

Opioid Agonist Therapy (OAT) guidelines

Medication-assisted treatment for opioid use disorder: Guidelines for pharmacists and pharmacy technicians

Acknowledgements

The Alberta College of Pharmacy (ACP) would like to acknowledge that work to complete this document occurred on Treaty 6, Treaty 7, and Treaty 8 territory—the traditional lands of First Nations people—and six Métis regions. The roots of many modern medications come from the Indigenous peoples' traditional use of plants from these lands.

ACP gratefully acknowledges the consent of the following organizations to allow inclusion of portions of their materials in these guidelines.

- · The British Columbia Centre on Substance Use
- The Institute for Safe Medication Practices Canada

The Alberta College of Pharmacy extends thanks to the following organizations and individuals for their contributions and expertise in updating Medication-assisted treatment for opioid use disorder: Guidelines for pharmacists and pharmacy technicians.

- College of Physicians & Surgeons of Alberta
- · College and Association of Registered Nurses of Alberta
- Alberta Pharmacists' Association
- · Tiana Cunningham, RPhT
- Colter Young, BSc Pharm, RPh (APA)
- Essi Salokangas, BSc Pharm, RPh (APA)
- · Tara O'Mara, MN-NP Family Nurse Practitioner
- · Amy Rego, BSc Pharm, RPh, MBA
- Petra Schulz, Co-founder, Moms Stop The Harm
- Nathaniel Day, MD CCFP ABAM FASAM
- · Hakique Virani, MD FRCPC DABAM
- · Shanell Twan, Core Team Supervisor, Streetworks
- Michael Trew, MD FRCPC

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Background

This document replaces the 2014 Medication-assisted treatment for opioid dependence: Guidelines for pharmacists and pharmacy technicians.

Since that time there have been considerable clinical, conceptual, and legislative changes. In addition, the public health impact of opioid-related deaths has grown drastically throughout Alberta, Canada, and worldwide.

Treatment protocols have evolved for methadone and buprenorphine-naloxone, new treatment modalities have emerged including buprenorphine depot, slow-release oral morphine (SROM) and injectable opioid agonist therapy (iOAT). Additionally, unscheduled naloxone is now commonly provided as a tool to manage opioid poisoning.

Other notable differences from the 2014 document include

- · expectations on meeting the needs of individuals with opioid use disorder (OUD);
- · updated references, requirements, and processes;
- reorganization of the guidance by treatment modality; and
- a shift from clinical information to regulatory and technical guidance.

Nothing in these guidelines relieves a regulated member from their obligation to meet the requirements of the Standards of Practice for Pharmacists and Pharmacy Technicians (SPPPT), the Standards for the Operation of a Licensed Pharmacy, the Alberta College of Pharmacy Code of Ethics (COE), the *Health Professions Act*, the *Pharmacy and Drug Act*, the *Controlled Drugs and Substances Act*, or any other applicable legislation governing the practice of pharmacy in Alberta.

Guidelines establish the professionally accepted means by which regulated members can achieve compliance with the standards. Guidelines use the language of "should." Guidelines are not recommendations; they establish the expected conduct of regulated members. A regulated member may only depart from a guideline if the regulated member can demonstrate that the regulated member

- achieved compliance with the applicable standard, and
- the member's departure from the guideline
 - did not detract from the safety, effectiveness, or appropriateness of patient care; or
 - did not undermine the integrity of the professions of pharmacists and pharmacy technicians.

Purpose and scope

The OAT Guidelines are a resource for regulated members in Alberta who work with people living with OUD. The guidelines incorporate current best practices for medication-assisted management of OUD with a focus on pharmacy practice.

These guidelines are intended to

- provide guidance that prioritizes the well-being of patients requiring these services,
- · ensure treatments for OUD meet the regulatory requirements for such services,
- inform and guide the efforts and professional judgement of regulated members while they provide care to people living with OUD,
- interpret the SPPPT as they pertain to the provision of OAT,
- · provide guidance to regulated members dispensing OAT,
- provide a framework to ensure consistency among regulated members who provide OAT services,
- summarize information about OAT to enhance regulated members' understanding about the treatments and optimize delivery of patient care, and
- · clarify the roles of regulated pharmacy members as part of the multidisciplinary team involved in managing OUD.

Important – read this first

These guidelines are not to be considered in isolation. They are intended to be used in conjunction with current and evolving evidence-informed clinical resources from reputable sources.

It is expected that that regulated members will read Part A – Meeting the needs of individuals with opioid use disorder provided before proceeding to Part B – Guidelines for pharmacists and pharmacy technicians providing care for patients using opioid agonist therapy. Part A discusses key concepts and expectations on how patient care should be delivered to individuals with OUD. This creates the lens through which Part B of the guidelines should be considered and applied.

Part A – Meeting the needs of individuals with opioid use disorder

1.0 Person-centred care for opioid use disorder

Opioid use disorder (OUD) is a significant and growing health concern in our society. For those living with this chronic and often relapsing health condition, the consequences can be significant. Unintentional opioid poisoning was responsible for the deaths of 3,139 individuals in Alberta between January 1, 2016, and June 30, 2020¹. Individuals living with OUD may face a host of other concerns including 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. While many individuals living with OUD are already members of other vulnerable, marginalized groups within society, others come from all walks of life.

Success in treating OUD involves aspects beyond that of selecting and administering a medication. Successful care requires a deeper understanding of both the condition itself as well as the stigmatization and marginalization these individuals face. Treatment for this multi-dimensional condition is optimized through the concerted efforts and collaboration of a multidisciplinary team of trained professionals. This team may include physicians, nurse practitioners, pharmacists, pharmacy technicians, nurses, case managers, social workers, peer support workers, and addiction counselors, all working together to provide the medical, psychological, behavioural, and social interventions that may be required.

Pharmacists and pharmacy technicians ("regulated members") who wish to 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.

Fundamental to this knowledge, regulated members must understand the concepts of stigma, trauma-informed care, and harm reduction.

1.1 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. Stigma creates barriers to accessing important health and social services².

While stigma can certainly take the form of active negative treatment of individuals by healthcare providers, it can also be more insidious and unintentional. Regulated members 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.

"Stigma is hard. Lots of people still look at us like we're using" -person with lived experience

Regulated members can take steps to reduce stigma. These steps include

- identifying and recognizing their own biases;
- · remembering that substance use disorder is a medical condition deserving of care and treatment; and
- changing the way staff talk about substance use and choosing respectful, person-centred language.

¹ Quarterly opioid surveillance reports; Q2 report: April to June 2020. Retrieved from: https://www.alberta.ca/substance-use-surveillance-data.aspx

² Government of Canada. Stigma Around Substance Use. Retrieved from: https://www.canada.ca/en/health-canada/services/substance-use/problematic-prescription-drug-use/opioids/stigma.html

1.2 Trauma-informed care

Trauma-informed care is a set of guiding principles which takes into account the effects of trauma on an individual. Seventy-six per cent of Canadian adults report some form of trauma exposure in their lifetime and 9.2 per cent meet the criteria for PTSD³.

Psychological trauma is often closely tied to substance use, mental health, stigma, health care access barriers, and other challenges. People who experience trauma can have varied responses; some will have minor disruptions to their personal life while others may have a debilitating response. Trauma-informed care means recognizing this link, making sure that people feel safe, and are not re-traumatized by their care⁴.

Disclosure of trauma is not necessary to implement trauma-informed care practices. Trauma-informed care is not counselling for trauma and, while it is not within the regulated member's scope to directly address patient trauma, it is important that the impact of trauma is recognized and respected when providing patient care.

1.3 Harm reduction

Harm reduction means those policies, programs, and practices that aim primarily to reduce the adverse health, social, or economic consequences of the use of legal and illegal psychoactive substances without necessarily reducing consumption⁵. 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.

Harm reduction principles recognize the inherent value of human beings and the importance of an inclusive community that can support people who use substances with compassion. People who feel supported and part of a community, rather than isolated, are more likely to seek help when they need it⁶.

Regulated members must understand and accept, without applying moral judgements, that individuals with substance use disorders need to be treated with the same level of respect as any other patients.

1.4 Harm reduction services and take-home naloxone

For some individuals who use substances, engagement with their pharmacy team may be their most consistent connection to health care. These patients may present at different stages of change. Regardless of the patient's stage of change or treatment intensity, regulated members should offer harm reduction information and services to minimize potential harms of substance use.

Various types of harm reduction services should be considered, including

- counselling on overdose prevention and treatment, including provision and training of take-home naloxone;
- education regarding safe use of substances;
- collaboration with community partners to provide supplies to support safe substance use;
- referral to an opioid/substance use disorder treatment provider or program;
- referral to other harm reduction services such as needle distribution programs or supervised consumption services;
- referral to other community agencies that can provide food, shelter, clothing, and other necessities of life;

³ Van Ameringen, M., et al., Post-traumatic stress disorder in Canada. CNS Neuroscience & Therapeutics, 2008. 14(3): p. 171-181.

⁴ http://www.bcmhsus.ca/health-professionals/clinical-professional-resources/trauma-informed-practice

⁵ Alberta Health Services, retrieved from: https://www.albertahealthservices.ca/assets/info/hrs/if-hrs-harm-reduction-policy-frequently-asked-questions.pdf

⁶ Alberta Health Services, retrieved from: https://www.albertahealthservices.ca/info/Page15432.aspx

- · screening and offering immunizations for preventable illness (hepatitis A & B, influenza, etc.); and
- ordering laboratory tests (bloodwork) when appropriate.

Patients may benefit from harm reduction in numerous ways. Harm reduction may

- empower patients to have agency over how their health goals are met,
- · reduce the risk of morbidity and mortality from overdose or non-medical use of opioids or other substances,
- reduce the transmission of blood-borne pathogens,
- reduce the need to engage in criminal activity to support a substance use disorder,
- reduce harm during pregnancy and breastfeeding to optimize neo-natal outcomes, and
- provide an opportunity to connect patients to other health services.

1.4.1 Take-home naloxone

Naloxone is an opioid antagonist which acts as an antidote to opioid poisoning. All patients prescribed OAT medications should be offered take-home naloxone and provided relevant education on its use by the pharmacy team at regular intervals. Naloxone may also be offered to family members, patient agents, caregivers, and other individuals who may be in position to respond to an opioid poisoning event.

More information on the use of naloxone can be found in the ACP document Providing naloxone as an unscheduled drug: Guidelines for pharmacy teams.

Part B – Guidelines for pharmacists and pharmacy technicians providing care for patients using opioid agonist therapy

1.0 Strategy for medication-assisted treatment for opioid use disorder

Medication-assisted treatment for OUD serves to minimize harms from non-medical use of opioids and bring stability to the lives of those with OUD. The benefits can be physiological, psychological, and social. When optimized, traditional opioids used in the treatment of OUD, such as buprenorphine-naloxone and methadone, cause little to no euphoric effect. Their long half-lives enable suppression of withdrawal symptoms and cravings that may contribute to relapse. SROM and iOAT therapy provide further options for individuals who have been unable to stabilize their OUD with first-line oral OAT therapy.

