



Team Name: Pharmacy and Therapeutics Team Lead: Director - Pharmacy Approved by: Regional Lead - Medical Services & Chief Medical Officer	Reference Number: CLI.6010.PL.019 Program Area: Pharmacy Policy Section: General
Issue Date: April 20, 2023 Review Date: Revision Date: July 26 2023	Subject: Take Home Naloxone Program

Use of pre-printed documents: Users are to refer to the electronic version of this document located on the Southern Health-Santé Sud Health Provider Site to ensure the most current document is consulted.

POLICY SUBJECT:

Take Home Naloxone Program

PURPOSE:

To increase access to overdose prevention, recognition and response training and provide Take Home Naloxone kits and training to eligible people at risk of opioid overdose and their family and friends.

BOARD POLICY REFERENCE:

Executive Limitation (EL-2) Treatment of Clients

POLICY:

Healthcare professionals who attain and maintain competency and follow the standards of care as outlined in this document are authorized to distribute Take Home Naloxone (THN) kits.

Everyone is legally permitted to administer naloxone to someone appearing to be suffering from an opioid overdose outside of a hospital setting. A bystander who provides emergency first aid, including administration of naloxone, is protected from liability by Manitoba’s “The Good Samaritan Protection Act C.C.S.M.cG65”.

DEFINITIONS:

Opioid Overdose: The term “opioid” is used here in reference to both natural derivatives from the opium poppy (opiates, such as heroin and morphine) and synthetic medications that mimic these drugs (fentaNYL, oxycontin). Overdose occurs when opioids bind to receptor sites of the brain stem, desensitizing the brain stem to carbon dioxide levels in the blood to the degree that breathing mechanisms are not normally triggered, and respirations are depressed leading to hypoxia.

Naloxone: is an opioid antagonist that reverses respiratory depression caused by opioid overdose by replacing opioids at the receptor sites. Naloxone has little to no adverse side effects or potential for alternate or recreational use and has a remarkably high safety profile, especially when used in low doses and titrated to effect. Naloxone is highly effective for opioid related overdose, but is ineffective for the treatment of non-opioid related overdose. The utility of naloxone is dependent on timing and availability, as respiratory depression caused by opioid overdose should be reversed within 4 minutes in order to avoid morbidity and mortality associated with hypoxic events. Naloxone is on the World Health Organizations' list of essential medicines.

Naloxone is a Schedule II drug, available in Canada without a prescription. According to the College of Pharmacists of Manitoba, Schedule II subsection 84(5) (December 7, 2020) excludes naloxone packaged for use in opioid overdose from the conditions for sale of Schedule II products, thereby permitting them to be sold: from any location or shelf in the pharmacy; without the involvement of a licensed pharmacist in the sale of the product; and without the requirement for the pharmacist to counsel individuals on the proper use and administration of the product in an opioid emergency; however the pharmacist would be available to provide counselling on proper use and administration if requested.

Site Lead: each site participating in THN kit distribution must have a regulated professional designated to support the clinical needs of the distribution site as follows:

- Oversight of provider training/preparation, standards and clinical support of site naloxone providers
- Site liaison to Manitoba Health and Seniors Care (MHSC) for reporting kit tracking and use, and for contact from MHSAL in case of kit recall or program changes.

Lay Responder: is a term used to describe a person who has received some formal training to respond to health conditions or situations, although this response is not the individual's primary role. Several studies have demonstrated that people who inject opioid drugs are very likely to be present during overdose events, have a vested interest in overdose prevention and response, with training and support can respond to overdose very effectively

IMPORTANT POINTS TO CONSIDER:

Distribution Site Criteria:

In order to be eligible to distribute FREE THN kits provided by MHSC to people at risk of opioid overdose and family and friends of people who are at risk of opioid overdose, the following site criteria must be met:

- THN kits must be provided by a regulated healthcare professional including: a nurse, physician, pharmacist or paramedic. Health professionals who provided the THN kits are responsible for undertaking a focused health history and confirming adequate knowledge uptake from the training with the client/lay responder. However, training on overdose recognition and response may be provided by support staff (including trained volunteers, peers/people who use drugs, families and friends of those people who use drugs and outreach staff) who have been adequately prepared to deliver this training.

