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New Brunswick College of Pharmacists
Ordre des pharmaciens du Nouveau-Brunswick

PRACTICE DIRECTIVE:
OPIOID AGONIST TREATMENT (OAT)

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Preface

To support appropriate and safe use of opioid agonist treatment (OAT), this ***Practice Directive: Opioid Agonist Treatment (OAT)*** details the requirements for pharmacy professionals who provide OAT services to patients with opioid use disorder (OUD).

This practice directive replaces the former *Methadone Practice Directive (2012)*. New therapeutic options, regulation of pharmacy technicians, changes to federal legislation, a revised Code of Ethics (1), new clinical practice guidelines (2,3), and increasing rates of harm related to opioid use (4) necessitate revised guidance for pharmacy professionals who care for patients with OUD.

This practice directive is grounded by the following principles:

- Patients receiving OAT services must be treated with respect and dignity.
- Pharmacists must employ the most recent OAT-related clinical practice guidelines, evidence and standards of practice to facilitate quality patient care.
- Pharmacy practice must align with provincial and national harm reduction strategies.
- Safeguards are needed against diversion of agents used in OAT.

The goal of this practice directive is to establish **requirements** for the safe and effective provision of OAT, while avoiding unintended consequences of more detailed practice directives such as:

- Changes to federal or provincial law resulting in outdated guidance.
- Guidance failing to keep pace with emerging clinical evidence and legislation
- Onerous regulation discouraging pharmacies from offering necessary (5) OAT harm-reduction services.
- Hindered application of professional judgment in nuanced or unique scenarios.
- Preventing professionals from acting to meet patient needs or fulfilling evolving roles.

This Practice Directive does not address:

- Therapeutic evidence: Clinical practice guidelines are published by other agencies and researchers. These sources provide therapeutic guidance to clinicians in providing evidence-based care to patients.
- Safer Opioid Supply (SOS): Provincial public health policy and programs (such as compassion clubs, supervised consumption sites (SCS) and safe injection sites) are evolving to prevent serious societal harms (organised crime, gang violence, and death) associated with legislated prohibitions on opioid possession (6,7) and supply chain poisoning with potent synthetic opioids. SOS programs' primary goal is harm reduction

rather than addiction treatment and recovery (8). SOS is an emerging practice. It differs from OAT and is not included within the care model used for OAT.

- Patient care and therapy for analgesia: Different risks and considerations apply to this population of patients.
- Prescribing OAT by pharmacists: Federal legislation applies to prescribing.[1]

[1] Health Canada. Subsection 56(1) class exemption for patients, practitioners and pharmacists prescribing and providing controlled substances in Canada

Acknowledgements

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- Ellen Boyd, Pharmacist
- Bradley Adams, Pharmacist
- Amy Bain, Pharmacist
- Lyndsay Torunski, Pharmacist (Student at time of writing)

The College also acknowledges the consent of the following organizations to allow reference to their work in this practice Directive:

- The Centre for Addiction and Mental Health (CAMH)
- New Brunswick's Coroner Services: Chief Coroner

The College gratefully acknowledges the work of other pharmacy regulatory authorities across Canada, particularly the College of Pharmacists of British Columbia (CPBC), for their permission to allow the New Brunswick College of Pharmacists to refer to "Policy Guide for Injectable Hydromorphone Maintenance Treatment" within this Practice Directive as well as their perspective on SOS.

Pharmacists, pharmacy technicians, physicians, nurse practitioners, social workers and government have been consulted in draft stages of this practice directive and included in release communications with the intent of facilitating interprofessional collaboration.

Update Notice (2024)

2024 - This document has been revised to include updated reference materials on the National Clinical Practice Guideline developed by the Canadian Research Initiative in Substance Matters (CRISM).

Introduction

Pharmacy professionals must comply with all applicable existing provincial (9,10) and federal legislation (11,12), policy (1,13), and evidence-based clinical practice guidelines (2,3,14,15,16) in addition to this Practice Directive. The agents commonly used in the provision of OAT services are classified as narcotics and are subject to specific legislative requirements as set out in Schedule I of the Controlled Drugs and Substances Act (11,12).

Therapeutic options more commonly used in OAT include oral buprenorphine-naloxone and methadone. Newer agents include buccal films and injectable forms of buprenorphine, sustained release oral morphine (SROM) and injectable OAT (iOAT). These agents present varying risk to patients and public safety and this practice directive describes greater safeguards for those agents that are known to have higher potential for diversion or adverse patient events. As new therapeutic options emerge, professionals should determine potential risk of each agent and apply appropriate safeguards.

Buprenorphine-Naloxone: This therapeutic agent has been shown to be lower risk (16) to patients in terms of safety. The potential for diversion exists, however overdose is less likely to be fatal.

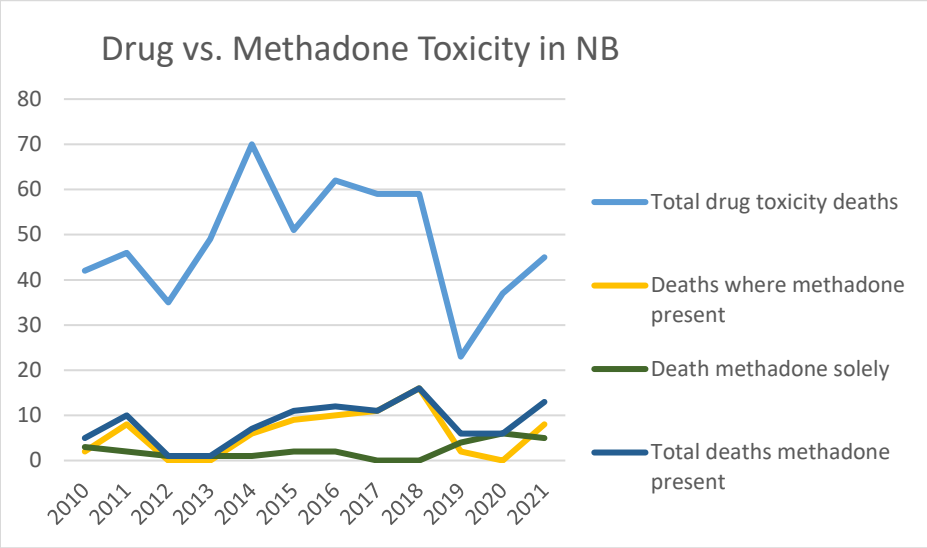
Methadone: Evidence indicates methadone is associated with medication incidents (errors and near-miss events) (17), as well as patient complaints[2] to the College. These incidents and complaints indicate a significant degree of actual or potential harm from errors in the dispensing process and diversion.

