Nova Scotia College of Pharmacists

Standards of Practice: Drug Therapy for the Treatment of Opioid Use Disorder

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Introduction

People who use drugs and those with opioid use disorder (OUD) are frequently stigmatized by society and health care providers for their use or blamed for their illness. As a marginalized group, people who use drugs have identified many barriers in accessing vital health services, including difficulties accessing Opioid Agonist Therapy (OAT). The ability to access OAT is critical to the health and wellbeing of this population.

Dispensing OAT is a privilege restricted to pharmacy, and as such, pharmacy practitioners play a foundational role in supporting this important public health strategy and improving access to treatment. As health care providers, and in accordance with the NSCP Code of Ethics, pharmacy practitioners have the professional responsibility to incorporate this critical service into routine practice to meet the needs of their patients in an environment that is free from stigma and discrimination. This will require thoughtful consideration by individual pharmacy practitioners, ongoing education, and professional development to maintain competence in:

- opioid use disorders and their treatment,
- opioid withdrawal and management, and
- harm reduction strategies.

The *Standards of Practice: Drug Therapy for the Treatment of Opioid Use Disorder* establishes the responsibilities and minimum expected practice of pharmacy practitioners when providing OAT for the treatment of OUD. They are in place to support the safe and effective provision of OAT services by pharmacy practitioners and to contribute to improved patient and societal health outcomes.

These Standards focus on the most common treatment options for OAT in the current Canadian landscape. While they do not thoroughly address other emerging therapies such as long-acting injectable buprenorphine, and injectable opioid agonist therapy (iOAT), there is nothing in them that precludes pharmacy practitioners from participating in their provision.

Further, these Standards do not speak to:

- Chronic pain: While OAT is also used in the treatment of chronic pain, these Standards do not apply the provision of these medications to patients for other indications when there is no concern of previous or current substance use disorder.
- Clinical information: Clinical practice guidelines, therapeutic information, and pharmacists' guides to providing OAT are widely published and are the most appropriate sources for up-to-date practice information. While not an exhaustive list, several resources are provided in the resource section. Practitioners should seek out the most up to date resources as they would for all other medications.
- Safer Supply: Safer supply refers to providing prescribed medications as a safer alternative to the toxic illegal drug supply to people who are at high risk of overdose. (iOAT reference provided in references section.)

Glossary

Independent Double Check

An independent double check is a process in which a second practitioner conducts a verification in the presence or absence of the first practitioner. The most critical aspect is to ensure that the first health care provider does NOT communicate what they expect the second practitioner to find.

Medication Incident

Any preventable event that may cause or lead to inappropriate medication use or patient harm that has reached the patient. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use. [1]

Opioid Agonist Therapy (OAT)

For the purpose of this document, OAT includes slow-release oral morphine (SROM).

Opioid Use Disorder

Opioid use disorder (OUD) is defined as a chronic relapsing illness which, though associated with elevated rates of morbidity and mortality, has the potential to be in sustained remission with appropriate treatment. OUD may involve the use of illicitly manufactured opioids, such as heroin or street fentanyl, or the non-medical use of pharmaceutical opioid medications. In recent years, the landscape of opioid use in Canada has increasingly involved the non-medical use of pharmaceutical opioids and a widening range of highly potent synthetic opioids such as illicitly manufactured fentanyl.[2]

Pharmacy Practitioners

The term pharmacy practitioner is used broadly throughout these Standards and can refer to pharmacists, pharmacy technicians, pharmacy students, pharmacy technician candidates, or pharmacy interns, depending on the context in which it is used. The use of this term does not imply that all pharmacy practitioners can take responsibility for all OAT activities. Pharmacy practitioners will ensure that they only undertake OAT activities that are within their scope of practice.

[1] https://www.napra.ca/wp-content/uploads/2022/09/NAPRA-Model-Standards-CQI-MIR-July-2021.pdf
[2] https://crism.ca/wp-content/uploads/2018/03/CRISM_NationalGuideline_OUD-ENG.pdf

Concepts

Bias, Stigma, and Discrimination

Explicit and unconscious biases shape personal attitudes towards people who use drugs, and ultimately impact a health care professional's willingness to provide safe and effective harm reduction services. Attitudes and preconceived notions held by a pharmacy practitioner have a direct impact on the accessibility and experience of people who use drugs.

The stigma faced by people who use drugs creates significant barriers and exists in many forms:

- Structural stigma, the stigma embedded in societal systems such as the healthcare system, results in inequitable access to services.
- Social stigma, negative stereotypes upheld by the public, results in discrimination against people who use drugs.
- Self-stigma, the stigma that people who use drugs have internalized, leads to poor self-esteem and self-image.

Stigma associated with drug use can negatively impact a person's ability to utilize harm reduction strategies (e.g., choosing to use alone due to social stigma). Further, the effects of bias and stigma are often amplified for people who use drugs who are also members of other marginalized groups, including, but not limited to, African Nova Scotian, Indigenous, racialized, and two-spirit, lesbian, gay, bisexual, transgender, queer and questioning, intersex, asexual, and other gender and sexual identities (2SLGBTQIA+) communities, due to the intersection of their identities.

