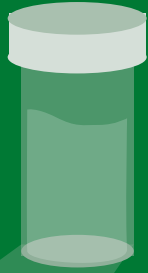


Changes to the Methadone Exemption Process



Information for all physicians

Nothing. You are still able to prescribe buprenorphine/naloxone, and just like above, you are expected to follow the standards and guidelines related to the prescribing of buprenorphine/naloxone for addiction. You will continue to be subject to review and audit by CPSS in relation to educational requirements and compliance with the standards.

Q - I don't have a methadone exemption, but I am in the midst of working toward completing the requirements to prescribe BUPRENORPHINE/NALOXONE. Now what?

All physicians need to meet the College's standards for prescribing buprenorphine/naloxone. Those requirements include educational requirements, the availability of resources to manage patients with addictions and agreeing to an audit of their practices. The requirements are contained in **Regulatory Bylaw 19.1** which states:

(b) No physician shall prescribe buprenorphine for the treatment of addiction unless:

- (i) The physician has taken an educational program on prescribing of buprenorphine approved by the Council; and,
- (ii) The physician has access to one or more addiction counselors and one or more pharmacists to provide patients the full range of treatment options; and,
- (iii) The physician has established a program for the regular testing of patients receiving buprenorphine for drugs of possible abuse; and,
- (iv) The physician has access to the Pharmaceutical Information Program to permit monitoring of drugs prescribed to those patients for whom the physician has prescribed buprenorphine.

(c) No physician shall prescribe buprenorphine for treatment of addiction unless:

- (i) The physician has received an exemption from Health Canada to allow that physician to prescribe methadone for the purpose of treating addiction; or
- (ii) The physician has spent a minimum of one day with another physician who has received an exemption from Health Canada to allow that physician to prescribe methadone for the purpose of treating addiction, who has met the requirements of this bylaw to prescribe buprenorphine and who prescribes buprenorphine as part of his/her regular practice.

(d) Physicians who prescribe buprenorphine for treatment of addiction shall, as a condition of prescribing buprenorphine, participate in a program of continuing medical education which includes a minimum of six hours every two years in addiction medicine.

What physicians need to know about the upcoming changes to the Health Canada methadone exemption process

Health Canada will soon no longer require physicians to apply for a methadone exemption. So what does this mean for Saskatchewan physicians wishing to prescribe methadone and/or buprenorphine/naloxone? Below are answers to the questions we anticipate physicians may be asking.

Q - I already hold a METHADONE exemption to prescribe for addiction and/or pain. What changes for me?

Nothing. You are still able to prescribe methadone and are expected to follow the standards, guidelines and policies related to methadone and its indication for use (pain versus addiction). You no longer have to renew your methadone exemption with Health Canada every three years, but will continue to be subject to review and audit by CPSS in relation to educational requirements and compliance with the standards.

Q - I also prescribe BUPRENORPHINE/NALOXONE for addiction, in addition to methadone. Does that change anything?

Nothing changes in relation to your prescribing of buprenorphine/naloxone. The expectations remain the same.

Q - I don't have a methadone exemption, but I previously met the requirements to allow me to prescribe BUPRENORPHINE/NALOXONE for addiction. What changes for me?





(e) Physicians who wish to prescribe buprenorphine for treatment of addiction shall, as a condition of doing so, sign an undertaking in which they agree that:

- (i) Their prescribing of buprenorphine may be audited on such terms and at such times as may be required by the College of Physicians and Surgeons; and,
- (ii) They will co-operate with any such audit or audits; and
- (iii) They will follow the requirements of this by-law pertaining to the prescribing of buprenorphine.

Q - I don't have a methadone exemption, but I am in the midst of working toward completing the requirements to prescribe METHADONE. Now what?

All physicians need to meet the College's standards for prescribing methadone. Those requirements include educational requirements, the availability of resources to manage patients with addictions and agreeing to an audit of their practices. The requirements are contained in the College document **Standard Opioid Substitution Therapy Guidelines and Standards for the Treatment of Opioid Addiction/Dependence**, available at <https://www.cps.sk.ca/iMIS/Documents/Legislation/Policies/SK%20OST%20Therapy%20Guidelines%20and%20Standards.pdf> and the document **Methadone Prescribing** available at https://www.cps.sk.ca/imis/CPSS/Legislation_ByLaws_Policies_and_Guidelines/Legislation_Content/Policies_and_Guidelines_Content/Methadone_Prescribing.aspx.