The pharmacologic and pharmacokinetic characteristics of methadone presents significant risk of overdose in opioid-naïve individuals.

Data from 2010 to 2021 from New Brunswick's Coroner Services indicate stable rates of methadone-related mortality.

[2] Complaints relating from the provision of methadone to patients relate to diversion, incorrect recipient receiving dose and incorrect dose provision.

Figure 1: New Brunswick Rates of Drug Toxicity (18)



Between 2010 and 2021[3], 17 per cent of all individuals who died in New Brunswick secondary to drug toxicity had methadone in their system. Whether methadone contributed to all these deaths is unknown. During the same period, 4.7 per cent of all fatal drug toxicities were solely attributed to methadone. The means by which methadone was procured is unknown.

Sustained Release Oral Morphine (SROM): Due to the risks of toxicity associated with bolus absorption and diversion, extra safeguards are included in the practice directive.

[3] Data spanning January 2010 to 2021.

iOAT: While not first line of therapy, injectable hydromorphone is a newer agent considered for use in OUD. It is considered to have high potential for diversion and risk to patient outcomes. Specific requirements of iOAT are expressed throughout the practice directive.

Unless otherwise stated, all information within the Practice Directive applies to all treatment options. Requirements particular to individual therapeutic agents are explicitly noted.

The Practice Directive is organized into four sections to facilitate utility:

1. Deciding to offer OAT services
2. Preparing for provision of OAT
3. Providing OAT
4. Transitions of Care

The glossary within the Practice Directive details terminology used in this document. Appendix A at the conclusion of this document cross-references content in the CAMH Opioid Agonist Maintenance Treatment that provides further clinical or therapeutic information building on the requirements expressed within this practice directive.

Practice Directive

1. Deciding to Offer OAT Services

Provision of OAT involves a high degree of patient interaction, prescriber collaboration, preparation complexity, clinical and dispensing documentation, vigilance and commitment. The resources required to provide care for patients with opioid use disorder (OUD) may not be present in every practice. However, as patient numbers with this diagnosis increase, the College anticipates that more pharmacies in New Brunswick may decide to provide care for patients requiring OAT.

Decisions to provide OAT services should be made collaboratively by the pharmacy team such that all members understand and commit to their role in this component of practice. Collaborative decisions encourage investment of the team in positive patient experiences and outcomes.

1.1 Pharmacy Team Roles in the Provision of OAT

Pharmacy Technician:

- Provide technical support as per, “Model Standards of Practice for Pharmacists and Pharmacy Technicians in Canada.” (13)
- Process and prepare prescriptions for patients requiring OAT.
- Follow-up monitoring of patients for compliance with oral/buccal administration. In institutional settings, observed dosing may be performed by professional staff as per institutional policy.

Pharmacist:

- Provide patient care as per "Model Standards of Practice for Pharmacists and Pharmacy Technicians in Canada." (13)
- Establish a therapeutic pharmacist-patient relationship.
- Prescribe, sell, provide or transfer OAT as per Health Canada's Section 56 Exemption.[4]
- Follow-up monitoring of patients for compliance. In institutional settings, observed dosing may be performed by professional staff as per institutional policy.

Pharmacy Manager:

- Manage the pharmacy as per, "Model Standards of Practice for Pharmacists and Pharmacy Technicians in Canada" (13), relevant provincial and federal legislation and this practice directive.
- Establish pharmacy team commitment to providing care to patients with OUD.
- Complete and document preparations completed for implementation of OAT services at the pharmacy (See Practice Directive Section 2.6).
- Execute (or delegate management of) an ongoing quality management program (QMP) relating to OAT as a component of the pharmacy's larger QMP. (See Regulations 13.5 (g) and 20.2 (d) and Section 2.6 for more guidance).
- When appropriate, inform and educate patients/community regarding OAT. Information and advertisement must conform to federal[5] and provincial[6] legislation.

1.2 Applying the Code of Ethics to the Provision of OAT

Pharmacy professionals have a duty to promote and protect the well-being, safety and interest of the public. Provision of OAT aligns with this duty. Pharmacy professionals are expected to take action to provide safe and effective care involving OAT to their patients. The four bioethical principles apply to the provision of OAT.

Figure 2: Code of Ethics Infographic

[4] Please refer to Health Canada's website for most up to date Section 56 Exemption. At writing, the exemption expires on September 30, 2026 or another date when it is replaced or revoked (whichever is earliest).
[5] Information and advertising must conform to the Office of Controlled Substances (OCS) Narcotic Control Regulations (9): Regulation 70.
[6] Information and advertising must conform to the New Brunswick College of Pharmacy Regulations: Part 19 (8)

1.2.1 Beneficence/Non-Maleficence

Treatment of OUD with OAT, is congruent with this bioethical principle in that patients can manage to focus on their life goals while avoiding debilitating withdrawal from opioids.

Practices not providing OAT should consider whether they can incorporate it and subsequently work toward offering OAT services. Ready access to OAT services, regardless of geographic area (urban or rural), prevents fracturing care between multiple pharmacies.

Pharmacy professionals must weigh the importance patients place on remaining in their own community to access care for their condition against determining whether the practice can safely meet the needs of these patients. If resources do not support safe and effective care implementation of OAT, services must be deferred and the patient referred to another provider.

