STANDARDS OF PRACTICE: Opioid Agonist Maintenance Treatment Services

June 2017 / Updated January 2022
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ACKNOWLEDGEMENTS

The Nova Scotia College of Pharmacists (NSCP) gratefully acknowledges the consent of the following organizations to allow inclusion of portions of their documents in these Standards:

- The Centre for Addiction and Mental Health (CAMH) publication, *Opioid Agonist Maintenance Treatment - A pharmacist’s guide to methadone and buprenorphine for opioid use disorder*, Third Edition

The NSCP appreciates the assistance and guidance of the many individuals who participated in creating these revised standards, and in particular the Nova Scotia College of Pharmacists’ (NSCP) advisory groups:

- The Drugs of Abuse Issues Advisory Group.
- The Standards of Practice Advisory Committee.

External Review and Contributors

The NSCP recognizes that opioid use disorder is a challenging issue for patients, communities and health care providers. Opioid agonist maintenance treatment (OAMT) is an essential service and pharmacists have a critical role to play as members of the patient’s care team. The NSCP appreciates the contributions of the following stakeholder organizations to these Standards:

- College of Pharmacy, Dalhousie University
- College of Physicians and Surgeons of Nova Scotia
- College of Registered Nurses of Nova Scotia
- Pharmacy Association of Nova Scotia
- Provincial pharmacy regulatory authorities
1 BACKGROUND

Opioid use disorder is a chronic and relapsing illness, which can cause severe decline in the individual’s physical and psychological health, unemployment and family disruption. Desperation of those in its grip can sometimes lead to participation in illegal activities. Treatment for opioid use disorder requires efforts and collaboration of a multidisciplinary team and multidimensional treatment options, including opioid agonist therapy with methadone or buprenorphine/naloxone. It is a critical service and, as described by the following patients, provides individuals with an opportunity to manage their condition, improve their quality of life and benefit society.

“Methadone has given me time to find myself. It pulled me off the streets and has given me a chance to be a better father, friend, brother and husband. Now I am close to the finish line with my treatment and have everything I’ve ever wanted . . . my life.”

“Without the help that I’ve received through the methadone program, many different doctors, counsellors and a great pharmacy team, I’m not sure where I’d be today. My life now is very different from what it could have been. I live now with purpose.”

Pharmacy professionals play a critical role in the healthcare team providing opioid agonist maintenance treatment (OAMT). The decision by a pharmacy to provide OAMT services requires thoughtful consideration of professional ethics (see Ethical Considerations, s.4) and also of the capacity of the pharmacy to undertake the associated activities safely and effectively.

When the NSCP established the Methadone Maintenance Treatment Services: Standards of Practice for Community Pharmacies in Nova Scotia, methadone was the primary medication therapy for treatment of opioid use disorder. In this 2017 edition, the NSCP has retitled and broadened the scope of the Standards to incorporate practice expectations when providing both methadone and buprenorphine/naloxone as opiate agonist maintenance treatment. In addition, the format of the Standards has been updated and streamlined. Clinical details and other resources, previously included in the body of the Standards, are provided in the appendices as reference and supporting information.
2  PURPOSE

The primary goal of this Standards of Practice: Opioid Agonist Maintenance Treatment document is to support the safe and effective provision of opiate agonist maintenance services by pharmacists and pharmacy technicians in Nova Scotia to opioid dependent individuals, contributing to improved patient and societal outcomes.

These standards establish the expected practice of pharmacists and pharmacy technicians when providing methadone or buprenorphine/naloxone in the treatment of substance use disorder (formerly methadone maintenance treatment (MMT) services). Note that the Controlled Drugs and Substances Act (CDSA) and its regulations do not authorize pharmacy technicians with respect to certain activities in the provision of this treatment. As such, these Standards explicitly state the activities a pharmacy technician is permitted to undertake.

While methadone and buprenorphine/naloxone are also used in the treatment of chronic pain, these standards do not address the provision of these medications to patients for these indications when there is no concern of previous or current substance use disorder.

Note that certain clinical details, including for example, information regarding OAMT in special populations, and other resources previously included in the body of the Standards, are provided in the appendices as reference and supporting information.
3 TERMINOLOGY

Descriptions of the terms used in the *Standards of Practice: Opiate Agonist Maintenance Treatment* are provided in the following table.

| **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. Here are some examples:

- Methadone maintenance treatment programs are based on research evidence indicating that when the goals of treatment retention and abstinence appear to be in conflict, it is usually more beneficial to give priority to treatment retention and withdrawal management.

- Psychoeducational approaches focus on providing practical information to help people manage the risks associated with substance use. Topics include safer injection procedures and alternative routes of administration; needle distribution; and infections caused by HIV, hepatitis B and C, tuberculosis and sexually transmitted diseases.”

  *From CAMH Portico Network*

| **Trauma** | Events that involve actual or threatened death or injury or threats to physical integrity and the experiences of helplessness, fear and horror these events elicit from trauma survivors.

  *Criteria A1 and A2 respectively in the definition of PTSD. American Psychiatric Association, 1994*

| **Trauma Informed Care** | Trauma-informed services do not need to be focused on treating symptoms or syndromes related to trauma. Rather, regardless of their primary mission... commitment is to provide services in a manner that is welcoming and appropriate to the special needs of those affected by trauma.

  *A Trauma Informed Approach to Screening and Assessment. Harris & Fallot, 2001*
4 ETHICAL CONSIDERATIONS

While society has gained increased understanding of the wide-ranging contributors to the development of substance use disorders, including trauma and toxic stress, many continue to view substance use disorder as a ‘bad choice’ or a moral failing. Accordingly, persons with substance use disorders often find themselves stigmatized or blamed for their condition by wider society and this stigmatization can make the afflicted person’s recovery even more difficult. Unfortunately, health care providers can themselves perpetuate some of this stigma. Pharmacists are encouraged to reflect on their own biases and understandings, consider how these might affect their approach and either impede or support a patient’s recovery.\(^1\)\(^2\)

As a pharmacist considers working with OAMT patients to support this critical service, the NSCP Code of Ethics serves as a key resource. In particular, the following values taken from the Code are highlighted for pharmacists to review and guide their decisions and behaviours related to providing care to OAMT patients:

**VALUE II - Professional Relationship with the Patient**

- Registrants will not discriminate inappropriately against any person in providing pharmacy services.
- Registrants treat all those they serve with courtesy and respect.
- Registrants advocate for and protect the well-being of each patient, especially those who are vulnerable or disenfranchised.

**VALUE IV - Privacy and Confidentiality**

- Registrants avoid public discussion or comments about patients that could reasonably be seen as revealing confidential or identifying information

**VALUE V - Responsibility to the Patient**

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

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\(^1\) 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

5 STANDARDS OF PRACTICE

The following Standards of Practice represent the expectations and requirements of pharmacy practice for Opiate Agonist Maintenance Treatment services. These are to be considered as clarifying and adding to, but not replacing, the expectations set out in the NSCP Standards of Practice: General Pharmacy Practice and NSCP policies.

Professional Competence and Accountability

1. Education and Knowledge:
   A pharmacist will have the requisite competency to provide OAMT. This includes having knowledge of the following:
   - opioid use disorders;
   - opioid withdrawal and its management;
   - harm reduction treatment strategies;
   - methadone and buprenorphine/naloxone therapy, including pharmacology, therapeutics, dosing and overdose management;
   - culturally competent care related to socioeconomic status, ethnicity, race, language (refer to Section 3 Terminology);
   - approaches for patient communication and support (refer to Appendix A – Substance Use Screening and Brief Intervention Tool);
   - interprofessional collaboration in OAMT;
   - community support and referral resources for opioid use disorder and treatment; and
   - legislation, standards and policies related to pharmacists providing OAMT.

   To help meet the competency requirements, pharmacists should complete education on opioid use disorder and treatment (refer to Appendix B - References for OAMT information and resources as well as details on accredited education and training programs).

2. Continuous Learning:
   A pharmacist is expected to remain current with the guidance provided by the College of Physicians and Surgeons of Nova Scotia (CPSNS), the College of Registered Nurses of Nova Scotia (CRNNS), and the Centre for Addiction and Mental Health (CAMH) regarding the provision of OAMT to patients.

3. Accessibility and Registration:
   A pharmacy providing OAMT services:
   - will be responsive to the needs of their OAMT patients who typically require service 7 days per week and on holidays;
   - will support continuity of care and, if required, make special arrangements to ensure their OAMT patients have timely access to needed services when required, in accordance with practice direction regarding continuity of care set out in Appendix I – Special Circumstances;
   - will stock a naloxone kit for opiate overdose emergencies (for details, refer to the NSCP Naloxone for Opiate Overdose Reversal Position Statement; and
• will, in advance of providing OAMT services, register with the NSCP (refer to Appendix C - Pharmacy OAMT Registration Form and Appendix D – OAMT Legal Requirements).

4. Communication:
   A pharmacist will communicate with the patient’s care team including details regarding:
   • whether the pharmacy provides OAMT services and is accepting new OAMT patients;
   • the hours the pharmacy supports OAMT services;
   • the process for the pharmacist to routinely communicate with the OAMT prescriber or other members of the team, as appropriate, regarding a patient’s treatment (e.g., vomited or missed doses, pregnancy, aberrant behaviour etc.); and
   • the pharmacist’s participation in a three-party treatment agreement.

5.Interprofessional Collaboration:
   A pharmacist will collaborate with the care team regarding treatment strategies such as:
   • three-party treatment agreements (pharmacist-patient-prescriber);
   • urine drug screening;
   • care arrangements when patients travel out of the area;
   • take-home dose inspection;
   • return of empty take-home dose bottles; and
   • plans for providing medication if there are days the pharmacy will be closed.

OAMT Procedure

6. Preparation:
   • Pharmacy staff will use a commercially available stock solution unless, in exceptional circumstances, it is not available from the supplier or is otherwise unavailable, or it is inappropriate for the patient (e.g. allergy to ingredients). In those instances, pharmacists and pharmacy technicians may prepare a 10mg/mL stock solution from methadone powder.
   • Pharmacy compounded stock solution and individual patient doses will be prepared in compliance with the criteria and procedures set out in Appendix E.
   • Pharmacies using methadone compounding devices to prepare individual patient doses will do so in compliance with Appendix F.

