



College of Pharmacists
of British Columbia

Methadone Maintenance Treatment: Enforcing Standards

Four Year Action Plan
2015 - 2018

Purpose

The purpose of this document is to outline an action plan that will address serious issues and concerns identified by stakeholders related to the provision of Methadone Maintenance Treatment (MMT) pharmacy services for the people of British Columbia.

Background and Context

MMT is a complex area of pharmacy practice that is multi-faceted, cross-professional, and cross-jurisdictional. Although the College has taken a number of significant steps towards improving MMT pharmacy care in BC over the past 9 years, concerns still exist. These concerns have been identified through the findings of the College's complaints resolution department, recent media reports, and the College's MMT patient liaison working group which also aligns with the recent Ministry report findings.

Complaints Resolution

Over the past 2 years the College has received over 130 complaints and "tips" regarding the dispensing of methadone maintenance therapy from pharmacies. All complaints are dealt with through the established complaints resolution process as defined in legislation, and "tips" are investigated to determine whether referral to the Inquiry Committee is necessary. Concerns that have emerged as a result of complaint or tip investigations are:

- Provision of inducements (both monetary and non-monetary) to patients to retain or attract methadone patients.
- Non-compliance with legislative requirements such as:
 - Falsely processing prescriptions on PharmaNet when patients did not attend at the pharmacy to receive their medications,
 - Pharmacists' failure to witness ingestion of methadone when prescribed by the physician,
 - Changing prescriptions to daily dispensing that is not in compliance with standards or authority.
- Premises where the pharmacy is located is not suitable or maintained appropriately for pharmacy practice. Examples of unsuitable or poorly maintained premises include, but are not limited to:
 - Does not meet professional standards for cleanliness (e.g., mold, evidence of rodents or insects, or other unsanitary conditions),
 - Not well maintained and does not facilitate a safe working environment (e.g., dilapidated facilities, cluttered, disorganized, or dirty work spaces),
 - Not adequately heated, lighted, or ventilated.

MMT Patient Liaison Working Group

In 2013, the College formed a methadone maintenance patient liaison working group that meets biannually with methadone patients and the College of Physicians and Surgeons of BC (CPSBC) to provide: a structured forum for dialogue, an opportunity to build collaboration, and to explore strategies for positive change. Through this working group, the patients identified significant concerns with their ability to maintain their continuity of care which has been compromised by:

- Pharmacists and pharmacy owners limiting patient choice:
 - Coercion to use a specific pharmacy in exchange for housing or incentives,
 - Discrimination against ethnic groups.
- Quality of pharmacy care:
 - Withholding dose to penalize patient for breaching loyalty to pharmacy,
 - Unsanitary conditions of pharmacy.

Ministry of Health Report 2015

In January 2015, the Medical Beneficiary and Pharmaceutical Services Division of the Ministry of Health reviewed and published a report regarding PharmaCare's Methadone Maintenance Payment Program (MMPP) and, more broadly, MMT in British Columbia. The report examines the current state of service delivery and highlights several challenges with the current MMPP model.

The report highlights several areas of concern for the College:

- Concentration of pharmacies in Surrey, Vancouver Downtown Eastside, and Vancouver-Midtown that service large numbers of methadone patients which appears to result in poor patient care and issues with the accuracy of submitted claims to PharmaCare.
- Pharmacies that concentrate in high volume methadone dispensing have premises that appear inappropriate for the delivery of a health care service.
- Improper billing of methadone claims and the offering of inducements for methadone prescriptions.
- Problematic pharmacy practices which included failure to witness ingestion on delivered methadone, pressuring clients to request daily witnessed ingestion even when not prescribed by the physician, and coercive practice to make clients use a particular pharmacy.
- Lack of appropriate pharmaceutical care being provided to complex patients in that methadone focused dispensing pharmacies are not performing medication management reviews which would reduce the risk of drug therapy problems.