It is important for pharmacy practitioners to reflect on their own unconscious biases related to substance use and how this might impact their interactions with people who use drugs. Not offering harm reduction services, including OAT, directly contributes to the ongoing discrimination and marginalization of people who use drugs.

Continued Substance Use

Recurrent or continued opioid use can occur at any time during the treatment process. Pharmacy practitioners should recognize this and continue to provide non-judgmental care, encouragement, and take the opportunity to discuss harm reduction strategies.

OAT is a harm reduction strategy aimed at reducing or eliminating opioid use and its associated adverse health outcomes and improving social determinants of health. Patients may be reluctant to discuss their ongoing substance use out of concern for its impact on their continued treatment. Fostering an open dialogue, free from judgment and consequence, will help to ensure that patients can be honest about their continued substance use.

Harm Reduction

Harm reduction includes:

- Providing services that are patient-centered and place the person's harm reduction goals at the core, including working collaboratively with a patient's other health care providers to reach these goals.
- Meeting people where they are[3] psychosocially on their individual path to wellness to ensure the person has autonomy to guide their care, including providing services and connecting with patients in a manner that enhances their wellness, and reduces barriers.
- Recognizing that:
  - Recovery is a continuum that is unique to each person and recurrent use is common.
  - Many physical, mental, and social factors, including social determinants of health,[4] impact decisions and behaviors around substance use and the ability of a person with substance use disorder to access care.
  - A holistic approach to providing care is needed.
  - Harm reduction strategies are critical in supporting all persons who use drugs
  - Harm reduction is an approach to care that recognizes that, in some contexts, some harm is inevitable, and effort should focus on attempting to limit or minimize the harm that occurs.

Harm reduction strategies are an important public health measure to combat the negative health consequences of drug use. All interventions that decrease harm to a person are beneficial.

Pharmacy practitioners are encouraged to reflect on their own biases and understand that their interactions with individuals experiencing OUD can be part of an individual's social determinants of health because they can either encourage recovery or further entrench bias and stigma. How a pharmacy practitioner views and treats an individual will either impede or support a patient's recovery. [5,6]

Opioid poisoning vs Overdose vs Toxicity

The terms "overdose", "poisoning", and "drug toxicity" are used interchangeably at times but they have different underlying meanings. The term "overdose" implies that a person took too much of a known substance, either intentionally or unintentionally in error. However, street drugs are often poisoned with additives and adulterants (e.g., fentanyl or benzodiazepines) that people had no intention to consume. Therefore, the terms "poisoning" or "drug toxicity" are often more accurate for describing the harms people experience from these substances.[7]

3 "Meeting people where they are" is an important principle of harm reduction. See Harm Reduction Resources for more information.
4 Canadian Public Health Association: What are the social determinants of health?
5 Stigma, Centre for Addictions and Mental Health
https://www.camh.ca/en/hospital/health_information/a_z_mental_health_and_addiction_information/stigma/Pages/stigma_brochure.aspx
6 Stigma among health professionals towards patients with substance use disorders and its consequences for healthcare delivery: Systematic review, Drug and Alcohol Dependence, Volume 131, Issues 1–2, 1 July 2013, Pages 23–35

[7] https://www.gov.mb.ca/health/publichealth/docs/training_manual_overdose.pdf

Patient-Centered Care

In patient-centered care, an individual's specific health needs and desired health outcomes are the driving force behind all health care decisions and quality measurements. Patients are partners with their health care providers, and providers treat patients not only from a clinical perspective, but also from an emotional, mental, spiritual, social, and financial perspective. Patient- and family-centered care encourages the active collaboration and shared decision-making between patients, families, and providers to design and manage a customized and comprehensive care plan.[8]

Trauma

Trauma is a term used to describe the challenging emotional consequences that living through a distressing event can have for an individual. Traumatic events can be difficult to define because the same event may be more traumatic for some people than for others.

However, traumatic events experienced early in life, such as abuse, neglect, and disrupted attachment, can often be devastating. Equally challenging can be later life experiences that are out of one's control, such as a serious accident, being the victim of violence, living through a natural disaster or war, or sudden unexpected loss.

When thoughts and memories of the traumatic event don't go away or get worse, they may lead to post-traumatic stress disorder (PTSD) which can seriously disrupt a person's ability to regulate their emotions and maintain healthy relationships.[9]

Trauma and Violence Informed Care

Trauma and violence-informed approaches are policies and practices that recognize the connections between violence, trauma, negative health outcomes and behaviors.

Trauma and violence-informed approaches are not about 'treating' trauma . . . instead, the focus is to minimize the potential for harm and re-traumatization, and to enhance safety, control, and resilience for all clients . . .[10]

Trauma and violence-informed care (TVIC) improves how service providers . . . serve clients who have experienced traumatic life events. TVIC does not focus on encouraging clients to disclose details of trauma they have experienced or on treating their trauma symptoms. Instead, TVIC fosters an environment where all clients feel safe and there is less possibility they will be traumatized again. TVIC recognizes the impacts of individual trauma (e.g., sexual abuse, physical abuse…etc.) as well as structural violence and inequities (e.g., racism, transphobia) on clients' health and well-being as well as how they engage with services.[11]

8 https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0559
9 https://www.camh.ca/en/health-info/mental-illness-and-addiction-index/trauma
10 https://www.canada.ca/en/public-health/services/publications/health-risks-safety/trauma-violence-informed-approaches-policy-practice.html
11 https://www.cpha.ca/sites/default/files/uploads/resources/stbbi/STBBI-TVIC-toolkit_e.pdf

Standards of Practice

Opioid Agonist Therapy (OAT) is an essential service provided by pharmacy practitioners in Nova Scotia. These Standards set out the minimum expectations and requirements of pharmacy practitioners when they are involved in the provision of OAT.