At the time of medication administration, pharmacists may assess a patient and determine that the provision of OAT places patients at risk of harm (19). The pharmacist's decision to delay administration or eliminate take-home doses may conflict with patient wishes or with plans established by other members of the interprofessional team. Despite these conflicts, non-maleficence to the patient must take precedence.

1.2.2 Respect for Persons

Patients undergoing treatment for OUD often experience stigma associated with educational background, socioeconomic status, health status, race or culture. Respect for Persons requires establishing a supportive and non-judgmental culture within the pharmacy. The pharmacy manager must ensure all staff possess knowledge, skills, attitudes, and resources to maintain a patient care environment that is anti-discriminatory and engenders cultural safety in providing OAT.

Pharmacy professionals must employ a harm reduction approach in caring for patients with OUD at all stages of their journey (recovering from, relapsed or ongoing use of illicit opioids).

If a patient's privacy (Regulations 14.1 (d)) (10) and dignity cannot be maintained in the course of receiving OAT, patient care must be deferred to another provider until acceptable solutions can be implemented. Interim arrangements must be established in collaboration with the patient and another professional/addictions service.

1.2.3 Justice

Justice requires pharmacy professionals facilitate equitable access to services regardless of patient socioeconomic strata or geographic location. OAT must be accessible to patients of all income, education and social status, in urban or rural settings. Pharmacy professionals have a role in facilitating OAT therapy reliably and safely. As with any pharmacy service, patients are entitled to select the pharmacy of their choice and pharmacy professionals must support the patient's decision.

2. Preparing for Provision of OAT Services

Upon deciding to offer OAT services, pharmacy managers are responsible for completing (or delegating, where appropriate) and documenting preparation for undertaking these services.

2.1. Education and Training

Pharmacy professionals must be competent in caring for patients with OUD to provide safe and effective patient care (Regulation 12.30, 12.32(1)) (10).

Evidence of harm associated with OAT (see Introduction), indicates pharmacy professionals and pharmacy managers require in-depth professional development on the topic. The courses listed in Appendix B of the practice directive are comprehensive, accessible, quality learning objectives, of Canadian origin, and are applicable to all pharmacy sectors.

Managers and other professional staff are encouraged to complete one of these courses.

All pharmacy professionals must also ensure competency in dealing with adverse patient outcomes associated with OAT. Pharmacy practitioners **must be competent in dealing with opioid overdose and the use of naloxone** (20).

Pharmacists who provide injectable hydromorphone (iOAT) services: The pharmacy manager (or their delegate) plus one other pharmacist in the practice (where more than one professional is employed in the practice) must complete **one** of the courses listed in Appendix B as a basis for engaging in providing iOAT.

Pharmacy managers are accountable for ensuring staff competency is documented. (See Section 2.7 and 3.4 of this Practice Directive)

2.2 Mandatory Resources

All pharmacy professionals involved in the provision of OAT must have ready access to, be familiar with and apply the most recent version of following resources:

1. This Practice Directive
2. Isaac P et al. Opioid agonist maintenance treatment: a pharmacist's guide to methadone and buprenorphine for opioid use disorder, CAMH Toronto. (2)
3. Canadian Research Initiative in Substance Misuse (CRISM) National Guideline for the Clinical Management of Opioid Use Disorder. (3)

In addition to the above resources, **pharmacy professionals that provide iOAT services** must have ready access to, be familiar with and apply the most recent version of the following resources:

1. College of British Columbia's Policy Guide: Injectable Hydromorphone Maintenance Treatment. (21)
2. British Columbia Centre on Substance Use (BCCSU) Guidance for Injectable Opioid Agonist Treatment for Opioid Use Disorder (22)
3. Canadian Research initiative in Substance Misuse (CRISM) 'National Injectable Opioid Agonist Treatment for Opioid Use Disorder: Operational Guidance (23)
4. Canadian Research initiative in Substance Misuse (CRISM) National Injectable Opioid Agonist Treatment for Opioid Use Disorder: Clinical Guideline (24)

Pharmacy professionals are responsible for maintaining currency of knowledge, skill and attitudes related to the treatment of OUD and the provision of OAT. The mandatory resources above should not preclude pharmacy professionals' application of emerging evidence in the field of OUD and OAT.

2.3 Equipment and Storage

The College does not mandate use of specific equipment in the provision of OAT however, equipment monitoring, calibration and maintenance must be included in the pharmacy's quality management program (QMP).

Measuring devices for preparation of methadone must be calibrated such that the error rate is no greater than 0.1mL therefore, the use of graduated cylinders is not acceptable for measuring of methadone. Typically, oral syringes or manual/electronic pumps that are regularly calibrated as per manufacturer specification meet this accuracy requirement.

Equipment used to prepare methadone may not be used to prepare or compound other medications. Separation of equipment minimizes risk of inadvertent methadone ingestion. This equipment must be identified as dedicated only to methadone preparation.

All medications used in provision of OAT must not be visible from outside the dispensary and must be stored securely until provided to the patient (25).

2.4 Physical Environment

2.4.1 Patient Access to Pharmacy

Patients requiring daily observed dosing must access a pharmacist every day. While the purpose of this practice directive is not to limit access to OAT for patients in communities that do not have pharmacy services seven days per week, pharmacy managers must balance patient need with pharmacy viability. Where seven day per week service is not possible, pharmacy managers must accommodate patients who are not assessed as appropriate for receiving take-home[7] doses. Options include:

- Allowing patients access during short window of time to allow for daily assessment and administration
- Coordinating "closed day" observed dosing with a secondary pharmacy. This situation requires intentional and well-documented communication between pharmacies to mitigate risk of dose error or omission. Both pharmacies are responsible for confirming the quantity and time of last dose ingested at their location. This information must be documented on administration logs. (See section 3.3.3 for "Guest Dosing"). Practitioners must adhere to the Controlled Drugs and Substances Act and Section 56 Exemptions (12) prescribing and transfer of prescriptions for controlled drugs

2.4.2 Emergency Planning

The inability to access daily dosing of OAT can result in significant hardship to patients with OUD. When weather events, environmental disasters, pandemic or security events in the community occur, there must be an emergency plan established to mitigate interruption of treatment. Pharmacy managers must:

- Consider patients requiring OAT within their overall emergency plan
- Establish a communication process to inform patients that arrangements are being made to ensure ongoing access to care due to an emergency event
- Standardised provision of orientation to patients regarding emergency plans to prepare them for potential future events

[7] Take-home doses are also commonly referred to as carry doses or carries.

