

Opioid Agonist Treatment Assessment Criteria

The following chart outlines the opioid agonist treatment (OAT) assessment criteria that are used by Community Operations Advisors (COAs) when conducting a community pharmacy assessment in a pharmacy that provides opioid agonist treatment. The document is divided into categories and for each category specific standards, which have been taken from relevant legislation, policies, guidelines or standards of practice, and are identified with a link to the appropriate reference. The guidance section illustrates specific insights or activities required to ensure adherence to the standard and is provided to assist Designated Managers and Pharmacy Staff in understanding expectations and preparing for a pharmacy assessment.

If you have received notice of an upcoming assessment, complete this document along with other applicable assessment criteria and have it ready to share with your COA when they visit. Ensure all staff members are aware of where the completed form is located should you not be present on the date the COA visits. For each standard, check the guidance that your pharmacy has in place and work on achieving the remaining criteria prior to the COA visit. Educational/Informational resources are also listed in the Guidance Column to assist you and your pharmacy in preparing for your upcoming assessment or to ensure that your pharmacy is up to standard.

Category: Opioid Policy	
STANDARD	GUIDANCE
<p>All members engaged in the dispensing of methadone have read the OCP Opioid Policy and the Key Requirements for Methadone Maintenance Treatment (MMT) Fact Sheet.</p> <p>Reference: Ontario College of Pharmacists Opioid Policy, Ontario College of Pharmacists Standards of Operation for Pharmacies</p>	<p><input type="checkbox"/> All members engaged in the dispensing of methadone must be familiar with (and have read) the current OCP Opioid Policy and the Key Requirements for Methadone Maintenance Treatment (MMT) Fact Sheet. These documents can be found at www.ocpinfo.com.</p>
Category: Reporting	
STANDARD	GUIDANCE
<p>The Designated Manager has informed OCP in writing that the pharmacy dispenses methadone.</p> <p>Reference: Ontario College of Pharmacists Opioid Policy, Ontario College of Pharmacists Standards of Operation for Pharmacies</p>	<p><input type="checkbox"/> Complete the Methadone Dispensing Notification Form (available at www.ocpinfo.com) and fax (416-847-8399) or email to pharmacyapplications@ocpinfo.com to notify OCP that the pharmacy dispenses methadone</p> <p><input type="checkbox"/> Complete the Methadone Dispensing Notification Form (available at www.ocpinfo.com) and fax (416-847-8399) or email to pharmacyapplications@ocpinfo.com to notify OCP in writing that you are no longer dispensing methadone.</p>

Category: Education and Training

STANDARD	GUIDANCE
<p>The DM and staff are up to date with opioid agonist treatment Education and Training Requirements.</p> <p>Reference: Ontario College of Pharmacists Opioid Policy, Ontario College of Pharmacists Standards of Operation for Pharmacies</p>	<p><input type="checkbox"/> The Designated Manager must be trained in methadone via the approved CAMH ODT course (either in-person or online) within 6 months of beginning a methadone practice.</p> <p><input type="checkbox"/> The Designated Manager must update MMT training every 5 years. Please attend the OPA Methadone, Buprenorphine and the Community Education Program or complete a minimum of 5 online modules (including “Policies Guiding Methadone Dispensing in Ontario”) from the OPA Opioid Addiction and Substitution Therapy Online Modules. The modules are located on the OPA website under Professional Development.</p> <p><input type="checkbox"/> At least one Staff Pharmacist must be trained in methadone via the approved CAMH ODT course (either in-person or online) (or approved course) within 1 year of beginning a methadone practice. Training to be updated every 5 years. Training update can be either the OPA Methadone, Buprenorphine and the Community Education Program or completion of a minimum of 5 online modules (including “Policies Guiding Methadone Dispensing in Ontario”) from the OPA Opioid Addiction and Substitution Therapy Online Modules. The modules are located on the OPA website under Professional Development.</p> <p><input type="checkbox"/> All Pharmacy Staff must be familiar with the Fact Sheet - <i>Key Requirements for Methadone Maintenance Treatment (MMT)</i> which can be found on the OCP website.</p> <p><input type="checkbox"/> OPA provides a toolkit for all pharmacists for Methadone Dispensing. The OPA Methadone Toolkit for Pharmacists is available at www.opatoday.com.</p>

Category: Required References

STANDARD	GUIDANCE
<p>The Pharmacy has access to current copies of the Required References to safely engage in the dispensing of opioid agonist treatment.</p> <p>Reference: Ontario College of Pharmacists Opioid Policy, Ontario College of Pharmacists Standards of Operation for Pharmacies</p>	<p><input type="checkbox"/> The Pharmacy must obtain a current edition of the <i>Opioid Agonist Maintenance Treatment: A Pharmacist’s Guide to Methadone and Buprenorphine for Opioid Use Disorder</i> by CAMH. Ensure all staff have read and understood its content.</p> <p><input type="checkbox"/> The Pharmacy must ensure access to the current CPSO <i>Methadone Maintenance Treatment for Opioid Dependence Policy</i> and the <i>Methadone Maintenance Treatment Program Standards and Clinical Guidelines</i>. (Both are available online at www.cpso.on.ca).</p>