1. Competencies, Ethics, and Professional Responsibilities

Pharmacy Managers ensure:

1.1. The pharmacy fulfills its responsibility to provide OAT.

1.2. The Nova Scotia College of Pharmacists is notified when a pharmacy provides OAT services. (Refer to Forms section.)

1.3. All staff are provided with educational resources so that they maintain a patient care environment that is anti-discriminatory and is culturally safe.

1.4. Policies and procedures are established, implemented, and enforced for all activities associated with the provision of OAT.

1.5. All pharmacy personnel involved in the preparation and distribution of OAT understand their assigned roles and responsibilities.

1.6. A process, consistent with the Code of Ethics, is implemented that assures a patient's health needs are met when the pharmacy is unable to provide OAT services,

1.7. A process is developed that ensures patients can continue to access OAT in instances where the pharmacy is closed due to planned or unplanned closures. (*See Appendix A – Special Circumstances*)

1.8. That the pharmacy has appropriate references including, at a minimum, the most recent version of *Opioid Agonist Maintenance Therapy: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorder* (CAMH) and access to Opioid Agonist Therapy: A Synthesis of Canadian Guidelines for Treating Opioid Use Disorder.

1.9. That a quality assurance program for OAT activities is included as part of the pharmacy's overall quality assurance program in accordance with the Standards of Practice: Continuous Quality Assurance Programs in Community Pharmacies.

Pharmacy Practitioners

1.10. Maintain their competence to provide OAT including routinely assessing their competence and the need to undertake continuing education.

1.11. Foster a pharmacy environment that is culturally safe, free of bias, stigma, and discrimination.

1.12. Ensure that respectful, non-stigmatizing verbal and non-verbal communication is used by all employees of the pharmacy.

1.13. Cultivate a harm reduction approach.

1.14. Facilitate continuity of care for patients receiving OAT *(See Appendix A – Special Circumstances)*

1.15. Seek out and maintain knowledge about resources and community support available for the treatment and management of OUD (e.g., treatment referral programs, injection supply programs, supervised consumption sites).

1.16. Dispense prescriptions for OAT, that are indicated for chronic pain, in accordance with these Standards when the patient has a current or history of OUD.

1.17. Offer a naloxone kit and training to all OAT patients, agents, family members, or caregivers. (Refer to the NSCP Naloxone for Opiate Overdose Reversal Position Statement.)

2. Communication and Collaboration

See Appendix B – Communication and Collaboration, for further details of expected practice relevant to this section.

Pharmacy Practitioners

2.1. Communicate and collaborate with the patient's care team (prescriber, nurse, social worker, or addictions counsellor), as appropriate, to increase the probability of successful patient outcomes.

2.2. Collaborate with pharmacy colleagues to support continuity of care and take all reasonable steps to ensure patients receiving OAT have timely access to services.

2.3. Collaborate and communicate with patients in a manner that is patient-centered and considers the impact that trauma, culture, literacy, socioeconomic status, ethnicity, race, language, and other factors can have on the patient.

3. Provision of Therapy

See Appendix C – Provision of Therapy, for further details of expected practice relevant to this section.

Pharmacy Practitioners

3.1. Prepare prescriptions for OAT in accordance with standardized policies and procedures.

3.2. Complete and maintain comprehensive preparation records.

3.3. Ensure the prescription includes the information necessary for dispensing.

3.4. Confirm the need for witnessed ingestion if it is not indicated on the prescription or not known.

3.4.1. Dispense and/or administer buprenorphine extended-release injection (e.g., Sublocade®) in accordance with the manufacturer's requirements and do not dispense directly to the patient.

3.5. Confirm patient identity for witnessed dosing and release OAT prescriptions directly to the patient in accordance with the NSCP policy *Releasing Medication to Patients and their Agents.* (Prescriptions may only be released to a patient agent in exceptional circumstances.)

3.6. Offer and encourage the use of a private consultation room for witnessed dosing and counseling.

Pharmacists

3.7. Assess a patient to be satisfied that it is safe to provide them with their dose.

3.8. Use a patient-centered approach to counsel patients so that they can make informed decisions about their care.

3.9. Monitor patients receiving OAT to ensure that therapy remains safe and appropriate (particularly during dose changes).

3.10. Take appropriate action in the event of an administration error or medication incident in accordance with the Standards of Practice: Continuous Quality Assurance Programs in Community Pharmacies.