2.5 Community Partnerships

Patients who receive OAT often present with mental health comorbidities and are socially and economically vulnerable. Pharmacy team members must develop community partnerships with agencies and/or professionals with a mandate to serve members of society with addiction and mental health challenges. Pharmacies must maintain a listing of locally available resources or professionals that patients with life challenges can be referred to.

2.6 Documentation

Pharmacy managers are responsible for the development or adaptation of forms to document clinical activities, steps completed in the dispensing process and for setting expectations of the patient-pharmacy professional relationship. Examples of documentation forms[8] exist in Opioid Agonist Maintenance Treatment: A pharmacist's guide to methadone and buprenorphine for opioid use disorder (CAMH: Pharmacist's Guide) clinical practice guidelines (2).

Dispensing documentation: Pharmacists and pharmacy technicians must document each step in dispensing of OAT. Given that medication used in OUD may require dilution, and that the agents are desirable for purposes of diversion, the documentation required is greater than that required for dispensing of typical (non-OAT) oral dosage forms.

Clinical documentation: Pharmacists must document patient assessment. Pharmacists or pharmacy technicians must document follow-up of patients for observed dosing (see sections 1.1 and 3.3.2.2) or take-home dispensing

College documentation: Provision of OAT does not require authorization from the College however, the College must be notified of provision of OAT service by the pharmacy manager via online declaration within the pharmacy's profile. This information may be made publicly available to assist patients in finding care.

2.7 Quality Management Program (QMP)

Pharmacies are required to have a QMP in place according to Regulation 13.5(g), 14.2 and 20.2(d)(10) and Model Standards of Practice for Pharmacists and Pharmacy Technicians in Canada (13).

QMP documentation relating to OAT is a required component of the pharmacy's overall QMP records. Pharmacy managers are responsible (in collaboration with staff) for establishing/adapting forms to meet the needs of their unique practice. Pharmacy managers are also charged with updating, monitoring and retaining these forms.

[8] The College, at time of writing, publishes an online resource for pharmacy professionals providing OAT services.

Section 3.4 of this directive describes the expectations for adhering to the QMP.

3. Providing OAT

3.1 Prescription Standards and Requirements

3.1.1 Prescribers (Who may prescribe OAT?)

Federal law and provincial policy establish prescribers of controlled substances, as defined in:

- Section 2(1) of the Controlled Drug and Substance Act (CDSA) (12),
- New Classes of Practitioners Regulations (28),
- Subsection 56(1) class exemption for patients, practitioners and pharmacists prescribing and providing controlled substances in Canada (12).

3.1.2 Prescription Requirements

All federal and provincial laws, regulations and policies for drugs listed on Schedule I of the CDSA apply to therapeutic agents used in OAT.

Methadone, SROM and iOAT: In addition, prescriptions must include start and stop[9] dates and indicate observed dosing[10].

Methadone: Prescriptions for methadone must include details regarding take-home dosing schedules.[11] *CAMH: Pharmacist's Guide* contains prescription examples that conform to legislation and best practice.

3.2 Preparation

Detailed guidance on preparation and storage may help to prevent medication incidents associated with OAT agents. Dilution of methadone is an additional processing of product that increases the risk of incident.

[9] No doses shall be dispensed after the stop date on the prescription, even if there are (missed) part-fills remaining when that date arrives

[10] SROM and iOAT are only provided via observed dosing. Methadone may be provided via observed or take-home dosing. Due to risk of medication error by other means, other methods are prohibited.

[11] The dispensing/ take home schedule for methadone will include: The dosage frequency; start and stop dates for the dispensing of take-home doses; and total quantity in mg, the number of part-fills, and the time interval between part-fills.

3.2.1 Computer Processing

Observed doses entered into computer software and the patient's electronic health record (EHR), but subsequently not administered to patients, must be reversed before the pharmacy closes for the day to ensure accuracy of the patient's EHR. This provides accurate data to other health care providers who may be caring for the patient.

The prescription's actual stop date (mandatory for methadone, SROM and iOAT) as expressed by the prescriber must be entered into the software. The software may require that the stop date be entered manually.

3.2.2 Labeling

3.2.2.1 Labeling of Observed Dosing

Observed doses are exempt from labeling requirements (as per Regulation 17.14) (10) **if** prepared and **immediately provided** to the patient, where no opportunity for dosing or patient identification error exists.

OAT prepared ahead of time for dispensing as observed doses must be labelled, and that label must contain, at a minimum:

- the name of the drug
- the dose
- lot number
- expiry date from the stock bottle/original packaging
- pharmacy team member who prepared the dose.

3.2.2.2 Labeling of Take-home Dosing

All labels on take-home doses[12] must:

- Comply with legal requirements outlined in New Brunswick legislation (as per Regulation 17.14) (10).
- Include number of remaining part-fills, and the prescriber's stop date.

Methadone**:** In addition to the above requirements, Methadone prescription labels **for take-home doses** must:

- Conform to practice guidelines *CAMH: Pharmacist's Guide* (2)
- Include beyond-use-date (BUD) as determined by existing stability data[13].

[12] Only buprenorphine/naloxone and methadone are permitted to be dispensed for take-home dosing

[13] Standard is 14 days in crystalline juice as per non-sterile compounding guidelines (27) for any oral liquids prepared in water. Product monograph contains further diluent options and BUD information.