A treatment strategy for OUD should include the following key elements:

- Development of a trusting and collaborative patient-provider relationship.
- Access to safe and effective medication-assisted treatments for OUD.
- Access to quality care delivered by knowledgeable and trained professionals equipped to deal with the needs of
 the whole person. When appropriate and accessible, treatment may be offered in conjunction with person-centred
 psychosocial support and guidance.
- Acknowledge and recognize that minimizing negative health, social, and economic consequences is desirable, and that complete abstinence or complete adherence to the OAT may not always be possible.

1.1 Treatment choices for opioid use disorder

OAT involves the substitution of opioids implicated in a patient's OUD with a pharmaceutical-grade opioid in an effort to assist in stabilizing the patient's opioid use. Several OAT options are currently used in Canada for treatment of OUD, the most prevalent being

- methadone (Metadol-D®, Methadose®, generics), and
- buprenorphine-naloxone (Suboxone®, generics).

For patients who have achieved stability of their OUD using sublingual buprenorphine, either buprenorphine depot (Sublocade®), or buprenorphine implants (Probuphine®) may be other options.

For patients unable to stabilize on methadone or buprenorphine-naloxone, expert-led options are available, such as

- · slow-release oral morphine (Kadian®), and
- · injectable hydromorphone, which is offered in specialized settings.

1.2 Factors in OAT medication choice

The choice of therapy between these options will depend on a number of factors including the patient's

- preference, including past experiences with OAT;
- degree of opioid dependence and tolerance;
- risk of harm from the chosen therapy including the risk of non-adherence;
- concomitant health conditions and comorbidities;
- lifestyle and social history;

- potential to experience significant drug interactions with other concomitant therapies;
- ability to access the specialized services and expertise of an OUD program (e.g., iOAT);
- response to therapy; and
- ability to afford the chosen therapy.

2.0 Licensee and regulated member responsibilities

2.1 Competence

Though there are no specific training or educational requirements for providing OAT, it is required that all regulated members will have the necessary competencies to support this unique patient population and complex medical condition.

Pharmacists must be aware of current, relevant, and evidence-based clinical practice guidelines including the resources available in Appendix 1.

Licensees are responsible to ensure all pharmacy team members are aware of their role and have the appropriate competencies to provide OAT services. Licensees must develop site-specific policies and procedures to support the safe and effective provision of OAT within their pharmacy.

2.2 Notification to ACP

Pharmacy licensees are required to inform the ACP registration department by email at pharmacy@abpharmacy.ca when their pharmacy begins providing OAT services to patients. Similarly, pharmacy licensees must notify the registration department as soon as possible if the pharmacy is no longer providing OAT services.

2.3 Pharmacy operating hours

Pharmacy operating hours must accommodate the needs of those requiring witnessed administration without compromising patient safety or causing undue hardship to the patient. Pharmacies that do not operate seven days a week must ensure that arrangements are made to enable the patient to access their medication on the days the pharmacy is closed. This may include

- collaboration with another pharmacy;
- opening at selected times on the day(s) the pharmacy is closed to provide care to pre-scheduled patients who
 require witnessed administration;
- authorization for a take-home dose on selected days that the pharmacy is closed, if safe and appropriate for the patient and approved by the prescriber; and
- on-call pharmacy personnel/services for emergencies and immediate need.

Considering the challenges associated with some of these options, it may be in the patient's best interests to use another pharmacy altogether which is able to accommodate the patient seven days per week.

Changes made to pharmacy operating hours must consider the potential impacts to patients receiving OAT from that pharmacy.

2.4 Physical environment requirements for OAT

Suitable sound barriers to prevent unauthorized individuals from overhearing conversations and suitable visual barriers to maintain patient privacy are required at all pharmacies. However, regulated members should be mindful of the potential stigma associated with witnessed administration and the sensitive nature of the conversations that may occur regarding the patient's substance use.

2.5 Security

Licensees must consider security measures to address potential risks of robbery or burglary associated with storage of significant quantities of controlled substances, and the risks to the community that can result from theft of these products.

Licensees should review ACP resources for additional information on pharmacy robberies and burglaries.

3.0 Collaboration

Regulated members providing OAT may have frequent and ongoing connections with their patients living with OUD.

Regulated members work closely and directly with the prescriber or within a broader team of service providers. Close communication between members of the patient care team, as well as with patients, is an essential factor in achieving patients' health goals. This relationship may be formally outlined in a three-way agreement involving the patient. More information on the pharmacy-patient agreements can be found in the Opioid agonist therapy – General guidelines section.

Prescribers have indicated they value the important assessments made by pharmacy team members who interact on a frequent basis with clients presenting for OAT medication.

4.0 Prescription standards and requirements

4.1 Prescription requirements

Regulated members must only dispense OAT medications pursuant to receiving a prescription order that meets all of the requirements for an appropriate, current, authentic, and complete prescription. This may include, depending on the medication, additional requirements outlined in the TPP Alberta Program Guide. Furthermore, regulated members should ensure OAT prescriptions clearly outline the following OAT-specific information:

- the start and end date of the prescription, before and after which dispensing of OAT is not approved;
- · the specific days or dates on which witnessed ingestion is to occur;
- the specific days or dates on which take-home doses are to be dispensed;
- indication for the OAT (e.g., opioid use disorder, analgesia, or both); and
- · any special instructions.

4.2 Prescriber requirements

All healthcare professionals who prescribe or dispense OAT should be aware of the regulatory requirements and standards of practice that govern the prescribing and dispensing of such treatments.

In Alberta, prescribing physicians require approval from the College of Physicians and Surgeons of Alberta (CPSA) in order to prescribe OAT medications (other than buprenorphine) for OUD, and the criteria may vary depending on the nature of their prescribing (e.g., initiating methadone therapy, maintenance of methadone therapy, slow release oral morphine, and injectable opioid agonist therapy).

While an authorization or approval is not provided by the College and Association of Registered Nurses of Alberta (CARNA), CARNA requires nurse practitioners to comply with the Prescribing Standards for Nurse Practitioners and meet all requirements for education and/or preceptorship to prescribe OAT for the category of prescribing applicable to their practice.

Where possible, regulated members must ensure that prescribers are eligible to prescribe OAT and can contact the prescriber's regulatory body if verification is necessary.

For more information about physician OAT prescribing approval, refer to cpsa.ca.

4.3 Filling out-of-province prescriptions

Regulated members may dispense out-of-province, Canadian OAT prescriptions provided that they confirm that the out-of-province prescriber is eligible to prescribe the OAT in their jurisdiction and the prescription complies with all requirements of the originating province. Out-of-province, Canadian OAT prescriptions do not need to be written on a TPP Alberta form.

4.4 Additional notes

- Pharmacists should discourage the use of abbreviations that may cause confusion or misunderstanding and should clarify abbreviated instructions with the prescriber as required (e.g., DWI or daily witnessed ingestion).
- Pharmacists should check that the last date for the OAT prescription falls on a day that the pharmacy is open for business to avoid missed doses or patient distress from seeking a new prescription and an alternate provider.

5.0 Opioid agonist therapy (OAT) - general guidelines

The evidence for use of medications in the treatment of OUD is well established and, over the last number of years, new treatment options have become available. Each option is nuanced, and assessment and monitoring must be personcentred. Regardless, there are certain general guidelines which apply in most scenarios.

5.1 The role of pharmacists

Pharmacists are responsible for confirming that the medication and dosage prescribed is appropriate based on their assessment of a patient's OUD and other factors such as concomitant medications that may pose a risk for drug interactions or other adverse effects. To facilitate this, pharmacists must have current knowledge of all applicable evidence-based clinical practice guidelines.

Pharmacists are also typically the front-line professional entrusted with witnessing ingestion of OAT, if required, and are therefore well positioned to assess the clinical effect of, and response to, the patient's treatment. They play a key role in monitoring response and adherence to therapy and communicating to prescribers when they encounter potential problems that may compromise efficacy or safety of the therapy.

Pharmacists are required to communicate to the prescriber any signs and symptoms of intoxication, withdrawal, or other adverse effects, and they are required to inform and consult prescribers about concerns regarding adherence, including missed, lost, or vomited doses.

5.2 The role of pharmacy technicians

Pharmacy technicians are integral to the pharmacy team and play a role in caring for patients with OUD. It is important for pharmacy technicians to maintain competence with respect to treatment of these patients. This may involve

- identifying and prioritizing patients who require pharmacist assessment,
- processing and checking of prescriptions,
- preparation of medications for dispensing or administration, and
- facilitating communication with prescribers or other members of the healthcare team.

Pharmacy technicians may not witness ingestion of OAT because witnessed ingestion requires a clinical assessment that includes an assessment of the medication effectiveness, screening for intoxication, an evaluation of adverse effects, any adherence concerns/impact of missed doses, and a review of the use of other prescribed and non-prescribed substances.

5.3 Alberta Electronic Health Record (Netcare)

Pharmacists must review the Alberta Electronic Health Record (Netcare) every time the pharmacist assesses a patient that is prescribed OAT. This review should include consideration of

- adherence to prescribed treatment,
- · relevant laboratory results,
- involvement of other pharmacies and/or prescribers, and
- · use of other medications that may affect OAT.

Regulated members must also ensure that dispensing information is uploaded daily to Netcare, so that accurate records of missed doses are created and maintained.

5.4 Counselling and patient education - general

Pharmacists involved in dispensing OAT must provide sufficient information to enable the patient to receive the intended benefit of the therapy and to optimize the safety of the drug to both the patient and the public.

The need for counselling will be ongoing as the treatment plan changes over time and as the patient becomes ready for more information. Pharmacists must be able to assess the ability of their patient to understand the information provided and, wherever possible, provide supplementary written instructions to allow the patient to further review the information on their own time. Consider the literacy of the patient and provide appropriate literature that is clear and concise. Information provided, both verbally and written, should be evidence based, obtained from a reputable source, and culturally sensitive.

The environment and the manner in which information is provided are important factors to support understanding and retention of information by the patient. As opioid withdrawal can be extremely uncomfortable, patients may experience acute difficulties fully internalizing the information being provided to them when in withdrawal. It may be prudent in such cases to provide OAT prior to extensive counselling, particularly during the initiation phase of treatment. Counselling may need to be provided iteratively, or repeatedly, in such cases. Important counselling considerations for each OAT medication are provided within their respective sections.

The process of addressing and changing behaviours related to opioid use can be extremely difficult for patients. Regulated members should consider using resources and training to develop their counselling skills in areas such as motivational interviewing.

5.5 Pharmacy-patient agreements

During the initial counselling session, pharmacists should review and sign a two-way agreement with the patient. This provides an opportunity to highlight essential information unique to OAT. The document sets expectations by detailing what the pharmacy team is required to provide as well as the responsibilities for the patient. This agreement should be kept on the patient's record, and revisited/updated regularly as treatment goals evolve. Pharmacists should consider a three-way agreement that includes the prescriber whenever possible to provide more complete information for the patient of what to expect and from whom. A sample agreement can be found in Appendix 3. All pharmacy team members assisting in the provision of OAT for a patient must be knowledgeable about the contents of the patient's two-way or three-way agreement. These agreements are not intended to restrict patients from transferring their care to another pharmacy. The purpose is to support mutual understanding of patient and regulated member expectations.