College Actions to Date

The College has lead the development of significant work to enhance MMT pharmacy care in BC. This work has focused on establishing minimum practice standards for MMT dispensing, initiating and completing undercover investigations of pharmacies to identify unethical and inappropriate practice, as well as establishing a patient liaison working group and building

broader stakeholder relationships. The following table summarizes the work the College has accomplished to date.

Year	Key Accomplishments
2007	<ul style="list-style-type: none"> • Guidelines specific to methadone dispensing were published for the first time and were subsequently updated.
2008	<ul style="list-style-type: none"> • College 2008-2013 Strategic Plan included the following goal and objective: <ul style="list-style-type: none"> ○ Strategic Goal 1: The enhanced and expanded care and services that registrants deliver are safe and effective and aligned with the health care needs of the public. ○ Goal 1 Objectives: Continue to address issues around methadone maintenance treatment.
2009	<ul style="list-style-type: none"> • A new bylaw was implemented in response to complaints regarding restriction of patient choice. The purpose of the bylaw was to ensure that registrants did not limit their patients' right to choose their own health care delivery with respect to pharmacy service.
2010	<ul style="list-style-type: none"> • The Ministry of Health and the College jointly determined that undercover operations should be performed at those pharmacies that had been the subject of the most serious and frequent complaints with respect to MMT practice infractions. • A total of 9 pharmacies and 31 registrants were subject to undercover investigations between 2010 and 2012. • November 2010, the Board approved Professional Practice Policy 66 – <i>Methadone Maintenance Treatment</i> (PPP-66). The purpose of PPP-66 was to ensure that: <ul style="list-style-type: none"> ○ Patients had access to standardized MMT pharmacy services, ○ Patients experienced reduced risk potential while receiving MMT services, ○ Pharmacists had up-to-date knowledge and information to meet their patients' needs, and ○ Pharmacies had adequate resources and capacity.
2011	<ul style="list-style-type: none"> • PPP-66 came into effect on September 30, 2011. By January 1, 2012, participating pharmacies and pharmacists were required to implement all necessary practice requirements. • In conjunction with the policy, the College developed a policy guide that further articulated the standards and guidelines for MMT dispensing. • The Board required mandatory training for all pharmacists involved in methadone dispensing for PPP-66 and the accompanying guide. • The College provided training to pharmacists via 26 live sessions around the province in March 2011. Approximately 1,200 pharmacists took part in these sessions. • For those who could not attend a live session or for new registrants, an on-line module was created and made available on the College website.
2012	<ul style="list-style-type: none"> • In 2012 the College provided inter-professional clinical education sessions for pharmacists regarding addiction medicine. 15 live sessions were held throughout the province with attendance by 575 registrants. • In Fall 2012, the pharmaceutical manufacturer Mallinckrodt announced the imminent Health Canada approval of a commercially available 10mg/ml methadone oral solution. As a result, a joint working group was established with representatives from College, the CPSBC and the Ministry of Health, Pharmaceutical Services Division.

	<ul style="list-style-type: none"> The working group met a number of times from November 2012 to June 2013 to identify issues, requirements and timelines for consideration to implement coverage of methadone 10mg/ml oral solution
2013	<ul style="list-style-type: none"> September 20, 2013 the Board approved the updated PPP-66 policy - effective February 1, 2014. Mandatory training was again required by the Board regarding this change - 23 in-person training sessions were conducted in Summer/Fall 2013 for pharmacists and pharmacy technicians. The online module was also updated for those that could not attend the live sessions. <ul style="list-style-type: none"> Overall, 3863 pharmacists and 389 pharmacy technicians were trained.
2014	<ul style="list-style-type: none"> The Inquiry Committee reviewed the undercover results of the 9 pharmacies and 31 registrants and arrived at the following dispositions (<i>note: 14/31 registrants have multiples of the dispositions noted below</i>) <ul style="list-style-type: none"> 15 registrants: letters of undertaking (to not repeat the conduct and complete remedial actions), 1 registrant: changes licensure status to former (signs consent agreement to never apply for reinstatement or registration in another jurisdiction), 3 registrants: retake jurisprudence exam, 7 registrants: letters of reprimand, 3 registrants: pay a fine of \$15,000 each, 1 registrant: pays a fine of \$5,000, 1 registrant: pays a fine of \$2,500, 3 registrants: suspended for 90 days, 1 registrant: cannot be a manager, owner, or director for a period of 2 years, 1 registrant (owner/director/manager): referred to discipline committee, 1 non-pharmacist owner – college to file a court injunction for “unauthorized practice” (practicing without a license). <p>Note: <i>The results of the undercover investigations enabled the Ministry of Health to successfully take action against pharmacies in contravention of their PharmaCare agreements. The Ministry achieved the following:</i></p> <ul style="list-style-type: none"> 6 pharmacies had their enrollment in PharmaCare terminated, One pharmacy was closed, One case is outstanding.