- Specify on the first line of the signature (sig) line *"Drink the full contents of bottle (XX mg) once daily"*. This ensures the dispensing record created within the patient's EHR explicitly communicates the dose prescribed to any member of the patient care team.

3.2.3 Preparation of Final Dose

Buprenorphine/Naloxone: Preparation of observed and take-home dose packaging must maintain integrity of the dosage form.

Methadone:

- Must be single-use daily dose regardless of patient care setting. Unit dosing removes the requirement for measurement by another care professional (in institutional settings) or the patient.
- Calculations must be performed by a pharmacist or pharmacy technician.
- Commercially available 10 mg/ml oral stock solutions must be used (17).
- A consistent manufacturer for the stock methadone solution is encouraged as dispensing of the same brand may allow patients to identify change in taste, which may signal a potential dosage error.[14] Changes in manufacturer of stock solution must be communicated to patients.
- Stock solution must be diluted to total volume of approximately 100 ml with a vehicle such as Tang®, Allen's apple juice or another crystalline juice.[15,16]
- Diluent juice must be refrigerated and labeled with name, date and before use date of preparation.
- Must be dispensed in a light-resistant and child-resistant packaging.
- Must be dispensed in a tamper-evident bottle. This facilitates take home audits and identification of misuse.

SROM:

- Use SROM with 24-hour dose interval (not a product intended for 12-hour dosing) (28) (3)
- The capsule must be opened to release the enclosed pellets for immediate consumption (29).
- The pellets must be swallowed whole. Crushing, chewing, or dissolving slow-release oral morphine capsules or pellets can cause rapid release and absorption of a potentially fatal dose of morphine
- The pellets are to be sprinkled onto a small amount of applesauce or pudding. Alternatively, pellets may be transferred into a medicine cup and ingested, followed by water to ensure all pellets have been swallowed

[14] Taste change is one way to identify dosing errors. If flavouring changes frequently patients may not attribute importance to these changes.

[15] Hospitalized patients going to surgery for any reason, or who are "nothing by mouth" (NPO), may receive their daily dose in a final volume of 15 mL (or for doses over 150mg, the volume of the concentrated stock solution), and if necessary, mixed in water rather than a crystalline or apple juice. All other patients must receive their dose diluted in juice.

[16] Dilution in these vehicles masks taste, prevents diversion and injection of methadone.

3.3 Patient Assessment, Administration and Dispensing, and Patient Follow-Up Adherence Monitoring

3.3.1 Patient Assessment

Patient assessment prior to administering or dispensing OAT must be performed by a pharmacist. Patient assessment is detailed within educational courses (See Practice Directive Appendix B) and *CAMH: Pharmacist's Guide*. (2) Please consult these references for guidance on patient assessments in the context of OUD and OAT.

A thorough patient assessment involves multiple **sources of information** such as the pharmacy patient profile, OAT administration log, EHR and interacting with the patient themself.

3.3.2 Administration and Dispensing and Patient Follow-Up Monitoring

3.3.2.1 Observed Dosing: Administration and Dispensing

Provision of observed dosing of OAT is detailed within educational courses (See Practice Directive Appendix B) and *CAMH: Pharmacist's Guide* (2). Please consult these references for guidance on observed OAT dosing.

<u>Methadone:</u>

While many of the medications used for the treatment of OUD are considered 'high alert' by the Institute for Safe Medication Practice (ISMP) (28), methadone in particular has been involved in a relatively high proportion of medication incidents in Canada (30,31). Therefore, independent double-checks should occur at the point of providing the observed dose. This can be accomplished by a pharmacy professional and a second pharmacy professional, by a pharmacy professional and an unregulated pharmacy team member, another second pharmacy **or** by a pharmacy professional and the patient themself. The double-check should include:

- Patient identity
- Correct dose
- Correct time of day

A pharmacy professional or an unregulated pharmacy team member may hand the dose to the patient once:

1. the pharmacist has confirmed their assessment indicates administration is appropriate and
2. the patient identity, dose and timing are confirmed.

<u>iOAT:</u> A pharmacist or designated health care professional must hand the dose to the patient for self-administration.

3.3.2.2 Observed Dosing: Follow-Up Adherence Monitoring

Monitoring patient compliance post-administration of observed oral dosing must be performed by a pharmacy professional[17]. Monitoring patient compliance pertains to confirming complete ingestion (swallowing or dissolving) of the oral dosage form. The stringency of monitoring should correspond to the degree of risk to the patient if not administered correctly in conjunction with the risk of diversion of the given therapeutic agent.

Buprenorphine/naloxone: Clinical judgement applies with respect to monitoring the degree of dissolution of the dosage form. There is good data to show buprenorphine/naloxone is significantly safer in terms of morbidity and mortality as compared to other OAT therapies (16). The need to ensure a fully dissolved dosage form may not be required for all patients. Semi-dissolved dosage forms are more difficult, although not impossible, to divert.

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

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

iOAT: A pharmacist must perform the follow-up monitoring after a patient self-administers iOAT. This function may not be performed by a pharmacy technician or unregulated member of staff.

3.3.2.3 Take-Home Doses: Dispensing

Criteria for providing take-home doses of OAT is detailed within educational courses (See Practice Directive Appendix B) and *CAMH: Pharmacist's Guide* (2). Please consult these references for guidance on take-home OAT dosing.

If the prescriber has indicated take-home doses and the pharmacist, after patient assessment, believes there is a risk to the patient of overdose, misuse or diversion, the pharmacist may refuse to dispense take-home doses, and revert to observed dosing. This intervention must be documented, and the prescriber must be informed.

[17] Patients receiving pharmacy services in institutional settings may receive follow-up adherence monitoring by pharmacy professionals or other qualified healthcare providers (e.g., nurses, physicians). The institution's established policies and procedures for OAT administration must be aligned with this Practice Directive and clinical practice guidelines if pharmacy professionals are involved in this aspect of patient care.