It may be appropriate to delay signing an agreement if a client presents initially in active withdrawal until after they have received their initial medication doses and are more able to be attentive to the importance of the discussion.

5.6 Monitoring - General

Pharmacists are directly involved in the monitoring of patients who are prescribed OAT. Monitoring activities considered a priority for pharmacists are generally those to optimize the response and outcomes to therapy—in particular, activities to evaluate the efficacy and safety of the treatment and the patient's adherence to the therapy. Pharmacists can play a key role in collaboration with the prescriber regarding the appropriateness of initiating carried doses.

Below are some of the monitoring activities performed by pharmacists:

- Monitor the patient's understanding, engagement, and adherence to treatment.
- Assess for symptoms or evidence of intoxication to determine if the dose should be dispensed:
 - Intoxication from opioids: pinpoint pupils, drowsiness, slurred speech, unsteady gait, slow heart rate, low blood pressure.

- Intoxication from alcohol: slurred speech, unsteady gait, uncoordinated movements, drop in blood pressure, alcohol smell on breath. Intoxication from benzodiazepines: sedation, drooling, low blood pressure, loss of muscle coordination, slurred speech
- o Intoxication from stimulants such as amphetamines: dilated pupils, pressured speech, hyperactivity, rapid heart rate, tremor, high blood pressure.
- Monitor daily response to administered doses, including signs of efficacy such as improvement in withdrawal symptoms, and signs of safety concerns such as symptoms of intoxication from the treatment that may require discontinuation of the medication or an adjustment of the dose.
- Monitor proper administration of ingested doses.
- Monitor for drug interactions with other concurrent therapies and for use of other opioids or substances that may contribute to increased risk of respiratory depression.
- Monitor for signs of diversion or use of the medication inconsistent with how it is prescribed.

It is important to note that some patients may exhibit signs consistent with intoxication due to other medical conditions. Pharmacists must always ensure they consider their observation in the context of the patient's complete medical history to avoid stigmatizing them.

5.7 Urine toxicology testing

Urine toxicology testing (UTT) is a tool that may be used in the context of OAT by healthcare practitioners, usually prescribers, for various reasons. It is used at a baseline to establish or corroborate a patient's recent opioid use and to screen for any drugs or substances which may increase the risk of harm to the patient who is prescribed OAT. As a monitoring tool, UTT can be used to assess adherence to treatment or may provide data to support efficacy or safety of treatment. Regulated members are frequently involved in notifying patients of upcoming urine tests ordered by their prescribers, administering point-of-care tests, or collecting specimens for laboratory analysis. Pharmacists may be involved in ordering UTT where appropriate. All these activities must occur in compliance with ACP's Laboratory and Point-of-Care Testing Standards.

Regardless of their role in UTT, pharmacists are expected to collaborate with the patient's prescriber to understand the role of UTT in their patient's treatment plan, and to establish who is best to order, administer, interpret, and communicate the results of the tests. Duplication of testing is discouraged. If a pharmacist becomes aware of a UTT result and they are unsure of the implications of it on the patient's treatment, or if a patient does not complete a required UTT that has been requested by the prescriber, they should collaborate with the prescriber prior to dispensing OAT.

While UTT may provide clinical value, it is also important to consider the impact that frequent screening may have on the lives and livelihoods of patients. It has the potential to contribute to untoward effects such as interference with work or other activities and may be interpreted by patients to be unnecessary and stigmatizing. All of this could lead to premature discontinuation of OAT by patients.

6.0 Buprenorphine-naloxone

6.1 Introduction - buprenorphine-naloxone

Buprenorphine-naloxone is a medication for treatment of OUD which has gained popularity as a preferred treatment due to its enhanced safety profile as compared to methadone.

Buprenorphine-naloxone is most often available as sublingual tablets of buprenorphine in combination with naloxone in a 4:1 ratio.

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 such as methadone because it exhibits a ceiling effect. This means that higher doses or serum concentrations will not necessarily result in additional adverse effects such as respiratory depression. This is why many clinicians consider buprenorphine-naloxone to be a safer drug than methadone. However, buprenorphine's ceiling effect may also result in limitations since its effectiveness plateaus once a certain serum level is reached.

Naloxone is an opioid antagonist that can displace opioids from their receptors, leading to withdrawal symptoms; however, it is not well absorbed orally and does not exert a pharmacologic response when administered sublingually. As such, buprenorphine-naloxone contains naloxone solely to deter diversion via the intravenous route, where naloxone is highly bioavailable and likely to cause immediate and significant withdrawal symptoms.

6.2 Counselling and patient education - buprenorphine-naloxone

Patients who are prescribed buprenorphine-naloxone for treatment of OUD require comprehensive education and information to ensure clear expectations and understanding of the treatment. Pharmacists should collaborate with prescribers to determine who is best positioned to deliver some, or all, of this information.

Counselling prior to initiation of buprenorphine-naloxone therapy is critical because of the

- risk of precipitated withdrawal following initial doses of buprenorphine-naloxone;
- importance of correct administration of the sublingual tablets;
- · potential risks and toxicities when combined with other CNS depressants;
- common need for frequent monitoring, reassessment, and dose adjustments over the course of first few days of treatment;
- specific requirements for storage and handling to enhance safety; and
- considerations regarding time commitment (e.g., transportation) and cost of daily administration.

Due to the volume of important information that pharmacists need to discuss with patients during the initial counselling session, consider the use of an information sheet for patients to take home and review. There is the potential for repetition of material already provided by other health professionals caring for the patient; however, repetition positively reinforces the information. Pharmacists must ensure that they have made the patient aware of information pertaining to their own scope of practice.

A sample patient handout regarding buprenorphine-naloxone for treatment of OUD is provided in Appendix 9.

6.3 Buprenorphine-naloxone dosing

6.3.1 Buprenorphine-naloxone: initiation phase

Buprenorphine is a partial opioid agonist, and its unique pharmacology means that it may cause a precipitated opioid withdrawal at the initiation of therapy. Therefore, the drug should only be initiated when the patient is actively in opioid withdrawal, indicating available opioid receptors for the medication to interact with.

Opioid withdrawal may take up to 24 hours after the last use of opioids and, because of its long and variable half-life, more than 36 hours after the last dose of methadone.

In contrast to full agonist opioids like methadone, rapid initiation with buprenorphine-naloxone is considered effective and safe due to a lower risk of respiratory depression. Induction should occur according to recognized clinical practice guidelines; however, some clinicians may prescribe alternative induction strategies. In these cases, pharmacists should collaborate with the prescriber to understand the induction approach.

Some prescribers may choose to administer initial doses of buprenorphine-naloxone in their own clinics to ensure a sufficient level of opioid withdrawal at the time of dose administration. Some patients will be asked to return to the clinic following administration for monitoring, or if a severe level of withdrawal persists.

The prescriber must clearly communicate to the pharmacist the timing of the initial buprenorphine-naloxone dose if the pharmacy is to monitor the first witnessed dose. For initial witnessed doses of buprenorphine-naloxone pharmacists must

- Ensure the patient is aware of any requirements for observation after receiving their initial dose(s) of buprenorphine-naloxone.
- Administer the initial dose only when the patient is in sufficient withdrawal, as verified by a Clinical Opiate Withdrawal Scale (COWS)(see appendix 4)and in collaboration with the prescriber⁷. If the patient was on methadone, the first dose of buprenorphine-naloxone may need to occur several days after the last dose of methadone to ensure sufficient withdrawal.
- Monitor the patient after dose administration. Some patients may need to be retained for several hours or be
 asked to return to the pharmacy to be observed for response or pending the development of withdrawal
 symptoms and the severity of these symptoms.
- Collaborate with the prescriber on the potential for dose escalation based on patient response.

Daily witnessed dosing of buprenorphine-naloxone is recommended for all patients during the initiation phase unless the prescriber deems it safe and appropriate to prescribe take-home doses.

Some prescribers may prescribe "home induction" of buprenorphine-naloxone to facilitate initiation outside office and pharmacy hours. In this situation, the pharmacist must ensure the patient understands the home induction instructions and must outline steps required if difficulty is encountered during the home induction process.

6.3.2 Buprenorphine-naloxone: stabilization phase

Buprenorphine-naloxone exhibits a ceiling effect at higher doses. Despite this, pharmacists should avoid administering doses higher than recommended by the Health Canada-approved monograph. Pharmacists may find literature recommending higher maximum daily doses, and it is possible that some prescribers may prescribe such an "off-label" dose in special circumstances.

Following the induction period, some patients can be maintained on doses taken every other day. To accomplish this, the prescriber would double the regular daily dose and administer it every other day, the limitation being that the maximum amount ingested in one day should not exceed the daily maximum according to the product monograph.

⁷ https://www.bccsu.ca/wp-content/uploads/2017/08/Clinical-Opiate-Withdrawal-Scale.pdf

6.4 Administration – witnessed doses of buprenorphine-naloxone

6.4.1 Identification - buprenorphine-naloxone

Regulated members dispensing drugs for OAT should positively identify the patient at each interaction. This may be accomplished by requesting the patient show photo identification when they initially obtain OAT services. If a patient does not have photo identification, regulated members must make alternative efforts to identify the patient, which may include collaborating with other members of the patient's health care team or reviewing other reputable sources.

To assist team members in identifying the patient at future encounters, it would be appropriate to either

- keep a photo on the patient's profile as a reference for all pharmacy staff who may serve the patient, or
- retain a copy of the patient's photo identification with all information redacted except for name and photo⁸.

6.4.2 Assessment - buprenorphine-naloxone

Each time a pharmacist dispenses buprenorphine-naloxone, a pharmacist must assess the patient. The decision whether to dispense OAT depends on a holistic assessment of multiple factors. This assessment must include

- Assessing the effectiveness of the buprenorphine/naloxone therapy.
- Screening for intoxication (from opioids or other substances which may contribute to a safety risk), which may include the following:
 - Observe the patient's eyes for pin-point pupils, alertness, or sedation.
 - o Engage the patient in conversation and ask questions to determine if speech is slurred or incoherent.
 - Ask the patient to walk to the counter and observe their gait.
 - Have the patient come close enough to allow detection of the smell of alcohol or other substances such as cannabis.
 - Assess the patient's general demeanor and behaviour in comparison to their usual behaviour in the pharmacy.
- Reviewing the patient's profile to see if there are any alerts or notes from other pharmacy staff.
- Reviewing the patient administration records and Netcare profile for any concerning activity (e.g., missed doses, take-home bottles not returned).
- Asking if the patient has
 - started or taken any new drugs or substances, including
 - prescription medications,
 - non-prescription medications,
 - natural health products, or
 - recreational, illicit, or non-prescribed substances;
 - experienced any unusual symptoms since the last dose (if yes, ask the patient to describe these symptoms);

⁸ A copy of government issued photo ID may be kept if no other options exist. However, as required by the <u>Health Information Act</u> sections 57 and 58, the least amount of information necessary should be retained for the shortest time required, with all non-essential information redacted on the pharmacy copy.

- experienced any relapses or used a non-prescribed opioid recently (if yes, ask what was taken, when, and how much); and
- o missed ingesting any take-home doses (if applicable).

