Newfoundland and Labrador Pharmacy Board

Standards of Practice

The Sale of Exempted Codeine Products in Community Pharmacies

November 2022

1) Introduction

Standards of Practice are minimum standards that all registrants are expected to meet. Regardless of position or practice environment, when a registrant performs a specific role, they must perform it to the level specified in the Standards of Practice and meet all of the standards associated with that role. These Standards describe the minimum expectations for pharmacists who provide exempted codeine products (ECPs) to patients and are intended to promote consistency in the provision of this service to the people of this province.

ECPs are defined in section 36 of the *Narcotic Control Regulations (Canada)*, as follows:

> *"A preparation containing not more than 8 mg or its equivalent of codeine phosphate per tablet or per unit in other solid form or not more than 20 mg or its equivalent of codeine phosphate per 30 mL in a liquid preparation if*
>
> *(a) the preparation contains*
>
> *(i) 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 the regular minimum single dose for each such ingredient, or*
>
> *(ii) 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 the regular minimum single dose for each such ingredient; and*
>
> *(b) there is legibly and conspicuously printed on the inner label and the outer label, as those terms are defined in section A.01.010 of the Food and Drug Regulations, a caution to the following effect: "This preparation contains codeine and should not be administered to children except on the advice of a physician, dentist or nurse practitioner.""*

The regulations go on to state that: "*No pharmacist shall sell or provide a preparation referred to in subsection (1) if the pharmacist has reasonable grounds to believe that the preparation is to be used for purposes other than recognized medical or dental purposes."*

In addition to Health Canada's regulations, ECPs are also listed in Schedule 2 of the National Drug Schedules. Schedule 2 medications, while less strictly regulated than those listed in Schedule 1, must be retained within an area of the pharmacy where there is no public access and no opportunity for patient self-selection and do require professional intervention from the pharmacist at the point of sale and possible referral to a practitioner. Additionally, when providing Schedule 2 medications, pharmacists are expected to meet the consultation requirements outlined in the NLPB *Standards of Pharmacy Operation – Community Pharmacy*.

2) Operational Standards

Before offering ECPs for sale, the pharmacist-in-charge must ensure the following operational standards are met:

a) *Storage and Security*. In accordance with the security requirements of the NLPB *Standards of Pharmacy Operation – Community Pharmacy*, all ECPs must be stored in a secure safe for the exclusive storage of narcotics and controlled drugs that is appropriately anchored to the floor and out of public view.

b) *Policies and Procedures*. The pharmacy must develop, maintain, and regularly review policies and procedures that outline how to handle requests for ECPs, workflow and documentation requirements, as well as anything else considered relevant to the provision of ECPs.

c) *Filing and Storage*. In accordance with the record retention requirements of the NLPB *Standards of Pharmacy Operation – Community Pharmacy*, records of the provision of ECPs must be filed with prescriptions for other narcotics and controlled drugs in sequence by date and number (either transaction or prescription number).

3) Practice Standards

3.1 Patient Assessment

a) Only a pharmacist may authorize the sale of an ECP.

b) Prior to authorizing the sale of an ECP, in accordance with section 36. of the *Narcotic Control Regulations (Canada)*, the pharmacist must be satisfied that the ECP is to be used for a recognized medical or dental purpose.

> **PLEASE NOTE**: A pharmacist may decide, after this initial assessment, to allow future pickup by an alternate person but documentation of all sales must be recorded on the correct patient's local medication profile and provincial electronic health record.

c) To ensure this understanding, the pharmacist must conduct and document a patient assessment appropriate to the circumstances, using a combination of patient interview, review of the patient's electronic health record, and other sources, as appropriate. This can include, but is not limited to, the patient's:

i) demographic information;
ii) physical characteristics, condition, and measurements (e.g., height, weight, etc.);
iii) presenting ailment/condition/disease/symptoms including any previous history and/or assessments, investigations, or treatments for the same;
iv) relevant laboratory and/or diagnostic test results;
v) objective and subjective findings;
vi) medical history, including previous usage of ECPs;
vii) current medical conditions, medications, non-medication therapies, use of health care products/devices and treatments;
viii) allergies and intolerances;
ix) pregnancy and lactation status;
x) risk factors; as well as
xi) any other personal circumstances, practical needs, values, preferences, or other information relevant to the assessment.

d) A pharmacist should refer the patient to their primary health care provider or another appropriate health care professional if they determine that there is insufficient information to support the use of the product or if:

i) the condition or symptom(s) are chronic or serious in nature;
ii) the ECP will inadequately treat the medical or dental reason for use; or
iii) continued use of ECPs is not in the best interests of the patient.

3.2 Package Size Restriction

a) Sales of ECPs in solid dosage form must be limited to sales of no greater than 100 units.

b) Sales of ECPs in liquid form must be limited to sales of no greater than 100 mL.

c) These limitations may only be exceeded pursuant to a prescription from an authorized prescriber.

3.3 Documentation and Labelling Requirements

a) Each time a pharmacist provides an ECP to a patient; it must be documented in the patient's provincial electronic health record and local medication profile in accordance with the patient medication profile requirements of the NLPB *Standards of Pharmacy Operation – Community Pharmacy*.

b) Prior to being supplied to the patient, the ECP must be labelled in accordance with the labelling requirements of the NLPB *Standards of Pharmacy Operation – Community Pharmacy*.

3.4 Pharmacist-Patient Consultation

a) Pharmacists are expected to consult with patients on each and every sale of an ECP.

b) In addition to the information required by the NLPB *Standards of Pharmacy Operation – Community Pharmacy*, the consultation should include information about the potential for the over-use of codeine as well as acetaminophen or ASA.

c) In addition to verbal consultation, the pharmacist should provide the patient with supplementary written information on codeine use.

4) Resources

a) Template - Documentation of Pharmacist-Authorized Exempted Codeine Product Requests