- Training of lay responders should include:
 - Factors that can increase or decrease risk of overdose
 - How to recognize an overdose; including depressant and stimulant overdoses
 - How to respond to an overdose including:
 - How to perform rescue breathing
 - How to put someone in the recovery position
 - How to communicate with 911 and why it is important to call 911
 - How to prepare and administer naloxone
 - How and when to evaluate and support
- The naloxone kits are provided to distribution sites at no cost, however, the human resources involved in distribution must be provided in-kind. The site must provide THN kits at no cost to the client (no counselling or dispensing fee may be charged to the client and MHSC does not reimburse for these services)
- **Eligibility for THN:** THN kits may only be provided to people at risk of opioid overdose, and family and friends of those people who are at risk of opioid overdose. Risk of opioid overdose may be defined as:
 - Any illicit opioid use
 - Use of any illegal drug with potential opioid adulterants (i.e. powdered cocaine, crystal methamphetamine, illegally manufactured tablets or blotter drugs)
 - Prescribed opioids at greater than 20 mg morphine equivalent/day
 - Intention or likely near future illicit opioid use
- Reporting requirements to MHSC, epidemiology and surveillance must be completed and submitted.
- Site should maintain a mechanism to track recipients of THN kits. This can facilitate timely kit replacement for existing clients, and assist in notifying kit recipients in the event of a naloxone kit recall. Individual identifiers of kit recipients should not be forwarded to MHSC. If a lot number is recalled from the manufacturer, MHSC will notify participating distribution sites that received the recalled product, but will not notify the individual kit recipients.
- Site is required to comply with naloxone ordering, receiving and storage requirements.

Site must agree to the THN kit distribution site criteria as indicated in this policy prior to being set up to order naloxone kits directly from the Provincial Distribution Warehouse.

PROCEDURE:

Pharmacy:

Naloxone kit ordering from Manitoba's Provincial Distribution Warehouse:

- Pharmacy manager will register as a naloxone distribution site by completing the THN Distribution Site Agreement Form CLI.6010.PL.019.FORM.01, scan and email to the attention of: Provincial THN Program at: naloxonekits@gov.mb.ca
- Orders for naloxone kits can be placed using the existing client ID number for ordering vaccines and by submitting the THN Kit Order Form CLI.6010.PL.019.FORM.02
- If a site does not have a client ID number, a New Provider Application Form CLI.6010.PL.019.FORM.03 must be filled and submitted to MHSC.

- Sites will have minimum and maximum order quantities set in the Inventory Management System (Panorama). Orders that exceed the maximum quantities will be reviewed on a case by case basis.

How much to order:

- Sites are encouraged to order enough kits for 2 to 3 months and if possible to avoid ordering during the coldest months of the year when ambient shipping is difficult.
- Typical order size for regular site is 20 kits maximum, larger sites 50 kits maximum. Kits can only be ordered in multiples of 5.
- MHSC will follow up with sites placing unusually large orders, or unapproved sites attempting to order. Ordering volumes can be adjusted based on site needs.

Ordering and receiving supplies from the Provincial Distribution Warehouse:

- After hours, emergency supply access is available for naloxone kits
- To avoid disruption of services, please plan ahead to ensure sufficient stock on hand for the next month.
- Delivery time is approximately 4 business days from the date of order approval.
- Order cut off is 3 pm daily, after which the order is considered submitted the next working day.
- Please check your order on receipt to ensure you received the correct quantities and supplies in good condition. If you notice discrepancies, please call the Provincial Distribution Warehouse at 204-948-1333 or 1-855-683-3306.
- The site must call the Provincial Distribution Warehouse when the shipment is received and let the warehouse know if the monitor was flashing green (OK) or red (ALERT). If flashing red, product is to be held until the warehouse calls to release it.
- Packaging and monitor must be returned to the Provincial Distribution Warehouse. A charge of \$150 may result if it is not returned.