6.4.3 Observing buprenorphine-naloxone ingestion

- Wear disposable gloves (if needed) or use a dedicated counting tray when handling tablets to avoid skin contact as sublingual tablets are sensitive to moisture and humidity once exposed.
- Place the tablet(s) inside a disposable, single-use medicine cup (preferably transparent). The cup should be returned for disposal by pharmacy staff after the tablets are placed under the tongue by the patient.
- Once the patient receives the medication, pharmacists must
 - Witness the sublingual administration of the buprenorphine-naloxone tablet. This task cannot be delegated to a pharmacy technician or assistant. It can take up to 10 minutes for the sublingual tablet to completely dissolve, and the patient must stay within sight of the pharmacist witnessing the dose. It may be helpful for the patient to drink water before taking their buprenorphine-naloxone dose to help moisten the mouth so the dose dissolves faster.
 - Multiple tablets may be taken sublingually at the same time. In collaboration with the prescriber, pharmacists may determine the need to split or crush tablets to facilitate sublingual dissolution.
 - Confirm the medication has been ingested as prescribed.
 - Pharmacists should be confident the sublingual tablets have dissolved sufficiently to avoid diversion.
 - This may involve asking the patient to open their mouth and lift up their tongue to confirm the tablets have sufficiently dissolved.
 - This request can be part of the patient agreement acknowledged and explained at the outset of the initial pharmacist-client meeting.
 - Record the witnessed administration in the administration record (see Appendix 5) including
 - the date and time of ingestion,
 - the dose administered.
 - the initials or signature of the witnessing pharmacist which must be sufficiently legible to accurately identify the person who witnessed the ingestion, and
 - the initials or signature of the patient confirming receipt of the dose.
 - Document the pharmacist's assessment and monitoring plan in the patient record.

6.5 Dispensing take-home buprenorphine-naloxone

Prescribers may consider offering take-home doses of buprenorphine-naloxone once the patient's OUD has stabilized and/or when the benefits of offering take-home doses outweigh the risks. Due to the safety profile, patients may be offered take-home doses of buprenorphine-naloxone more quickly than other forms of OAT.

For patients prescribed buprenorphine-naloxone, regulated members should

• assess and document the social situation, environment, and arrangements in which the patient lives to determine safety and risk of take-home doses to others who cohabitate with the patient; and

 educate to ensure the patient understands how the product should be taken and stored to optimize efficacy and safety.

Based on the results of this assessment, regulated members may request that the patient pick up, transport to and from the pharmacy, and store their take-home doses in a locked box or secured container if they determine it is necessary for safety reasons.

Other considerations for buprenorphine-naloxone take-home doses are to

- Dispense take-home tablets in a manner that maintains their integrity, paying special care to avoid situations
 where the tablets are exposed to water or excess humidity. This may include dispensing in the original packaging.
- Dispense take-home tablets in a light-resistant and child-resistant bottle or vial.
- Dispense each tablet in individually labelled containers to support adherence.

Only permit deviations from the requirement for a child-resistant container at the patient's request. If an exception is made

- document the rationale within the patient's records,
- document the patient's acknowledgement and acceptance of this deviation, and
- provide adequate counselling regarding the potential dangers and toxicity to children and the public from inadvertent ingestion of doses intended for the patient.

In addition to the items outlined in the label requirements for methadone, labels for take-home doses of buprenorphinenaloxone must include

- the instructions for administration, which can include the date(s) that individual tablets should be administered or,
 if not taken daily, the days of the week for administration by the patient; and
- one of the following cautionary warnings:
 - "Buprenorphine-naloxone 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 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."

Pharmacists must ensure the number of take-home doses (carries) provided at each dispense is recorded in the administration record (see Appendix 5).

6.6 Managing missed buprenorphine-naloxone doses

As the inherent risks of missing doses of buprenorphine-naloxone are considered to be less harmful when compared to methadone, and because of buprenorphine-naloxone's long half-life, buprenorphine-naloxone may be considered a preferred treatment in patients who may experience challenges attending the pharmacy daily.

Due to the long half-life and safety profile of buprenorphine-naloxone, pharmacists should, in collaboration with the prescriber, consider options to minimize the risk of precipitated withdrawal. This may include delaying the next dose until at least 12 hours have passed since the time of opioid ingestion and confirming that the signs of opioid withdrawal are clearly evident before resuming doses. In deciding how long to withhold buprenorphine-naloxone, the pharmacist and the prescriber should consider the half-life of the opioid taken by the patient, the patient's clinical presentation, and the clinical judgement of the pharmacist and the prescriber.

Pharmacists must use their own professional judgement when withholding doses. Trusted clinical resources such as The British Columbia Centre on Substance Use (BCCSU) Opioid Use Disorder Guidelines⁹ should be consulted in context with

⁹ https://www.bccsu.ca/opioid-use-disorder/

gathered patient information and in collaboration with the prescriber to determine the most appropriate treatment approach for the patient.

Pharmacists must

- document any missed doses on the patient's administration record,
- clearly document the patient's reason(s) for missing the doses,
- · report all missed doses to the prescriber and collaborate on any treatment changes, and
- obtain a new prescription for any resulting dose changes.

Pharmacists should inactivate all old prescriptions to avoid errors.

Report missed doses to the prescriber and other relevant healthcare professionals who may be in the patient's circle of care.

It is strongly recommended pharmacists develop a missed dose strategy/agreement with the prescriber in the event that the patient misses a dose(s) and the prescriber is unavailable for consultation.

6.7 Lost/stolen buprenorphine-naloxone doses

Patients reporting lost or stolen take-home buprenorphine-naloxone doses should be encouraged to report them to the authorities. Even if the patient does not report their lost or stolen buprenorphine-naloxone to the authorities, it is the responsibility of pharmacists and other health care professionals to report this to the proper authorities if it is deemed to be a risk to the community/public.

Pharmacists may not replace a buprenorphine-naloxone dose without consulting with the prescriber and obtaining a new prescription for the replacement dose. In consultation with the prescriber, the pharmacist should assess the potential benefits of replacing the dose(s) against the potential risks to the patient or the public.

6.8 Vomited buprenorphine-naloxone doses

Buprenorphine is absorbed sublingually within one to 10 minutes, bypassing the gastrointestinal tract. Vomited doses generally do not require a replacement dose.

6.9 Managing buprenorphine-naloxone overdose

The partial agonist properties of buprenorphine may contribute to a reduced overdose potential when compared to methadone. Buprenorphine has a lower potential for respiratory depression and standard doses are well below the threshold lethal dose for opioid-naïve adults compared to standard methadone doses, which often exceed the threshold lethal dose.

Regardless, overdose of buprenorphine-naloxone must be taken seriously, and if the patient is exhibiting any symptoms consistent with overdose, especially CNS or respiratory depression, naloxone should be administered immediately (by the patient, if possible, or by a pharmacist), and 911 should be called.

While naloxone is still recommended in the event of an overdose of buprenorphine-naloxone, patients could be less responsive to naloxone due to the pharmacodynamics of buprenorphine (i.e., high affinity for opioid receptors, long duration of action). This underscores the importance of calling 911 for ongoing assistance.

As buprenorphine is absorbed sublingually, induced vomiting will likely be ineffective to reverse the course of the overdose.

7.0 Alternative buprenorphine treatments

For patients already stabilized on sublingual buprenorphine-naloxone, further treatment options with buprenorphine are now available.

7.1 Buprenorphine subcutaneous injection

Buprenorphine extended-release depot injection (Sublocade®) is a long-acting formulation of buprenorphine available for the treatment of OUD. The product is administered to the patient subcutaneously on a monthly basis. Patients must be stabilized on buprenorphine-naloxone sublingual tablets for a minimum of seven days prior to being initiated on the injectable product.

7.2 Buprenorphine subdermal implant

Buprenorphine implants (Probuphine®) must be surgically implanted by healthcare professionals who are appropriately trained to do so and are acting within their professional scope of practice. Pharmacists and pharmacy technicians have a limited role in management of this therapy; should they become aware of it, they should document this in the patient record of care.

8.0 Methadone

8.1 Introduction - methadone

Though methadone has a large body of evidence to support its use in OUD, like other opioids, it can present significant risk to the individual and the community. Methadone must be dispensed, administered, and monitored by trained health professionals. Evidence suggests that patients are at highest risk of morbidity and mortality during the initiation phase, typically the first two weeks, of methadone maintenance treatment. Close monitoring and support are required to ensure patient safety and retention in care.

Methadone is a full opioid agonist and, as such, has no ceiling effect. This means, relative to other treatment options, methadone poses an increased risk of harm from overdose, drug interactions, or other circumstances which can lead to elevated serum methadone levels.

There can be significant variability in the response to methadone among patients. Peak plasma levels following oral administration range from one to five hours, and the elimination half-life can range from 15 to 60 hours.

Blood levels of methadone continue to rise during initial daily dosing until steady state is achieved which may take several days; careful dose titration and monitoring for efficacy and toxicity are crucial, particularly during the initiation phase. During the maintenance phase of treatment, blood levels are typically relatively stable with few fluctuations minimizing the likelihood of withdrawal symptoms. Regardless, pharmacists must continue to be diligent about assessing the patient and ensuring they are aware of any new medications or medical conditions which may affect the patient's response to methadone.

Pharmacists and prescribers must be vigilant in assessing the risk of exposure to others, particularly in patients authorized for self-administration of take-home doses of methadone (carries). Improper handling and storage of methadone within the patient's home can result in unintended ingestion. This is especially of concern where children may be inadvertently exposed to the medication. Methadone can harm adults as well. Doses as low as 40 mg can be lethal to an adult who is opioid naïve.

8.2 Counselling and patient education - methadone

Patients who are prescribed methadone for treatment of OUD require comprehensive education and information to ensure that they are fully aware of what they can expect when therapy begins. Pharmacists should collaborate with prescribers to determine who is best positioned to deliver some, or all, of this information.

Counselling prior to initiation of methadone therapy is critical because of

- a delayed efficacy which can be uncomfortable or frustrating for a patient experiencing opioid withdrawal;
- potential side effects that, if the patient is unprepared for them, may lead to discomfort or early discontinuation of therapy;
- a requirement for careful and gradual titration requiring patience;
- the inherent risks and potential for toxicity including overdose or death if patients consume excessive doses or supplement with additional opioids or other CNS depressants;
- · specific requirements for storage and handling to enhance safety; and
- · considerations regarding time commitment (e.g., transportation) and cost of daily administration.

Due to the volume of important information that needs to be reviewed with patients during the initial counselling session, consider the use of an information sheet for patients to take home and review. There is the potential for repetition of material already provided by other health professionals caring for the patient; however, repetition positively reinforces the information. Pharmacists must ensure that they have made the patient aware of information pertaining to their own scope of practice.

A sample patient handout regarding methadone for treatment of OUD is provided in Appendix 8.

8.3 Selection of product - methadone

Commercially available methadone liquids are approved by Health Canada for treatment of OUD. Unless in the case of a drug shortage during which Health Canada-approved products are not available, or a clinical reason such an allergy to a component of the commercially available product, compounded methadone must not be dispensed as OAT.

