DISPENSING OR SELLING NALOXONE

Guidance for pharmacy professionals when dispensing or selling naloxone as a Schedule II drug.

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Purpose

The intent of this document is to provide guidance for pharmacists and pharmacy technicians regarding their respective responsibilities when dispensing or selling naloxone as a Schedule II drug.

Introduction

In response to the influx of opioid related overdoses across Canada, naloxone has been made available for emergency use for opioid overdose. Accidental overdoses can occur in both individuals who use opioids as prescribed by their physician, and those using opioids for non-medical reasons. The goal of providing naloxone in community pharmacies is to increase public access to this life-saving medication.

Naloxone is a non-addictive opioid antagonist that temporarily reverses the effects of opiates including respiratory depression, sedation and hypotension. Naloxone is a safe and effective therapy: with proper administration naloxone is a drug that can save lives in opioid overdose situations when a person appropriately identifies the overdose and takes the required action. In the absence of an opioid, naloxone exhibits no effects and the only contraindication to the use of naloxone is in patients known to be hypersensitive to it. Naloxone does not increase the likelihood of risk-taking behaviours, and cannot be abused.

Naloxone Availability in Community Pharmacies

As of February 8, 2017 naloxone, when indicated for emergency use for opioid overdose, is available as a Schedule II drug. Any patient or patient’s agent (agent) are now permitted to obtain Schedule II naloxone directly from any community pharmacist without a prescription.

Pharmacists are authorized to dispense naloxone kits obtained through the Ministry of Health and Long-Term Care Ontario Naloxone Program for Pharmacies or privately procured naloxone and kit supplies. The Ministry of Health and Long-Term Care will provide funding for naloxone for patients according to criteria defined by the Ministry.

Pharmacists should always provide two units of any formulation (ampoules, vials or nasal spray) of naloxone to the patient or agent to ensure that a second dose of naloxone is available for administration if needed.
When dispensing naloxone the pharmacist is strongly encouraged to also ensure that the patient or agent receives the following supplies (dependent on formulation of naloxone) in a hard case to aid in the administration of naloxone, including:

- Two Safety syringes with 25G one inch needles attached if dispensing injectable formulation – they reduce the risk of needle stick injury, can be disposed of in the trash, prevent re-use as there is no way to push the needle back out, and are unlikely to be used for any other purpose (unlike insulin syringes);
- Two safe ampoule opening devices – small plastic snappers which prevent people from cutting their hands on broken glass when snapping an ampoule; these are not needed if vials or any other formulation are being provided; and
- One pair of non-latex gloves
- One rescue breathing barrier
- Alcohol swabs — optional; to reduce the risk of infection given that an injection can be provided through clothing.
- One naloxone identifier card – a card that can be filled out with the name of the person who has been trained in responding to opioid overdoses, the date the naloxone supplies were issued, and the expiry date of the naloxone
- One insert with instructions ([English here](#) and [French here](#)) (List updated April 2018).

**Responsibilities of the Pharmacist when Dispensing Naloxone**

The pharmacists’ responsibilities include ensuring the following requirements are met when dispensing naloxone:

**Standards of Practice**

Schedule II drugs, when dispensed or sold in a pharmacy, must be stored and provided to patients from the dispensary where patient self-selection is restricted. Each transaction must occur under the direct supervision of a pharmacist and pharmacists are expected to counsel each patient or agent when dispensing naloxone in order to enable the patient to receive the intended benefit of the drug therapy.

Pharmacists and pharmacy technicians are expected to practice in accordance with the NAPRA Supplemental Standards of Practice for Schedule II and III Drugs, which set out the minimum
acceptable standards of practice, including standards regarding the distribution or sale of Schedule II drugs.

**Patient Assessment**

When dispensing naloxone the pharmacist must determine the following:

- If the person who naloxone is intended for has any known allergies to naloxone, or concomitant ingredients in specific formulations of naloxone (methylparaben or propylparaben). Allergies are very rare and the benefits of naloxone are likely to outweigh the risks of an allergic reaction.

- Where the intended person has a known allergy to naloxone or concomitant ingredients the pharmacist should encourage the person to seek medical advice from a physician.

- Naloxone should not be dispensed where the intended person has a known allergy to naloxone unless the pharmacist confirms with a physician that the emergency kit should be dispensed.

**Pharmacist Training**

It is the professional responsibility of a pharmacist to ensure that he or she has sufficient knowledge, skills and abilities to competently deliver any pharmacy service. As is required when delivering any new service, a pharmacist must ensure he or she has undergone the appropriate training and has the required resources to ensure that the service is provided in a safe and effective manner. There are a number of training programs and resources available to pharmacists (see links on College website).

**Providing Patient and/or Agent Education**

It is critical that the pharmacist is properly trained on the essential information required to effectively educate the patient or agent and prepare him or her for dealing with an opioid overdose, prior to providing naloxone. Patients and/or agents must be educated on more than just naloxone therapy and how to administer it. Pharmacists should ensure patients and/or agents purchasing naloxone are also educated on such topics as:

- Harm reduction strategies when using opioids;
- How to identify an opioid overdose;
- Importance of immediately calling 9-1-1;
- Importance of cardiopulmonary resuscitation (CPR) and how and when to give breaths;
• When and how to administer naloxone;
• Aftercare and the importance of staying with the person until emergency first responders arrive;
• Withdrawal symptoms occur following naloxone administration and reversal of the effects of the opioid overdose. Doses of naloxone administered via one or two vials or ampoules will, in most cases, only produce mild withdrawal symptoms and the benefits outweigh the risks associated with withdrawal;
• Naloxone may have variable efficacy in reversing the clinical effects of an overdose due to preparations containing buprenorphine;
• Naloxone is not effective against respiratory depression due to non-opioid drugs;
• Risk of secondary overdose if opioids used when patient regains consciousness; and
• Any other information the pharmacist deems relevant.

Pharmacists must also provide educational information and the steps for dealing with an opioid overdose in writing to the patient and/or agent. Written resources are not a replacement for pharmacist interaction with the patient or agent, and are to be used as a supplemental resource only.

Documentation Requirements
The record keeping requirements for naloxone are the same as for any other Schedule II product as outlined in the College’s Documentation Guidelines and the NAPRA Supplemental Standards of Practice for Schedule II and III Drugs. There are no additional documentation requirements.

Pharmacists may be required to report additional information in accordance with requirements set out by the Ontario Naloxone Program for Pharmacies.