

Newfoundland and Labrador Pharmacy Board Guidelines for Pharmacy Practice



The Sale of Naloxone in Community Pharmacies

September 2016

Revised February 2017

1) Introduction

In response to significant increases in the incidence of opioid overdose, the large majority of which result in death, steps are being taken across Canada to provide greater access to naloxone, an opioid antagonist indicated for the complete or partial reversal of opioid overdose, including its consequences: respiratory depression, sedation and hypotension.

In March 2016, Health Canada revised its listing for naloxone on the Prescription Drug List (PDL) such that naloxone or its salts ("naloxone") no longer required a prescription when indicated for emergency use for opioid overdose.

National Drug Scheduling Advisory Committee (NDSAC) subsequently reviewed this change and made recommendations regarding the scheduling of naloxone hydrochloride injection¹ and naloxone hydrochloride nasal spray² when indicated for emergency use for opioid overdose. As per the Pharmacy Regulations, 2014, the Newfoundland and Labrador Pharmacy Board reviewed the NDSAC recommendations on August 22, 2016 and February 18, 2017, and approved the following revisions to the Newfoundland and Labrador Provincial Drug Schedules:

- Added to Schedule I: "Naloxone or its salts, including, but not limited to naloxone hydrochloride, EXCEPT when indicated for emergency use for opioid overdose."
- Added to Schedule II: "Naloxone hydrochloride injection, when indicated for emergency use for opioid overdose."
- Added to Schedule II: "Naloxone hydrochloride nasal spray, when indicated for emergency use for opioid overdose."

Drugs listed in Schedule II of the Provincial Drug Schedules, while less strictly regulated than Schedule I drugs, do require professional intervention from the pharmacist at the point of sale and possibly referral to a practitioner. While a prescription is not required, the drugs are available only from the pharmacist and must be retained within an area of the pharmacy where there is no public access and no opportunity for patient self-selection.

While naloxone is very safe and the only contraindication to the use of naloxone is a known hypersensitivity to the drug, pharmacists are expected to meet certain expectations in the provision of this product to their patients.

2) Practice Expectations

2.1 Competency

- a) Pharmacists providing naloxone should take reasonable steps to ensure they are competent to do so. This should include the completion of an appropriate education and training program (see section 3 – Additional Resources for examples of appropriate programs).

2.2 Patient Assessment

- a) While it would be ideal for the pharmacist to personally consult with the patient (i.e. the person for whom the drug is intended) prior to providing naloxone, considering the nature of the drug and its intended use, this may not always be possible. Consideration should be given to providing naloxone to:
 - i) any individual who uses opioids for either legitimate medical purposes or for recreational use;
 - ii) close personal friends or family members of the individuals identified in i); or
 - iii) any person who knows an opioid user who would like to be prepared in the event of an accidental overdose.
- b) Before providing naloxone, the pharmacist should have sufficient knowledge and understanding of the circumstances such that he or she can be reasonably satisfied that providing naloxone is appropriate.

¹ Review completed and scheduling recommendation made on June 26, 2016

² Review completed and scheduling recommendation made on December 22, 2016

- c) When considering whether or not the sale of naloxone is appropriate, in situations where the patient is identified, the pharmacist should take into account the patient's:
 - i) history of opioid use;
 - ii) history of past naloxone use;
 - iii) allergies and/or sensitivities; and
 - iv) pregnancy and lactation status (if applicable).

PLEASE NOTE: Given the safe and effective nature of naloxone, it is very unlikely that it would not be appropriate to provide the drug to someone who requests it.

2.3 Additional Equipment and Supplies

- a) When providing naloxone, pharmacists should provide the product as part of a “kit” that includes:
 - i) two 1 mL single-use ampoules or vials of naloxone hydrochloride 0.4mg/ml solution or two doses of naloxone hydrochloride 4mg/0.1ml nasal spray;
 - ii) two 3cc syringes with auto-retractable 25G needles attached (1” length recommended) (for injectable naloxone);
 - iii) alcohol swabs (for injectable naloxone);
 - iv) latex or vinyl gloves;
 - v) ampoule opening device (optional);
 - vi) rescue breathing barrier with one-way valve (optional); and
 - vii) step-wise instructions for recognizing and responding to an opioid overdose including written and visual instructions for administering naloxone administration (see section 3. – Additional Resources for examples of written instructions).