The **Opioid Substitution Therapy Standards** state:

1. Initiating Physicians must have a license to practice medicine in Saskatchewan.
2. Initiating Physicians must have an exemption granted by the Office of Controlled Substances, Health Canada, to prescribe methadone for the treatment of opioid dependence.
3. Initiating Physicians will have the following training and experience:
 - a) Completion of a MMT workshop/course recognized by the CPSS
 - b) A period of direct training (2 days), supervision and

mentorship with an experienced, CPSS-approved Initiating Physician until approved as competent in MMT

c) Documentation of clinical competence

d) College approved mentorship and support from an established Methadone prescriber, during the first two years of practice.

4. Initiating Physicians will pursue ongoing education relevant to MMT. Physicians must provide documentation of MMT-related education that is acceptable to the CPSS. Examples of education acceptable to the CPSS are:

a) Completion of a recognized course on the fundamentals of addiction medicine within 2 years of acquiring a methadone exemption

b) a minimum of 30 hours of formal Continuing Medical Education (CME) in addiction medicine every five years.

c) education equivalent acceptable to the Council of the CPSS

5. Initiating Physicians must access the PIP Viewer prescribing database.
6. An interview with the Registrar of the CPSS or his/her designate may be required.
7. Initiating Physicians must have access to laboratory services and a pharmacy.
8. If the Initiating Physician is going to be away or is suspending their practice, he/she must ensure the patient receives continued care from another physician trained in MMT according to standards described in the CPSS's Standards of Practice.
9. Initiating Physicians must collaborate with Maintaining Physicians that are continuing to provide MMT to former patients, and with the pharmacists that are dispensing to current patients.
10. New Methadone prescribers will be limited to a maximum of 50 patients until the first audit.
11. Initiating Physicians should make reasonable efforts to provide non-pharmacological support to their patients (e.g.: pharmacy, addiction services, counselling, etc.).



The document **Methadone Prescribing** states:

Physicians authorized to prescribe Methadone in the management of opioid use disorder are:

1. Required to attend a methadone workshop for physicians approved by the College of Physicians and Surgeons of Saskatchewan;
2. Required to work under the preceptorship of a methadone prescriber in Saskatchewan for at least two days prior to seeing patients in their own practice;
3. Strongly encouraged to be a member of a multidisciplinary treatment team that offers medical and psycho-social assessment to patients;
4. Required to have access to counseling and aftercare services for their patients;
5. Required to have adequate provision for appropriate methadone dispensing, administration, and urine drug testing according to Health Canada guidelines and the Saskatchewan Opioid Substitution Therapy Guidelines and Standards for the Treatment of Opioid Addiction/Dependence;
6. Strongly encouraged to be a member of the Canadian Society for Addiction Medicine or the American Society for Addiction Medicine;
7. Recommended to obtain five hours per year of continuing medical education in the field of addiction medicine;
8. Aware that an interview with the Registrar of the College of Physicians and Surgeons of Saskatchewan or his/her designate may be required.
9. Required to agree in writing to an audit of their methadone practice by the College of Physicians and Surgeons of Saskatchewan as may be required by the College.

Q - I don't have a methadone exemption, nor have I been approved to prescribe buprenorphine/naloxone, but I think I might pursue this in the future. Will the requirements be different in the future (e.g. in a few months from now)?

Currently, the CPSS is putting a bylaw amendment proposal forward for consideration by the CPSS Council and if approved, the Ministry. This bylaw will establish further expectations, including a requirement that a physician cannot prescribe methadone or buprenorphine/naloxone for addiction unless the Registrar has approved the physician to do so. When this bylaw is approved physicians will be notified and will be expected to meet the requirements outlined in both the bylaw and the standards in order to prescribe either methadone or buprenorphine/naloxone.

For more information, please contact:

Julia Bareham
Pharmacist Manager
Prescription Review Program
prp@cps.sk.ca
306-244-7355