3.11. Communicate with members of the patient's care team, when necessary, to manage patient care.

3.12. Notify prescribers about missed doses as soon as possible.

3.13. Notify the patient's OAT provider without delay in instances where the pharmacist extends an OAT prescription for the patient.

3.14. Prescribe OAT in accordance with Appendix H of the Standards of Practice: Prescribing Drugs.

Appendix A – Special Circumstances

Opioid Agonist Therapy in Correctional Facilities

When a patient on OAT transitions in or out of a correctional facility, effective sharing of information among the patient's health care providers is critically important to patient safety and continuity of care. Patients who have transitioned from a correctional facility back into the community that are unable to be seen by a community OAT provider, may be forced into unnecessary withdrawal or be at risk of overdose or opioid poisoning. To ensure continuity of care, pharmacists are supported by the Standards of Practice: Prescribing Drugs – Appendix H to prescribe OAT in these situations.

Pharmacists prescribing for these individuals should:

- attempt to contact the previous provider (prescriber, pharmacy, or nurse in the correctional facility),
- confirm the patient's last ingested dose,
- be reasonably assured of when the patient last received a dose, and
- provide the medication as daily witnessed ingestion.

Guest Dosing and Transfers

There are situations where it may be necessary for a patient to be provided with their OAT by another pharmacy including when:

- the pharmacy is closed due to planned closures or emergencies.
- the patient will be away for longer than enough take-home doses can be provided.

In these situations, the pharmacist ensures that a process is in place so that patients can continue to access OAT. This includes but is not limited to:

- collaborating with the patient's care team to make arrangements for the patient to receive their witnessed dose at another pharmacy or the local hospital, if appropriate.
- establishing a communication plan between the primary and guest pharmacy to ensure continuity, security, and accountability of all doses so that double-dosing or missed dosing does not occur.

A pharmacist receiving a transfer for a prescription for OAT will confirm:

- the date and time of the last witnessed dose, and
- the number of take-home doses still in the possession of the patient, where applicable.

Applicable References:

- Subsection 56(1) Class Exemption for Nurses providing Health Care at a Community Health Facility
- Subsection 56(1) Class Exemption for the Person in Charge of a Hospital and/or a Pharmacist who Supplies Controlled Substances to a Community Health Facility
- Section (3) of the Narcotic Control Regulations

Termination of the Patient-Pharmacist Relationship

In rare circumstances it may be necessary to terminate a relationship with a patient. While these Standards do not preclude terminating a patient relationship, a decision to do this can have a profound impact on the patient and their access to care and must be done in accordance with the Code of Ethics, that states:

"Registrants continue to provide services to their patient until the services are no longer required or wanted; until another provider has assumed responsibility for the patient; or until the registrant has provided reasonable notice of termination of the relationship."

Delivery of OAT

Pharmacists may determine that delivery is required in exceptional situations such as when:

- the patient is unable to come to the pharmacy (e.g., public health emergency, temporary employment demand, bereavement, medical reasons).
- the prescriber arranges for delivery.

When determining whether delivery is appropriate, pharmacists will consider:

- the stability of the patient and their circumstances (e.g., housing, ability to safely store doses, etc.).
- the extent to which it is critical for the patient's health that they are assessed prior to being provided with their dose.
- the ability for a virtual assessment or for the person doing the delivery to do this assessment.
- the ability of the person delivering the dose to confirm the identity of the patient.
- whether systems are in place to ensure the security of the doses and the safety of the delivery person.

Witnessing when delivering OAT

In situations where the pharmacy is delivering to the patient, effective witnessing may not always be possible, and every effort should be made to collaborate with the prescriber. Pharmacists will establish how a patient assessment and witnessing in the context of delivery is accomplished. This could include virtual communication or the involvement of another regulated health care provider who has been appropriately trained. If a decision is made by the pharmacist that witnessing will not take place, the reason is documented and communicated to the prescriber at the earliest opportunity.

Pharmacists will ensure that individuals providing witnessed dosing understand and are competent to:

- witness the dose, and
- recognize when it may be unsafe to provide the dose to the patient (e.g., patient impairment by drugs or alcohol) and how they should proceed in these situations.

Documentation of Delivery

Pharmacy practitioners ensure documentation is completed for witnessed ingestion including:

- the date and time of ingestion.

- positive identification of the patient.
- who witnessed the dose.
- who assessed the patient (if applicable).
- the dose given, and
- relevant patient care notes (e.g., vomited or part dose ingestion).

Pharmacists may decide the method to be used to confirm and document the identity of the patient or their agent and confirm the receipt of the medication by the patient or their agent.

Delivery Process

For all deliveries, the pharmacist will establish a process that ensures that the:

- delivery process is agreed upon by the patient prior to the delivery.
- individual delivering knows who they are authorized to release it to (the patient or an individual authorized by the patient and pharmacist).
- individual delivering understands, as with any medication delivery, that they should not put themselves in a position that they reasonably believe could threaten their health or safety (e.g., delivery drivers do not have to enter homes - witnessing can take place from outside of a door, via virtual communication, etc.)
- dose is returned to the pharmacy if release to the patient or authorized person was not immediately possible or if there was only a part dose ingested.
- delivery is appropriately documented.
- delivery complies with the NSCP's Delivery of Prescriptions Guidelines.
- Health Canada requirements are met. (See below.)