Note: The COVID-19 pandemic necessitated review of absolute maximum take-home patients could be supplied Pharmacy professionals must consult clinical practice guidelines (14, 15) to ensure a balance between pandemic-related public health risk, diversion risk and patient risk of opioid withdrawal.

Buprenorphine/naloxone:

The maximum number of take-home doses is six. Some patients may be sufficiently stable to allow for up to 13 take-home doses. Please refer to *CAMH: Pharmacist's Guide* for assessment of take-home dosing regimens. Take-home doses of buprenorphine-naloxone are not required to be provided in a "lock box."

Methadone:

- The maximum number of take-home doses is six. For patients with short-term extenuating circumstances (see Section 3.3.3), that maximum may be 13. Please refer to *CAMH: Pharmacist's Guide* (2) for assessing take-home dosing regimens.
- Take-home doses must be provided in a "lock box". The "lock box" should be discreet so as not to draw attention to the patient. The lock box must be made of materials which will impede access to the methadone and decrease the risk of unintended ingestion by children and opioid-naïve individuals. Soft-sided containers, which can be cut with a blade or scissors, are not appropriate.
- Each patient must have their own identifiable (etching of initials inside the box, or application of a pharmacy label with the patients' name securely affixed inside the lock box, for example) "lock-box"
- Patients must be informed that they may be asked at any time to appear in the pharmacy and bring with them the remainder of their take-home doses and empty bottles, in their own lock box. This procedure, referred to as a "carry audit", may be used to assess for diversion or misuse.

SROM**:** To limit potential for diversion, slow-release oral morphine is only to be provided via daily observed ingestion (29).

iOAT: To limit potential for diversion and encourage safe injection technique, iOAT is only to be provided via daily observed self-administration in accordance with policy and practice guidelines (21,23,24)

3.3.2.4 Take-Home Doses: Follow-Up Adherence Monitoring

Methadone: Methadone packaging may be used for illicit purposes. To prevent diversion of methadone packaging in community pharmacy, take-home bottles must be returned to the pharmacy prior to new take-home doses being issued. A pharmacy team member must reconcile the empty bottles returned with the

number that were issued and this reconciliation must be documented. In institutional settings, any packaging of methadone should be discarded according to institutional policy.[18]

3.3.3 Extenuating Patient Circumstances

Some patients may occasionally experience extenuating circumstances such as short-term illness or life events (e.g. public health emergencies, travel, bereavement or temporary employment demands) that present a barrier to attending a pharmacy for patient care and supply of OAT. Pharmacy professionals faced with challenging decisions regarding how to balance patient benefit with public safety should apply the Values Based Decision Model (VBDM) as described within the College's Code of Ethics. Decision rationale must be documented within the patient profile to facilitate intraprofessional care.

Potential solutions to extenuating circumstances include:

Delivery:

If a patient is unable to attend the pharmacy due to extenuating circumstances (such as short-term illness or public health emergency (14,15) as per Health *Canada's Subsection 56(1) class exemption for patients, practitioners and pharmacists prescribing and providing controlled substances in Canada* (32). OAT may be delivered. The pharmacist must ensure the patient is assessed prior to the dose administration (as per Section 3.3.1) and follow-up monitoring subsequently occurs (as per Section 3.3.2)

Take-Home Doses:

Pharmacists, in collaboration with the patient's prescriber may assess the patient for suitability for take-home doses. If the patient is not considered sufficiently stable to possess take-home doses or the maximum number of 13 doses is not sufficient (in the case of travel or employment demands) other solutions must be sought.

Guest Dosing:

There may be occasions when a patient receiving OAT via either observed dosing or take-home dosing may receive treatment on a temporary basis at another pharmacy.

In addition, if the patient's home pharmacy is not open seven days per week and on holidays, guest dosing arrangements may be employed for observed dosing until the patient is eligible for take home doses. However, consideration for permanently transitioning care to the pharmacy with longer operating hours may be

[18] The institution's established policies and procedures for disposal of narcotic and controlled substances must be aligned with this practice Directive and clinical practice guidelines if pharmacy professionals are involved in this aspect of patient care.

preferred. (See Practice Directive Section 4: Transitions of Care for detail on transferring care between pharmacy settings.)

Arrangements for guest dosing at another pharmacy is primarily the responsibility of the patient. This ensures a patient-led circle of care expansion, prevents actual or perceived privacy breaches, and allows the patient to maintain choice of pharmacy.

https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1041/FullText.htmlhttps://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1041/FullText.htmlhttps://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1041/FullText.htmlhttps://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1041/FullText.html

3.3.4 Documentation of OAT Provision

3.3.4.1 Dispensing Documentation

Pharmacists or pharmacy technicians must record and retain documentation of the steps in preparation and provision of OAT as per standards of practice (13) and regulations (10). Pharmacy professionals (community pharmacy only)[19] must document the return of take-home methadone bottles.

3.3.4.2 Clinical Documentation

Pharmacists must record and retain documentation of their patient assessment, clinical decision-making (including documentation of care decisions made in response to exceptional circumstances as per Section 3.3.3) and follow-up monitoring as per established standards of practice and regulation (10,13).

3.3.4.3 Inter/Intraprofessional Documentation via Prescription Monitoring Program (PMP)

Inter/Intraprofessional documentation of the provision of OAT is vital to the safe and effective care of patients as they transition between care environments and providers. (Practice Directive Section 4 provides further detail on transitions of care)

In New Brunswick, interprofessional documentation of OAT provision is achieved using the government of New Brunswick's Prescription Monitoring Program (PMP) within the patient's EHR. The dose and the date of last observed dose must be documented in the PMP such that any healthcare professional involved in the patient's care can use the PMP to conduct an accurate patient assessment. If a dose is not administered as expected, before end of the day, the pharmacy must ensure the dispensing record is amended to ensure accuracy.