7. Patient Assessment:
   Prior to providing methadone or buprenorphine/naloxone to a patient, a pharmacist will assess the patient in accordance with the procedural requirements set out in Appendix G – Patient Assessment to ensure it is safe for the patient to ingest the prescribed dose.

8. Dispensing and Administration:
   A pharmacist will dispense and administer methadone or buprenorphine/naloxone to a patient in accordance with the procedural requirements set out in Appendix H – Dispensing and Administration of Doses to ensure safe and effective treatment, which includes:
   • ensuring the prescription and prescriber meet legislative requirements for the provision of methadone or buprenorphine/naloxone (refer to Appendix D – OAMT Legal Requirements for specific details).
• determining the patient’s indication for methadone treatment, and if indicated for pain, establish whether the patient has current or past substance use.
• dispensing methadone or buprenorphine/naloxone to the patient as a daily, witnessed ingestion unless the prescriber has specifically prescribed take-home doses.
• providing a patient with the dose(s) of methadone or buprenorphine/naloxone directly and if delivery is required, delivering the medication personally. A patient’s dose(s) will NOT be released to others, including spouses, friends or relatives.
• providing a clean, professional, comfortable environment for the patient to have their dose ingestion witnessed, offering the patient the option to use a separate and private room.
• providing clear and sufficient information to a patient with the initial OAMT supply allowing him/her to make an informed decision about starting treatment.
• undertaking additional procedures required for specific patient conditions (e.g. intoxication) or situations (e.g. home delivery, guest dosing) as detailed in Appendix I – Special Circumstances.

9. Monitoring and Follow-up:
A pharmacist will contact the prescriber regarding treatment concerns such as when a patient:
• has not picked up their daily dose or otherwise misses a dose;
• refuses all or a portion of their daily dose;
• exhibits evidence of diverting methadone or buprenorphine/naloxone;
• appears to be impaired, intoxicated, showing signs of withdrawal (refer to CAMH Opioid Agonist Maintenance Treatment for information on opioid withdrawal symptoms) or any other unusual behaviour;
• vomits a dose, and/or
• has concurrent drug therapy or medical conditions that interact with methadone or buprenorphine/naloxone (e.g., prolonged QT interval).
A pharmacist does not release or administer methadone or buprenorphine/naloxone to a patient until they are satisfied that any concern has been appropriately addressed.

10. OAMT Services Under Exceptional Circumstances
Please see Appendix M for provisions for providing OAMT services under exceptional circumstances.

The provision of OAMT presents unique challenges than those associated with dispensing other medications. Solutions to these challenges are a shared responsibility between the patient, their primary prescriber, and pharmacists and need to be made in consideration of the fine balance of the unique exceptional circumstance and the public/patient risk of diversion and overdose. To support pharmacists in their efforts to continue to provide this critical service and to enable pharmacists to use their knowledge and skills to solve these challenges, the following provisions related to the Standards of Practice: Opioid Agonist Maintenance Treatment have been made.
APPENDIX A – SUBSTANCE USE SCREENING AND BRIEF INTERVENTION TOOL

Pharmacists working with patients receiving Opiate Agonist Maintenance Treatment can effectively use frequent screening and brief interventions to identify current or potential issues that may impact their safety or treatment success, and to motivate patients to change their behaviours, which is particularly important for patients with opioid use disorder.

Effective therapeutic relationships are best established when the same clinicians are consistently available to the patient.

The following are examples of positive brief interventions that address different barriers to change in patients’ lives:

1. **Building a therapeutic relationship**
   - Demonstrate sustained interest and concern for patients’ progress.
   - Schedule regular visits and ensure that two-way communication exists.

2. **Education**
   - Provide factual drug information and information on post-acute withdrawal syndrome.
   - Educate patients regarding the symptoms of impending relapse, such as exhaustion, complacency, impatience, dishonesty, self-pity, frustration, and depression.
   - Discuss behaviours such as denying, minimizing, rationalizing, intellectualizing and compartmentalizing.

3. **Goal planning**
   - Consider all areas of patients’ lives, not just substance use issues.
   - Prepare and document plans on how to avoid drug using situations.
   - Identify and help remove impediments to change.
   - Remind patients that it is better to reach a modest goal than to aim for, but fail to reach, a more ambitious target.
   - Coach patients to take small steps on the road to recovery.

4. **Promoting self-awareness and positive behaviours**
   - Identify internal and external triggers for substance use.
   - Avoid dwelling on failures. Help patients take pride in and build on their successes.
   - Encourage harm-reduction behaviour.
   - Encourage the development of self-esteem, which is the primary ingredient necessary for any successful therapy.

— Modified with permission from the CPSBC MMP: Clinical Practice Guidelines
APPENDIX B – REFERENCES

A pharmacist or pharmacy technician provides methadone or buprenorphine/naloxone in accordance with the Standards of Practice: Opiate Agonist Maintenance Treatment Services, as well as existing legislation, regulations, the Code of Ethics, other standards of practice and policy directives relevant to pharmacy practice. Refer to www.nspharmacists.ca and the following references as appropriate.

General References

- Methadone Maintenance Treatment Handbook, College of Physicians and Surgeons of Nova Scotia, 2017
- Opioid Agonist Maintenance Treatment: A Pharmacist’s Guide to Methadone and Buprenorphine for Opioid Use Disorders, Centre for Addictions and Mental Health, 2015
- Buprenorphine/Naloxone for Opioid Dependence – Clinical Practice Guideline, Centre for Addictions and Mental Health, 2012
- Addiction Treatment Forum www.atforum.com
- Mental Health and Addiction 101 Series, Centre for Addiction and Mental Health (Relevant topics include: Concurrent Disorders, Diversity and Health Equity, Introduction to Addiction, Stages of Change and Stigma).
- Office of the Controlled Substances, Health Canada exemption@hc-sc.gc.ca Methadone Line: (613) 946-5139** or toll free at 1 (866) 358-0453** **accurate at date of printing.

Accredited Substance Use Disorder Education Programs

The following are recommended education programs that will assist the pharmacist to satisfy the competency requirement as outlined in Standard 1:

NSCP: Optimizing Opioid Agonist Maintenance Treatment

Opioid Dependence Treatment Course, Centre for Addictions and Mental Health (CAMH)

Buprenorphine-Assisted Treatment of Opioid Dependence: An Online Course for Front-Line Clinicians Centre for Addictions and Mental Health (CAMH)
APPENDIX B-1 – DESIGNATED RESOURCES

These Standards set the expectations of the pharmacy team with respect to opioid agonist maintenance treatment. Additional details regarding aspects of OAMT referenced in these Standards including pharmacology, criteria for take-home doses and dosing information are found in the key resources listed below.

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1 Methadone Maintenance Treatment Handbook, CPSNS, 2017


3 Combined List of Drugs That Prolong QT and/or Cause Torsades de Pointes (TDP), Crediblemeds.Org [accessed: 2016 June 18]

4 Canadian Guideline for Opioids for Chronic Pain, Canada: Michael G. DeGroote National Pain Centre, McMaster University [accessed: 2016 June 18]
APPENDIX C – PHARMACY OAMT REGISTRATION FORM

Pharmacies providing Opioid Agonist Maintenance Treatment services will notify the NSCP by completing and submitting this form. Information from this registry will be released to other health care providers to facilitate identifying pharmacies that could serve a patient, as required, in certain situations (i.e., OAMT patients moving into province, etc.).

Date of Notification: mm/dd/yyyy
Pharmacy Trade Name:

| Address: |
| Phone: |
| Email: |
| Fax: |
| Pharmacy Manager: |

Please respond to the following questions:

1. a) Is your pharmacy currently providing methadone dispensing? YES ☐ NO ☐
   b) Is your pharmacy accepting new methadone patients? YES ☐ NO ☐
   c) Is your pharmacy currently providing buprenorphine/naloxone dispensing? YES ☐ NO ☐
   d) Is your pharmacy accepting new buprenorphine/naloxone patients? YES ☐ NO ☐

2. a) Is your pharmacy open 7 days a week, 365 days per year? YES ☐ NO ☐
   b) If “no”, please indicate which days the pharmacy is closed: _________________________________

Note: Pharmacies not open 7 days a week must adjust their practices for patients who require daily witnessed ingestion on days when the pharmacy is not open. For further direction, refer to Standards 3, 5 and Appendix I.

Pharmacy managers are responsible to ensure that the provision of OAMT services by the pharmacy complies with the NSCP Standards of Practice including:

- staff pharmacists have taken the necessary steps to satisfy the competency requirements for the provision of OAMT services as identified in the Standards of Practice.
- the pharmacy undertakes the expected activities associated with providing OAMT services, as identified in the Standards of Practice.

The pharmacy library includes the required references Opioid Agonist Maintenance Treatment: A Pharmacist's guide to methadone and buprenorphine for opioid use disorder (CAMH) and this document.

I hereby certify that the statements set out in this document are true and correct.

Dated at __________________________ this _______ day of _____________________. 20 _______

Pharmacy Manager Signature __________________________________________________________________________

Pharmacy Manager Name (please print) ___________________________________________________________________
APPENDIX D – OAMT LEGAL REQUIREMENTS

Pharmacists will comply with federal and provincial legal requirements specific to providing OAMT services. The following information is provided to support the pharmacist in navigating some of the most pertinent requirements.

Physician or Nurse Practitioner Authorization

As of May 19, 2018, Health Canada no longer requires prescribers to have an exemption from the Controlled Drugs and Substances Act to prescribe methadone. (Section 56 Exemption)

Pharmacy Registration

There is no special authorization required for pharmacists to order or dispense methadone or buprenorphine/naloxone. However, pharmacies providing OAMT services will notify the Nova Scotia College of Pharmacists (NSCP) (Refer to Appendix C - Pharmacy OAMT Registration Form) so they can be entered into the NSCP’s OAMT: Pharmacy Provider Registry.