Moving Forward: Four Year Action Plan

The action plan sets a 4 year time frame focused on enforcing standards and includes goals that focus on pharmacies not meeting legislative requirements, practice and ethical standards and pharmacists that have been identified as engaging in unethical or fraudulent activity; and longer term goals that focus on enhancing the legislative structure for greater enforcement capability, continuing effective investigations and discipline and enhancing stakeholder relationships. These goals have been chosen for their ability to foster ongoing sustainable positive change, alignment with the College Values and alignment with Ministry objectives to enhance safety and effectiveness in MMT. Over the next 4 years (2015-2018) the College will undertake the following actions:

Undercover Investigations

To identify problematic practices which cannot be observed during regular inspections the College, in collaboration with the Ministry of Health, will develop, plan and implement a minimum of 6 new undercover investigations. The undercover investigations will occur over the 4 year period of the action plan and will focus on the identification of non-compliance with legislative requirements, practice standards, and ethical standards. Based on the findings of the investigations, the College will take appropriate action, including, if justified, referral to the Inquiry Committee.

Focused Inspections

To reinforce the College's commitment to ensure registrants are adhering to the standards of practice in MMT dispensing, the College will conduct priority inspections of MMT dispensing pharmacies. A minimum of 40 priority inspections will be completed over the 4 years and will focus on the following areas:

- Premises which are not appropriate for the practice of pharmacy,
- MMT focused dispensing pharmacies that have been denied enrollment in or have had their enrollment terminated by PharmaCare, and
- The top 20 MMT dispensing pharmacies (by PharmaCare expenditure).

If the priority inspections return unacceptable findings, the College will take appropriate action to mitigate these concerns, including referral to the Inquiry Committee as necessary.

Stakeholder Relations

MMT practice is complex and delivered through the collaborative efforts of a number of organizations; therefore good working relationships with stakeholders is a key element in this action plan. The College will continue to build and enhance relationships with patients, municipalities, the Ministry of Health, Health Authorities, other regulatory bodies, and health care providers. The College will participate in regular meetings and collaborate with key stakeholders in order to address a number of concerns including:

- Keeping stakeholders informed and involved,
- Supporting transparency and accountability,
- Co-ordinating organizational resources, and
- Pre-empting unintended consequences.

Legislation Review

The College will review and provide recommendations to the Board to:

- Strengthen pharmacy licensure requirements for MMT dispensing, and
- Strengthen pharmacist and pharmacy technician registration requirements for dispensing of MMT.

The legislation review will identify the limitations of the current regulatory tools to manage licensure issues in a preventative manner and deliver a gap analysis that will result in drafting of enhanced licensure bylaws and policy to support enhanced enforcement. The review will also explore the feasibility and value of pharmacist certification for MMT dispensing to ensure registrants have the necessary knowledge, skills and abilities for this complex area of care. If the feasibility review is positive then pharmacist certification requirements will be drafted and presented to the Board for approval.

Report to the Board

The Registrar will report to the Board on progress on the action plan at regularly scheduled board meetings.

Conclusion

In response to complaints received at the College, investigations conducted, recent media reports, and a 2015 Ministry of Health report focused on PharmaCare's MMPP and MMT in BC, a 4 year action plan has been developed by the College to address issues and concerns and bring about positive, sustainable change for MMT pharmacy practice in BC.