

## Guidance for Pharmacists and Pharmacy Technicians

### Dispensing or Selling Naloxone as a Schedule 2 Drug

#### Background

In response to an influx of illicitly produced fentanyl in street drugs and an increasing number of deaths in Alberta associated with overdose, Alberta Health (AH) and Alberta Health Services (AHS) have implemented Alberta's Take Home Naloxone (THN) kit program. The Program facilitates the distribution of THN kits to Albertans at risk of opioid overdose at no charge. Kits contain two vials of naloxone, syringes, alcohol swabs, latex gloves and a one-way rescue breathing mask. Since January 2016, pharmacists who have completed the THN kit training program provided by the Alberta Pharmacists' Association have participated in the THN kit program by dispensing kits prescribed by other health professionals or, if authorized, prescribing and dispensing kits.

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 overdose. The only contradiction to the use of naloxone is in patients known to be hypersensitive to it.

Effective May 13, 2016 naloxone, when indicated for emergency use for opioid overdose outside hospital settings, has been moved from Schedule 1 to Schedule 2 in Alberta. Schedule 2 drugs, when dispensed or sold in a pharmacy must be stored and provided from the dispensary under the supervision of a pharmacist. The ACP Standards of Practice for Pharmacists and Pharmacy Technicians set out the minimum acceptable standard of practice and include standards regarding the distribution or sale of Schedule 2 drugs. The intent of this document is to provide guidance for pharmacists in the interpretation of the standards with regard to dispensing or selling THN kits.

#### Guidance

1. A pharmacist must consider appropriate information to assess whether it is appropriate to dispense or sell naloxone.
2. A pharmacist must provide sufficient information to enable the patient to receive the intended benefit of the drug therapy. When naloxone is provided to a person for the first time a pharmacist must enter into a dialogue with that person.
3. A pharmacist who dispenses or sells naloxone must record the sale or dispensing event.

#### Additional Interpretation:

1. **A pharmacist must consider appropriate information to assess whether it is appropriate to dispense or sell Naloxone.**

- The THN program was created by AH and AHS as a harm reduction initiative to prevent overdose complications or death by making naloxone available to any Albertan who is at risk of an opioid overdose. Naloxone is a safe and effective antidote to opioid overdose. Therefore, it is very unlikely that it would not be appropriate to provide a THN kit to someone who requests it.
  - It is appropriate for the pharmacist to:
    - determine whether the patient has had a hypersensitivity reaction to naloxone in the past and if so whether it was a true hypersensitivity reaction which may prohibit administration of naloxone;
    - determine whether the patient has a pre-existing cardiac disease and, if female, whether they are pregnant or breastfeeding. Although naloxone is not contraindicated in these situations caution should be exercised;
    - consider any other patient specific information that may affect the pharmacist's decision to provide Naloxone.
  - The THN program makes kits available free of charge to pharmacies for provision of individual kits to Albertans who are at risk of opioid overdose or who may encounter others who have overdosed on opioids.
    - It is inappropriate for pharmacists to prepare and/or sell kits to Albertans outside of this program.
    - Organizations, groups or individuals who wish to obtain multiple kits for distribution should be referred to AHS.
- 2. A pharmacist must provide sufficient information to enable the patient to receive the intended benefit of the drug therapy. When a Naloxone kit is provided to a person for the first time a pharmacist must enter into a dialogue with that person.**
- As outlined in the training for participation in the AHS THN program, important information when providing Naloxone includes, but is not limited to:
    - 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
    - how to landmark on the thigh and administer an IM injection
    - when to use the second vial of naloxone
    - the importance of calling 911 for medical assistance due to the short half-life of the drug
  - Written information must not replace a dialogue with a pharmacist when naloxone is provided for the first time
- 3. A pharmacist who dispenses or sells a Naloxone kit must make a record of the sale or dispensing activity**
- A pharmacist or a pharmacy technician must ensure an appropriate entry is made in the patient's record indicating that naloxone was provided, the date, and the identification of the pharmacist who provided it.

- If the requestor is not willing to identify the patient for whom they are requesting the kit, a pharmacist or pharmacy technician must create a record indicating that a THN kit was provided to an unknown patient, the date, and the identification of the pharmacist who provided the kit.

## References and Additional Resources

1. ACP; Standards of Practice for Pharmacists and Pharmacy Technicians;  
<https://pharmacists.ab.ca/standards-practice>
2. AHS; Registered Nurse or Registered Psychiatric Nurse Decision Support Tool for Prescribing Take Home Naloxone (THN) Kit; <http://www.albertahealthservices.ca/frm-20257.pdf>
3. AHS; RN or RPN Prescribing & Dispensing a Take Home Naloxone Kit Flow Chart;  
<http://www.albertahealthservices.ca/assets/healthinfo/mh/amh-thn-rn-naloxone-clinical-decision-flow-sheet.pdf>
4. Alberta Blue Cross; Benefact Number 575 January 2016;  
<https://www.ab.bluecross.ca/pdfs/pharmacy-benefacts/pharmacy-benefact-575.pdf>
5. Alberta Health Services; drugsfool.ca; <http://www.albertahealthservices.ca/info/page12491.aspx>
6. Alberta Pharmacists' Association; Take Home Naloxone – Information for the Pharmacist;  
<https://www.rxa.ca/professional-development/thn-program.aspx>
7. Omega Laboratories Ltd.; Product Monograph Naloxone Hydrochloride Injection USP; September, 2012; [http://www.omegalaboratory.com/index.php/download\\_file/view/2153/327/](http://www.omegalaboratory.com/index.php/download_file/view/2153/327/)