Information from this registry will be released to other health care providers to identify pharmacies that could serve a patient requiring OAMT in certain situations (e.g., OAMT patient moving into province, etc.).

The Prescription

Prescriptions may be written as part-fills. Each part-fill will be referenced back to the original prescription and signed by the pharmacist, and pharmacy technician if applicable, dispensing the part-fill.

Prescriptions for methadone or buprenorphine/naloxone must be clear and complete. A methadone prescription must include:

- the total quantity of methadone (in milligrams) for the entire duration of the prescription, written in numbers and words (to help to prevent tampering of prescriptions);
- that the daily dose is mixed in orange drink crystals such as Tang® or other crystalline juice to a consistent final volume of 100 mL. This final volume is standardized to minimize errors, to standardize the taste and for consistency with practice in most other provinces. Patients unable to tolerate the ingestion of 100 mL could receive their daily dose in a final volume of 50 mL. Patients going to surgery for any reason or who are “nothing by mouth” (NPO) should receive their daily dose in a final volume of 15 mL.
- The dispensing schedule, which includes:
  - the start and end dates, which must be clearly written and followed (Note: the date on which the prescription is written may not represent the start date);
  - the days of the week that require witnessed ingestion; and
  - the number of take-home doses authorized per week and the take-home schedule, if applicable.

See specific direction regarding End Dates below.
A buprenorphine/naloxone prescription must include:

- the total quantity of tablets required;
- the daily dose; and
- the dispensing schedule, which includes:
  - the start and end dates, which must be clearly written and followed (Note: the date on which the prescription is written may not represent the start date);
  - the days of the week that require witnessed ingestion; and
  - the number of take-home doses authorized per week and the take-home schedule, if applicable.

For further information regarding methadone prescribing and images of typical methadone prescriptions, refer to the Methadone Maintenance Treatment Handbook, CPSNS.

End dates

No doses shall be dispensed after the end date of the prescription, regardless of whether there are any authorized doses that remain yet to be dispensed. It is essential that missed doses are not added to extend the end date of the prescription, i.e. if the original prescription is for seven days and two doses are missed, the additional two doses are not provided to the patient (refer to Appendix I - Special Circumstances, Missed Doses).

Prescription for Take-Home Doses

Refer to Appendix H - Dispensing and Administration of Doses for information on providing patients for whom take-home doses have been authorized with take-home doses of methadone or buprenorphine/naloxone.

Specific instructions regarding the dispensing of take-home doses must be clearly indicated on the prescription by the prescriber, including:

1. the requirement for the pharmacist to witness the ingestion of the first dose of each dispense of take-home doses.
2. the days of the week the patient receives take-home doses, or the specific dates the patient is to receive them.
3. if the treatment period of a prescription overlaps with that of a previously issued prescription, instructions should be included on the new prescription to cancel the previous prescription. Regardless, no doses shall be provided after the end date indicated on the most recent prescription.

Consistent with best practice, prescribers will authorize a maximum of six consecutive methadone take-home doses/days supply (or up to 13 buprenorphine/naloxone take-home doses). An exception to this maximum can be made for reasons including the following:

1. the patient is going on vacation to or has employment opportunities in an area where methadone or buprenorphine/naloxone is not readily available (e.g. off-shore oil rig); or
2. other rare, exceptional circumstances as agreed upon by the pharmacist and physician or nurse practitioner in collaboration. Regarding methadone, refer to the *Methadone Maintenance Treatment Handbook*, CPSNS for details on take-home doses in exceptional circumstances. Regarding buprenorphine/naloxone, refer to CAMH *Opioid Agonist Maintenance Treatment - General Principles for Take-Home Doses*.

If the number of take-home doses prescribed exceeds six consecutive methadone doses or 13 buprenorphine/naloxone take-home doses, and the reason is not provided, the pharmacist contacts the prescriber, and if the pharmacist agrees that it is appropriate to dispense the doses, documents the reason(s).

**Changes to Existing Prescriptions**

A pharmacy should plan for situations when a prescription needs to be changed by establishing an agreed upon process established in collaboration with the other members of the team.

It is important that any process established to address changes in a prescription complies with federal and provincial legislation, Nova Scotia Prescription Monitoring Program requirements and practice policies and is consistent with optimal patient care. As such, an agreed upon process must comply with the requirements in the chart on the following page.
**Prescription Order Changes/ New Prescription Required:**

<table>
<thead>
<tr>
<th>Change to Order</th>
<th>New Prescription Required</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change to Order</strong></td>
<td><strong>New Prescription Required</strong></td>
</tr>
<tr>
<td></td>
<td><strong>YES</strong></td>
</tr>
<tr>
<td></td>
<td><strong>NO</strong></td>
</tr>
<tr>
<td><strong>New PMP Rx</strong></td>
<td><strong>OAMT Faxable Order Adjustment Form (Appendix J)</strong></td>
</tr>
<tr>
<td>Total quantity dispensed is increased or dose is replaced (e.g. vomiting)</td>
<td>New duplicate prescription required</td>
</tr>
<tr>
<td>Increase or decrease in dose during stabilization, tapering or maintenance</td>
<td>Change in prescription must be in writing, referencing a specific prescription for a specific</td>
</tr>
<tr>
<td>period</td>
<td>patient (i.e. not a blanket statement for a group of patients).</td>
</tr>
<tr>
<td>AND</td>
<td>Refer to Appendix J – OAMT Faxable Order Adjustment Form</td>
</tr>
<tr>
<td>Total quantity dispensed does NOT exceed original prescription</td>
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<tr>
<td>OR</td>
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<tr>
<td>Change in dispensing dates/ range of dates, or regimen (i.e. divided doses)</td>
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<tr>
<td>with NO change in total quantity</td>
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<tr>
<td>OR</td>
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<tr>
<td>Witnessed ingestion requirement is changed to authorized take-home doses (i.e.</td>
<td></td>
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<tr>
<td>for holidays, etc.)</td>
<td></td>
</tr>
<tr>
<td>Authorized take-home doses changed to witnessed ingestion</td>
<td>Verbal order is permitted. No signature required.</td>
</tr>
<tr>
<td>Discontinuation of treatment</td>
<td>Verbal order is permitted. In certain situations, it may be appropriate for pharmacists to</td>
</tr>
<tr>
<td></td>
<td>hold (i.e. not give) a dose based on information including:</td>
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<td></td>
<td>• Observation and assessment of patient by pharmacist; or</td>
</tr>
<tr>
<td></td>
<td>• Information provided by other members of the OAMT care team</td>
</tr>
</tbody>
</table>
APPENDIX E – PREPARATION OF DOSES

Pharmacy staff will prepare methadone individual patient doses in a manner that ensures safety, stability and appropriate labeling, including that it is:

- in accordance with the requirements detailed below,
- in compliance with best practice and standard compounding techniques described in the standards for compounding adopted by the NSCP.

Stock Solution Preparation

It is the position of the NSCP that the public is best served by using a commercially available 10mg/mL methadone stock solution to prepare individual patient doses because:

- patient safety is enhanced (fewer steps to be potentially impacted by human error),
- the stability of the commercial product is longer, and

As such, all individual patient doses must be prepared from a commercially available 10 mg/mL stock solution unless, in exceptional circumstances, the commercially available solution is not available from the supplier or is otherwise unavailable, or it is inappropriate for the patient (e.g. allergy to ingredients).

In those instances, recognizing that pharmacists and pharmacy technicians have the knowledge and skills to compound drugs, it is permissible for them to prepare a 10 mg/mL stock solution from methadone powder.

Pharmacy compounded methadone stock solution must be prepared in compliance with the following criteria and procedures:

1. to harmonize practice across Nova Scotia pharmacies for enhanced patient safety, methadone stock solutions for eventual preparation of individual patient doses are compounded to a strength of 10 mg/mL.

2. all containers used in the preparation and storage of methadone solutions are used for methadone only and labeled accordingly.

3. calculations for the preparation of the compound are completed by a pharmacist or pharmacy technician. It is preferable if these calculations are checked using an independent double check by another pharmacist, pharmacy technician or pharmacy staff member.

4. a compounding log is retained to record the specifics of solutions prepared, including how much was prepared and who prepared the product (refer to Appendix E-1 – Methadone Stock Solution Compounding Log). Note the date of preparation and the use-by-date on the container to assist dispensary staff in ensuring that all methadone is dispensed within a reasonable amount of time. The log also serves as a perpetual inventory of the pharmacy’s methadone powder.

5. procedure:
   a. The correct amount of methadone powder is weighed to prepare a 10 mg/mL solution and placed in a calibrated container. Calibrate the container with a known volume of water, measured in a scientifically approved graduated device. Mark the calibrated volume with a permanent marker so the measuring device does not need to be recalibrated for each use.
b. Dissolve methadone crystals in distilled water to a strength of 10 mg/mL.

6. the compounded stock solution is stored in a light resistant bottle in the fridge, in a secure location.

7. the stock bottle is CLEARLY LABELLED with the:
   a. drug
   b. strength
   c. preparation date
   d. expiry date of 14 days from the date of preparation (under refrigeration)
   e. unique batch number (as assigned and subsequently recorded in compounding log)
   f. auxiliary label “Keep Refrigerated”.

8. all methadone solution is stored in containers that are easily distinguishable from those for water, juice, etc., as accidental poisoning may occur if a solution of methadone is mistaken for distilled water.

**Individual Dose Preparation**

Individual patient doses are prepared from a methadone 10 mg/mL stock solution.

1. Calculations for the preparation of the patient’s dose are completed by a pharmacist or pharmacy technician. It is preferable if these calculations are checked using an independent double check performed by another pharmacist, pharmacy technician or pharmacy staff member.

2. Procedure:
   a. Measure the amount of 10 mg/mL stock solution required for the individual dose using an appropriately sized syringe.
   b. Put measured stock solution in a childproof, amber, calibrated bottle.
   c. Add sufficient quantity of Tang® to bring the final volume of the dose to 100 mL.