2.4 Documentation and Labelling

- a) In accordance with section 3.5 of the *Standards of Pharmacy Operation – Community Pharmacy* (SOPO-Community), each time a pharmacist provides a Schedule II product, it must be documented in the patient's medication profile. Generally speaking, this is also the expectation when providing naloxone.
- b) In order to retain traceability and accountability, in cases where:
 - i) someone other than the patient is purchasing naloxone,
 - ii) the patient is not identified, or
 - iii) it is not clear that the patient has consented to the medication being added to their patient profile,the pharmacist should create a record indicating that naloxone was provided to an “unknown patient”. This record should include the date the naloxone was provided and the identification of the pharmacist who provided the product.
- c) In accordance with section 3.6 of the SOPO-Community, each time a pharmacist provides a Schedule II product, it must be appropriately labelled. In the case of naloxone, the label should include, at a minimum:
 - i) pharmacy name, phone number and street address (if available, or, if not, a way of uniquely identifying the pharmacy location);
 - ii) patient's first and last name (or “unknown patient”);
 - iii) drug name (i.e. naloxone kit);
 - iv) date of provision;
 - v) the initials of the pharmacist responsible for the sale; and
 - vi) a cautionary label indicating that the product should be kept out of the reach of children.

2.5 Pharmacist-Patient Consultation

- a) Pharmacists are expected to provide counselling prior to each and every sale of naloxone. This interaction will allow the pharmacist to review important education and training points and allow the purchaser the opportunity to ask questions / discuss concerns.
- b) In the case of naloxone, such counselling should include:
 - i) a review of the contents of the naloxone kit;
 - ii) how to identify an opioid overdose;
 - iii) the importance of calling 911 immediately for medical assistance due to the short half-life of the drug;
 - iv) the importance of rescue breathing;
 - v) when to administer naloxone;
 - vi) for injectable naloxone:
 - how to prepare the dose for administration by withdrawing the dose of naloxone from the ampoule/vial into the syringe;
 - how to landmark the thigh and administer an intra-muscular injection; and
 - how to avoid and manage needle stick injuries;
 - vii) for intranasal naloxone:
 - how to administer properly, noting that the device does not need to be “primed” and that once the plunger is depressed, the dose has been released;
 - viii) when to use the second dose of naloxone;
 - ix) the need to remain with the victim to provide supportive measures and to assess the need for subsequent doses while waiting for emergency first responders to arrive: and
 - x) any other information the pharmacist deems relevant to the circumstances.

3) **Additional Resources**

3.1 Education and Training Programs

- a) Alberta Pharmacists' Association - [Take Home Naloxone - Information for Pharmacists webinar](#)
- b) Canadian Pharmacists Association - [Naloxone for Opioid Overdose – What Pharmacists Need to Know webinar slides](#)
- c) College of Pharmacists of British Columbia - [Community Pharmacy Distribution of Naloxone webinar slides](#)

3.2 Other Resources and References

- a) [Naloxone Injection Training Checklist](#)
- b) [Naloxone Nasal Spray Training Checklist](#)
- c) Product Monograph – Adapt Pharma – [Naloxone Nasal Spray Product Monograph](#) (includes Patient Information)
- d) Product Monograph – Sandoz Canada – [S.O.S. Naloxone Hydrochloride Injection Product Monograph](#) (includes Patient Information)

4) References

- a) Alberta College of Pharmacists - [Guidance for Pharmacists and Pharmacy Technicians Dispensing or Selling Naloxone as a Schedule 2 Drug](#)
- b) College of Pharmacists of Manitoba - [Guidelines for Pharmacists Selling Naloxone as a Schedule II Drug](#)
- c) Nova Scotia College of Pharmacists - [Naloxone for Opioid Overdose Reversal Position Statement](#)
- d) Ontario College of Pharmacists - [Dispensing or Selling Naloxone](#)