



Low-Dose (Exempted) Codeine Products – Conditions of Sale

1. PURPOSE

In November 2019, Council expanded its standards of practice in response to increasing concerns from members regarding misuse of low-dose (exempted) codeine products. These standards will require pharmacists who wish to sell low-dose (exempted) codeine products, to take mandatory training and use evidence-based guidelines developed by [medSask](#).

By increasing the conditions of sale for low-dose (exempted) codeine products, pharmacists will have tools to determine appropriate use and safer alternative therapies when available, including over-the-counter and non-pharmacological therapies. It will also help pharmacists to determine when a referral to other resources, and/or health care providers, is in the best interest of the patient.

Packaging requirements come from the [Food and Drugs Act \(FDA\)](#) and the [Food and Drug Regulations \(FDR\)](#), and apply to all non-prescription drugs sold to the public. Section 36 of the [Narcotic Control Regulations \(NCR\)](#) defines formulation and additional labeling requirements for low-dose (exempted) codeine products. Sections 7 and 8 of Part J of the SCPP [Regulatory Bylaws](#) set restrictions on the purchase, stocking, and sale of low-dose (exempted) codeine products with a limit of 50 solid dosage units or 100 mL of liquid.

Reminder

The onus is on the PHARMACIST to refuse sale for an low-dose (exempted) codeine product where there are reasonable grounds for believing that the drug may be used by a person for other than a recognized medical or dental purpose. Pursuant to section 36 of the [Narcotic Control Regulations](#), the sale may be made only for a bona fide medical or dental reason.

Summary and Application of Restrictions in SCPP Regulatory Bylaws:

For the purposes of section 7 of Part J, of the [Regulatory Bylaws](#), “prohibited drugs” are low-dose (exempted) codeine products sold as Schedule I or II. As described in section 7 and 8 of Part J of the [Regulatory Bylaws](#):

- The maximum amount of low-dose (exempted) codeine products for nonprescription sales cannot exceed fifty (50) solid dosage units or one hundred (100) mL of liquid preparations;

- Pharmacies are not permitted to **purchase, store or repackage** pack sizes exceeding the above quantities for prescription and non-prescription sales.
- Only one (1) consumer package of low-dose (exempted) codeine product may be sold per occasion. Multiple sales are not permitted.

Low-dose (exempted) codeine products sold pursuant to a prescription by a physician, dentist or nurse practitioner may be dispensed in quantities beyond these limits.

However, this must be done so according to pack size restrictions. For example, a prescription for 100 tablets must be filled from two 50 tablet bottles and not a 100-tablet bottle.

The training is not mandatory in pharmacies that choose to stock low-dose (exempted) codeine products solely for the purpose of dispensing prescriptions, however it is required for those that sell low-dose (exempted) codeine products as a Schedule II drug.

Pursuant to section 36 of the [Narcotic Control Regulations](#), when selling without a prescription, pharmacies may not repackage low-dose (exempted) codeine products to dispense smaller quantities than what is commercially available.

2. TRAINING REQUIREMENT

- 2.1. Low-dose (exempted) codeine products may only be sold as a Schedule II drug, by a licensed pharmacist, or a pharmacist intern under the immediate supervision of a licensed pharmacist, who have completed the low-dose (exempted) codeine products education and training developed by medSask.

Codeine Safety Information

Pharmacists selling low-dose (exempted) codeine products are responsible for keeping up to date on safety information, guidelines and legislation regarding their use and sale. Such information includes advisories from Health Canada regarding codeine use in children under 18 years of age:

- [Prescription Cough and Cold Products Containing Opioids and the Risk of Opioid Use Disorder in Children and Adolescents](#), August 24, 2020.
- [Non-prescription pain relief products containing codeine are not recommended for use in people under 18 years of age](#), July 31, 2020.

3. STANDARDS OF PRACTICE

Practice Tip

Professional judgement must be used to determine the appropriate degree of verification required to fulfill the intent of the SCPP [Patient Identification Verification Policy](#).

- 3.1. The licensed pharmacist, or pharmacist intern under the immediate supervision of a licensed pharmacist, must:
 - 3.1.1. Use the [medSask](#) guidelines to make inquiries to reasonably determine the appropriateness of low-dose (exempted) codeine products for the patient's self-assessed condition or self-care treatment;
 - 3.1.2. Review the local and [Pharmaceutical Information Program \(PIP\)](#) profiles upon each request, and communicate with the patient or the patient's agent any usage which the pharmacist deems problematic;

Low-Dose (Exempted) Codeine Products for Patients on Opioid Agonist Therapy (OAT)

It may be revealed during the assessment or while reviewing the PIP that the patient is taking OAT (e.g. methadone or buprenorphine/naloxone). Pharmacists must take the opportunity to educate the patient on the contraindications associated with taking low-dose (exempted) codeine products while on OAT, and recommend non-opioid alternatives if not tried, or refer the patient to an appropriate member of the health care team. See the medSask Exempted Codeine Guidelines and SCPP [OAT Standards](#) for further information.