Orange flavored Tang® is the preferred diluent because:
- It frustrates extraction of the methadone from solution;
- It is consistent with the practice of the majority of OAMT programs (a consistent product enables patients to more easily identify unanticipated changes in the taste of their solution (i.e. in the event of an error); and
- If the patient is unable to tolerate Tang®, another crystalline drink may be used.

3. A compounding log of individual doses is retained to record the specific details of the preparation, including how much was prepared and who prepared the product (refer to Appendices E-2 and E-3 – Methadone Individual Dose Compounding Log Forms). This log also serves as a perpetual inventory of the methadone stock solution.

4. The quantity of remaining methadone stock solution (as calculated on the Perpetual Inventory record) is reconciled with the actual on-hand inventory promptly after each preparation of individual patient doses.
5. Any discrepancy between the recorded inventory of remaining methadone stock solution and the actual inventory are explored immediately to ensure it is not the result of a compounding error.

6. The final volume for each individual dose is equal to 100 mL, unless a lesser final volume is warranted (see #7 below). This is both for on-site consumption and for take-home doses (e.g. a dosage of 80 mg requires 8 mL of a 10mg/mL stock solution, then qs. to 100 mL with liquid Tang®). A consistent volume enables patients to more easily identify unanticipated changes in the taste of their solution (i.e. in the event of an error). This volume is sufficient to ensure the dose is not retained in the mouth and subsequently not consumed and/or diverted.

7. Patients unable to tolerate the ingestion of 100 mL should receive their daily dose in a final volume of 50mL. Patients pending surgery or who have for any reason been directed to consume nothing by mouth (NPO) should receive their daily dose in a final volume of 15 mL, and if necessary, mixed in water rather than Tang®.

8. All individual patient doses are bottled separately in 100 mL amber, childproof bottles. The dilute solutions are generally stable for at least one month in the fridge – refer to chart in the “Storage and Stability” section below.

9. When the physician or nurse practitioner establishes a process for periodic auditing of unconsumed take-home dose bottles (i.e. from time to time they may request the patient to bring in unused take-home doses), the pharmacy will apply tamper evident seals to each take-home dose dispensed.

10. The pharmacy will apply tamper evident seals to each take-home dose dispensed when there are concerns regarding the security of doses for a specific patient, as identified by the pharmacist, pharmacy technician, prescriber or clinic.

11. If individual patient doses are prepared in advance of being processed for dispensing, they are stored securely in the pharmacy refrigerator until dispensed and clearly labeled with the following details, at a minimum:
   a. the patient’s name and date,
   b. strength and quantity of methadone (e.g. methadone 8 mg in 100 mL Tang),
   c. batch or lot number of stock solution used,
   d. batch number of the individual dose prepared (if applicable)
   e. expiry date, and
   f. initials of the individual preparing the dose(s).

12. Individual patient doses (i.e. witnessed dose plus all take-home doses) are labeled in accordance with the NSCP Prescription Labels policy and stored securely in the refrigerator until administered to the patient. 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.

13. Based on certain criteria, take-home privileges may be granted by prescribers to stable patients in order to improve the patient’s quality of life. Individual patient doses dispensed as take-home doses are labeled with the following auxiliary warnings:
- keep in refrigerator; and
- store in a locked box; and
- methadone can be fatal when taken by individuals for whom it is not prescribed, or
- the contents of this bottle may cause harm or toxicity if taken by someone other than the person whose name appears on the prescription label.

Storage and Stability

Both the compounded stock solution and individual patient doses require secure refrigeration. For security reasons, refrigerators must only be accessible to dispensary staff. It is recommended that doses are stored in a separate refrigerator within the dispensary away from high traffic areas. Pharmacy managers ensure there is adequate storage space in the pharmacy’s refrigerator to safely and securely store the quantity of individual doses associated with the number of OAMT patients they serve.

Stability of Compounded Stock Solutions

- An aqueous compounded stock solution using distilled water has an expiry date of 14 days under refrigeration.
- An aqueous compounded stock solution using bacteriostatic water is expected to have an expiry date of 30 days.

Stability of Individual Patient Doses

The following chart identifies the stability of methadone solutions based on the diluent used and storage conditions:

<table>
<thead>
<tr>
<th>Diluent</th>
<th>Period of Stability Room Temperature (22C* or 20-25C**)</th>
<th>Period of Stability Refrigerated (6C* or 5C**)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orange Flavoured Tang®</td>
<td>91 days*</td>
<td>91 days*</td>
</tr>
<tr>
<td>(Note: that this solution showed signs</td>
<td>of bacterial growth at 21 days)</td>
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<tr>
<td>Orange Flavoured Tang® with 0.1% sodium</td>
<td>91 days*</td>
<td>91 days*</td>
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<tr>
<td>benzoate</td>
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<tr>
<td>Grape Flavoured Kool Aid®</td>
<td>17 days**</td>
<td>55 days**</td>
</tr>
<tr>
<td>Allen’s® Apple Juice</td>
<td>9 days**</td>
<td>47 days**</td>
</tr>
<tr>
<td>Grape Flavoured Crystal Light®</td>
<td>8 days**</td>
<td>34 days**</td>
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<tr>
<td>Grape Flavoured Crystal Light®</td>
<td></td>
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<tr>
<td>with 0.1% sodium benzoate</td>
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<tr>
<td></td>
<td>29 days**</td>
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</tbody>
</table>

** Stability of methadone in four vehicles for oral administration. Am J Hosp Pharm. 1991
### APPENDIX E-1 – METHADONE 10MG/ML STOCK SOLUTION COMPOUNDING LOG

<table>
<thead>
<tr>
<th>Date Prepared</th>
<th>Manufacturer of Powder</th>
<th>Manufacturer Lot Number and Expiry Date of Powder</th>
<th>Quantity of Solution Prepared</th>
<th>Quantity of Powder Used</th>
<th>Quantity (mg) of Powder Remaining (subtract amount used from previous balance [line above])</th>
<th>Expiry Date of Solution</th>
<th>Batch Number Assigned</th>
<th>Initials of Preparer</th>
<th>Initials of Checking PhC/Tech</th>
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</thead>
<tbody>
<tr>
<td>sheet start date</td>
<td>beginning balance</td>
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</table>

* It is recommended that the calculated quantity be reconciled with the actual amount remaining after each preparation of stock solution.

Transfer this amount to next sheet as “beginning balance”.
### APPENDIX E-2 – METHADONE INDIVIDUAL DOSE COMPOUNDING LOG

<table>
<thead>
<tr>
<th>Date Prepared</th>
<th>Lot or Batch Number of Stock Solution</th>
<th>Patient’s Name</th>
<th>Strength of Dose Being Prepared (mg)</th>
<th>Number of Bottles Prepared</th>
<th>Quantity of Stock Sol’n Used (mL)</th>
<th>Quantity (mL)* of Solution Remaining (subtract amount used from previous balance [line above])</th>
<th>Initials of Preparer</th>
<th>Initials of Checking PhC/Tech</th>
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</table>

**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. * It is recommended that the calculated quantity of solution remaining be reconciled with the actual amount remaining after each preparation of individual doses.

Transfer this amount to next sheet as “beginning balance”. 

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Nova Scotia College of Pharmacists / June 2017 Updated January 2022
APPENDIX E-3 – ALTERNATE METHADONE INDIVIDUAL DOSE COMPOUNDING LOG

<table>
<thead>
<tr>
<th>Date Prepared</th>
<th>Lot or Batch Number of Stock Solution Used</th>
<th>Strength of Dose Prepared (mg)</th>
<th>Number of Bottles Prepared</th>
<th>Quantity of Stock Solution Used (mL)</th>
<th>Quantity (mL)* of Solution Remaining (subtract amount used from previous balance [line above])</th>
<th>Initials of Preparer</th>
<th>Initials of Checking PhC/Tech.</th>
</tr>
</thead>
<tbody>
<tr>
<td>sheet start date</td>
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</tr>
</tbody>
</table>

* It is recommended that the calculated remaining quantity of solution be reconciled with the actual amount remaining after each preparation of individual doses.

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. Transfer this amount to next sheet as "beginning balance"."
APPENDIX F – PREPARATION OF DOSES USING METHADONE COMPOUNDING DEVICES

A pharmacy may use a methadone compounding device to prepare methadone doses. In such cases, the use of the device must comply with the following procedural requirements regarding safety and quality assurance.

Safe Use of Device

In addition to the provisions set out in Appendix E – Preparation of Doses, when providing methadone doses using a methadone compounding device, the following steps are taken to ensure safe use of the device:

- Any methadone compounding device and related materials (e.g. device, software, etc.) used by the pharmacist or pharmacy technician is classified and licensed, if appropriate, under the Medical Devices Regulations to the Food and Drugs Act.
- The pharmacy manager establishes, implements and maintains a manual containing:
  - A standard operating procedure for the use of the compounding device which includes:
    - title and purpose of the standard operating procedure;
    - date created, along with the time interval and name of individual responsible for reviewing the standard operating procedure;
    - purpose and limitations of the device;
    - device performance specifications (e.g. level of accuracy);
    - appropriate handling techniques to support safe and effective use of the device;
    - procedural steps on how to accurately compound a dose of methadone;
    - device calibration and quality control processes to monitor the integrity of the device and appropriate record keeping of device testing;
    - processes to address an inoperable device;
    - instructions on the proper use, cleaning, maintenance and storage of the device and associated equipment or software;
    - information on device limitations, potential interferences and any potential sources of variability or error;
    - requirements for training and documentation of such training; and
    - applicable literature references.
  - Policies and procedures that address the following:
    - methadone pump setup;
    - loading a profile using fingerprint sensor;
    - ensuring patient profiles are accurate and complete and that documentation requirements are met;
    - identification of the patient using photo / fingerprint scan. Refer to NSCP policy: Releasing Medication to Patients and their Agents;
    - cross-referencing information as required between the compounding device and the pharmacy’s main system;
the assurance of accurate and regular perpetual inventory checks through reports generated by the device;
- adding/changing a fingerprint or photo. **Note** that the use of fingerprint technology to identify the patient does not take the place of the witnessed ingestion logs; and
- any dispensing procedures unique to the device.

The manual is kept in an area where it can be easily accessed by those dispensing methadone.