Health Canada has made provisions for prescriptions to be delivered to the patient or to someone authorized by the patient as long as the person doing the delivery:

- has authorization to deliver the medications in writing from the pharmacist that includes the names of people to whom they are delivering, and the pharmacy contact information: and
- has a copy of the *Health Canada Section 56 Class Exemption* in their possession while making the delivery.

In situations where a witnessed dose is necessary, but delivery by the pharmacy is not possible, if the pharmacist is satisfied that it is appropriate, solutions could include:

- facilitating the transfer of care to a pharmacy that can accommodate the patient.
- having a member of the patient's health care team pick up, deliver, and witness the dosing.
- in exceptional circumstances, having someone authorized by the patient pick up, deliver, and witness the dosing,

Appendix B – Communication and Collaboration

Patient Communication and Collaboration

Pharmacy practitioners are often the only health care provider who interacts with a patient on a daily basis, creating an opportunity to have a significant positive impact on them. Good communication can empower patients by helping to foster trust in the treatment process and in their health care providers. Further, this daily encounter may enable the identification of subtle changes in mood or behavior that may be a sign of a deterioration in a patient's health, inadequate treatment, or a change in social circumstances that can impact their treatment.

Prescriber Communication and Collaboration

The health interests of a patient are best served when there is a multidisciplinary team approach that includes open and effective communication between a patient and their health care team as well as between the members of the health care team.

Ideally, at the beginning of treatment, pharmacists take reasonable steps to establish an agreed upon communication and collaboration plan with patients and other members of their health care team.

Topics could include, but are not limited to:

- vomited, missed, or part doses
- pregnancy or other health related issues
- urine drug screening
- dosing errors
- signs of intoxication, withdrawal, or ongoing drug use
- adverse events
- care arrangements when:
    - the patient is unable to get to the pharmacy
    - days when the pharmacy is closed (e.g., holidays or emergency closures)
- locked boxes
- take-home dose inspections
- lost/stolen doses or signs of diversion
- return of empty take-home dose bottles
- financial or housing concerns

Appendix C – Provision of Therapy

The provision of OAT in community pharmacies can present unique challenges and risks not otherwise experienced with other medications. To meet the needs of patients in a manner that is both convenient for the patient and efficient for the pharmacy, multiple prescriptions must often be prepared in advance of daily witnessed administration. Patient safety is dependent upon pharmacy practitioners establishing and adhering to policies and procedures for this process.

Prescription Preparation

It is critical that prescriptions for OAT are prepared safely and accurately. Pharmacy managers are responsible for ensuring that:

- policies and procedures for prescription preparation are developed, documented, and implemented.
- all pharmacy staff involved in the preparation of OAT prescriptions have received appropriate training.
- adherence to policies and procedures is monitored and enforced.

Preparation of Methadone Doses

Given its toxicity profile, it is critical that prescriptions for methadone are prepared in a manner that ensures safety, stability, and appropriate labeling.

Pharmacy Practitioners ensure that:

- only dedicated equipment is used for the preparation of methadone.
- verification steps are performed and documented throughout the preparation process.
- whenever possible, an independent double check takes place for any calculations or measurements.
- unless in exceptional circumstances, individual patient doses:
    - are prepared from a commercially available 10mg/mL stock solution. (Compounded stock solution should only be used when suitable commercially available products are either unavailable or unsuitable for the patient.)
    - are diluted to a uniform volume of 100 mL with a suitable diluent, preferably Tang®. (Different volumes can be considered in collaboration with the prescriber.)

Orange flavored Tang® is the preferred diluent because:

- It frustrates extraction of the methadone from the solution.
- It is consistent with the practice of most OAT programs (a consistent product enables patients to identify unanticipated changes more easily in the taste of their solution (i.e., in the event of an error).

If the patient is unable to tolerate Tang®, other diluents could include Crystal Light®, Kool-Aid®, and other brands of artificially sweetened crystals.

(Note: To enable patients to easily identify unanticipated changes in the taste of their solution and identify a potential error, diluents should be consistently made, with all persons involved using the same ratio of crystals to water.)

- are bottled in 100 mL amber, childproof bottles (tamper-evident systems are used in instances where, in the professional judgment of the pharmacist, it is appropriate to do so or when the prescriber or clinic has identified the need).
- that are prepared in advance of being processed for dispensing, are stored in a secure refrigerator, and labeled with the:
    - Patient name
    - Lot # of stock solution
    - Strength of dose
    - Beyond Use Date (BUD)
    - Date of preparation
    - Initials of the individuals involved with the preparation
- that are provided to the patient for witnessed ingestion or for at home dosing are labeled in accordance with the Prescription Labels Policy. When multiple (take-home) doses of methadone are provided, only the quantity of methadone that is in the bottle must appear on the label. For example, for a prescription for 60mg daily with two take-home doses, only 60mg should appear on the label, **NOT** 180mg.