Some patients including those who have been stable for years, have reported symptoms of opioid withdrawal after being switched from one methadone formulation to another. Regulated members should be aware that

- Some patients may experience withdrawal symptoms after being switched from one formulation to another; these patients should be clinically managed and monitored regularly.
- If patients are stable on their methadone treatment and can be maintained on that product, it is advisable to avoid switching products.
- Early withdrawal symptoms can lead to a failure to remain in treatment and subsequent problematic substance use, which may lead to serious harms¹⁰.

8.4 Measuring methadone

Even small variations in the dispensed volume of methadone can result in increased risk or decreased efficacy for the patient. Both scenarios could result in serious harm. Pharmacists, pharmacy technicians, and other pharmacy team members involved in the measuring and preparation of methadone doses must ensure that accurate, calibrated equipment with an error rate of no greater than +/- 0.1mL is used. Additional guidance for measuring methadone includes the following:

- For any devices used to measure methadone, including oral syringes, obtain documentation from the manufacturer that supports the accuracy of the measurements.
- Oral syringes may not be re-used.
- · Graduated cylinders are not recommended.
- Equipment used to measure methadone should be dedicated for this purpose and labelled as such to avoid possible cross-contamination with other preparations.
- Equipment used to measure methadone should be cleaned, used, and maintained according to manufacturer specifications.

¹⁰ https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/72675a-eng.php

8.5 Diluting methadone

Commercially available methadone products indicated for treatment of OUD are available in 10mg/mL concentrations. Some products (e.g., Methadose® Sugar-Free) are isotonic solutions and require dilution with a crystalline liquid (e.g., Tang®) to a total volume of 100mL, to minimize risk of diversion and administration via the intravenous route. While hypertonic solutions (e.g., Methadose® Cherry-Flavoured) do not specifically require dilution with a crystalline liquid, pharmacists may decide to do so at their discretion. Considerations include

- when dispensing small volumes, surface adhesion of the concentrate to the dispensing device or bottle may
 result in inaccurate or variable dose delivery; and
- risk of potential misuse and/or diversion.

When diluting methadone solution, regulated members should record

- the date of dilution,
- · the lot number, and
- the expiry date of both the commercially available methadone solution and the diluent based on the expiry of the product or opened bottle, whichever is shorter.

This information should be documented on the dilution record (see sample in Appendix 6), the patient's electronic profile, or directly on the prescription, whichever is most feasible, and it must be available to audit or track the diluted preparation.

In general, dispensing methadone in fruit juices, water, or diluents not identified in Appendix 7 or within a product monograph is discouraged due to the lack of sufficient evidence for stability and sterility upon extended storage of the mixture, especially beyond immediate ingestion upon dilution.

8.6 Stability and potential for microbial growth - methadone

The stability and potential for microbial growth of commercially available methadone solutions diluted with a crystalline liquid such as Kool-Aid®, Tang®, or Crystal Light® is not well understood. Dispensing guidelines within many provincial jurisdictions have identified the duration of stability of methadone in various diluents from a collection of past literature (see Appendix 7); however, available literature does not address the issue of microbial growth in the prepared solution stored under refrigerated or unrefrigerated conditions. The information in Appendix 7 is provided as best existing guidance to allow professional judgement when assigning a beyond-use date (BUD) for diluted methadone preparations.

Pharmacists are required to use best judgement to determine the BUD for diluted products. All diluted methadone products must be refrigerated, and take-home (carried) doses are permitted a maximum BUD date of 14 days from the date of dilution. A pharmacist must determine a BUD 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. Pharmacy technicians may assign a BUD if that data is available from reputable sources.

To avoid the potential for mix-ups during dosing, and to optimize the stability and sterility of dispensed carries, diluted methadone doses should not be prepared far in advance of the anticipated date of consumption.

8.7 Methadone dosing

There are many individual considerations for dose initiation and maintenance treatment with methadone. Methadone has been used for many years for treatment of OUD, and dosing guidelines are available in most jurisdictions. Pharmacists should collaborate with the prescriber to ensure the patient's treatment plan follows relevant, current, evidence-based clinical practice guidelines.

8.7.1 Methadone dosing: initiation phase

Patients are at the highest risk of methadone overdose and toxicity (including death) during the first two weeks of treatment. The initial dose prescribed should take into consideration the patient's level of opioid tolerance, concomitant therapies that may impact drug levels and/or pose a risk of toxicity from methadone, and concomitant medical conditions including cardiovascular disease and mental health issues.

All doses in the initiation phase must be daily witnessed doses.

Doses should be titrated up slowly to minimize the risk of overdose. Some patients may require more conservative titration schedules to account for other risk factors.

Monitoring of the patient during the initiation phase should include assessing for both intoxication (from supratherapeutic dose and interaction with other medications or substances) and withdrawal effects resulting from a suboptimal dose. Since peak serum methadone levels may not be achieved for three to four hours following dose administration, pharmacists may ask the patient to return to the pharmacy, or remain in the pharmacy, in order to assess the patient's post-dose response.

8.7.2 Methadone dosing: stabilization phase

An effective stabilization dose is reached when withdrawal symptoms are controlled for more than 24 hours and craving for opioids is reduced or eliminated, without causing excessive sedation or other intolerable side effects. Most patients achieve stability with daily doses of 60mg to 120mg, although higher doses may be required to achieve therapeutic goals.

Pharmacists must continue to be diligent in monitoring patients during the stabilization phase, as patients may require further adjustments to their treatment plan, in collaboration with their prescriber.

In some cases, patients may be transferred to the care of a maintenance OAT prescriber, such as a family physician or nurse practitioner.

8.7.3 Methadone dosing: "split dosing"

Methadone is usually prescribed as a once daily dose; however, in some clinical scenarios, the prescriber may consider prescribing a split dosing regimen based on patient response. Split dosing refers to when the total daily dose of methadone is "split" between two or three doses in a 24-hour period.

The prescribing and dispensing of split doses should be supported by the demonstration of withdrawal symptoms ("wearing off") within 24 hours of the daily dose, along with signs and symptoms of methadone toxicity (e.g., excess sedation) within the four hours following an administered daily dose. Clinical situations where this may be considered include pregnancy, particularly during the initiation phase of therapy and during the third trimester, as well as for "fast metabolizers" of methadone.

In such a situation, the prescriber and the pharmacist should assess the convenience, risks, and clinical value of two or more observed doses within one day. One or more of the doses may be provided as take-home doses, but this decision should be made considering safety for both the patient and the community.

8.8 Administration - witnessed doses of methadone

Daily witnessed administration of methadone by a pharmacist is typically required for all patients during the initiation phase of treatment with methadone for OUD. If patients are prescribed take-home doses, witnessed doses will be required less frequently.

Witnessed administration of OAT requires an assessment by a pharmacist including observation prior to, during, and after administration of the medication. For this reason, pharmacy technicians or other pharmacy staff must not witness the administration of OAT.

8.8.1 Identification- methadone

Regulated members dispensing drugs for OAT should positively identify the patient at each interaction. This may be accomplished by requesting the patient show photo identification when they initially obtain OAT services. If a patient does not have photo identification, regulated members must make alternative efforts to identify the patient, which may include collaborating with other members of the patient's health care team or reviewing other reputable sources.

To assist team members in identifying the patient at future encounters, it would be appropriate to either

- keep a photo on the patient's profile as a reference for all pharmacy staff who may serve the patient, or
- retain a copy of the patient's photo identification with all information redacted except for name and photo¹¹.

8.8.2 Assessment - methadone

Each time a pharmacist dispenses methadone, a pharmacist must assess the patient. The decision whether to dispense OAT depends on a holistic assessment of multiple factors. This assessment must include

- assessing the effectiveness of the methadone therapy;
- screening for intoxication (from opioids or other substances which may contribute to a safety risk), which may include the following:
 - o observe their eyes for pin-point pupils, alertness, or sedation;
 - engage the patient in conversation and ask questions to determine if speech is slurred or incoherent;
 - o ask the patient to walk to the counter and observe their gait;
 - have the patient come close enough to allow detection of the smell of alcohol or other substances such as cannabis;
 - assess their general demeanor and behaviour in comparison to their usual behaviour in the pharmacy;
- reviewing the patient's profile to see if there are any alerts or notes from other pharmacy staff;
- reviewing the patient administration records and Netcare profile for any concerning activity (e.g., missed doses, take-home bottles not returned); and
- · asking if the patient has
 - o started or taken any new drugs or substances, including
 - prescription medications,
 - non-prescription medications,
 - natural health products, or
 - recreational, illicit, or non-prescribed substances;
 - experienced any unusual symptoms since the last dose (if yes, ask the patient to describe these symptoms);
 - experienced any relapses or used a non-prescribed opioid recently (if yes, ask what was taken, when, and how much); and
 - missed ingesting any take-home doses (if applicable).

¹¹ A copy of government issued photo ID may be kept if no other options exist. However, as required by the Health Information Act sections 57 and 58, the least amount of information necessary should be retained for the shortest time required, with all non-essential information redacted on the pharmacy copy.

8.8.3 Observing methadone ingestion

If pharmacists deem it appropriate for patients to receive their prescribed doses, pharmacists must

- Witness the oral ingestion of the methadone dose that has been dispensed. The methadone dose will be diluted, if applicable.
- Confirm the medication has been ingested as prescribed.
 - Engage patients in conversation after they have swallowed to confirm they have ingested the drug.
 - o If additional confirmation is required, pharmacists may ask patients to open their mouths.
 - This request can be part of the patient agreement acknowledged and explained at the outset of the initial pharmacist-client meeting.
- Record the witnessed administration in the administration record (see Appendix 5) including
 - the date and time of ingestion,
 - dose administered,
 - the initials or signature of the witnessing pharmacist which must be sufficiently legible to accurately identify the person who witnessed the ingestion, and
 - the initials or signature of the patient confirming receipt of the dose.
- Document the pharmacist's assessment and monitoring plan in the patient record.

8.9 Dispensing take-home methadone doses

Take-home methadone doses, sometimes referred to as "carries" or "carried doses," are doses of methadone that the patient is authorized to take home for self-administration. Take-home doses are typically only prescribed once a patient demonstrates a consistent, high degree of stability including a stable dose, which can take months. Before authorizing them, prescribers must ensure that take-home doses are safe for both patients and the public, as unsafe storage, non-prescribed use, and diversion of methadone may result in mortality or serious morbidity to a child, pet, or other individual for whom the medication was not prescribed. Pharmacists must also assess this risk prior to dispensing take-home doses and communicate any concerns to the prescriber.

Take-home doses of methadone must be authorized by the prescriber. A valid prescription with updated instructions regarding take-home doses is preferred, but prescribers may also provide instructions regarding take-home doses verbally or in written form to the pharmacist, as long as the patient's dose has not changed, and the current methadone prescription still has doses remaining. Any verbal or written changes to the instructions must be documented by the pharmacist on the patient's record of care. If any dose or quantity changes are required, the prescriber must issue a new TPP Alberta prescription.

Take-home doses must 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 determines that the benefits of providing the doses to the patient agent outweigh the risks to the patient and the public, the take-home dose may be picked up by the patient's agent.