**Quality Assurance**

The pharmacy manager is responsible for the pharmacy’s quality assurance processes, which, for the methadone compounding device, includes:

- ensuring a standard operating procedure for the methadone compounding device is established and maintained;
- processes for error reporting;
- ensuring only trained and fully competent individuals use the device;
- monitoring the competence of pharmacists or pharmacy technicians, including ongoing demonstration of:
  - an understanding of the appropriate use of the device and its clinical utility,
  - an understanding of any technical limitations of the device, and
  - the skills required to follow quality procedures;
- adherence to approved policies, procedures, and standards;
- ensuring that the device manufacturer’s instructions for procedure and quality control are followed; and
- reporting any adverse events as quality related events in accordance with the NSCP Standards of Practice for Continuous Quality Assurance Programs in Community Pharmacies.

The pharmacist or pharmacy technician uses the device in a manner that complies with the pharmacy’s standard operating procedure for that device.

The pharmacy manager ensures that the pharmacy environment is clean and safe for device use. The environment complies with any conditions defined by the manufacturer of the compounding device.
APPENDIX G – PATIENT ASSESSMENT

Prior to dispensing and/or administering methadone or buprenorphine/naloxone to a patient, a pharmacist will assess the patient to be satisfied that it is safe to provide the patient with his or her daily witnessed dose. This assessment is key to ensuring safe and effective treatment in every instance, and is especially important when the patient’s dose is being increased (e.g. during induction, etc.). In these situations, the pharmacist is particularly attentive to the known signs of methadone or buprenorphine/naloxone intoxication:

• slurred speech,
• impaired coordination,
• mental signs e.g. disorientation, confusion or lack of focus, change in level of consciousness (drowsy, nodding off), and/or
• physical signs (pinpoint pupils).

If any of these signs of intoxication are present, the pharmacist withholds the dose until the prescriber is contacted. Opioid withdrawal is very uncomfortable but not life threatening while methadone or buprenorphine/naloxone toxicity can be fatal. Note: For information regarding an exception in pregnancy, refer to Methadone Maintenance Treatment Handbook, CPSNS.

The following are the procedural requirements for a patient assessment, which include gathering patient information, completing the assessment process, documenting the assessment details/results and managing a planned dosage titration.

Gathering Patient Information

In order to ensure that it is appropriate to provide the patient with the methadone or buprenorphine/naloxone dose, the pharmacist will gather and consider appropriate information through:

1. Dialogue with the patient -

   The value of dialogue is enhanced when the pharmacist develops a therapeutic relationship with the patient [Appendix A – Substance Use Screening and Brief Intervention Tool].

   Questions that support the pharmacist in obtaining the appropriate information include:

   • asking about how they are sleeping at night, and counsel accordingly (i.e. provide sleep hygiene information);
   • asking about drowsiness during the day (timing of drowsiness could indicate a need for dosage adjustment);
   • reminding the patient about signs of toxicity (e.g. sleepiness, nodding off several times during the day, forgetfulness, difficulty in waking up from sleep, slurred speech, stumbling walk and that they need to seek prompt medical attention if these symptoms occur;
   • asking about constipation and counseling accordingly;
   • asking if they are taking any new medications (OTC or otherwise) that may not be in their patient profile;
   • asking if they have any questions. Any comments by the patient about the taste or appearance of the dose should be promptly investigated to ensure a compounding or dosing error has not occurred;
reminding the patient that if they are taking doses home, they need to use a locked box in a safe secure location and reiterate the risk to others of inadvertent methadone or buprenorphine/naloxone ingestion, especially children; and

determining whether the patient has missed doses (refer to Methadone Maintenance Treatment Handbook. CPSNS – Management of Missed Doses);

In addition, when the patient is undergoing induction, the pharmacist obtains the following information from the patient before administering a prescribed dose increase:

• whether they are using any other substances, prescribed or non-prescribed (opioids, benzodiazepines, sleep medications, antihistamines, alcohol, other sedating medications). Record details. If concerned, ask more detailed questions and if concerns cannot be resolved, contact the prescriber.

• whether they are drowsy or sedated 2-6 hours after the dose (or at the time of day that their methadone effect is expected to peak).

2. Observation of the patient for signs and symptoms of intoxication including:

• **speech:** normal; slurred and/or slow; mumbled; disjointed and/or unintelligible;

• **coordination:** regular walking and movements; tripping; unsteady, tottering and/or staggering; falling and/or difficulty coming to or maintaining a standing position;

• **mental Signs:** focused; inattentive: loss of train of thought and/or cannot remain on topic; confused and/or disoriented;

• **level of consciousness:** alert and attentive; drowsy and easily roused; nodding off and/or sleeping in waiting room; difficult to rouse and/or requires touch to awaken;

• **physical signs:** respiratory rate; pupil reactivity; and

• **overall general presentation:** significant change in appearance and behavior

For additional information regarding intoxicated patients, refer to Appendix I – Special Circumstances.

3. Observation of the patient for signs and symptoms of withdrawal (i.e. suggests dose is too low, patient is not consuming the take-home dose, etc.). Refer to CAMH Opioid Agonist Maintenance Treatment, Clinical Opioid Withdrawal Scale. (Note that a patient may exhibit signs of withdrawal during initial stabilization and tapering periods and in such situations, the dose should not be withheld).

4. Collaboration with the OAMT team - the presence of other substances, medications or health conditions may result in sedation or interactions with methadone (Refer to Addiction Treatment Forum).

**Evaluation of Information**

1. Based on the patient’s status and the planned treatment/dosage, the pharmacist will decide whether or not to provide the patient with their dose. A Patient Assessment Tool - Appendix G-1 is included following this appendix as a suggested approach to facilitate this decision and as a documentation template.

2. Using the Patient Assessment Tool:

   - for total scores of 1/15 or 2/15, the pharmacist should hold the dose and contact the OAMT prescriber to collaboratively consider the course of care.
— for an overall score of greater than or equal to 3/15, the pharmacist withholds the dose and directly contacts the OAMT prescriber to collaboratively consider the course of care before proceeding.

3. If the pharmacist is concerned about the patient’s status of recovery and/or safety, the pharmacist withholds the dose and contact the prescriber regardless of the score.

Documentation of Patient Assessment

The assessment findings and results are valuable information for ongoing patient care and treatment, and a critical contribution of the pharmacist to the patient’s collaborative care team.

A pharmacist should use the Patient Assessment Tool (Appendix G-1) to document their assessment when they are concerned about administering a dose.

The pharmacist maintains the completed tool as part of the patient’s record and will use it to support their communications with the OAMT prescriber.
## APPENDIX G-1 – PATIENT ASSESSMENT TOOL

The pharmacist may use the following tool to assess the appropriateness of administering a daily dose or the appropriateness of a dose increase using the following objective findings:

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

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

Refer to [Evaluation of Information](#) for interpretation of scores.

<table>
<thead>
<tr>
<th>Score: / 15</th>
<th>Dosage withheld?</th>
<th>Methadone dosage administered:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
</tr>
</tbody>
</table>

Notes:

____________________________________________________________________

Pharmacist Signature

____________________________________________________________________

Pharmacist Name (please print)
APPENDIX H – DISPENSING AND ADMINISTRATION OF DOSES

The dispensing and administration of methadone or buprenorphine/naloxone to patients is conducted on a daily basis that includes witnessed ingestion until the prescriber authorizes take-home dose privileges. Following are the specific procedural requirements for dispensing and administering these medications including those for take-home doses (refer to Appendix H-1 Take-home Doses).

Patient Assessment

Prior to dispensing, the pharmacist ensures that it is safe for the patient to ingest methadone or buprenorphine/naloxone, including assessing whether it is appropriate for the patient to receive a dose (refer to Appendix G - Patient Assessment).

Patient Verification

The release of any OAMT medications to the patient is undertaken in compliance with the NSCP policy Releasing Medication to Patients and their Agents, including confirming the patient’s identity before the dose is given.

Counseling Regarding Pharmacy OAMT Service

A treatment agreement is used to assist in explaining the goals of treatment to their patients, including their responsibility as the pharmacist and the responsibilities of the patient (refer to OAMT Sample Treatment Agreement on the NSCP website).

The pharmacist communicates with the patient that:

- For reasons of safety, the methadone and buprenorphine/naloxone dose may be withheld if the patient appears to be sedated or intoxicated.
- Federal law requires that patients inform any prescriber if they have received a narcotic from another prescriber within the preceding thirty-day period.
- Relevant information about the pharmacy, including hours of operation.

Counseling Regarding Medication Treatment

In dialogue with the patient, the pharmacist:

- Educates the patient regarding the expected side effects and treatment effects, including symptoms of opiate withdrawal and signs of toxicity and overdose (refer to CAMH Opioid Agonist Maintenance Treatment).
- Ensures that the patient is aware that the average daily dose of methadone or buprenorphine/naloxone may result in death if taken by a person not dependent on an opioid.

Note: Once tolerance is lost from missing doses, re-initiation of the usual doses of methadone can be toxic.
The pharmacist also communicates that:

- All missed doses are:
  - Reported to the prescriber (refer to Appendix K – Incident Report Form);
  - Noted on the patient’s record; and
- The patient will develop a tolerance to the medication. If the patient abruptly discontinues the medication, withdrawal symptoms will develop.
- Due to the sedation and/or withdrawal symptoms which may be present during the stabilization period, driving an automobile or operating machinery may be dangerous. Such dangers can also arise during dosage adjustment or periods of instability.
- Fertility improves with stabilization on OAMT. This should be considered in any family planning conversations.
- Other substance use, including prescribed or non-prescribed medications, combined with methadone or buprenorphine/naloxone can be dangerous. The use of other substances while taking methadone or buprenorphine/naloxone should be discussed with the patient’s primary care provider and pharmacist as drug interactions may occur.

Witnessing Ingestion

The directions on the prescription indicate that the dose is dispensed daily and the ingestion is witnessed by a pharmacist. If the prescriber does not clearly indicate his or her intentions, the pharmacist assumes daily witnessed ingestion is required and witnesses every dose.

