

Providing naloxone as an unscheduled drug

Guidelines for pharmacy teams

Background

Naloxone is an opioid antagonist that temporarily prevents, or reverses the effects of opioids, including respiratory depression, sedation, and hypotension. In the absence of opioids, it exhibits essentially no pharmacologic activity. Naloxone is indicated for the complete or partial reversal of opioid depression, including respiratory depression induced by opioids, and for the diagnosis of suspected acute opioid overdose¹. The only contraindication to the use of naloxone is in patients known to be hypersensitive to it, and even then, the benefits of use often outweigh the risks. Naloxone cannot be abused, and it does not increase the likelihood of overdose or of increased drug consumption.

In response to the ongoing opioid crisis and an increasing number of deaths associated with opioid overdose in Alberta and across Canada, all provinces and territories provide publicly funded naloxone to at-risk individuals. To improve access for vulnerable populations, naloxone for use in emergency treatment of opioid overdose outside of a hospital setting is unscheduled in Alberta.

Overdoses occur in individuals who use opioid medications prescribed by a practitioner as well as in those who use opioids for non-medical reasons.

Despite being an unscheduled product, proper use of injectable and nasal naloxone requires training and the naloxone must be kept in the dispensary.

The Alberta College of Pharmacy (ACP) Standards of Practice for Pharmacists and Pharmacy Technicians (SPPPT) and the Code of Ethics (COE) set expectations for pharmacy professionals

- to provide drugs, non-prescription medications, or health-related products that are from safe, proven sources;
- to seek cost-effective therapies that ensure quality care; and
- to safeguard the well-being of each patient and any patient who is vulnerable.

Naloxone is a safe and effective antidote to opioid overdose, and it is very unlikely that it would not be appropriate to provide naloxone to someone who requests it.

While providing an intramuscular injection is a restricted activity, the training required for self-administration is not. Therefore, ACP Council has determined that, after completing appropriate education, naloxone may be provided in pharmacies by pharmacists, pharmacy technicians, and pharmacy assistants.

The following guidelines are based on ACP Standards of Practice for Pharmacists and Pharmacy Technicians, Standards for the Operation of Licensed Pharmacies, and our Code of Ethics.

These guidelines are to support pharmacists and pharmacy technicians in complying with the SPPPT, the COE, the Pharmacy and Drug Regulation (PDR), and the Standards for the Operation of Licensed Pharmacies (SOLP).

¹ Baxter Corporation; [Product Monograph Naloxone Hydrochloride Injection](#), USP; July 12, 2021

Expectations for the use of the Standards and Guidelines

Standards

Standards establish requirements. Standards use the language of “must.” A regulated member must comply with each standard. Failure to comply with a standard may be considered unprofessional conduct.

Guidelines

Guidelines establish the professionally accepted means by which regulated members can achieve compliance with the standards. Guidelines use the language of “should.” Guidelines are not recommendations; they establish the expected conduct of regulated members. A regulated member may only depart from a guideline if the regulated member can demonstrate that the regulated member

- achieved compliance with the applicable standard, and
- the member’s departure from the guideline
 - did not detract from the safety, effectiveness, or appropriateness of patient care; or
 - did not undermine the integrity of the professions of pharmacists and pharmacy technicians.

Failure to comply with a guideline may be considered unprofessional conduct if the regulated member did not achieve compliance with the standard or if the departure from the guideline detracted from the quality of patient care or undermined the integrity of the professions of pharmacists and pharmacy technicians.

In general, mandatory requirements that are found in legislation or the SPPPT are noted by the use of the word “must” and are referenced to the relevant legislation. Guidelines reflecting practices that support adherence to the standard use the term “should”.

This guideline notwithstanding, pharmacists and pharmacy technicians must always use their professional judgement when dealing with each unique individual and each situation and provide care accordingly.

Guidelines for providing naloxone

1. Pharmacy team members, who provide naloxone, must have adequate training to effectively educate the individual receiving the naloxone².
2. Pharmacy team members must respect the autonomy, privacy, and dignity of anyone requesting naloxone.
3. Pharmacy team members must ensure the individual being provided naloxone has sufficient information to enable them to receive the intended benefit of the drug therapy.
 - a. When naloxone is provided to an individual for the first time, a trained pharmacy team member should make every effort to start a dialogue with that person.
4. Pharmacy team members must identify when it is appropriate to refer an individual requesting naloxone to the pharmacist, another healthcare provider, or a harm reduction agency.
5. Pharmacists should consider circumstances when it is appropriate to offer an individual naloxone.
6. Pharmacy team members must inform individuals requesting naloxone of the options available to them to allow the individual to make an informed decision.

Additional information for pharmacy teams on interpreting these guidelines include the points outlined below.