Reporting requirements to MHSC, Epidemiology and Surveillance:

- Sites must submit completed THN Kit Tracking Form CLI.6010.PL.019.FORM.04 semi-annually (January to June and July to December)
- Sites must submit completed Overdose Response Forms CLI.6010.PL.019.FORM.06 for those kits used in overdose events
- Send both completed forms by mail or fax to MSHC Surveillance Unit: Fourth Floor – 300 Carlton St, Winnipeg, MB. CONFIDENTIAL Fax: 204-948-3044

Nursing:

Competency:

- BLS and ACLS certification
- Refer to the MHSAL Training Manual: Overdose Prevention, Recognition (on the Health Providers Site Self Learning Resources)
- Review the THN Program Policy
- Review the MHSAL THN Program: Distribution Site Criteria (see above Important Points to Consider)
- Lay responder training

- Documentation

Health History and Assessment of Therapeutic Suitability of Naloxone for the Patient:

- Create an individual health record for clients who are eligible to receive a THN kit
- Responsible to ensure the pharmaceutical and therapeutic suitability of naloxone for the individual client
- Complete an assessment using the THN Program – Intake Form CLI.6010.PL.019.FORM.07 to include:
 - Review of the patient’s medication history and other relevant personal health information
 - Consider potential drug interactions, contraindications, allergies, therapeutic duplications and any other potential problems, such as adverse side effects, drug withdrawal symptoms and irritability.
 - Consider the patient’s ability to administer naloxone appropriately and safely.
 - Store Intake Form in the patient’s health record
- If the patient does not demonstrate ability to safely and appropriately administer the naloxone, an individualized safety plan for the patient will be made i.e. bringing in a person close to them for training

Provision, Tracking and Replacement of THN Kits:

- Prior to providing a patient with a THN kit, verify
 - The contents of the THN kit for completeness
 - The integrity and expiry date of the medication in the kit
 - The patient has received overdose recognition and response training in the last 12 months
- For every THN kit provided, record the following information on the Distribution Log CLI.6010.PL.019.FORM.05:
 - Patient name
 - PHIN (if available)
 - Kit number
 - Naloxone lot number
 - Expiry date
 - Date distributed
 - Distributed by
- Tracking is a significant component of program evaluation and enables to contact recipients of THN kits if product is recalled. THN kits will not be entered into the DPIN system.
- The reason for providing the THN kit must be reviewed and recorded i.e. used, expired, lost, stolen, confiscated. If the patient provided another reason for the replacement i.e. damaged, frozen, please write the reason in full.
- Fax completed Distribution Log to pharmacy.
- In the rare event that a patient experienced a hypersensitivity reaction, report the occurrence on the Mandatory Reporting of a Serious Adverse Drug Reaction (SADR) policy ORG.1810.PL.010.

Prescriber:

- If the THN kit was used in an overdose event, complete the Overdose Response Form CLI.6010.PL.019.FORM.06.
- Fax completed form to pharmacy.