Category: Policy and Procedures

STANDARD	GUIDANCE
<p>The Pharmacy has policies and procedures in place to ensure safe dispensing of OAT therapy.</p> <p>Reference: Ontario College of Pharmacists Opioid Policy, Ontario College of Pharmacists Standards of Operation for Pharmacies</p>	<input type="checkbox"/> The Pharmacy must have policies and procedures in place to ensure the safe dispensing of OAT therapy including continuity of patient care, appropriate storage of OAT medications and secure custody.
	<input type="checkbox"/> The Pharmacy must discuss with the patient the use of precautionary measures and security (such as locked boxes and/or bottle return) when dispensing methadone for MMT.

Category: Patient Agreement

STANDARD	GUIDANCE
<p>A written agreement serves as best practice to outline expectations and prevent miscommunication.</p> <p>Reference: Ontario College of Pharmacists Opioid Policy, Ontario College of Pharmacists Standards of Operation for Pharmacies</p>	<input type="checkbox"/> Revise the MMT agreement to reflect the current Opioid Policy and your practice.
	<input type="checkbox"/> The agreements should be signed and dated by the Patient and Pharmacist (and prescriber if using a 3 way agreement) and outline the expectations of all parties involved.
	<input type="checkbox"/> Copies of the signed Methadone/Buprenorphine agreement should be readily retrievable.
	<input type="checkbox"/> A written patient agreement serves as best practice to outline expectations and prevent miscommunication. Please review <i>Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorder</i> by CAMH.
	<input type="checkbox"/> Revise the Buprenorphine agreement to reflect the current Opioid policy and your practice.

Category: Preparation of Final Dosage

STANDARD	GUIDANCE
<p>Daily doses of methadone (drink and carries) are accurately prepared and packaged according to legal and professional requirements.</p> <p>Reference: Ontario College of Pharmacists Opioid Policy, Ontario College of Pharmacists Standards of Operation for Pharmacies</p>	<input type="checkbox"/> Methadone doses (daily and carries) must be prepared using a manufactured product.
	<input type="checkbox"/> Methadone doses (daily and carries) must be dispensed in a total volume of approximately 100mL.
	<input type="checkbox"/> All doses of methadone for MMT must be diluted with an appropriate vehicle (e.g., Tang).
	<input type="checkbox"/> Methadone doses must be measured using a device that is calibrated to deliver doses accurately and precisely.
	<input type="checkbox"/> All methadone carry doses shall be dispensed with child-proof safety caps.

Category: Exceptional Dispensing of a Compounded Product

STANDARD	GUIDANCE
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<p>The Pharmacy dispenses a compounded methadone product only under exceptional circumstances.</p> <p>Reference: Ontario College of Pharmacists Opioid Policy, Ontario College of Pharmacists Standards of Operation for Pharmacies, Health Canada Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051) (2009)</p>	<p><input type="checkbox"/> The Pharmacy should only dispense a compounded methadone product in the event of a therapeutic need or lack of product availability.</p>
<p>Category: Labelling</p>	
<p>STANDARD</p>	<p>GUIDANCE</p>
<p>The labels for dispensed methadone meet all the requirements of the DPRA, s. 156, the Opioid Policy as well as the Standards of Operation.</p> <p>Reference: Ontario College of Pharmacists Opioid Policy, Ontario College of Pharmacists Standards of Operation for Pharmacies</p>	<p><input type="checkbox"/> Each dose of methadone must be clearly labelled with the total dose in mg of methadone contained in the bottle.</p> <p><input type="checkbox"/> The directions for use on the prescription label must be clear and easily understood by the patient/agent -- Drink entire contents of bottle daily.</p> <p><input type="checkbox"/> Carry doses must be clearly labelled with the date of ingestion.</p> <p><input type="checkbox"/> Carry doses must be clearly labelled 'Keep Refrigerated'</p> <p><input type="checkbox"/> Ensure the following information is included on the container -- 'Methadone may cause serious harm to someone other than the intended patient. Not to be used by anyone other than the patient for whom it was intended. MAY BE FATAL TO CHILD OR ADULT' or 'Methadone may cause serious harm to someone other than the intended patient. MAY BE FATAL TO CHILD OR ADULT'.</p> <p><input type="checkbox"/> The label must reflect the current day of dispensing as outlined in the DPRA, s. 156.</p> <p><input type="checkbox"/> Pharmacy staff should review the CAMH guide for guidance on labelling.</p>
<p>Category: Assessment and Administration of Dose</p>	
<p>STANDARD</p>	<p>GUIDANCE</p>
<p>There is a process in place for patient assessment followed by the administration of the opioid agonist treatment dose.</p> <p>Reference: Ontario College of Pharmacists Opioid Policy, Ontario College of Pharmacists Standards of Operation for Pharmacies</p>	<p><input type="checkbox"/> The Patient must be positively identified prior to witnessing the ingestion of the treatment dose and/or providing carry doses. The system in place must protect patient confidentiality.</p> <p><input type="checkbox"/> The Pharmacist must witness and verify the consumption of the treatment dose.</p> <p><input type="checkbox"/> The Pharmacist must assess the patient before (to determine appropriateness) and after the consumption of the treatment dose.</p> <p><input type="checkbox"/> Administration of treatment dose should be done in an area and manner which ensures patient privacy and</p>