As mentioned, take-home doses can pose a risk that doses may be lost, misplaced, stolen, or improperly stored such that accidental exposure by someone for whom the methadone is not prescribed may occur. Pharmacists must assess this risk each time methadone is dispensed. They are also strongly encouraged to maintain a signed agreement with the patient to acknowledge the expectations and obligations of both the patient and the pharmacy in the dispensing of take-home doses (see Appendix 3 for the relevant section of the pharmacist-patient agreement).

Pharmacists must

- Ensure they determine if the patient has a take-home naloxone kit at home and provide a replacement or new kit if required or requested.
- Ensure the prescription authorizing take-home doses is appropriately written to identify ingestion days and dispensing intervals.
- Assess the stability of the patient.
- Assess the social situation, environment, and arrangements in which the patient lives to determine safety and risk
 of take-home doses to others who cohabitate with the patient.
- Educate to ensure the patient understands how the product should be taken and stored, to optimize efficacy and safety.
- Prepare all take-home doses to their final formulation; further dilution or manipulation by the patient should not be necessary.
- Package and label to optimize safety and adherence with proper administration.
- Dispense take-home methadone as single-use doses (i.e., each dose must be in its own container).
- Dispense take-home methadone doses in a child-resistant container. Deviation from this standard should only be
 permitted at the patient's request and when assessed as appropriate by the pharmacist. Document the rationale
 within the patient record and include the patient's acknowledgement and acceptance of this deviation. Provide
 adequate counselling on the potential dangers and toxicity to children and the public from inadvertent ingestion of
 doses intended for the patient.
- Monitor adherence with take-home doses.
- Instruct patients to return all used/empty take-home methadone containers to the pharmacy for proper disposal prior to receiving additional take-home doses.
- NOT reuse take-home methadone containers, even for the same patient. All used containers must be discarded appropriately with all confidential labelling removed.
- Communicate with prescribers if issues and concerns arise. Patients who experience challenges with the
 management of take-home doses, or who frequently request replacement for lost, stolen, or spoiled doses, may
 require re-evaluation of their treatment plan in the interests of safety and efficacy.
- Maintain a record when preparing diluted take-home doses to enable the tracking of products and diluents used to prepare the final product.
- Ensure the number of take-home containers returned and the number take-home doses (carries) provided at each dispense is recorded in the administration record (see Appendix 5).

Pharmacists may

- request that patients return take-home bottles to the pharmacy for inspection at any time as a tool to assess patient adherence;
- ask that the patient present to the pharmacy during the take-home dose period for an unscheduled witnessed ingestion if required for patient reassessment; and
- request that the patient pick up, transport to and from the pharmacy, and store their take-home doses in a locked box or secured container if they determine it is necessary for safety reasons.

8.9.1 Duration of take-home methadone doses

Methadone take-home doses may be provided in quantities authorized by the prescriber, but this may be limited by the stability and sterility of the methadone preparation. The maximum duration for carries of methadone is generally limited to 14 consecutive days given the BUD limitations of prepared diluted solutions.

8.9.2 Labelling requirements for take-home methadone doses

In addition to the labelling requirements outlined in the Standards of Practice for Pharmacists and Pharmacy Technicians, further labelling requirements for take-home methadone doses include

- The total milligrams of methadone to be ingested in a single dose.
- Instructions to consume the entire contents of the bottle.
- The date on which the contents of each individual bottle should be ingested as a single dose. This ingestion date should be clearly distinct from the date of dispensing or other dates on the bottle (e.g., prescription expiry date, BUD of the methadone, etc.).

Example: Drug is already diluted. Drink the entire contents of this bottle (X mg) on [Insert Date]

The following auxiliary labels are required for take-home methadone doses:

- "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."
- A "Keep refrigerated" label (if diluted).
- A beyond use date of the prepared bottle (if diluted).

Example: Label for methadone 100mg daily take-home dose

ABC Pharmacy

1100 College Plaza

780-555-0000

JOHN DOE

RX#: 1234567

Dr. A. Thompson

Methadone 100 mg in Tang™

Drug is diluted. Consume the ENTIRE contents of this bottle on January 5, 2021

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

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

RETURN ALL USED/EMPTY AND UNUSED/FULL BOTTLES TO THE PHARMACY

Date dispensed Expiry date of bottle

January 4, 2021 January 18, 2021

8.10 Withholding the medication dose

Pharmacists can withhold the medication if the patient's presentation causes the pharmacist to question if the risks of administering the dose at that time may outweigh the benefits. Pharmacists must contact the prescriber if they withhold a dose.

It may be appropriate to allow the patient to stay in the pharmacy until their symptoms resolve or suggest that the patient return to the pharmacy later that day for their dose.

If a patient reports unanticipated sedation with their dose particularly during the induction phase or with dose increases, regulated members should advise the prescriber and could consider withholding the dose until collaboration with the prescriber has occurred.

It is valuable to, at the onset of treatment, outline potential reasons for withholding medication in the pharmacy-patient agreement.

8.11 Managing missed methadone doses

Because missing methadone doses can result in rapid and unpredictable loss of tolerance to opioids, it can be harmful to administer methadone to a patient who has missed several doses. Pharmacists must communicate all missed doses to the prescriber in a timely fashion and prior to any future doses being dispensed. If a pharmacist identifies that a patient has missed any number of recent methadone doses, especially consecutive doses, the pharmacist should conduct an assessment to determine whether it is safe and appropriate to administer the next prescribed dose.

Trusted clinical resources such as The British Columbia Centre on Substance Use (BCCSU) Opioid Use Disorder Guidelines¹² should be consulted in context with gathered information and in collaboration with the prescriber to determine the most appropriate treatment approach for the patient.

Pharmacists must

- document any missed doses on the patient's administration record.
- clearly document the patient's reason(s) for missing the doses,
- · report all missed doses to the prescriber and collaborate on any treatment changes, and
- obtain a new prescription for any resulting dose changes.

Regulated members should inactivate all non-current prescriptions to avoid errors.

Report missed doses to the prescriber and other relevant healthcare professionals who may be in the patient's circle of care.

It is strongly recommended pharmacists develop a missed dose strategy/agreement with the prescriber in the event that the patient misses a dose(s) and the prescriber is unavailable for consultation. This may be outlined in a three-way agreement with the prescriber, and it is important to be aware that expectations regarding handling of a missed dose may be different during the initiation phase of treatment as compared to the stabilization phase.

8.12 Lost/stolen methadone doses

Patients reporting lost or stolen take-home methadone doses should be encouraged to report them to the authorities. Even if the patient does not report their lost or stolen methadone to the authorities, it is the responsibility of pharmacists and other healthcare professionals to report this to the proper authorities if it is deemed to be a risk to the community/public.

¹² https://www.bccsu.ca/opioid-use-disorder/

Pharmacists may not replace a methadone dose without consulting with the prescriber and obtaining a new TPP Alberta prescription for the replacement dose. In consultation with the prescriber, the pharmacist should assess the potential benefits of replacing the dose(s) against the potential risks to the patient or the public.

8.13 Vomited methadone doses

The decision to replace a methadone dose following vomiting must be made on a case-by-case basis, in collaboration with the prescriber. The pharmacist and prescriber should consider the time the original dose was ingested, the time of vomiting, whether the vomiting was witnessed by the pharmacist, and other relevant clinical information including any symptoms being experienced by the patient. Replacement of any part of the dose must only occur when accompanied by a new TPP Alberta prescription for the replacement.

To prevent this situation, pharmacists should screen patients for nausea prior to administering methadone and, if needed, offer strategies to minimize risk of vomiting. Strategies may include pre-dosing with an anti-nauseant, sipping methadone slowly, or returning to the pharmacy later when the patient is feeling less nauseous. Pharmacists should recommend that nauseous patients who receive methadone in the pharmacy remain under direct observation for at least 15 minutes after they take their methadone; this way, in the event vomiting does occur, the pharmacist will be able to verify the timing.

Vomited doses and the subsequent actions taken must be documented on the patient's administration record.

8.14 Managing methadone overdose

Methadone overdose can be fatal if not managed appropriately.

If a regulated member becomes aware that a patient received a higher dose of methadone than prescribed, the regulated member should advise the patient to use their naloxone kit (if they have one) and call 911 immediately.

If the poisoning occurs in the pharmacy a regulated member should administer naloxone and call 911 immediately.

9.0 Alternative approaches for the treatment of opioid use disorder

For patients who are unable to tolerate, or who experience suboptimal results from conventional OAT, there are additional treatments available. These alternatives are generally higher intensity treatment options that require the involvement of a prescriber with a specialized practice in addiction medicine. Pharmacists and pharmacy technicians involved in dispensing these medications must do so in a highly collaborative relationship with these prescribers.

Where specific guidance is not provided for these expert-led approaches, regulated members should refer to guidance provided for buprenorphine-naloxone and methadone for direction.

9.1 Slow-release oral morphine - SROM

Slow-release oral morphine refers to a 24-hour slow-release formulation of morphine (Kadian®). Other formulations of oral morphine, such as twice-daily, 12-hour sustained- or extended-release formulations (e.g., M-Eslon®), have not been empirically studied in this context and are not recommended for treatment of opioid use disorder. Morphine, like methadone, is a full opioid agonist and exhibits no ceiling effect. SROM in OUD has less evidence to support its use compared to methadone or buprenorphine-naloxone. Because of the limited evidence available, SROM is not considered a first-line therapy and pharmacists dispensing SROM to patients should work collaboratively with the prescriber and other members of the healthcare team to mitigate the risks of harm associated with this medication.

9.1.1 Identification - SROM

Regulated members dispensing drugs for OAT should positively identify the patient at each interaction. This may be accomplished by requesting the patient show photo identification when they initially obtain OAT services. If a patient does not have photo identification, regulated members must make alternative efforts to identify the patient, which may include collaborating with other members of the patient's health care team or reviewing other reputable sources.

To assist team members in identifying the patient at future encounters, it would be appropriate to either

- · keep a photo on the patient's profile as a reference for all pharmacy staff who may serve the patient, or
- retain a copy of the patient's photo identification with all information redacted except for name and photo¹³.

9.1.2 Dosing - SROM

Selection of the SROM dose should be carefully evaluated in collaboration with the prescriber. If patients are switching to SROM from methadone or iOAT, available literature supports transition without a "washout" period. The starting SROM dose in this case should be based on relevant clinical practice guidelines, and careful clinical evaluation of the patient. For patients who are not transitioning from methadone, lower initial doses are recommended. Titration, or increasing doses, should generally occur no more frequently than every 48 hours.

9.1.3 Administration - SROM

- Slow-release oral morphine should be swallowed whole. Crushing, chewing, or dissolving slow-release oral morphine capsules can cause rapid release and absorption of a potentially fatal dose of morphine sulphate.
- To reduce risk of diversion, patients should receive SROM daily, witnessed by a pharmacist. This involves the
 pharmacist opening capsules and sprinkling the enclosed pellets into a medication cup for immediate ingestion
 by the patient. The patient should then be instructed to drink a cup of water to ensure all pellets have been
 swallowed.
- Pellets must not be chewed or crushed.