² SPPPT 1.7(d), 1.8(d)

Additional interpretation

1. Pharmacy team members who provide naloxone must have adequate training to effectively educate the individual requesting the naloxone.
 - Licensees should ensure that each team member providing naloxone has completed the appropriate education and training required³.
 - Licensees should implement a process to supervise and monitor each team member and be confident in the abilities of the team member to competently deliver that service⁴.
 - Licensees should ensure that all team members consistently adhere to the relevant standards of practice and the Code of Ethics when providing naloxone⁵.
2. Pharmacy team members must respect the autonomy, privacy, and dignity of anyone requesting naloxone.
 - Licensees should ensure that all pharmacy team members understand and apply the principles of harm reduction⁶.
 - Pharmacy team members should protect everyone's privacy during any consultation and seek only information that is necessary and aligns with the individual's treatment goals⁷.
 - Pharmacy team members should treat individuals requesting naloxone in a non-judgemental manner that does not stigmatize or discriminate against them⁸.
 - Pharmacy team members should respect the right of an individual to accept or reject any treatment, care, or other professional services⁹.
 - Providing naloxone does not require the pharmacy team member to collect or document any personally identifying information, and this should not be required or documented unless the individual requests it.
3. Pharmacy team members must ensure the individual requesting naloxone has sufficient knowledge to receive the intended benefit of the drug therapy. When naloxone is provided to a person for the first time, pharmacy team members must make every effort to start a dialogue with that person.
 - Important information when providing naloxone includes, but is not limited to, the following:
 - how to identify an opioid overdose,
 - the importance of rescue breathing,
 - when to administer naloxone,
 - how to prepare the dose for administration by withdrawing the dose from the vial (injectable),
 - how to landmark on the thigh and administer an intramuscular injection (injectable),
 - when to use the second and third vial of naloxone, and
 - the importance of calling 911 for medical assistance due to the short half-life of the drug¹⁰.

3 SOLP 3.5 and 3.6

4 SOLP 6.1 and 6.2

5 SOLP 1.1(b) and 1.1(c)

6 SOLP 3.5

7 COE principle 2(1), 4(5) and 4(6)

8 COE principle 2(7)

9 COE principle 2(5)

10 [Alberta Health Services; Frequently Asked Questions for Pharmacists](#)

- When naloxone is provided for the first time, pharmacy team members should make every effort to start a dialogue with the individual¹¹.
 - Education from a trained pharmacy team member is important to ensure effective and safe use of the naloxone.
 - Written information should not replace a dialogue, if possible, but can be considered as a last resort if the individual refuses to accept training.
 - An individual's unwillingness to accept training should not result in a refusal to provide naloxone.
4. Pharmacy team members must identify when it is appropriate to refer an individual requesting naloxone to the pharmacist, another healthcare provider, or a harm reduction agency.
- Licensees must ensure pharmacy technicians and pharmacy assistants are trained and instructed on when it is required to refer individuals receiving naloxone¹².
 - A pharmacist should be available and accessible to anyone who wishes to obtain naloxone in a pharmacy¹³.
 - Pharmacy team members who are not regulated should be given clear direction, by the licensee, about the scope of their role and the limitations of their role within the pharmacy¹⁴.
 - Pharmacy technicians and pharmacy assistants should identify when it is appropriate to refer an individual receiving naloxone to a pharmacist. This includes, but is not limited to, when an individual
 - requests a dialogue with a pharmacist;
 - has a history of hypersensitivity to naloxone;
 - has questions that require therapeutic knowledge, clinical analysis, or assessment; or
 - meets any of the criteria listed in point #5 below¹⁵.
 - Pharmacy team members who provide naloxone kits should be familiar with harm reduction agencies and resources in their area and may direct individuals to contact Alberta Health Link at 811 or the AHS 24 Hour Addictions Helpline (1-866-332-2322).

11 SPPPT 2.1, 2.2, and 8.3(d)

12 SOLP 3.15

13 PDR 11.1

14 SPPPT 20.6; SOLP 3.5 and 3.8

15 SPPPT 1.7(e), 1.8(e); SOLP 3.15 and 3.16

16 SPPPT 4.1(a)

5. Pharmacists should consider circumstances when it may be appropriate to offer naloxone to individuals they determine to be at risk of an overdose¹⁶.
 - In addition to requests from individuals for naloxone, pharmacists should consider offering naloxone to individuals, who through their assessment, they have identified may be at risk. This includes, but is not limited to, individuals
 - using chronic opioid therapy,
 - receiving large quantities or high doses of opioid medications,
 - with a history of overdose,
 - being actively treated for addiction,
 - with a history of addiction, or
 - determined to be at risk of addiction or misuse.
6. Pharmacy team members must inform individuals requesting naloxone of the options available to them to allow the individual to make an informed decision.
 - Pharmacists and pharmacy technicians have a responsibility to make individuals aware of any applicable publicly funded programs available to them before offering an alternative that is not included in the public programs¹⁷.

Additional resources

Alberta Blue Cross; [Benefact Number 715](#) December 2017

Alberta Blue Cross; [Benefact Number 672](#) February 2017

Alberta Blue Cross; [Benefact Number 612](#) May 2016

Alberta Blue Cross; [Benefact Number 575](#) January 2016

Alberta Health Services; [Get Naloxone](#)

Alberta Health Services; [Community Based Naloxone Program](#)

Alberta Health Services; [Community Based Naloxone Training for Kit Distribution](#)

Alberta Health Services; [Frequently Asked Questions for Pharmacists](#)

Alberta Health Services; [SAVE ME Patient Poster](#)

Government of Alberta; [Pharmacy and Drug Regulations](#)

Baxter Corporation; [Product Monograph Naloxone Hydrochloride Injection](#), USP; July 12, 2021