INTRODUCTION

In response to significant increases in the incidence of opioid overdose, the large majority of which result in death, many provinces took steps 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.

One of the steps taken by provinces was to request that Health Canada re-evaluate naloxone’s prescription status. As a result, Health Canada, in March 2016, revised its listing for naloxone on the Prescription Drug List (PDL) such that naloxone hydrochloride injection (also referred to as “naloxone” in this document) no longer requires a prescription when “indicated for emergency use for opioid overdose outside hospital settings”. In doing so, Health Canada noted the following:

- **Naloxone could safely be administered without the direct supervision of a physician if the person administering the drug has appropriate training.**

- **The main risks associated with the unsupervised use of the drug are:**
  - the administrator may have difficulty filling the syringe and administering the drug under pressure in an emergency situation;
  - the administrator may not seek professional care for follow-up of the patient after injection;
  - chance of the patient relapsing since the effects of naloxone may only last for up to one hour depending on amount and type of opioid causing the overdose;
  - the patient may become very agitated and aggressive after coming out of the opioid depression (Acute Opioid Withdrawal Syndrome).

- **These risks can be mitigated with appropriate training of the potential administrator before naloxone is distributed, and the benefit of quickly responding to an overdose far outweighed these risks.**

- **Evidence from provincial take-home programs indicates that naloxone can be administered (intra-muscularly or subcutaneously) by a layperson and its effects monitored successfully without practitioner supervision.**

- **Although an opioid overdose might be mistakenly diagnosed by a layperson, the injection of naloxone in a person not overdosing on an opioid will cause no serious harm.**

Upon the request of Health Canada and the subsequent recommendation of the National Drug Scheduling Advisory Committee (NDSAC), naloxone hydrochloride injection and naloxone hydrochloride nasal spray, when indicated for emergency use for opioid overdose outside the hospital setting, were moved from Schedule I to Schedule II of the National Drug Schedules on June 24, 2016 and December 22, 2016 respectively.
Drugs listed in Schedule II of the National Drug Schedules are, by direct reference, considered Schedule II under the Nova Scotia Drug Schedule Regulations\(^4\), and are subject to the associated requirements, including that:

- they are only available from a pharmacist;
- they must be kept within an area of the pharmacy to which there is no public access and no opportunity for self-selection;
- the direct involvement and professional intervention from a pharmacist is required prior to the release of the drug to the patient; and
- they must be sold in accordance with the applicable standards of practice approved by Council, namely the NAPRA Supplemental Standards of Practice for Schedule II and III Drugs and the NSCP Standards of Practice: General Standards of Practice.

**DEFINITIONS**

| **Client** | Knowing that the individual purchasing naloxone may often be someone other than the intended recipient, *client*, for the purpose of this position statement, refers to the point-of-contact individual at the pharmacy, and may be the intended recipient of naloxone (the patient), that patient’s agent, family member or friend. |
| **Naloxone** | For the purposes of this document, “naloxone” refers to only those products that have received approval from Health Canada for the specific indication “emergency use for opioid overdose outside the hospital setting”. |
| **Naloxone “Kit”** | A self-contained package containing naloxone and the necessary supplies to safely and effectively administer naloxone in a timely manner, and includes:
- a self-contained package obtained through the provincial naloxone take home program;
- a self-contained package approved for sale by Health Canada; or
- privately procured naloxone and supplies as identified in section 5 or any subsequent revision to this position statement. |
POSITION STATEMENT

When providing naloxone for the reversal of opioid overdose outside of a hospital, the expected practice of pharmacists competent to provide this service includes:

- complying with applicable standards of practice; and
- providing appropriate counseling and education to enable the intended benefit of naloxone therapy to be realized.

PROCEDURE

1. **Pharmacist Competency**

Pharmacists providing naloxone will take reasonable steps to ensure they are competent to do so. The following are examples of available on-line educational resources:

- College of Pharmacists of British Columbia – Community Pharmacy Distribution of Naloxone webinar
- School of Pharmacy, University of Waterloo - Naloxone teaching tools

2. **Compliance with Applicable Standards**

In addition to the practice directives provided in this position statement, pharmacists providing naloxone will do so in compliance with:

- NAPRA Supplemental Standards of Practice for Schedule II and III Drugs and
- NSCP Standards of Practice: General Pharmacy Practice

3. **Counseling and Education**

The pharmacist must assess the client’s understanding of the essential information required for safe administration of naloxone for emergency opiate overdose reversal.

Pharmacists providing naloxone will be satisfied that the client has an appropriate understanding of the following:

- how to identify an opioid overdose;
- the importance of calling 911 immediately for medical assistance due to the short half-life of the naloxone;
- the importance of basic life support (CPR/AED), including chest compressions and rescue breathing;
• when to administer naloxone;
• how to prepare the dose for administration by withdrawing the dose from the vial or ampoule;
• how to administer naloxone, including:
  a. how to landmark the thigh and administer an intra-muscular injection (for injection)
  b. administering the spray nasally and NOT orally; and NOT “testing / priming” the nasal spray because there is only one dose and this will result in it being lost.
• when to administer the second dose of naloxone;
• the need to remain with the victim to provide supportive measures and assess the need for subsequent doses while waiting for emergency first responders to arrive; and
• how to manage and avoid needle stick injury.

When providing subsequent supplies of naloxone, a pharmacist must determine the client’s ongoing understanding of the proper administration of naloxone and review as appropriate.

4. Documentation

Pharmacists are expected to meet the documentation requirements as set out in the NAPRA Supplemental Standards of Practice for Schedule II and III Drugs.

5. Naloxone and Supplies

Naloxone when provided as naloxone hydrochloride injection for opioid overdose reversal will be provided as:
• a kit obtained from the provincial naloxone take home program;
• a kit approved for sale by Health Canada; or
• a kit assembled by the pharmacy that contains the following supplies:
  – two 1 mL single-dose ampoules or vials of naloxone 0.4mg/mL solution;
  – two retractable safety syringes with 25G 1” needles attached;
  – latex or vinyl gloves;
  – alcohol swabs;
  – step-wise instructions for recognizing and responding to an opioid overdose, including written and visual instructions for administering naloxone administration; and
  – one rescue breathing barrier (optional).
ADDITIONAL RESOURCES

Nova Scotia Take Home Naloxone Program and resources, September 2017

Checklist for Naloxone Training, College of Pharmacists of British Columbia, April 2016

Naloxone teaching tools developed to support healthcare providers and opioid users, School of Pharmacy, University of Waterloo, November 2016

Naloxone Resources, Pharmacy Association of Nova Scotia (member login required)

Naloxone Resources, College of Pharmacists of British Columbia, March 2016

Needle-stick and Sharps Injuries, Canadian Centre for Occupational Health and Safety


Naloxone, Government of Canada, March 2017

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iii Nova Scotia Drug Schedule Regulations, 2011
iv NAPRA Supplemental Standards of Practice for Schedule II and III Drugs, June 2005
v NSCP Standards of Practice: General Pharmacy Practice, March 2014