¹³ A copy of government issued photo ID may be kept if no other options exist. However, as required by the Health Information Act sections 57 and 58, the least amount of information necessary should be retained for the shortest time required, with all non-essential information redacted on the pharmacy copy.

- For patients with difficulty ingesting their dose, pellets may be sprinkled onto a small amount of applesauce and ingested immediately.
- Due to lack of clinical experience or clinical trials for slow-release oral morphine re-induction protocols, patients should be seen daily to assess for intoxication or withdrawal, with dose increases or decreases titrated accordingly. All doses provided to patients must be documented on the patient administration record.

9.1.4 Monitoring - SROM

Pharmacists must be diligent in monitoring for serious adverse outcomes including respiratory depression.

9.1.5 Missed SROM doses

The underlying short morphine half-life results in the potential for rapid loss of tolerance following missed doses, and the possibility of harmful over-sedation or overdose. Pharmacists should work very closely with prescribers to notify them of any missed doses and provide details regarding their daily patient assessments.

If a pharmacist identifies that a patient has missed any number of recent SROM doses, especially consecutive doses, the pharmacist should conduct an assessment to determine whether it is safe and appropriate to administer the next prescribed dose.

Trusted clinical resources such as the British Columbia Centre on Substance Use (BCCSU) Opioid Use Disorder Guidelines¹⁴ should be consulted in context with gathered information and in collaboration with the prescriber to determine the most appropriate treatment approach for the patient.

9.2 Supervised injectable opioid agonist therapy

Injectable Opioid Agonist Therapy (iOAT) involves the use of prescribed injectable hydromorphone to treat OUD. There is evidence to support the use of iOAT in individuals with OUD who have a history of injecting opioids and have not responded optimally to first-line oral OAT therapies.

Because treatment of OUD with iOAT is complex and multifaceted, iOAT is currently only delivered to patients within structured, multi-disciplinary iOAT programs. Pharmacists practising within such programs must collaborate closely with the other members of the patient's healthcare team and must follow all relevant legislation and standards.

It is not appropriate for pharmacists to dispense or facilitate iOAT outside of an Alberta Health sanctioned iOAT program.

If regulated members become aware that their patient is receiving iOAT, they should collaborate with the iOAT program to minimize errors, optimize patient outcomes, and support continuity of care.

9.3 Naltrexone

Naltrexone is an opioid receptor antagonist that blocks the euphoric effects of opioids at adequate doses. Potential benefits of naltrexone include ease of administration, lack of induced tolerance during long-term treatment, and lack of potential for dependence or misuse. However, as an opioid antagonist, naltrexone can block the effects of opioids, including opioid analgesics prescribed for pain. The reduced tolerance to opioids resulting from the use of naltrexone may increase the risk of overdose for patients who stop taking the medication and resume opioid use.

There is limited evidence for the efficacy of naltrexone in the context of OUD, and risks may outweigh benefits. If involved in dispensing naltrexone for treatment of OUD, pharmacists must be familiar with the clinical evidence, understand the risks, educate the patient, and collaborate with the prescriber.

¹⁴ https://www.bccsu.ca/opioid-use-disorder/

9.4 Non-conventional opioid substitution therapy

Regulated members may encounter prescriptions for opioids for unclear indications, or multi-factorial indications such as pain with a substance use disorder component. Pharmacists should collaborate with the prescriber on the patient's treatment plan to minimize risks to the patient and provide harm reduction education and resources where appropriate.

10.0 Additional clinical scenarios involving OAT

The following are situations that may arise when providing OAT to patients. Some of these situations may contribute to additional risk to the patient. In all of the following scenarios, pharmacists must collaborate with the patient's prescriber (and other relevant members of the patient's healthcare team) to ensure any additional risk is mitigated. Pharmacists should refer to appropriate clinical guidance documents to support patient care during these scenarios.

10.1 Transitioning from one form of OAT to another

Switching between medications used for treatment of OUD can be a useful approach to maximize clinical outcomes or address changes to the patient's circumstances or preferences. This activity can be nuanced and should be personcentred, considering the unique pharmacology of the medications involved. Pharmacists should consult appropriate clinical guidelines and collaborate with the prescriber and the patient to clearly outline the treatment plan and address any potential challenges.

10.2 Off-site witnessed administration of OAT

If a pharmacist delivers OAT to another facility or location where witnessed administration is to occur, they may witness the dose ingestion outside of the pharmacy premises, provided they are able to meet all standards of practice and all requirements for witnessed ingestion, including assessment of the patient. After witnessing the dose administration, the pharmacist must comply with the documentation requirements for witnessed administration.

10.3 Delegated administration of OAT

Only a pharmacist can supervise and witness the daily administration of OAT by a patient. When appropriate a prescriber may request the pharmacist delivers a dose to another regulated health professional acting within their scope for a delegated witnessed administration. Pharmacists may refuse these requests if they have concern for the security of the medication and/or the safety and risk to the patient or the public. However, pharmacists must clearly communicate these concerns and discuss them with the prescriber to resolve issues and facilitate continuity of care in the best interest of their patient.

Document the request and final decision in the patient record. If the patient requires delivery, make every effort to ensure the dose reaches the intended individual(s). Use a reliable, secure, and confidential method of transportation and follow-up to ensure that the dose has been delivered untampered. Receipt must be documented, including the date of receipt, intended date of administration, drug, dose, and name and signature of the individual delegated to witness the dose. A locked container is advisable to transport the medication to the intended recipient, along with packaging and labelling consistent with that used for take-home doses of OAT. Transportation of controlled substances must comply with the requirements outlined in Health Canada's Controlled Drugs and Substances Act.

It is the delegated individual's responsibility to record the ingestion. The pharmacist must confirm that the dose has been ingested as intended.

10.4 Voluntary patient discontinuation of treatment

If a patient wishes to discontinue their OAT, regulated members must respect their decision. However, a pharmacist must discuss with the patient any potential consequences including risk of relapse to disordered substance use. Inform other members of the healthcare team of the patient's decision and status. Abrupt discontinuation should be discouraged to prevent a rapid loss of tolerance creating a high risk for overdose morbidity and mortality. Sudden cessation of therapy can also result in severe and lasting withdrawal symptoms. If applicable, the pharmacist should collaborate with the prescriber to develop a taper schedule for the individual and/or prescribe medications to provide symptomatic relief. Pharmacy staff should continue to support the patient until the patient no longer requires the pharmacy's services.

10.5 Involuntary discontinuation of treatment

At the onset of therapy, a regulated member should discuss potential scenarios that may lead to discontinuation of pharmacy services with the patient. These scenarios can be outlined in the patient-pharmacy agreement. If discontinuation of pharmacy services is necessary, regulated members must assist the patient in receiving care from another pharmacy to ensure continuity of care. The pharmacist must also inform the other members of the treatment team. As in the case of voluntary discontinuation of OAT, the pharmacist should consider collaborating with the prescriber to develop a taper schedule for the individual and/or prescribe medications to provide symptomatic relief.

10.6 Transfer of care

If a patient requires a transfer of care, it is the obligation of regulated members to assist the patient and to maintain continuity of care. This may require regulated members to facilitate the transfer of records and patient information to a new pharmacy or care provider. It may also require regulated members to support the patient in locating a new pharmacy or care provider.

A key piece of information to provide to the new care provider are the details of the patient's last confirmed ingested dose.

Note that only licensed dealers with appropriate permits are authorized to import or export narcotics across international borders; patients transferring out of country will have to secure a prescriber and comply with the applicable rules and regulations within their new country.

All take-home doses required to facilitate a transfer of care must be approved by the prescriber and documented by the pharmacist. A pharmacist is not required to provide take-home doses if they deem it unsafe for either the patient or the public.

10.7 Incarceration

OAT should continue if a patient is incarcerated. OAT services are often available in provincial correctional facilities, remand centres, and federal prisons.

Pharmacies providing medication-assisted treatment services that become aware of the incarceration of a patient should notify the patient's prescriber to facilitate a seamless and coordinated transition of care. Pharmacists should also collaborate with the correctional facility to share any pertinent clinical information at the time of intake, and to discuss discharge planning to ensure a smooth transition of care when the patient is released from incarceration.

Individuals leaving incarceration may have a reduced tolerance to opioids due to discontinuation of opioid use while incarcerated or disruption to their OUD treatment plan. This may lead to higher risk of adverse effects and mortality due to overdose even at previously tolerated doses of OAT or other opioids. Pharmacists should be aware of this and take steps to educate the patient about these increased risks as they transition their care back to the community.

10.8 Hospitalization

Regulated members providing OAT services who become aware that a patient is hospitalized, must notify the patient's prescriber to facilitate a seamless and coordinated transition of care. Community pharmacists should also collaborate with the hospital pharmacist to share any pertinent clinical information at the time of admission, and to discuss discharge planning when the patient is being released. Regulated members working in the hospital must ensure the patient's community pharmacist is advised of the hospitalization and the need to hold or discontinue the community pharmacy OAT prescription while the patient is in hospital. Where appropriate, regulated members working in a hospital must ensure that OAT therapy continues uninterrupted for the duration of the hospital visit and at discharge. The patient should be closely monitored for any adverse effects.

Hospital physician prescribers do not require CPSA approval to maintain patients on methadone, SROM, or iOAT. If changes are required to any OAT dose, these prescribers are required by CPSA to consult with the initiating prescriber or their delegate.

Some hospitals may have limited access to OAT medications based on their location or resources. Community pharmacies and prescribers who provide OAT should collaborate with hospitals to facilitate continuity of treatment where such gaps exist, and this may include the provision of interim OAT doses at the time of admission or ongoing as required.

Works cited

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Appendices

Appendix 1: Recommended reading

Regulatory

- Alberta College of Pharmacy Standards of Practice for Pharmacists and Pharmacy Technicians
- Alberta College of Pharmacy Standards for the Operation of Licensed Pharmacies. Edmonton
- Alberta College of Pharmacy Code of Ethics
- College of Physicians & Surgeons of Alberta Opioid Agonist Treatment Program

Clinical guidelines

- British Columbia Centre on Substance Use (BCCSU) Opioid Use Disorder Guidelines
- Canadian Research Initiative in Substance Misuse (CRISM) <u>National Opioid Use Disorder Guideline</u>

Training and education

- Alberta Health Services <u>Alberta ODT Virtual Training Program</u>
- Alberta Health Services PACES Training Assessment and treatment of primary addiction
- Alberta Health Services <u>Trauma Informed Care (TIC)</u>
- The Centre for Addiction and Mental Health (CAMH) Opioid Dependence Treatment (ODT) Certificate Program
- Alberta Pharmacists' Association various

Person-centred Care

- National Harm Reduction Coalition <u>Principles of Harm Reduction</u>
- Centre of Excellence for Women's Health <u>Trauma informed Practice Guide</u>
- Government of Canada Addressing Stigma in Canada's Health System

Patient resources

- Alberta Health <u>Alberta's opioid and addiction response</u>
- Alberta Health Services Get Naloxone
- Opioid response Options for care

Appendix 2: Important numbers and contact information

Alberta College of Pharmacy	Telephone: 780-990-0321
1100-8215 112 St. NW	Toll-free: 1-877-227-3838
Edmonton, AB T6G 2C8	Fax: 780-990-0328
	Web: abpharmacy.ca
College of Physicians & Surgeons of Alberta	Telephone: 780-423-4764
2700-10020 100 St. NW	Toll-free: 1-800-561-3899
Edmonton, AB T5J 0N3	F: 780-420-0651
	Web: cpsa.ca
College and Association of Registered Nurses of Alberta	Telephone: 780-451-0043
11120 178 Street	Toll-free: 1-800-252-9392
Edmonton, Alberta T5S 1P2	Fax: 780-452-3276
	Web: nurses.ab.ca
Office of Controlled Substances, Health Canada	Telephone: 1-613-952-2177
	Email: hc.ocs-bsc.sc@canada.ca
	Web: canada.ca/en/health-canada/corporate/contact-us/
	office-controlled-substances.html



Pharmacy-patient agreement for OAT services

Pharmacists are encouraged to adapt this agreement to reflect their pharmacy's operations and the specific circumstances of their patient(s) more accurately. The information provided below is intended to provide a framework on which to build a site-specific pharmacy-patient agreement.