Pharmacy professionals are obliged to collaborate inter/intraprofessionally to confirm details (date, time, dose) of a patient's OAT regimen. If electronic PMP documentation does not provide sufficient information regarding

[19] See section 3.3.2.4 for requirements relating to return/disposal of take-home bottles in institutions

the last patient dose, pharmacy professionals must use alternate means of communication (telephone, secure electronic messaging or in-person discussion) to ensure safe patient care.

Methadone:

- At time of writing, multiple take home doses cannot be captured in one PMP transaction. Therefore, these must be processed daily to reflect an accurate account of intended ingestion.[20]
- Doses that are not administered or picked up must be reversed in the PMP before the pharmacy closes each day. This allows for another health care professional to have an accurate account of the patient's recent administration history. (See Practice Directive Section 3.2.1 for Computer Processing requirements)
- Methadone dose must be specified in milligrams on the first line of the directions (sig field). This will provide consistency in determining patient dose. (See also Practice Directive Section 3.2.2 for Labeling requirements)

3.3.6 Transfer of Custody

Pharmacy professionals may collaborate with other health care professionals to provide patient-specific prepared and labeled doses of OAT to an externally located patient care site. This is considered a transfer of custody.

The following professionals[21] can be involved in administering OAT to patients and may possess patient doses of OAT:

- Another pharmacist (11) as per NCR Section 31
- Hospital employee authorized to receive substances listed within Schedule 1 of the CDSA (11) as per NCR Section 3
- Medical practitioner (physician) (12) as per CDSA Definitions
- Nurses practicing as per Health Canada's Subsection 56(1) *Class Exemption for Nurses Providing Health Care at a Community Health Facility* (32).
- Nurse practitioners as per (Section 2 of the New Classes of Practitioners Regulations to Controlled Drugs and Substances Act) (26).

Upon transfer of OAT doses to another health care provider, the responsibility for safe and effective provision of these doses shifts from the pharmacist to the receiving health care provider. Healthcare professionals must adhere to their respective regulatory requirements in the interests of patient and community safety. Pharmacy professionals are obligated to monitor for safe provision of OAT agents and intervene using education,

[20] The number of take-home doses in a patient's possession will be unclear in the PMP because each take-home dose is recorded as dispensed on a daily basis rather than the total dispensed to the patient as take-homes.

[21] Pharmacy professionals should consult federal legislation (NCR, CDSA and Section 56 Exemptions) for updated information regarding who may possess Schedule I drugs.

discussion, problem-solving in situations where safety may be compromised. Pharmacy professionals must facilitate patient and community safety as best possible by supporting these providers to:

- Confirm receipt of doses through a signature of the health care professional
- Accomplish dose adjustments through provision of a new pharmacy- prepared dose
- Avoid alteration of patient-labeled doses
- Avoid altering dose volumes for administration
- Prohibit use of a dose intended for one patient by another
- Return unused patient doses within 72 hours

If an **intermediary agent** is used to deliver OAT doses, pharmacy professionals must comply with Health Canada's Subsection 56(1) class exemption for patients, practitioners and pharmacists prescribing and providing controlled substances in Canada (32). The pharmacist is responsible for:

- Employing a method of shipment that ensures the location and person with custody of the drug at any point in time can be established
- Transporting directly (no stops) to and from the patient care location
- Secure packaging of prepared doses in tamper-proof, hard-sided, locked box
- Use of locks that only the pharmacy and receiving health professional have the means to open
- Retention of a list of all doses provided to the treatment location
- Sending the list of patient doses along with the doses to the health care professional receiving the shipment to confirm receipt through a signature

3.4 OAT Quality Management Program (QMP)

Please refer to College's, "Expectations for a Quality Management Program" (33). The following section expands upon the general principles expressed within that guidance document.

3.4.1 Education and Training Documentation

Pharmacy professionals must document within the pharmacy's QMP that they have established and maintained competency (see Practice Directive Section 2.1 and 2.2) for providing OAT for patients with OUD.

3.4.2 Medication Incidents (Errors and Near-Misses) and Continuous Quality Improvement (CQI)

All medication incidents must be addressed according to the College's "Practice Directive: Mandatory Medication Incident Reporting (MMIR)" (34), the NAPRA Model Standards of Practice for Pharmacists and Pharmacy Technicians in Canada (13). Please refer to *CAMH: Pharmacist's Guide* for specific management of OAT medication incidents (2).

Medication incidents arising within a practice or illustrated through safety-focused publications are signals for pharmacy professionals to engage in continuous quality improvement so that future similar incidents are avoided.

3.4.3 Equipment

Provisions for the ongoing monitoring of equipment used in providing OAT are outlined in the College's Expectations for a Quality Management Program (33).

3.4.4 Facilities

Provisions for the ongoing monitoring of the physical facilities where OAT is provided are outlined in the College's Expectations for a Quality Management Program (33);

4. Transitions of Care

Patients experience heightened risk of medication incidents at points where care transitions (35). The complexities of OAT (i.e. frequent assessment and dosing, pharmacokinetics and pharmacodynamics, dosage forms and preparation of methadone final dosage form) coupled with patient factors (i.e. multiple medical and psychiatric co-morbidities, social instability, vulnerability and/or communication barriers) compounds patient risk at transitions of care. Please refer to *CAMH: Pharmacist's Guide* (2) for direction on safe and effective transitions of care between community and institutional pharmacy services.

Glossary

Administration: In the context of this Practice Directive, refers to the process when providing observed dosing in the provision of OAT. This process includes patient identification and assessment, observed dosing, documentation and follow-up. (See also "dispensing".)

Crystalline Juice: A sweet liquid that is reconstituted by adding water to sugar or sweetener crystals and flavouring.

Cultural Safety: Constant self-evaluation by a provider to ensure they are focusing on the individual and are not being influenced by assumptions about that individual's cultural background or social or economic status. Cultural safety also helps alter the colonial relationship and makes safe space for Indigenous peoples within the system and thereby allows them to help reshape the system itself (36).