confidentiality.

- The pharmacy must develop a process to assess the patients to ensure that it is appropriate for them to consume the treatment dose: gather information about any changes to the patient's prescription and over the counter and natural health product use or general health status, side effects and effectiveness of treatment.

Category: Communication and Documentation

STANDARD	GUIDANCE
<p>Communication and documentation related to opioid agonist treatment is complete, timely and readily retrievable.</p> <p>Reference: Ontario College of Pharmacists Opioid Policy, Ontario College of Pharmacists Standards of Operation for Pharmacies</p>	<ul style="list-style-type: none"> <input type="checkbox"/> The observation of methadone ingestion must be documented daily in the patient record so that it can be determined where each dose of methadone went, for both patient care and auditing purposes. <input type="checkbox"/> Documentation of methadone ingestion must include the patient's name, daily dose, date, time and place where the administration was observed. <input type="checkbox"/> All documentation pertaining to methadone must provide an audit trail and be readily retrievable. <input type="checkbox"/> A procedure must be in place to detect and notify the prescriber of missed doses. <input type="checkbox"/> The pharmacy must develop a process to document all clinically relevant data gathered during patient assessment (i.e. management of relevant drug interactions, review of relevant NMS data, changes in clinical status) in the patient record, in a readily retrievable way, to ensure continuity of care.

Category: Unused Doses of Methadone

STANDARD	GUIDANCE
<p>Unused methadone (individually labelled doses of methadone and returned doses) are managed and destroyed in accordance with applicable laws, standards of practice, and OCP Policy.</p> <p>Reference: Ontario College of Pharmacists Opioid Policy, Ontario College of Pharmacists Standards of Operation for Pharmacies</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Unused methadone (individually labelled and returned doses) must be destroyed in accordance with applicable laws, standards of practice, and OCP policy. Approval from Health Canada is not needed prior to the destruction. Please refer to the OCP Fact Sheet - <i>Destruction of Narcotics, Controlled Drugs, and Targeted Substances</i>. <input type="checkbox"/> Unexplained wastage or loss of Methadone (powder or solution) must be reported to the Office of Controlled Substances (Health Canada). <input type="checkbox"/> Patient confidentiality must be maintained on returned bottles.

Category: Institutional Services

STANDARD	GUIDANCE
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The Pharmacy provides methadone doses to institutions such as long term care facilities, correctional institutes or hospitals.

Reference: [Ontario College of Pharmacists Opioid Policy](#), [Ontario College of Pharmacists Standards of Operation for Pharmacies](#)

The institution should have established policies which outline the secure handing and safe administration of methadone doses.

Category: Transferring Custody

STANDARD

The Pharmacy has policies and procedures in place to address transfer of custody arrangements.

Reference: [Ontario College of Pharmacists Opioid Policy](#), [Ontario College of Pharmacists Standards of Operation for Pharmacies](#)

GUIDANCE

- The individually labelled methadone doses must be transferred to a Physician or their delegate.
- The Pharmacist is accountable for the safety and integrity of prepared methadone doses until custody has been transferred to a physician/physician's delegate. The transportation of doses must be secure, tamper-proof, auditable and traceable. The Pharmacy must have signed records for receipt of the transferred doses.
- The Physician or delegate must sign the patient manifest on a daily basis to confirm that they have received each dose.
- A record of administration for each dose received by the Physician or his/her delegate must be provided to the Pharmacy on a daily basis.
- All documentation pertaining to methadone must provide an audit trail and be readily retrievable.
- A daily reconciliation of the methadone dispensed to and received from a treatment location must be conducted in such a manner that would allow for immediate detection of any losses or diverted quantities.
- Unused doses must be returned to the Pharmacy by the Physician or his/her delegate daily, signed for upon receipt and entered into the appropriate record.
- Records of the returned methadone doses must include the total number of doses (bottles) and the total number of mg of methadone. Records of returned doses must be verified and signed by the Pharmacist.