Patient name:	
Pharmacy name:	
Hours of operation:	
You have been prescribed the following Opioid Agonist Therapy (OAT) for treatn	nent of opioid use disorder (OUD):
Methadone (Methadose®, Metadol-D®, generics)	
Buprenorphine-naloxone (Suboxone®, generics)	
Slow-release oral morphine (Kadian®)	
Other:	

Our pharmacy will provide the pharmacy services you require as part of your treatment. The length of time you will need to take medication for OUD can vary, but in many cases, these medications are taken for months, years, or indefinitely.

As part of your treatment plan, a pharmacist may be required to observe you directly as you ingest your medication. This is done for your safety, and so the pharmacist can monitor your progress closely and work with you to achieve your health goals. As such, you may be required to attend the pharmacy as frequently as once per day. Your pharmacist will work closely with your prescriber and observation will continue until your prescriber determines that take-home doses are safe and appropriate.

In order to assess the safety and effectiveness of your medication, your pharmacist may ask you questions about your ingestion of other substances, prescribed and non-prescribed. Pharmacists are knowledgeable in how these substances will impact your treatment. It is in your best interest to share this information openly with your pharmacist, as they will work with you and your prescriber to determine the best, and safest, course of action.

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

This agreement is between

- you, our patient, and
- your pharmacy and its staff.

This agreement outlines responsibilities and obligations of each party to ensure a mutual understanding and awareness of the expectations involved in our collaboration. This agreement may be shared with your prescriber. You may ask to review this agreement at any time and are entitled to a copy of it.

Your pharmacy agrees to provide you with

- Professional services that prioritize respect and personal dignity.
- Access to trained professionals who are competent in OUD and OAT to address your questions and concerns.

- Professional expertise, skills, and knowledge about your treatment that will always have your best health interests in mind for decisions that are made.
- Privacy and confidentiality regarding your private health information. Your confidential information will only be shared with your consent on a need-to-know basis, or as required by law.
- Ongoing monitoring, support, and encouragement to maximize your health outcomes.
- Professional services until they are no longer required or wanted, or until another suitable pharmacist or other regulated health professional has assumed responsibility for your care.
- Reasonable notice if unable to continue providing you care.
- Respect for your decision to end treatment if you decide to do so.

Patient initial Pharma	acist initial
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As the patient receiving OAT medication, I agree to

- Take my OAT medications as prescribed for my opioid use disorder.
- Let my pharmacist know if I am experiencing any unexpected or unpleasant effects of treatment.
- Make every effort to come to the pharmacy when I am to receive my OAT medication and call the pharmacy if I
 am going to be late. If I am not consistent with my dosing regimen, I am aware that my treatment may need to be
 adjusted for my safety. This may, in some cases, include discontinuing my prescription.
- Bring and show my photo ID to the pharmacy team as requested when I visit my pharmacy for my OAT medication dose.
- The pharmacy team calling my prescriber if they have any concerns about my safety on OAT.
- The pharmacy team contacting and collaborating with my prescriber if a dose is missed, lost, stolen, and/or partially administered.
- Call the local law enforcement, as well as my pharmacist and my prescriber, if I lose a dose or if a dose in my
 possession is stolen, as my medication may be dangerous to the community. Alternatively, I agree to allow the
 pharmacist to call local law enforcement and my prescriber on my behalf.
- Inform my pharmacy team and prescriber of any other medication that I am prescribed or taking, including natural health products and vitamins, as I realize that some treatments may interact with OAT medications and have the potential to cause harm to me.
- Complete laboratory or point-of-care tests (e.g., urine tests, electrocardiogram, or ECG, etc.) as directed by my prescriber or pharmacist, as these are necessary to monitor the safety and effectiveness of my treatment.
- Be polite and respectful of other patients and the pharmacy staff while on the premises of the pharmacy.
 Behaviour such as verbal or physical harm to others, criminal activity within the pharmacy, uttering profanities, or threats may result in restriction or discontinuation of services from the pharmacy.

Patient initial	Pharmacist initial

As the patient on OAT, I am aware that

- I must not drive or operate machinery that requires my alertness when I am being initiated on therapy (typically at least the first two weeks), when I am having doses adjusted, or if I am experiencing treatment effects that are making me sleepy or not alert.
- Taking narcotics, sleeping pills, alcohol, or other sedating substances may interact with my OAT to cause overdose, coma, or even death. I will not take other medications or substances unless my OAT prescriber and my OAT pharmacy are aware.
- The pharmacy will not provide me with my OAT medication if I arrive impaired by a medical condition or substances such as medications, drugs or alcohol, or if the pharmacist has any other reason to believe that it is not safe for me to take my OAT.

Patient initial	Pharmacist initial
·	

Take-home doses (if applicable)

Your doctor has authorized us to provide you with take-home doses (carries) of your OAT medication that you can take yourself on selected days as indicated. OAT medication can be very dangerous to someone for whom it is not prescribed. Even small doses can harm or kill a child or pet. Some OAT can also be fatal to an adult if accidentally ingested.

You are responsible for properly securing and storing your OAT medication so that others cannot be harmed from an accidental exposure.

As a patient prescribed take-home doses of OAT, I agree to

- pick up my take-home doses in person and to show my valid identification to the pharmacist when I pick up the take-home doses;
- store my carries in a secure location, preferably a locked or secured container or enclosure. The pharmacist will
 advise me of any special storage instructions (e.g., refrigerator for diluted methadone or at room temperature in a
 locked cupboard for other forms of OAT);
- store and take the methadone in such a way that it cannot be accidentally ingested by anyone else;
- take my OAT medication as prescribed by my doctor and on the ingestion date that is specified on the label of each container;
- keep naloxone on hand at home or wherever I take my OAT dose;
- return all my OAT containers to the pharmacy with their original labels left intact for proper disposal; and
- call my doctor or my pharmacist if I have any withdrawal symptoms or side effects.

Patient initial	Pharmacist initial	

I am aware of the following:

- For my personal safety, my pharmacist may call me to come in for an unscheduled assessment during the carry period. The pharmacist may ask me to bring in all my OAT containers, full or empty, at this time.
- My pharmacy will not replace lost, stolen, spoiled, spilled, or vomited doses.

- The side effects of my OAT that may be considered medical emergencies. I will go immediately to the hospital emergency room if I experience any of these side effects.
- How and when to administer naloxone if I experience any signs of opioid overdose.
- For my personal safety and for the safety of the public, take-home doses of methadone may only continue if I am responsible with the medication and if I remain clinically stable on the drug.

Patient initial	Pharmacist initial
Summation	
and other narcotic prescriptions. This info external reviewer working within the regu pharmacy's prescription files. I am aware that it is part of the regular auditing and i	de aware that, in Alberta, TPP Alberta monitors the prescribing and use of OAT ormation will be recorded. This may involve occasional review of my file by an latory colleges for physicians or pharmacists to view my health files or the this is a legal requirement that my prescriber and pharmacist do not control, and inspection process of their respective governing bodies. I understand that my ed in such circumstances as required by law.
Patient signature	Pharmacy representative signature
Date	Date
Prescriber signature (optional)	
As the patient's OAT prescriber, I acknow received a copy of this agreement.	edge I have
Prescriber signature	
Date	



CLINICAL OPIATE WITHDRAWAL SCALE¹

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

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

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

Reference:

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

More information: www.bccsu.ca











Patient record of drug administration



Assigned Prepared by / beyond use checked by date (BUD)						
Assigned beyond use date (BUD)						
Diluent						
DIN, lot number, expiry Diluent date						
Drug name and strength						
Number of doses prepared						
Dose (mg) / final quantity (ml)						
Date Patient name / Rx prepared number						
Date prepared						

Appendix 7: Methadone stability in various diluents

Diluent	Stability at room temperature (20 to 25°C)	Period of stability at refrigerated temperature (5°C)	Period of acceptable sterility for oral consumption under refrigeration (i.e., bacterial growth or pathogenic growth)
Grape flavoured Kool-Aid™	17 days	55 days	Unknown for dilution with MethadoseTM 14 days for diluted Metadol™ preparations
Orange flavoured Tang™	11 days	49 days	Unknown for dilution with MethadoseTM 14 days for diluted Metadol™ preparations
Allen's Apple Juice™	9 days	47 days	Unknown for dilution with MethadoseTM 7 days for diluted Metadol™ preparations
Grape flavoured Crystal Light™	8 days	34 days	Unknown for dilution with MethadoseTM 14 days for diluted Metadol™ preparations
Grape flavoured Crystal Light™ with 0.1% sodium benzoate	29 days	Not available	Unknown for dilution with MethadoseTM

Reference: Lauriault, G., M. J. Lebelle, B. A. Lodge, et al. "Stability of Methadone in Four Vehicles for Oral Administration." Am. J. Hosp. Pharm 1991 (48): 1252-1256.

Methadone for Opioid Use Disorder: Your Questions Answered

METHADONE

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

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



1. Changes?

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



2. Continue?

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



3. Proper Use?

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



4. Monitor?

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



5. Follow-up?

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

It is important to:



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



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



Talk to your health care provider or pharmacist about Take Home Naloxone kits and overdose response training.



Take all unused and expired medications back to the pharmacy for safe disposal. For locations that accept returns: 1-844-535-8889 Phealthsteward.ca

Did you know?

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

Questions and Notes:

CADTH Evidence Driven.



















To access this handout visit: www.opioidstewardship.ca

Buprenorphine/Naloxone for Opioid Use Disorder: Your Questions Answered

BUPRENORPHINE/ NALOXONE

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

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



1. Changes?

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



2. Continue?

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



3. Proper Use?

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



4. Monitor?

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



5. Follow-up?

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

It is important to:



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



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



Talk to your health care provider or pharmacist about Take Home Naloxone kits and overdose response training.



Take all unused and expired medications back to the pharmacy for safe disposal. For locations that accept returns: 1-844-535-8889 Phealthsteward.ca

Did you know?

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

Questions and Notes:

CADTH Evidence Driven.



















To access this handout visit: www.opioidstewardship.ca



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