Pharmacists **MUST REPORT ANY MISSED DOSES** to the prescriber within 24 hours so that the prescriber can reassess the patient's clinical stability (see sample Prescriber Notification Form in

Appendix V). Pharmacists must be familiar with up-to-date clinical practice guidelines for how to handle missed doses in order to assess the appropriateness of prescribed doses upon re-initiation.

If a patient misses

- **three or more** consecutive doses of methadone,
- **six or more** consecutive doses of buprenorphine/naloxone, or
- **two or more** consecutive doses of slow-release oral morphine,

the prescription must be cancelled.

NOTE: Any OAMT dose 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 Pharmacy Network patient record reflects accurate and current information in terms of consumed and picked-up doses as other healthcare practitioners rely on this information in making treatment decisions.

Vomited Doses. Pharmacists must be familiar with clinical practice guidelines for replacement of vomited OAMT doses.

If the patient vomits their **methadone** or **slow release oral morphine** dose, a replacement cannot be provided unless a new prescription is received from the prescriber. This is because the replacement dose would be considered an additional dose as the initial dose was received by the patient, and pharmacists are unable to prescribe controlled substances. The vomited dose is not required to be reported to Health Canada as a loss or theft because it is explainable what happened to the dose. 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 the prescriber's decision regarding dose replacement.

If a patient vomits a **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.

- d) *Lost or Stolen Doses.* If a patient reports that their dose(s) have been lost, stolen, or misplaced, a replacement dose(s) cannot be provided. The 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.
- e) *Administration Errors.* In the event of a confirmed or suspected medication dosing error, the pharmacist must take appropriate and necessary action to minimize harm to the patient, ensuring transparency throughout the entire process. This includes prompt consultation with the patient's other health care provider(s) to determine appropriate actions to be taken. Following the incident, a root-cause analysis should be performed to determine any risks associated with the pharmacy workflow that may have contributed to the error, and process improvements should be made to prevent future errors.
- f) *Discontinuation of OAMT.* Even though the efficacy of long-term OAMT is well recognized, a patient may eventually want to discontinue therapy. In general, the decision to discontinue OAMT and the rate of the medication taper should be guided by the patient.

Pharmacists must be familiar with the clinical practice guidelines for tapering OAMT. If pharmacists see doses being prescribed outside of recognized clinical practice guidelines they should consult with the prescriber, assess the appropriateness of the tapering plan based on patient-specific clinical factors, and document the rationale for clinical decisions in the patient record.

Pharmacists should counsel patients about the risk of relapse to drug use and encourage patients to discuss relapse prevention techniques with a counsellor. Abrupt discontinuation should be discouraged as withdrawal symptoms can be severe and long-lasting. Pharmacists should discuss concerns about patients' wellbeing during the tapering process with the patient and methadone prescriber.

12) Special Patient Populations

- a) *Pregnancy and Lactation.* Pharmacists must be familiar with clinical practice guidelines for the use of OAMT in pregnancy. For more information on the use of OAMT in pregnancy, see section 7 of the CAMH *Opioid Agonist Maintenance Treatment*⁷ reference.
- b) *Treatment of Pain in an OAMT Patient.* Pharmacists must be familiar with clinical practice guidelines for the treatment of pain in OAMT patients. For more information on the treatment of pain in OAMT patients, see section 8 of the CAMH *Opioid Agonist Maintenance Treatment* reference.

13) Ensuring Continuity of Care

13.1 Secondary Pharmacy

If a pharmacy has a patient who requires daily witnessed ingestion, but is not normally open seven days a week, the pharmacist must work with the prescriber to ensure that the patient is still able to acquire their doses on the days the pharmacy is closed.

This may include collaboration with another community or hospital pharmacy, opening at pre-arranged selected times on the day(s) the pharmacy is otherwise closed and/ or authorization for a take-home dose on selected days that the pharmacy is closed (if the prescriber deems it safe and in the patient's best interest to receive a take-home dose).

13.2 Guest Dosing

There are occasions, such as a vacation or business travel, when an OAMT patient might ask to be medicated on a temporary basis at another pharmacy. Guest dosing generally involves situations in which the patient cannot be provided with take-home doses for the period of absence. Such situations may arise when the patient:

- is not considered stable enough to be given take-home doses for the time period, or
- may be away for a long period that prevents issuing sufficient take-home doses. For example, for methadone, the diluent may expire, or it may not be practical to travel with a large number of containers, or concern exists about loss or theft of a large number of containers.

With the patient's consent, the pharmacist can facilitate identifying a conveniently located pharmacy that would be able to dispense methadone on a temporary basis.

The 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 methadone or buprenorphine/naloxone. This communication is imperative to prevent double-dosing or

⁷ Opioid Agonist Maintenance Treatment, 3rd edition (<http://store-camh.myshopify.com/collections/english-anglais/products/p6500>)

missed dosing and must be documented in the patient's administration record at both the home pharmacy and the guest pharmacy.

