COLLEGE OF PHARMACISTS OF MANITOBA

Practice Direction: ~~Exempted~~ Low Dose Codeine Products ~~Preparations~~

1.0 Scope and Objective:

1.1 Expected Outcome

This document is a practice direction by Council concerning the sale of ~~Exempted~~ a finished product containing a low dose of codeine (low dose codeine product) ~~Codeine Preparations~~ as defined under Section ~~36~~ 98 of ~~Narcotic Regulations to CDSA~~Controlled Substances Regulations, by the licensed pharmacist through the authority of *The Pharmaceutical Regulations* to *The Pharmaceutical Act* and *The Pharmaceutical Act*

1.2 Document Jurisdiction (Area of Practice)

All licensed pharmacists who prescribe ~~an Exempted Codeine Preparation~~a low dose codeine product are expected to adhere to this practice direction.

~~**1.3 Regulatory Authority Reference**~~

~~Clause 118(1)(a), subsection 56(1)6., and section 119 of *The Pharmaceutical Regulations* to the *Pharmaceutical Act* empowers the Council to create a practice direction for the prescribing of Exempted Codeine Preparations.~~

1.4 Definitions

A finished product containing a low dose of codeine (low dose codeine product) is a finished product, as outlined in section 98 of the Controlled Substances Regulations, that contains

a. not more than 8 mg or its equivalent of codeine phosphate per unit in sold form, or not more than 20 mg or its equivalent of codeine phosphate per 30 mL in liquid form, and
b. two additional medicinal ingredients other than a narcotic in a quantity of not less than the regular minimum single dose for one such ingredient or one-half of the regular minimum single dose for each such ingredient, or three additional medicinal ingredients other than a narcotic in a quantity of not less than the regular minimum single dose for one such ingredient or one-third of the regular minimum single dose for each such ingredient.

A finished product has the same meaning as the Controlled Substances Regulations.

2.0 Practice Direction

2.1 No pharmacist shall sell {distribute) or provide a~~n~~ low dose codeine product~~Exempted Codeine Preparation,~~ including in hospital practice, unless it is pursuant to a prescription.

2.2 The pharmacist must determine the appropriateness of a patient's request to self-medicate for a recognized medical or dental reason, and then make the decision whether to prescribe

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a low dose codeine product. ~~an Exempted Codeine Preparations~~

2.3 A licensed pharmacist shall only prescribe a low dose codeine product~~an Exempted Codeine Preparation~~ for a patient whom they have seen and assessed in person. The pharmacist's assessment of the patient shall include, but is not limited to the following:

2.3.1 Signs and symptoms of the condition to be treated
2.3.2 Length and severity of present symptoms
2.3.3 Laboratory or other test results {if applicable)
2.3.4 Medical history
2.3.5 Allergies and/or sensitivities
2.3.6 Current medications {must include a review of the patient's DPIN profile)
2.3.7 Extent and results of previous treatment for the current condition
2.3.8 Pregnancy and lactation status {if applicable)

2.4 A licensed pharmacist shall only prescribe a low dose codeine product ~~an Exempted Codeine Preparation~~ when it is in the patient's best interest, having considered the risks and benefits to the patient and other relevant factors specific to the patient's care.

2.5 A licensed pharmacist shall issue a prescription only after advising the patient with the

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therapeutic alternatives and providing adequate information so the patient can make an informed decision. The licensed pharmacist must comply with all rules and, specifically, the practice direction *Prescribing and Dispensing*.

2.6 The licensed pharmacist shall make responsible attempts {including DPIN checks) to ensure the patient has not received additional low dose codeine products ~~Exempted Codeine Preparations~~, similar prescription/non-prescription medications, or other substances within an unreasonable time period that would put the patient at risk of additive toxicity, dependent upon the medical or dental reason for use.

2.7 The licensed pharmacist shall refer to another health care provider if the condition or symptom~~{~~s) are deemed to be serious in nature or if the low dose codeine product ~~Exempted Codeine Preparations~~ will inadequately treat the medical or dental reason for use. ~~{~~(Refer to Standard of Practice #10: Transfer of Patient Care). The referral should also be done where continued use of exempted codeine preparations is not in the best interest of the patient.

2.8 All low dose codeine product ~~Exempted Codeine Preparation~~ prescriptions must be entered into DPIN. When prescribing to out of province patients, pharmacists must enter a "pseudo-PHIN" 888888884 into DPIN as *Drug Utilization only*.

2.9 A licensed pharmacist who issues a prescription for a low dose codeine product ~~an Exempted Codeine Preparation~~ must reduce the prescription to writing in a clear, concise format that includes all required information. The prescription must include the following legal requirements:

2.9.1 Name and address of the patient receiving the prescription
2.9.2 Name and address of the prescriber {i.e. pharmacist)
2.9.3 Name of the drug
2.9.4 Strength, quantity and dosage form of the drug
2.9.5 Manufacturer of the dispensed product
2.9.6 Part fill/Interval {if applicable)
2.9.7 Directions for use
2.9.8 Signature of the prescribing pharmacist
2.9.9 Date the prescription was written
2.9.10 Treatment goal, diagnosis or clinical indication

2.10 A prescription for~~-~~ low dose codeine products ~~Exempted Codeine Preparations~~ written by a pharmacist should not exceed a quantity of 100 tablets or 250 mL, depending on the dosage form, to be dispensed initially and, if part fills are issued, the total quantity of the prescription should not exceed 200 tablets or 500 mL, depending on the dosage form. Quantities greater should only be prescribed under extenuating circumstances, with documentation of professional judgment and rationale for the decision.

2.11 The licenced pharmacist dispensing the~~–~~ low dose codeine product~~Exempted Codeine Preparation~~ must comply with the patient counselling required of a prescription drug.

2.12 It is the responsibility and duty of the pharmacist to refuse to provide Exempted Codeine Preparations where there are reasonable grounds for believing the drug may be used by a

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person for a purpose other than a recognized medical or dental reason, or may result in harm to the patient.

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3 Documentation

3.1 Documentation is to be recorded in a readily retrievable manner either electronically, or in written form.

4 Compliance Adjudication

4.1 All documentation must be readily accessible and open to regulatory review

5 Appendices

Not applicable

A Practice Direction is a written statement made by Council for the purposes of giving direction to members and owners about the conduct of their practice or pharmacy operations. Compliance with practice directions is required under the Pharmaceutical Act.

The process for development, consultation, implementation, appeal and review is been published on the College website.

Development Source:	Standards of Practice Committee
Regulatory Reference:	Clause 118{1){a), ss56{1)6., s119 of *The Pharmaceutical Regulations*
Consultation Close:	August 28, 2015
Authorized by Council:	October 5, 2015
Effective Date:	February 1, 2016
Revised:	
Review Due:	

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