Patients should take the methadone dose as early in the day as possible during induction and stabilization, since the risk of harm from overdose is increased if the peak effect coincides with a time when the patient is usually sleeping.

A single dose of methadone or buprenorphine/naloxone is effective for 24 hours. Therefore, patients are counseled to arrive at the pharmacy at the same time each day to ensure consistent blood levels (for additional information, refer to CAMH Opioid Agonist Maintenance Treatment).

Methadone

It is the responsibility of the pharmacist to personally assess the patient to determine whether it is appropriate to provide them with their dose. Once completed, a pharmacist or licensed pharmacy technician will witness the ingestion of the dose, ensuring that the methadone has been swallowed by having the patient talk and/or drink water after ingestion.
**Buprenorphine/naloxone**

It is the responsibility of the pharmacist to personally 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 observe the patient self-administer the dose. For clarity, a pharmacist or licensed 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.

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 observed the self-administration of the dose, unless specifically indicated otherwise by the prescriber.

The pharmacist ensures that patients receive their methadone or buprenorphine/naloxone in person. Doses are not released to spouses, friends or relatives. In the rare emergency case where delivery is agreed upon, the pharmacist will personally deliver the methadone or buprenorphine/naloxone to the patient, assess the patient and witness the ingestion (Refer to Appendix I – Special Circumstances – Home Delivery).

Both the patient and pharmacist sign a log upon each witnessed ingestion (refer to Appendix H-2 Daily Witnessed Ingestion and Take-Home Dose Log and Appendix H-3 Take-Home Dose Log [4 or More Doses].

The pharmacist should inform the prescriber about any vomited doses and obtain a new prescription if a replacement dose is to be given. As with all doses, the timing of the ingestion of the dose should be recorded.

**Administration Errors**

In the event of a medication dosing error, confirmed or suspected, the pharmacist takes appropriate and necessary action to minimize harm to the patient, and ensures transparency throughout the entire process. This may include prompt consultation with the patient’s other health care provider(s) for determination of appropriate action (refer to Appendix H-4 - Appropriate Action in Administration Errors for readily accessible information for these situations).

In addition to these standards, pharmacists manage the error in accordance with the NSCP Standards of Practice Continuous Quality Assurance Programs in Community Pharmacies and the individual pharmacy’s medication error management policy.

For additional information regarding cautions, side effects, drug interactions, including QT Prolongation, intoxication, overdose and under dose, refer to CAMH Opioid Agonist Maintenance Treatment and for specific methadone drug interaction information, refer to CredibleMeds.org.
APPENDIX H-1 – TAKE-HOME DOSES

Background

In the interest of patient and public safety, the dispensing and administration of witnessed ingestion of methadone or buprenorphine/naloxone to patients is done on a daily basis unless the prescriber authorizes take-home dose privileges. In some situations, based on certain criteria, take-home doses are granted by prescribers to stable patients in order to improve the quality of the patient’s daily life and to encourage the patient’s recovery. The general approach and considerations for take-home doses are as follows:

- Once a patient is assessed to be functionally stable, on methadone or buprenorphine/naloxone including that eligibility criteria (below) have been met, not all doses have to be witnessed by a pharmacist, and the prescriber may grant take-home doses.

- The first dose of each dispensing of take-home doses is always witnessed by the pharmacist.

**Dispensing continuous take-home doses without witnessed first dose ingestions is considered risky and dangerous because:**

- It places the patient at risk of overdose or toxicity.
- It places the public at risk of diversion.
- It is not consistent with current best practice.

- Take-home doses are not recommended during the first two months of treatment in the case of buprenorphine/naloxone, and the first three months of treatment in the case of methadone.

- Take-home doses are a progression of treatment. A decision to grant take-home doses by the prescriber should ideally be made in consultation with other professionals involved, including counselors and pharmacists.

Patient Eligibility Criteria for Take-Home Doses

1. OAMT program participation, where the patient has demonstrated:
   a. Attendance at the pharmacy for their medication dose on schedule;
   b. Attendance at scheduled appointments with the physician, nurse practitioner or counselor;
   c. Compliance with the treatment agreement; and
   d. Compliance with urine drug screening (UDS).

2. Demonstration of cognitive stability to assume responsibility for the care and use of the medication.

3. Drug use improves, as evidenced by a minimum of four consecutive weeks of documented random UDS.

4. Evidence of social integration such as employment, school attendance, child-care responsibilities and volunteer work.

5. The patient is able to accept responsibility for the take-home doses, which includes proper security and use of the methadone:
a. Patients with unstable living arrangements, such as those living on the street or in hostels without storage facilities, are not appropriate candidates to receive take-home doses. If the pharmacist is aware of such circumstances, they must notify the prescriber.

b. Patients are counseled to store their methadone in a ‘locked box’ at home and to store the locked box in the fridge.

6. Specific considerations for take-home doses apply to split doses. Patients who receive authorized split doses and who require daily witnessed dosing must attend the pharmacy in the morning for a portion of their dose and again in the evening for the remainder until the patient otherwise meets eligibility criteria for take-home doses. The pharmacist does not dispense take-home doses for the remainder of the patient’s daily dose unless specifically directed to do so in writing by the prescriber.

Counseling Regarding Risks of Take-Home Doses

Prior to receiving any intermittent witnessed ingestion, patients are made aware of the following risks:

- You will lose tolerance to the dose of methadone or buprenorphine/naloxone on which you have been stabilized if you have not consumed a dose for the past three days.

- If you have not consumed this same dose of methadone or buprenorphine/naloxone which you are about to ingest on each of the past three days, this dose could place you at risk of overdose, result in your hospitalization or death.

- If you have not consumed this same dose of methadone or buprenorphine/naloxone on each of the past three days, you should speak with your physician or nurse practitioner and obtain a prescription that reflects the actual dose you have been consuming.

For any instances of 4 or more take-home doses, both the pharmacist and patient initial a log (refer to Appendix H-3 Take-Home Dose Log – 4 or More Doses) to acknowledge that these risks have been reviewed.

Prescription Requirements for Take-Home Doses

If the number of take-home doses prescribed exceeds six consecutive doses, the pharmacist contacts the prescriber and documents the reason(s). In the interest of patient and public safety, the Methadone Maintenance Treatment Handbook, CPSNS, provides clarification as to the criteria that must be met for a situation to warrant this exception.

Specific instructions regarding the dispensing of take-home doses are clearly indicated on the prescription by the prescriber (refer to Appendix D - OAMT Legal Requirements). Such instructions include:

- The ingestion of the first dose of each dispensing of take-home doses is witnessed by the pharmacist.

- The number of take-home doses dispensed per week, or the days of the week the patient receives them, or the specific dates the patient is to receive take-home doses (to a maximum of six doses per week).

- Cancellation of the previous prescription, if for some reason the treatment period of a prescription overlaps with that of a previously issued prescription.
Take-Home Dose Schedules: Standard and Accelerated

Note: For additional information on take-home dose schedule and prescription requirements, refer to *Methadone Maintenance Treatment Handbook*, CPSNS and CAMH Opioid Agonist Maintenance Treatment.

**Criteria for Prescribing Exceptional Take-Home Doses**

<table>
<thead>
<tr>
<th><strong>IF:</strong></th>
<th><strong>THEN:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>The patient has been on methadone for at least two months and is not yet eligible for any take-home doses, but is stable and is low risk for diversion as measured by self-report, UDS, and social indicators.</td>
<td>Give take-home doses on compassionate grounds only (e.g., a personal crisis). Give no more than 6 days of take-home doses at a time.</td>
</tr>
<tr>
<td>The patient has been on methadone for at least two months, has negative random UDS for at least four weeks, and is at, or approaching, a stable methadone dose.</td>
<td>Give take-home doses for sound personal reasons only (e.g., vacation/holidays, family matters). Give no more than 6 days of take-home doses.</td>
</tr>
</tbody>
</table>
The patient has not had drug use for 12 months, is clinically stable, and is receiving 3-6 take-home doses per week and a local pharmacy cannot be found. Give up to a 13-days of take-home doses for travel, work, or vacation purposes. If more than 13 days of take-home doses is required, a second opinion with another MMT prescriber is suggested.

Administration of Take-Home doses

Patients must consume the first dose of each dispensing of take-home doses under pharmacist observation and take the remaining doses with them.

Patients are informed that a locked container for their take-home doses (i.e., a locked box) is strongly recommended, particularly in situations where other individuals may have access to the take-home doses, or in the circumstances of shared accommodation.

- Patients are advised that a dose as low as 10 mg can be fatal to a child and a dose of 40 mg can be fatal if taken by a non-tolerant adult patient (i.e. someone who has not ingested methadone in the past 3 days).

Both the patient and pharmacist sign the patient’s Daily Witnessed Ingestion and Take-Home Dose Log - Appendix H-2 for each witnessed ingestion and subsequent dispensing of take-home doses.

Special Administration Requirements: Locked Boxes and Return of Take-Home Dose Containers

The methadone prescriber or the pharmacist may require patients who are authorized to receive take-home doses to:

- Use and maintain locked boxes for their take-home doses, and/or
- Return their empty labeled take-home dose bottles to the pharmacy or to the prescriber on each visit before being provided with another supply of take-home doses.

Note: Patients are advised that they might be asked at any time to appear at the pharmacy with the balance of their take-home medications. This is to deter patients from diverting their methadone and to identify diversion when it occurs.

In these situations, effective communication and collaboration between pharmacies and prescribers or clinics is essential to assist the pharmacist in reinforcing the treatment plan for the patient as well as promoting compliance. Pharmacists and pharmacy technicians ensure that expectations and precautionary measures regarding locked boxes and safe medication storage are clearly understood by the patient. These can be reinforced at the time of reviewing the pharmacist patient treatment agreement with the patient. Key information to highlight includes:

- The importance of using of a locked box, especially in a household with children;
- Who has responsibility for supplying locked box, e.g. patient or clinic / prescriber;
- Consequence of failing to bring back locked box / all take-home dose containers;
• Consequence of locked box being damaged;
• Consequence of failing to use locked box / bring back take-home dose containers; and
• Any changes in the existing agreements.