13.3 Provision of OAMT in Hospitals

- a) *Policies and Procedures.* As per section 6) f) of these Standards, all hospital pharmacies must have a policy and procedure manual related to the provision of medications for the treatment of OAMT.

Hospital policies should reflect these Standards as well as the most recent practice guidelines, such as those provided in section 9 of the CAMH *Opioid Agonist Maintenance Treatment*⁸ reference.

NOTE: As per section 2.5 of the SOPO-Hospital, service to out-patients must be performed in accordance with the SOPO-Community as well as established policies and procedures.

- b) *Admission.* When an OAMT patient is admitted to hospital or visits an emergency/outpatient department, pharmacists and other health care providers on staff at the institution must work closely with the patient's community pharmacist and OAMT prescriber to provide uninterrupted care that is optimal, safe and effective for the patient. Whenever possible, the community pharmacy and hospital pharmacy should initiate transition of care planning prior to the patient being admitted to the hospital (e.g. for a scheduled surgery or procedure) or prior to the patient receiving OAMT from the hospital as an out-patient.

- c) *Information Gathering.* To ensure continuity of treatment and to minimize the risk of error, the institutional pharmacist or health care provider receiving the OAMT patient must gather certain information before dispensing OAMT:

- What is the patient's current dose? Is the patient's dose being tapered, titrated, or maintained?
- When was the last dose given? Were any doses missed? What is the pattern of pick-up? (adherence)
- Does the patient receive take-home doses? If so,
 - How many take-home doses were last dispensed?
 - When was the last take-home dose actually ingested?
 - Were any take-home doses brought in by the client?
 - Are any take-home doses left at home?
- Does the patient have an active prescription at their usual community pharmacy?
- What other medications or drugs the patient is currently taking?

The pharmacist or other health care provider may also want to consider:

- Is the patient showing any signs or symptoms of intoxication?
- Is the patient showing any signs or symptoms of withdrawal?
- Is the patient pregnant?
- Does the patient have any other medical conditions?

⁸ Opioid Agonist Maintenance Treatment, 3rd edition (<http://store-camh.myshopify.com/collections/english-anglais/products/p6500>)

- Any psychiatric conditions?
- Is there a need to treat pain?
- Are there medical reasons for delaying OAMT?

NOTE: Hospital pharmacists must confirm last dose information (amount, date, and time) prior to a dose being provided to a patient in hospital.

- d) *Prescriber Eligibility.* As described in section 8.1 a), there may be specific prescriber eligibility criteria to consider.
- e) *Orders.* Orders for OAMT must be clear and specific with regard to dose and start and end dates.

NOTE: Prescriptions for outpatients must be written in accordance with the Tamper Resistant Drug Pad Program as noted in sections 8.1 b), 9.1 b), 10.1 a).

- f) *Preparation.* OAMT must be prepared in accordance with sections 8.2, 9.2, and 10.2 of these Standards. In accordance with section 9 of the CAMH *Opioid Agonist Maintenance Treatment*⁹ reference, the institution should use its own supply of medications for OAMT, even if a patient has brought in their own take-home doses.
- g) *Distribution.* Whenever possible, OAMT should be dispensed to the patient care area as individual patient specific doses each day.
- h) *Storage.* Storage of OAMT doses in the pharmacy and patient care areas must meet security requirements outlined in section 6) d) of these Standards and section 9 of the CAMH *Opioid Agonist Maintenance Treatment*. Specifically, methadone doses must be stored in a locked refrigerator in the patient care area. If the patient care area does not have a locked refrigerator, individual doses must be stored in a secure location until administration.
- i) *Witnessed Ingestion.* In a hospital setting, the witnessing of OAMT ingestion may be carried out by pharmacists or other qualified healthcare providers (e.g. nurses, physicians). The hospital's established policies and procedures for OAMT administration must be aligned with these Standards and recognized clinical practice guidelines.

NOTE: Methadone is considered a “high-alert” medication by ISMP; therefore, recommendations for independent double-checks of doses and double-signatures by nursing staff should be followed.

- j) *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 OAMT take-home doses as part of a leave of absence (pass) medications. Alternatives to take-home doses might be:

⁹ Opioid Agonist Maintenance Treatment, 3rd edition (<http://store-camh.myshopify.com/collections/english-anglais/products/p6500>)

- 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 13.2).

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 for the leave of absence.

- k) *Discharge and Release to the Community.* Before discharge, the hospital pharmacist MUST ensure the patient has a valid prescription at a community pharmacy and communicate the following to the community pharmacist and the client's usual OAMT prescriber:
- the date of discharge;
 - whether a prescription for OAMT was given to client when discharged;
 - what the current OAMT dose is, and whether or not any changes of dose occurred during the stay in the institution; and
 - when the last dose was given in the institution, and whether any take-home doses were dispensed, destroyed or returned.