Dispensing: The interpretation and clarification of a prescriber's order and the assembly and preparation of the order for delivery to the client (9). (See also "administration")

Drug Information System (DIS): The DIS is an information system that collects patient and dispensed prescription information from all NB community pharmacies and then stores it in a secure central location under the appropriate patient in the EHR. All community pharmacies are connected and submitting dispensed prescription

information to the DIS. This information can be viewed by authorized health care professionals within the EHR (37).

Electronic Health Record (EHR): The EHR is a component of the Government of New Brunswick's DIS. It displays a patient's medication history in real-time of all prescriptions filled in New Brunswick community pharmacies. It is supported by the DIS (38).

Harm Reduction: Harm reduction refers to policies, programs and practices that aim to reduce drug-related harm without requiring the person to stop using the substance. Harm reduction strategies aim to reduce drug-related harms not just for the user, but also for families, friends and communities. The approach is based on the belief that it is in both the user's and society's best interest to minimize the adverse consequences of drug use when the person is unable or unwilling to discontinue using (39).

Institutional Settings: Include hospitals, long-term and special care homes and incarceration facilities. Patients who have been admitted to a hospital as in inpatient are considered hospitalized. Some patients who are waiting for extended periods of time in the Emergency Room, while not admitted, may be considered "hospitalized", in order to facilitate transition of care from community pharmacy to hospital.

Medication Incident: Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. 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 (40).

Near Miss: An event that could have resulted in unwanted consequences but did not because either by chance or through timely intervention the event did not reach the patient (40).

OAT (Opioid agonist treatment): "OAT involves the prescribing of an opioid agent as part of a comprehensive program that includes counselling designed to help the person in treatment reduce or stop the harmful use of opioids (2). This definition may evolve to include other treatment modalities.

Observed dosing: also called "witnessed ingestion"; a process performed by the pharmacist which includes patient identification, patient assessment, administration of OAT medication, and follow-up.

Opioid Use Disorder: Opioid Use Disorder (OUD) is a substance use disorder, specifically, a problematic pattern of opioid use leading to clinically significant impairment or distress, occurring within a 12-month period. It is a complex chronic condition characterized by the cycles of substance use, reduced use/abstinence and relapse (41).

Pharmacy Team Member: Any employee working within the dispensary area in a pharmacy. This can include regulated employees (pharmacists, pharmacy technicians, pharmacist students, pharmacy technician students, interns) or non-regulated employees (assistants and cashiers).

Practice Directive: A mandatory rule that must be followed by members. Unlike the Model Standards of Practice, however, a Practice Directive is issue specific. A Practice Directive may tend to be focused more on process than outcome. Prescriber: In the context of this document, prescriber refers to physicians, nurse practitioners and pharmacists who are permitted to prescribe OAT agents in the province of New Brunswick. See Practice Directive Section 3.1.1.

Prescription: a direction given by a prescriber directing that a drug, device, or treatment specified in the direction be dispensed for the person named, or animal described, in the direction (6).

Prescription Monitoring Program (PMP): The PMP is a component of the Government of New Brunswick's DIS. Dispensing records of monitored drugs are available through this system.

Provision: Supply of OAT either by observed dosing or dispensed for take-home dosing.

Quality Management Program (QMP): A Quality Management Program supports the safe practice of pharmacy. It facilitates adherence to professional standards and requirements of pharmacy legislation in New Brunswick.

Transfer of Custody: Refers to processes and documentation required for administration and dispensing of prepared doses of OAT by another health care professional at a treatment location at a distance from the pharmacy preparing the medication.

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Appendix A: CAMH Opioid Agonist Maintenance Treatment Cross-Reference

This Practice Directive sets minimum standards of the pharmacy team with respect to opioid agonist maintenance treatment. Additional details regarding aspects of OAT referenced in this Directive, including pharmacology and therapeutics, criteria for take-home doses and dosing information are found in the resources listed below.

Information	CAMH Opioid Agonist Maintenance Treatment, 3rd ed. [1]	Other
Breastfeeding	Section 7	
Dosing (Methadone)	Section 7	Reference 3; Appendix 1
Dosing (SROM)		Reference 3; Appendix 3
Dosing (buprenorphine/naloxone)	Section 7	Reference 3; Appendix 2
Ending Treatment	Appendix 10	
Hospitalization	Section 9	
Incarceration	Section 9	
Induction (buprenorphine/naloxone)	Section 7 and Appendix 14 (COWS)	Reference 3; Appendix 2 and Appendix 6 & 7
Injectable OAT (hydromorphone)		Reference 2 & Reference 4
Interactions	Section 2 and Appendix 2	
Lost or stolen doses	Section 6 (p. 58 optional)	
Missed doses	Section 7	
Overdose	Section 2	Reference 3; p23, p32, Appendix 1 and Appendix 2
Pain (treatment of)	Section 8	
Pharmacology/Pharmacokinetics	Section 2	

Pregnancy	Section 7	
Special Populations (Geriatric, adolescent)	Section 7	
Take-home Criteria		Reference 3; Appendix 4
Tapering doses	Section 7 and Table 7.1 and Table 7.4	
Toxicity	Section 2	
Vomited dose	Table 7.1 and 7.4	
Withdrawal	Appendix 3	

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3. https://www.bccsu.ca/wp-content/uploads/2023/11/BC-OUD-Treatment-Guideline_2023-Update.pdf
4. https://www.bccsu.ca/wp-content/uploads/2021/07/BC_iOAT_Guideline.pdf

Appendix B: Listing of Educational Courses

- Opioid Use Disorder Treatment (OUDT) Course: This online course is provided by the Center for Addictions and Mental Health (CAMH)
- Traitement du trouble lié à l'utilisation d'opioïdes: une approche de collaboration interdisciplinaire: This French language course is offered by National Public Health Institute of Quebec (INSPQ)
- Provincial Opioid Addiction Treatment Support Program (: BC's Online addictions medicine diploma is provided by the University of British Columbia (UBC) Faculty of Medicine's continuing professional development division.
- Opioid Dependence Treatment Course: PharmAchieve offers an online course