Empty labeled take-home dose containers returned to the pharmacy are to be disposed of in a manner consistent with the NSCP Disposal of Confidential Patient Information policy.

As per the NSCP Code of Ethics, pharmacists and pharmacy technicians cooperate with colleagues and other health care professionals so that maximum benefits to patients can be realized.

Discontinue or Refuse to Fill Take-Home Doses

A pharmacist may refuse to fill a prescription for a take-home dose if there is concern for the safety of the patient, or the safety of others. This decision is communicated to the prescriber (for an example of a reporting tool option, refer to Appendix K – Incident Report Form).

Take-home doses may be discontinued or decreased by the prescriber or pharmacist for various reasons including:
• Evidence the patient has failed to meet the terms of the treatment agreement. Such occurrences, including inappropriate behaviour by the patient are an opportunity to revisit and reinforce the agreement;
• Use of unauthorized drugs;
• The patient has produced an unacceptable urine sample or has tampered with the collection of the urine sample;
• Evidence that the patient has approached another methadone or buprenorphine/naloxone treated patient suggesting or proposing to sell, buy or share their methadone or buprenorphine/naloxone or any urine sample or tamper with any urine sample; or
• The patient has diverted, or permitted to be diverted, any part of the methadone or buprenorphine/naloxone.

For further information regarding voluntary discontinuation of methadone, refer to CAMH Opioid Agonist Maintenance Treatment - Voluntary Tapers and CPSNS Methadone Maintenance Treatment Handbook.
# APPENDIX H-2 – DAILY WITNESSED INGESTION AND TAKE-HOME DOSE LOG

**Patient Daily Witnessed Ingestion and Take-home Log:**

<table>
<thead>
<tr>
<th>Date and Time</th>
<th>Rx Number</th>
<th>Dose (mg) Consumed</th>
<th>Number of Take-Home Doses Given</th>
<th>Urine Sample Date (if applicable)</th>
<th>Number of Bottles Returned (if applicable)</th>
<th>Patient Signature</th>
<th>Pharmacist Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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Note: If the patient does not arrive for their daily witnessed ingestion or take-home dose pick up, it is noted on this log.
APPENDIX H-3 – TAKE-HOME DOSE LOG - 4 OR MORE DOSES

Patient Daily Witnessed Ingestion and Take-Home Dose Log (for witnessed ingestion less often than every three days):

<table>
<thead>
<tr>
<th>Date and Time</th>
<th>Rx Number</th>
<th>Dose (mg) Consumed</th>
<th># of Take-Home Doses</th>
<th>Urine Sample Date (if applicable)</th>
<th># of Bottles Returned (if applicable)</th>
<th>Patient Signature</th>
<th>Pharmacist Signature</th>
</tr>
</thead>
<tbody>
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</table>

Patients who require witnessed ingestion less frequently than every three days (e.g. pick-up of 3 or more take-home doses) should be advised of the risks of missing three or more consecutive doses. The following risks should be communicated prior to each witnessed ingestion. The pharmacist and patient should both initial that these cautions have been reviewed when 3 or more take-home doses are given and when deemed necessary by the pharmacist.

- You will lose tolerance to the dose of methadone on which you have been stabilized if you haven’t consumed that dose for three consecutive days.
- If you have not consumed this dose of methadone which you are about to ingest on each day of the past three days, you could become seriously ill, require hospitalization or die.
- If you have not consumed this dose of methadone which you are about to ingest on each day of the past three days, you should talk with your physician or nurse practitioner and obtain a prescription that reflects the actual dose you have been consuming.

Patient Signature: ___________________________ Date: __/__/____

Pharmacist Signature: _________________________ Date: __/__/____
APPENDIX H-4 – APPROPRIATE ACTION FOR ADMINISTRATION ERRORS

If the pharmacist or pharmacy technician becomes aware of a medication dosing error, appropriate and necessary action is taken to minimize harm to the patient and ensure transparency throughout the entire process. This includes notification of the event by the pharmacist to the patient’s OAMT prescriber.

In addition to the following standards, it is expected that pharmacists manage errors in accordance with the NSCP Standards of Practice: Continuous Quality Assurance Programs in Community Pharmacies.

Methadone or Buprenorphine/Naloxone Higher Dose Error

- Tell the patient immediately. If the patient has left the pharmacy, contact him or her by telephone. If the patient has no phone, take the necessary steps to contact the patient’s physician, nurse practitioner or OAMT clinic to obtain a contact number or send police to the home.
- If the patient has not left the pharmacy, advise the patient to seek medical attention immediately. Take the necessary steps to protect the patient’s safety, including transporting patient to the Emergency Room if necessary. If the patient refuses medical attention, document the time and details (refer to Appendix L – Against Medical Advice). Ask the patient to remain in the care of a friend or relative for the day (for a minimum of 10 hours) and until any symptoms of overdose have been resolved.
- Advise the patient, and if possible, another person who will be with the patient throughout the day, of the symptoms of overdose including sedation or sleepiness, slowed or slurred speech, incoordination, pinpoint pupils, ataxia, euphoria or dysphoria and respiratory depression.
- Advise the patient to have naloxone on hand and provide a kit if necessary. Educate the patient or their agent regarding naloxone use, including recognizing the symptoms of overdose, calling 911 and administration of the drug.
- Make follow-up contact with the patient throughout the day.
- Advise the patient’s physician, nurse practitioner or OAMT clinic once steps have been taken to see to the patient’s safety. and
- Reassess the patient’s health condition before administering the next daily dose.

Refer to the Patient Information – Methadone document on the NSCP website, for important methadone overdose information for the patient.

Methadone or Buprenorphine/Naloxone Lower Dose Error

- If the patient has left the pharmacy, advise the patient’s prescriber or OAMT clinic and the patient as you would with an overdose.
- Once the patient is contacted, offer the patient the “difference” between the amount administered and the amount prescribed
- Should the patient refuse to return for the balance of medication, advise them of the possibility of withdrawal and review the symptoms related to opioid withdrawal.
• If the patient cannot be reached during business hours, advise them of the error at their next administration.
• If the patient is still in the pharmacy, a second dose is prepared to make up the balance of the dose.
APPENDIX I – SPECIAL CIRCUMSTANCES

When providing OAMT services, a pharmacist will undertake the following additional procedures required for special patient conditions or situations.

**Intoxicated Patients**

If a patient presents at the pharmacy asking for their methadone or buprenorphine/naloxone dose and they are intoxicated, the dose is withheld and their prescriber is contacted to be informed of the situation and to discuss an alternate plan (refer to Appendix G - Patient Assessment). If the prescriber is unavailable, the dosage is still withheld.

It is safer to refuse to dispense a patient’s methadone or buprenorphine/naloxone than to medicate an intoxicated patient. Opioid withdrawal, while uncomfortable, is not life threatening — but adding methadone or buprenorphine/naloxone to the other drugs already consumed by an intoxicated patient may be dangerous.

The handling of such situations is communicated to the patient well in advance, during the discussion of the treatment agreement. In such a situation, the pharmacist:

- Explains that it would be dangerous to medicate at this time;
- Warns the patient against driving a car;
- Informs the prescriber that the patient appeared intoxicated in your pharmacy; and
- Clearly documents their actions.

For additional information, refer also to CAMH Opioid Agonist Maintenance Treatment.

**Opioid Agonist Maintenance Treatment in Federal or Provincial Correctional Facilities**

If a patient on OAMT transitions in and/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 and preventing diversion. Refer to CPSNS Methadone Maintenance Treatment Handbook and CAMH Opioid Agonist Maintenance Treatment for further direction on practice in this situation.

**Home Delivery**

Home delivery of methadone or buprenorphine/naloxone is generally reserved for emergency situations in which:

- A patient is incapable of coming to the pharmacy;
- The prescriber agrees to home delivery; and
- The pharmacist is willing to deliver methadone or buprenorphine/naloxone and supervise ingestion at the patient’s location.
When delivery is necessary, the pharmacist takes an active role in ensuring that:

- There are systems in place to protect the patient, other residents and the product’s integrity;
- The delivery complies with the NSCP’s *Delivery of Prescriptions Guidelines* and
- The delivering pharmacist is reasonably confident that it is a safe environment.

A pharmacist providing methadone by delivery must do so personally, providing the methadone directly to the patient and also meeting the requirements for the pre-dispensing patient assessment (refer to *Appendix G – Patient Assessment*).

For methadone or buprenorphine/naloxone prescriptions that require witnessed ingestion, the pharmacist is present to witness the dose, whether the ingestion occurs at the pharmacy or elsewhere. **It is the responsibility of the pharmacist to personally witness the patient ingest their dose of methadone or buprenorphine/naloxone. This responsibility cannot be delegated to a non-pharmacist.**

**Missed Doses – Methadone**

A clinically significant loss of physiological tolerance to methadone may occur with as little as two days without medication. Patients who have missed doses may show withdrawal symptoms. If withdrawal is suspected, contact the prescriber (refer to CAMH *Opioid Agonist Maintenance Treatment*).

**NOTE:** If patients miss **two or more** consecutive doses during induction (i.e. 0 to 2 weeks), their methadone should not be dispensed until they are reassessed by their prescriber for a dosage adjustment.

All missed doses are:

- Reported to the prescriber (refer to *Appendix K - Incident Report Form*, for example of a reporting tool option).
- Noted on *Appendix H-2 - Daily Witnessed Ingestion and Take-Home Dose Log*.