- A log (electronic or paper-based) of the preparation of individual doses is completed and retained to record the details of the preparation. A template dose preparation log is included with these Standards; however, pharmacy practitioners may use alternate methods so long as the following information is captured:
    - Date of preparation
    - Lot or batch number of stock solution used
    - Strength of dose being prepared
    - Number of bottles being prepared
    - A perpetual inventory of the quantity of stock solution used and remaining after dose preparation (Note: Commercially available stock solution bottles often contain an amount that is different than the label indicates. A process must be established that ensures that this potential discrepancy is identified and accounted for as part of the perpetual inventory management.)
    - An auditable trail of those involved in the preparation and their role (i.e., prepared by, checked by)

Automated Methadone Dispensing Systems and Bottletop Dispensers (e.g., MethaMeasure, Dispensette®)

In addition to the requirements listed above for the preparation of individual methadone doses, in pharmacies where automated or other dispensing device/technology is used to prepare methadone doses, the pharmacy manager is responsible to ensure that:

- the device is classified and licensed, if appropriate under the Medical Devices Regulations to the *Food and Drugs Act*.
- only authorized persons, designated by the pharmacy manager, use the device.
- the proper use, maintenance, and any error attributed to the use of the device are included in the pharmacy's Quality Assurance Program.
- all individuals authorized to use the device receive appropriate training and have demonstrated their competence to use the device.
- a standard operating procedure for the device is in place, implemented, and maintained and that the device is operated and maintained in accordance with the manufacturer's instructions.
- a process is in place to ensure that the device is calibrated in accordance with the manufacturer's requirements and that it continues to provide accurate doses.

Pharmacy Practitioners using the device are responsible for ensuring:

- they are authorized to use the device.
- they have received training and have had an opportunity to demonstrate their competence to use the device appropriately.
- they have read and adhere to all standard operating procedures.
- that prior to use, the device is calibrated in accordance with the manufacturer's requirements.
- that the device is cleaned and maintained in accordance with the manufacturer's directions.

Note: doses prepared in advance for future dispensing are bottled and labeled in 100mL amber bottles as described above. For doses intended for **immediate ingestion** that are prepared with the use of an **automated methadone dispensing system** (e.g., MethaMeasure), pharmacy practitioners use a patient-centred approach to determine whether the use of a bottle is appropriate.

Stability of Methadone in Various Diluents

There is limited published information regarding the stability and sterility of diluted commercially available methadone. The vehicle component could develop microbial contamination. In the absence of stability and sterility data, non-sterile compounding standards[12] require that the beyond use date is not longer than 14 days for water containing oral preparations when stored in the refrigerator. Therefore, take-home doses should be stored in the refrigerator.

Patient Assessment

Prior to providing OAT to a patient, a pharmacist assesses a patient to ensure that it is safe and appropriate to provide them with their dose. Regardless of whether this assessment takes place in person or virtually, it includes but is not limited to:

- reviewing the patient's local and provincial profile,

[12] Nova Scotia College of Pharmacists. Standards of Practice: Non-Sterile Compounding

- ensuring the current dose is appropriate (e.g., no missed doses that would result in a dose change), and
- observing and speaking with the patient to assess for signs of intoxication or withdrawal. (The Patient Assessment Tool included in the templates may be used to facilitate this.)

Any concerns identified during the assessment are managed and documented as part of the patient record and communicated to the prescriber if applicable.

Patient Counseling

Pharmacists use a patient-centered approach to provide ongoing counselling when dispensing OAT, allowing patients to make an informed decision about their therapy. This information is provided in a manner which respects literacy, culture, and language. Knowledge of trauma and violence-informed care as well as motivational interviewing techniques may be valuable with ongoing patient interactions.

Pharmacy OAT Services

Pharmacy practitioners ensure new patients are oriented to the pharmacy. This may include but is not limited to:

- relevant information about the pharmacy (e.g., hours of operation and holiday/power outage procedures)
- daily witness procedures at the pharmacy (e.g., ID requirements)
- take-home doses if appropriate (See Appendix C)
- an overview of how and when the pharmacy communicates with other members of their care team including:
    - that missed, part or vomit doses will be communicated to the prescriber.
    - the urine drug screen notification process (if applicable).
- ensuring the patient understands the importance of maintaining up to date contact information in case of emergency (ex: dosing error or store closure)

Monitoring

OAT introduces risks to the patient that are not associated with dispensing other medications. Pharmacists have a responsibility to ensure they assess for signs of overdose or withdrawal as part of their ongoing patient monitoring, and they take appropriate action including:

- withholding the dose and contacting the prescriber in situations where signs of overdose are present.
- collaborating with the prescriber if any signs of withdrawal are observed.

Dispensing and Witnessed Ingestion

Pharmacy Practitioners ensure that:

- they confirm the need for witnessed ingestion if not indicated on the prescription or not known.