Education of Patient/Lay Responder:

- Provided by Nursing, Prescriber or ER pharmacist (if available).
- Responsible to ensure the patient's understanding of overdose recognition and response including proper use of the THN Kit.
- The following components must be covered and are detailed in the Training Manual: Overdose Recognition and Response CLI.6010.PL.019.SD.01:
 - Factors that can increase or decrease risk of overdose
 - How to recognize an overdose, including depressant and stimulant overdoses
 - How to respond to an overdose including:
 - How to perform rescue breathing
 - How to put someone in recovery position
 - How to communicate 911 and why it is important to call
 - How to prepare and administer naloxone
 - How and when to evaluate and support
 - Safe-keeping and storage of naloxone
 - Allow time to address any questions and concerns and demonstrate knowledge uptake.
- Provide copies of the 2 Patient Handouts: What is Naloxone and why do you need it? CLI.6010.PL.019.SD.02 and Naloxone Injection Training Checklist CLI.6010.PL.019.SD.03.
- Complete the TPN Program Overdose Recognition and Response Training Record CLI.6010.PL.019.FORM.09.
- Complete the TPN Program Post Training Questionnaire CLI.6010.PL.019.FORM.08 including THN Program Post Training Questionnaire Answer Key CLI.6010.PL.019.SD.04 with the patient and store in the patient's chart.
- For patients who receive overdose response training but DO NOT receive a THN kit, an individual health record does not need to be created.

SUPPLIES:

Each THN Kit should contain:

- Black case
- 2 x naloxone 0.4 mg/mL, 1 mL ampoules
- 2 x Vanish Point 3 mL syringe with 1 inch needle
- Medication bottle with label
- 2 x plastic ampoule breakers
- 1 pair of non-latex gloves
- 2 x alcohol swabs
- Breathing mask in pouch
- Bilingual instruction insert

For each THN kit, the following training supplies will be provided: 1 water ampoule, 1 ampoule breaker and 1 Vanish Point syringe

General notes about supplies:

- Always use oldest supply first to prevent product expiry. Naloxone kits should be stored between 15 and 30 degrees Celsius
- Naloxone has a shelf life of approximately 2 years. Check the expiry of each kit before providing to clients.
- Naloxone kits within 3 months of expiry SHOULD NOT BE PROVIDED to clients. Please do not return expired kits to the Provincial Distribution Warehouse. Remove and discard the expired naloxone ampoules from the kit for disposal. Repurpose the remaining supplies as you see fit.
- Naloxone kits have a lot number stickered on the outer case that refers to the assembly of the kit by the supplier. This lot number will be different than the medication lot number on the ampoules of naloxone.

SUPPORTING DOCUMENTS:

CLI.6010.PL.019.FORM.01	THN Distribution Site Agreement Form
CLI.6010.PL.019.FORM.02	THN Kit Order Form
CLI.6010.PL.019.FORM.03	New Provider Application Form
CLI.6010.PL.019.FORM.04	THN Kit Tracking Reporting Form
CLI.6010.PL.019.FORM.05	THN Kits Distribution Log
CLI.6010.PL.019.FORM.06	Overdose Response Form
CLI.6010.PL.019.FORM.07	THN Program Intake Form
CLI.6010.PL.019.FORM.08	THN Program Post Training Questionnaire
CLI.6010.PL.019.FORM.09	THN Program Overdose Recognition and Response Training Record
CLI.6010.PL.019.SD.01	Training Manual: Overdose Recognition and Response
CLI.6010.PL.019.SD.02	Patient Handout: What is Naloxone and why do you need it?
CLI.6010.PL.019.SD.03	Patient Handout: Naloxone Injection Training Checklist
CLI.6010.PL.019.SD.04	THN Program Post Training Questionnaire Answer Key

REFERENCES:

Mandatory Reporting of a Serious Adverse Drug Reaction (SADR) policy ORG.1810.PL.010

Amendment to Prescribing Principles – Statement 805 for Naloxone. Available at:

<http://cpsm.mb.ca/cjj391lckF30a/wp-content/uploads/St805.pdf>.

College of Pharmacists of Manitoba (May 2021). Understanding drug schedules.

<http://cphm.ca/uploaded/web/legislation/practice%20Resources/Understanding%20drug%20schedules%20.pdf>

Manitoba Health. (accessed September 2022) Take Home Naloxone Distribution Program. [Take-Home Naloxone Distribution Program | Health | Province of Manitoba](#)