Even if there is a valid prescription at the community pharmacy, this prescription may no longer be appropriate. The community prescriber should be contacted for direction on whether an existing prescription should be resumed or cancelled, and regarding the provision of any previously prescribed take-home doses.

The hospital pharmacist is expected to communicate pertinent information ahead of time, but the ultimate responsibility rests with the community pharmacist to obtain what is needed prior to dispensing OAMT upon discharge.

13.4 Incarceration

Pharmacists are expected to be familiar with up-to-date practice recommendations for OAMT provision in federal or provincial correctional facilities in order to inform policies and procedures for this area of service.

If a patient on OAMT transitions in and/or out of a correctional facility, effective information sharing of information among the patient's health care providers is critically important for patient safety, continuity of care and preventing diversion.

For more information on incarceration, see section 9 of the CAMH *Opioid Agonist Maintenance Treatment*¹⁰ reference.

¹⁰ Opioid Agonist Maintenance Treatment, 3rd edition (<http://store-camh.myshopify.com/collections/english-anglais/products/p6500>)

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Berkley Coish
Susan Gillingham
Natalie Holden
Denise McGrath
Kelda Newport
Barbara Thomas
Graham Tweedie

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

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2. British Columbia Centre on Substance Use (BCCSU). (2017). A Guideline for the Clinical Management of Opioid Use Disorder. Retrieved from: http://www.bccsu.ca/wp-content/uploads/2017/06/BC-OUD-Guidelines_June2017.pdf
3. BC College of Pharmacists. (2018). Professional Practice Policy #66: Policy Guide- Slow Release Oral Morphine (SROM) Maintenance Treatment. Retrieved from: <http://www.bcpharmacists.org/professional-practice-policies-and-guides>
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11. Nova Scotia College of Pharmacists. (2017, June). Standards of Practice: Opioid Agonist Maintenance Treatment. Retrieved from: <http://www.nspharmacists.ca/?page=standardsofpractice#SOPOAMT>
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13. New Brunswick College of Pharmacists. (2015). Methadone Practice Directive. Retrieved from: <http://www.nbpharmacists.ca/site/practice-rqmts>

Appendix I
Opioid Agonist Maintenance Treatment
Pharmacy-Patient Service Agreement Template

This document is intended to describe our mutual expectations while you are receiving OAMT services from our pharmacy and to summarize any counselling points that may have been discussed.

The pharmacy staff will provide you with:

- Professional, non-judgmental service that recognizes your rights to respect and dignity.
- Privacy and confidentiality of your health information. When necessary, pharmacy staff may communicate with other health professionals concerning the treatment of your opioid dependence.
- Pharmacy services that take your best interests into account as well as the safety of others. A pharmacist may refuse to fill your prescription or provide take-home doses if there is concern for your safety or the safety of others (e.g. intoxication, concern for diversion). This decision will be communicated to you and your prescriber.
- Ongoing monitoring of your treatment progress.

Additionally, as a patient in our pharmacy, we expect you to:

- Treat the pharmacy staff and the pharmacy premises with respect. Threats, illegal activity, or disruptive or violent behaviour will not be tolerated.
- Present at the pharmacy for your medication between the hours of _____ and _____.
- Ensure that you have a valid prescription.
- Present photo identification, when requested.
- Pay for your medication at the time you receive the dose.
- Present for your doses as prescribed. Missed doses will not be made up and will be reported to your prescriber.
- Confirm that witnessed doses have been swallowed or have dissolved by showing the inside of your mouth and/or under your tongue, or speaking to the pharmacist.
- If you have been authorized to receive take-home doses,:
 - Pick up your own take-home doses.
 - Store all take-home doses safely and securely, preferably in a locked box, to ensure there is no chance of accidental ingestion by others. Lost or missing take-home doses cannot be replaced without a prescription from your prescriber.
 - Take each dose as prescribed, according to the label on the bottle or vial.
 - Return all bottles or vials to the pharmacy with their original labels intact.
 - Bring in all full and empty take-home dose bottles or vials, if a take-home dose audit is requested.

Patient Signature

Date

Pharmacist Signature

Date

Appendix V
Opioid Agonist Maintenance Treatment
Prescriber Fax Notification Form

To: _____
Prescriber Name _____ Fax # _____

Date: _____

Re: _____
Patient Name _____ MCP # _____

From: _____
Pharmacy Name _____ Pharmacist Name _____
_____ Phone # _____ Fax # _____

Type of Incident:

- The patient missed his/her dose on (date): _____
- The patient vomited his/her dose on (date): _____
 - Emesis was witnessed by a pharmacist or another member of the pharmacy team; suggest that prescription for replacement dose of _____ mg be faxed to the pharmacy.
 - Emesis was not witnessed by a pharmacist or another member of the pharmacy team.
Recommended action: _____
- The patient reported a lost or stolen take home dose on (date): _____
- The patient partially consumed his/her dose on (date): _____ because _____

Additional Details: _____
(if applicable) _____

Follow-up Plan: _____
(if applicable) _____