- they determine how prescriptions for SROM are to be administered. (i.e., if capsules must be opened or swallowed whole.)
- doses are provided in person and are not released to others except in exceptional circumstances.
- when the medication is being delivered, the pharmacist will arrange for delivery of the OAT to the patient, ensuring patient assessment, witnessing of the ingestion, and appropriate documentation is completed. (See Appendix A)
- documentation includes the following:
    - the date and time of ingestion
    - the dose given
    - pharmacist performing the assessment
    - missed, vomited, or part doses (if applicable)
    - number of take-home doses given (if applicable)
    - pharmacy staff member witnessing the ingestion

It is the responsibility of the pharmacist to assess the patient to determine whether it is appropriate to provide them with their dose. Once completed, the pharmacist may involve another team member to witness the patient self-administer the dose. For clarity, a pharmacist or pharmacy technician must confirm, at the time of self-administration, the accuracy of the dose being released to the patient BEFORE a pharmacy assistant or other pharmacy team member may witness the patient self-administer the dose.

Note: Patients receiving split doses, who require daily witnessed ingestion, will generally need to attend the pharmacy for each dose.

Sublingual Buprenorphine/Naloxone

A prescription for buprenorphine/naloxone, written with directions for daily witnessed ingestion, does not require the patient to remain under supervision until the medication has dissolved. The patient may leave the pharmacy once a pharmacy team member has directly witnessed the self-administration of the dose, unless specifically otherwise indicated by the prescriber.

Missed Doses

Pharmacy Practitioners:

- inform the prescriber about any missed, partial, lost, or vomited doses and collaborate with the prescriber if a replacement dose is to be given.
- document the missed dose as part of the patient record.
- ensure missed dose prescriptions are reversed from the NS Drug Information System in a timely manner, if applicable, to ensure accuracy of provincial records.
- consult clinical practice guidelines for guidance on missed doses and loss of tolerance.
- use a patient-centered, trauma-informed approach, and non-stigmatizing language when discussing missed doses with patients.

Prescriptions

Prescriptions for OAT must be complete. Pharmacy practitioners must be provided with or have access to the following information:

- the total quantity in milligrams or tablets for the entire duration of the prescription
- the total daily dose
- the dispensing schedule, including:
    - the start and end date of the prescription
    - the days of the week that require witnessed ingestion (if applicable)
    - the number of take-home doses authorized per week and the take-home schedule (if applicable)

Regardless of whether there are any authorized doses remaining, a prescription cannot be dispensed after its end date.

Take-Home Doses

As a progression of treatment, patients receiving OAT may have the requirement for daily witnessed ingestion removed and have dispensing intervals lengthened. This flexibility can help to improve their quality of life, social functioning, and employment, as well as retention in the program.

When doses are provided for at home consumption, the first dose of each dispense is witnessed unless, in the case of buprenorphine/naloxone or very rarely SROM, the prescriber has indicated that witnessing is not necessary, **AND** the pharmacist is satisfied that it is appropriate.

In general, the dispensing intervals as set out in clinical practice guidelines vary but are typically:

- Methadone: 7 days
- Buprenorphine/naloxone: 7-14 days
- SROM: daily

Note: For dispensing intervals that differ from what is listed above, pharmacists use their professional judgement in collaboration with the patient and the prescriber, to determine whether the dispensing interval is appropriate.

Patient Education for Take-Home Doses

Prior to releasing take-home doses, pharmacists ensure that patients are educated and understand:

- the need for safe medication storage because very small doses of opioids can be fatal in someone who is not tolerant.
- that medication should be stored securely in the refrigerator (e.g., in a locked box).
- that tolerance is lost quickly, and they should contact their pharmacist or prescriber for guidance if they miss a dose.

The prescriber or pharmacist may determine that it is in the patient's best health interest to decrease or temporarily discontinue take-home doses. This can be discouraging for the patient. Opioid use disorder is a chronic and potentially relapsing condition and the continued support and encouragement by health care providers may help patients continue or return to therapy. Pharmacy practitioners play a critical role during these times and should avoid stigmatizing language and behaviors.

Resources

In addition to the required on-site references: *Opioid Agonist Maintenance Therapy: A Pharmacist's guide to methadone and buprenorphine for opioid use disorder* (CAMH), and Opioid Use Disorder: A Synthesis of Canadian Guidelines for Treating Opioid Use Disorder. (CAMH), the following resources may also be useful to maintain competence.

NSCP Position Statement: Professional Responsibilities to Meet Patient Needs Related to Compounding, Opioid Agonist Therapy, and Prescribing

Accredited Substance Use Disorder Education Programs

Centre for Addictions and Mental Health (CAMH): Buprenorphine-Naloxone Therapy for Opioid Use Disorder
Centre for Addictions and Mental Health (CAMH): Opioid Dependence Therapy Certificate Program

General References

British Columbia Center on Substance Use

- Missed Doses: A Guideline for the Clinical Management of Opioid Use Disorder (2023)
- Pregnancy: https://www.bccsu.ca/wp-content/uploads/2018/06/OUD-Pregnancy.pdf

CAMH

- Opioid Agonist Therapy: A prescriber's Guide to Treatment

CRISM

- National Guideline for the Clinical Management of Opioid Use Disorder: https://crism.ca/wp-content/uploads/2018/03/CRISM_NationalGuideline_OUD-ENG.pdf
- SROM: https://crism.ca/wp-content/uploads/2018/03/CRISM-SROM-info-sheet.pdf
- iOAT Guidelines: https://crism.ca/wp-content/uploads/2019/09/CRISM_National_IOAT_Clinical_Guideline-10Sep2019-English-FINAL.pdf