**NOTE:** It is essential that missed doses are not added to extend the end date of the prescription, i.e. if the original prescription is for seven days and two doses are missed, the additional two doses are not provided to the patient. All prescriptions are processed using a stop date in the patient record equal to the end date of the prescription.
The following table provides the required dosage changes for missed methadone doses as set out in the CPSNS Methadone Maintenance Treatment Handbook:

### Management of Missed Doses:

<table>
<thead>
<tr>
<th>Phase of Treatment</th>
<th>Missed Methadone Doses</th>
<th>Action/Dose change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Induction</td>
<td>1 day missed</td>
<td>Resume same dose.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Before proceeding to the next dose level patients must have both:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• At least 3 total days at the current dose, and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• At least 2 consecutive days at the current dose immediately before the dose increase.</td>
</tr>
<tr>
<td></td>
<td>2 days missed</td>
<td>Reduce the dose by 10mg for 2 consecutive days before increasing the dose again.</td>
</tr>
<tr>
<td></td>
<td>3 or more days missed</td>
<td>Restart the induction process at the initial dose (10-30mg).</td>
</tr>
<tr>
<td>Stabilization and Maintenance</td>
<td>1 or 2 days missed</td>
<td>Provide usual dose</td>
</tr>
<tr>
<td></td>
<td>3 or 4 days missed</td>
<td>Restart at 50% of the dose or 50 mg, whichever is higher. Increase dose by no more than 10 mg every 3 days until the original dose is reached.</td>
</tr>
<tr>
<td></td>
<td>5 or 6 days missed</td>
<td>Restart at 30 mg. Increase dose by no more than 10 mg every 3 days until the original dose is reached.</td>
</tr>
<tr>
<td></td>
<td>7 days or more missed</td>
<td>Restart MMT as a new patient according to the induction protocol.</td>
</tr>
</tbody>
</table>


### Missed Doses – Buprenorphine/Naloxone

Refer to CAMH Opioid Agonist Maintenance Treatment.
Guest Dosing

There are situations in which it may be appropriate for a patient to be provided with their methadone or buprenorphine/naloxone by another pharmacy on a temporary basis, including:

- the primary pharmacy will not be open and the patient is not considered functionally stable to be given take-home doses for the time period.
- the patient will be away for a longer period of time than for which a sufficient number of take-home doses can be appropriately provided. Note: Addiction Treatment Centers in other provinces can often facilitate identification of OAMT prescribers and pharmacies in their province.

In consultation with the patient, the pharmacist will collaborate with the prescriber to facilitate identifying a conveniently located guest pharmacy that would be willing to provide OAMT for the patient.

- The guest pharmacy must receive a separate prescription for the doses they are to provide.
- The pharmacist may resume the original prescription after the patient’s return if the prescriber has clearly indicated the appropriate dates on the prescription, although the end date on the original prescription must be followed. The pharmacist must take necessary steps to ensure that the patient is not receiving duplicate doses.

Alternatively, in planning for continuity of witnessed ingestion during infrequent and/or unplanned episodic closure of the pharmacy that may occur (e.g. Christmas, storms, etc.), the OAMT healthcare team (e.g. pharmacist, physician or nurse practitioner, other pharmacies, local hospital, etc.) may arrange for the patient to receive their witnessed dose at the local hospital. In these situations, the pharmacist must establish and implement a process that provides for continuity, security, and accountability of all doses, including:

- personally delivering the methadone and buprenorphine/naloxone doses, and the associated “Witnessed Ingestion” documentation log, to a licensed healthcare professional at the hospital; and obtaining their signature confirming receipt of the doses; and
- personally retrieving the completed “Witnessed Ingestion” documentation from the hospital and any non-administered doses.

The pharmacists at both pharmacies communicate clearly with one another at the beginning and end of the guest-dosing period, so that all those involved understand where (and when) the patient is receiving the methadone or buprenorphine/naloxone. It is imperative that double-dosing (an overlap) or missed dosing (a gap) not occur.

Note: All prescriptions for methadone or buprenorphine/naloxone are to be written on the duplicate prescription form approved by the Nova Scotia Prescription Monitoring Program (NSPMP) or e-prescribed through the provincial Drug Information System. For Canadian prescribers that have patients routinely traveling to Nova Scotia, they may register with NSPMP (i.e. for situations where an OAMT patient from outside Nova Scotia will be in Nova Scotia temporarily and requires provision of OAMT services while still under the care of their out-of-province prescriber). The out-of-province prescriber would be required to register with NSPMP to prescribe monitored drugs in Nova Scotia.
APPENDIX J – OAMT (METHADONE, BUPRENOORPHINE/NALOXONE) PRESCRIPTION ADJUSTMENT FORM

This form is used by the prescriber to adjust a patient’s OAMT therapy in accordance with the following criteria:

• The order references an original prescription which is written on a PMP prescription form and in the possession of the pharmacy;
• There are part-fills remaining on the original prescription;
• The change does not **increase** the total quantity of OAMT medication to be dispensed; and
• The change is for a specific patient (not a blanket order for a group of patients).

Please complete and fax to the pharmacy:

<table>
<thead>
<tr>
<th>Pharmacy Name:</th>
<th>Fax:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Health Card:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Original Prescription Number:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date of Original Prescription:</th>
<th>mm / dd / yyyy</th>
<th>Prescription Number:</th>
</tr>
</thead>
</table>

Treatment Adjustment Order:

As the prescribing physician/nurse practitioner, I certify that:

• the prescription represents the original of the OAMT Adjustment order;
• the addressee (i.e. pharmacy) is the only intended recipient and there are no others; and
• the original OAMT Adjustment order will be invalidated by marking it in such a way that it cannot be reissued.

Prescriber Name: ____________________________ Prescriber Licence Number: ________________

Prescriber Signature: ____________________________
APPENDIX K – INCIDENT REPORT FORM

Pharmacy Name:

Address:

Phone: Fax:

To: Primary Care Provider Fax:

Patient Name:

Today's Date: mm / dd / yyyy Date of Occurrence: mm / dd / yyyy

Pharmacist’s Report:

Pharmacist Name:

Pharmacist Signature:
APPENDIX L – AGAINST MEDICAL ADVICE

The pharmacist completes the following form in situations when the patient refuses to accept advice to seek medical care, especially in emergent situations such as an overdose.

Date:  mm / dd / yyyy

I, ________________________________________________________________, acknowledge that
__________________________________________________________________ explained my condition to me and advised me
of the potential risks and/or complications which could or would arise from refusal of medical care. I have
also been advised that other unknown risks and/or complications are possible. Being aware that there are
known and unknown potential risks and/or complications, it is still my desire to refuse the advised medical
care.

I hereby release ________________________________________________________ (pharmacist name)

and _______________________________________________________ (pharmacy name) from all liability
resulting from any adverse medical condition(s) caused by my refusal of the recommended medical care.

Signature of Patient/Parent/Legal Guardian:

Date:  mm / dd / yyyy

Witness:

Did witness act as translator?  □ YES    □ NO

Name of Translator:

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APPENDIX M – PROVISION OF OAMT SERVICES UNDER EXCEPTIONAL CIRCUMSTANCES

The provision of OAMT presents unique challenges than those associated with dispensing other medications. Solutions to these challenges are a shared responsibility between the patient, their primary prescriber, and pharmacists and need to be made in consideration of the fine balance of the unique exceptional circumstance and the public/patient risk of diversion and overdose. To support pharmacists in their efforts to continue to provide this critical service and to enable pharmacists to use their knowledge and skills to solve these challenges, the following provisions related to the Standards of Practice: Opioid Agonist Maintenance Treatment have been made.

Signatures

In instances where a signature is required, 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.

Witnessed Dosing (at the pharmacy or by delivery)

Pharmacists may decide who can provide witnessed dosing.

Pharmacists ensure that the person doing the witnessing has been given instruction on how to witness, how to 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, particularly if the witnessing is occurring outside of the pharmacy environment.

Pharmacists ensure documentation is completed for witnessed ingestion including documenting who witnessed the dose, and any other relevant patient care notes. (e.g., instances in which the patient did not consume the dose or did not consume the entire dose).

Take-Home Doses

Prescribers sometimes relax restrictions on take-home doses for certain patients. They have indicated that pharmacists’ expertise in patient assessments is highly valued and is an important contribution to making the following decisions:

- Whether patients receiving daily witnessed doses can be provided carries.
- Whether patients receiving carries can have the number of carries provided at one time increased.

Pharmacists may dispense prescriptions for OAMT as written (including providing the quantity of take-home doses as prescribed (written or verbal) and in accordance with the prescribed witnessing requirements) if they are satisfied it is appropriate to do so.

Provision of Doses for Patients Under Isolation

Should a patient be unable to come to the pharmacy to receive their dose because they are under isolation, the pharmacist may decide if delivery or alternative arrangements for pick-up at the pharmacy is a reasonable solution.
Delivery of Doses

Pharmacists may decide who can deliver to patients, however, in deciding whether delivery is a reasonable option, consideration needs to be given to:

- the ability of the person delivering the doses to identify the patient and to be safe while doing so.
- the security of the medications and the consequences resulting from their loss or diversion.
- the stability of the patient and their circumstances (e.g., housing, their ability to safely store doses, etc.), the extent to which it is critical for the patient’s safety that they be assessed prior to being provided their dose, and the ability for the person doing the delivery to do this assessment.

In situations where the pharmacy is delivering to the patient, effective witnessing may not be possible. Every effort should be made to collaborate with the physician to reserve the requirement for witnessing to only those where it is imperative. If consultation with the physician is not possible and a decision is made by the pharmacist that witnessing will not take place, this decision must be communicated to the physician at the earliest opportunity.

If witnessed dosing on delivery is imperative, pharmacists will decide how this will be accomplished. If feasible, efforts should be made to conduct a patient assessment remotely (e.g., telephone, virtual communication).

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

- the delivery process is explained to the patient prior to the delivery.
- the person making the delivery knows who they are authorized to release it to (the patient or an individual authorized by the patient).
- the person making the delivery understands that they do not need to put themselves in a position that threatens 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.).
- the dose is returned to the pharmacy if release to the patient or authorized person was not possible. For clarity, doses cannot be left at the door.
- the delivery is appropriately documented.
- the requirements below from Health Canada are met.

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:

1. 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
2. Has a copy of the Health Canada Section 56 Class Exemption in their possession while making the delivery.
In situations where the pharmacy cannot deliver the medication and the patient must have a witnessed dose, solutions could include:

- Having someone authorized by the patient, pick up, deliver, and witness the dosing.
- Having a member of the patient’s recovery team pick up, deliver and witness the dosing.
- Facilitating the transfer of care to a pharmacy that can accommodate the patient.