- 3.1.3. Complete the pharmacist assessment record (PAR) to document rationale for selling low-dose (exempted) codeine products. (Note: since low-dose (exempted) codeine products are Schedule II drugs, the PAR does not need to be communicated to the patient's primary practitioner, however, it must be kept on file as the SCPP may request to see the documentation.)

Scope of Practice Clarification

Although section 2(1) of the [Controlled Drugs and Substances Act \(CDSA\)](#) defines **sell** as:

includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration.

In Saskatchewan, the SCPP permits the actual purchase, where there is payment for the product, to be delegated to a non-professional.

4. DOCUMENTATION

- 4.1. As required in section 8 of Part J of the [Regulatory Bylaws](#), the sale must be documented on the Patient Profile for the person purchasing the low-dose (exempted) codeine product. At a minimum, the documentation must include:
 - 4.1.1. Date of purchase;
 - 4.1.2. Product name;
 - 4.1.3. Quantity sold.
- 4.2. All sales of low-dose (exempted) codeine products must be accompanied by a PAR documenting the assessment. See SCPP [Record Keeping Requirements](#) for additional requirements for patient records.
- 4.3. The Drug Plan and Extended Benefits Branch (DPEBB) requires pharmacies to record low-dose (exempted) codeine product sales in the [PIP](#) and DPEBB profiles of the individual who is purchasing the product, **and** for whom it is intended, if different. See Appendix A: DPEBB's Pharmacy Information Bulletin No. 634 from March 30, 2017.

Patient Safety

The recording of low-dose (exempted) codeine product sales in PIP is important not just for the integrity of PIP data, but also for the safety of the patient. Health care professionals rely on the accuracy of the patient medical history to make informed decisions when assessing appropriateness of opioid and non-opioid analgesics. See [PIP Quality Improvement Program](#) and [SCPP's PIP FAQ](#) for information on maintaining PIP integrity.

5. RELATED RESOURCES

- 5.1. medSask – Exempted Codeine Products Guidelines

6. AUTHORITY

- 6.1. Government of Canada – [Food and Drugs Act](#)
- 6.2. Government of Canada – [Food and Drug Regulations](#)
- 6.3. Government of Canada – [Controlled Drugs and Substances Act](#)
- 6.4. Government of Canada – [Narcotic Control Regulations](#) – Section 36
- 6.5. Government of Canada. Recalls and safety alerts: [Prescription Cough and Cold Products Containing Opioids and the Risk of Opioid Use Disorder in Children and Adolescents](#), August 24, 2019.
- 6.6. Government of Canada. Recalls and safety alerts: [Non-prescription pain relief products containing codeine are not recommended for use in people under 18 years of age](#), July 31, 2020.
- 6.7. Saskatchewan College of Pharmacy Professionals [Regulatory Bylaws](#) – Sections 7 and 8 of Part J
- 6.8. [The Pharmacy and Pharmacy Disciplines Act](#) - Section 14(2)(v)

Drug Plan and Extended Benefits Saskatchewan Ministry of Health

Pharmacy Information
Bulletin No. 634
March 30, 2017

Prescription Drug Amendment Regulations, 2017 Exempted Codeine Products

Effective April 5, 2017, the *Prescription Drugs Amendment Act, 2011* will be proclaimed and the *Prescription Drugs Amendment Regulations, 2017* will come into force.

The amended Act allows the Minister to classify certain drugs as designated non-prescription drugs through these regulations. This means that information from the sale of designated non-prescription drugs to Saskatchewan residents must be entered into the Pharmaceutical Information Program (PIP) to help prevent and identify their inappropriate use.

Exempted codeine products are designated in the amended regulations. As of April 5, 2017, it is mandatory for pharmacies to record exempted codeine product sales in the PIP and Drug Plan and Extended Benefits Branch (DPEBB) profiles of the individual who is purchasing the product. The exempted codeine product will appear in the purchaser's profile in PIP and also in their PIP profile in the eHR Viewer.

Pharmacies must continue to record all prescribed drugs in the PIP and DPEBB profiles of the individual for whom the medication is prescribed.

The Ministry is tracking the sale of exempted codeine products via the DPEBB on-line claims system. All sales of exempted codeine products are to be submitted to the DPEBB on-line claims system as a capture claim. See Appendix 1 for submission information.

For clients who are eligible under Supplementary Health Benefits and the Paraplegia, Cystic Fibrosis, and Chronic End-Stage Renal Disease Programs through Saskatchewan Aids to Independent Living (SAIL), pharmacies will continue to submit claims for adjudication to the DPEBB on-line claims system for exempted codeine products when prescribed by a physician.

WHO TO CONTACT:

- If you or your patients have any questions, call:
Drug Plan and Extended Benefits Branch at 787-3317 (Regina) or 1-800-667-7581.
- If you have questions on how to record the sale of exempted codeine products in PIP, contact your vendor.
- Information is also available on the secure Drug Plan WEB page (the site from which you print your payroll): <https://www.drugplan.health.gov.sk.ca>