METAPHI

- Resource Library: https://www.metaphi.ca/resources/
- Home Start Buprenorphine template: https://www.metaphi.ca/wp-content/uploads/ED_OUD_RxHome.pdf

Health Canada

- Prescription management by pharmacists with controlled substances under the Controlled Drugs and Substances Act and its regulations https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/prescription_management_pharmacists_controlled_substances.html

Harm Reduction

- CAMH: Addressing Opioid Stigma in Pharmacies: Strategies for Pharmacy Professionals
- Government of Canada: Addressing Stigma in Canada's Health System
- National Harm Reduction Coalition: Principles of Harm Reduction

Nova Scotia References

- Addiction Medicine Consult Service https://mha.nshealth.ca/en/clients-and-providers/resources-providers/addictions-medicine-consult-service

- Nova Scotia Opioid Agonist Therapy Providers Forum: https://atlanticmentorship.com/
- Nova Scotia Opioid Use and Overdose Strategy: https://novascotia.ca/opioid/
- Nova Scotia Mental Health and Addictions: https://mha.nshealth.ca/en
- Nova Scotia Mainline Needle Exchange and Cape Breton Ally Center

Forms

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The forms included in this section are available in fillable pdf format on the NSCP website.

METHADONE INDIVIDUAL DOSE COMPOUNDING LOG

Note: New bottles of stock solution are entered on this form, adding the quantity to the "Quantity of Stock Solution Remaining" from the line above.
*Commercially available stock solution bottles are known to contain an amount that is different than the label indicates. A process must be established that ensures that this potential discrepancy is identified and accounted for as part of the perpetual inventory management.

Date Prepared	Lot or Batch Number of Stock Solution	Patient's Name	Strength of Dose Being Prepared (mg)	Number of Bottles Prepared	Quantity of Stock Solution Used (mL)	Quantity (mL)* of Solution Remaining (subtract amount used from prev. balance [line above])	Initials of Preparer	Initials of Checking Pharmacist/PT
sheet start date						beginning balance		

Transfer this amount to next sheet as "beginning

OAT DAILY WITNESSED INGESTION AND TAKE-HOME LOG

Patient Name: _____ Month: _____

Affix Rx Label

Date	Time	Rx Number	Dose(mg)/ consumed	# Take-Home Doses Given	Total Days Supply Remaining	UDS Notification Date (If Applicable)/ Comments	Assessed by: (PhC)	Witnessed by: (PhC, RPhT, Assistant)	Patient Signature
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
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30									
31									

OPIOID AGONIST TREATMENT
MISSED DOSE / INCIDENT NOTIFICATION FORM

Notification Date				
Pharmacy Name/Location				
Phone		Fax		
Patient				
DOB		HCN		
Opioid Agonist Treatment	Methadone ☐	Bup/Nal ☐	SROM ☐	Other ☐
Description	☐ Missed Dose, patient did not present to the pharmacy ☐ Dose withheld ☐ Vomited Dose ☐ Other_____			
Details				
Pharmacist Name				

Patient Assessment Tool

Patient Name: Date: Time:

- Total scores of 1/15 or 2/15: hold the dose and contact the OAT prescriber to collaboratively consider the course of care.
- Overall score of greater than or equal to 3/15: hold the dose and directly contact the OAT prescriber to collaboratively consider the course of care before proceeding.
- If there is concern about the patient's status of recovery and/or safety, withhold the dose and contact the prescriber regardless of the score.

Parameter	**Score**				
Speech	**0** Normal	**1** Slurred; Slow	**2** Mumbling	**3** Disjointed; Unintelligible	**/3**
Coordination	**0** Regular walking and movements	**1** Tripping	**2** Unsteady; tottering; staggering	**3** Falling; difficulty standing o remaining upright	**/3**
Mental Signs	**0** Focused	**1** Inattentive	**2** Loss of train of thought can't remain on topic	**3** Confused; Disoriented	**/3**
Level of Consciousness	**0** Alert; attentive	**1** Drowsy; easily roused	**2** Nodding off; sleeping in waiting room	**3** Difficult to rouse; requires touch to awaken	**/3**
Physical Signs	**0** Respiratory Rate > 12; Pupils reactive			**3** Respiratory Rate < 12 (call EHS); Pupils pinpoint	**/3**

Add the scores of the 5 parameters for the **TOTAL SCORE:** **/15**

Refer to *Evaluation of Information* for interpretation of scores.

Score: / 15	Dosage withheld? YES ☐ NO ☐	Methadone dosage administered:

Notes:

Pharmacist Signature:

PHARMACY OAT SERVICE NOTIFICATION

Pharmacies providing OAT will notify the NSCP by completing and submitting this form. Information from this registry will be released to other health care providers or the public to facilitate identifying pharmacies that could serve a patient.

Date:	
Name of Pharmacy:	Pharmacy License #
Pharmacy Address:	
Pharmacy Phone:	
Pharmacy Fax:	
Pharmacy email:	
Pharmacy Manager: (please print)	License #
Pharmacy Manager Signature:	

Please submit this form via email to qualityassurance@nspharmacists.ca or by fax to 902 422 0885