

UPDATED Executive Officer Notice: Ontario Naloxone Program for Pharmacies

Effective July 24, 2024

This is an update to an earlier Executive Officer ("EO") notice dated February 9, 2024.

This notice is to provide information on updates to the Ontario Naloxone Program for Pharmacies (the "ONPP").

This EO Notice and the accompanying Questions and Answers ("Qs and As") set out the terms and conditions for a participating pharmacy's submission of claims for payment under the ONPP. Each document is a ministry policy that pharmacy operators must comply with under section 3.2. of the Health Network System (HNS) Subscription Agreement for Pharmacy Operators.

Only Part A pharmacists, registered pharmacy interns, and pharmacy students (under the supervision of a pharmacist), can provide publicly funded naloxone kits to eligible individuals at participating pharmacies.

Prior to providing naloxone kits to eligible individuals, pharmacies must ensure that their pharmacy staff are trained to provide the necessary training to eligible persons who are to receive the naloxone kits.

Overview of Changes

Effective July 24, 2024, updates to the ONPP include:

- Clarifying that the provision of naloxone kits under ONPP must occur on-site at
 the physical premises of the pharmacy. This requirement does not apply if the
 eligible individual is already receiving care from the pharmacy and is unable to
 physically attend the pharmacy and requires the naloxone kit to be delivered to
 them at an address in Ontario.
- Clarifying training for eligible individuals receiving a kit on how to use it must be
 provided on an individual basis, in real-time, and not in group settings. Training
 consisting solely of instructional videos or websites are not permitted, but realtime virtual training may be provided.
- Clarifying pharmacy documentation requirements related to claims for naloxone distribution (details in the Pharmacy Documentation Requirements section).
- Updates to the kit contents and specification of drug products (Appendix A)



Intra-nasal naloxone kits may include two (2) doses of any Health Canada approved naloxone hydrochloride intra-nasal spray 4 mg/0.1 mL drug product until September 2, 2024; after this date, intra-nasal naloxone kits will only be funded under the ONPP if they contain two (2) doses of Narcan[®].

Background

On June 3, 2016, the Ministry of Health (the "ministry"), introduced the ONPP, making publicly funded injectable naloxone kits available in pharmacies.

As of June 24, 2016, naloxone hydrochloride moved to Schedule II in the NAPRA's National Drug Schedule (NDS) and no longer requires a prescription to be dispensed in pharmacies if indicated for emergency use for opioid overdose outside of a hospital setting.

On March 27, 2018, intra-nasal naloxone spray (INNS) (Narcan® Nasal Spray) was added to the ONPP for all eligible recipients and the ONPP was modified to permit pharmacists to, in limited circumstances:

- Provide naloxone kits to Ontarians who do not have an Ontario health card or to those who do not wish to provide identification; and
- Provide up to two naloxone kits to an eligible recipient at one time.

Pharmacy Eligibility

To be eligible to submit claims under the ONPP, a pharmacy operator (also referred to in this document as a "participating pharmacy") must have a valid HNS Subscription Agreement with the ministry.

Recipient Eligibility

The following individuals may receive eligible services (defined below) under the ONPP from participating pharmacies ("eligible individuals"):

- an individual who is at-risk of opioid overdose due to either currently using opioids or at-risk of returning to opioid use or
- a family member or friend, or other individual in a position to assist, an at-risk individual described above.



The individual does not need to be insured under the Ontario Health Insurance Plan (OHIP) or a recipient of the Ontario Drug Benefit (ODB) program. There is no cost to eligible individuals who receive eligible services under the ONPP.

Eligible Services

Subject to the Exclusions and Restrictions below, a participating pharmacy may provide the following services ("eligible services") to eligible individuals:

- Provision of naloxone kits within the physical premises of the pharmacy. This
 requirement does not apply if the eligible individual is already receiving care from
 the pharmacy and is unable to physically attend the pharmacy and requires the
 naloxone kit to be delivered to them at an address in Ontario.
- The training for eligible individuals receiving a kit on how to use it must be
 provided on an individual basis, in real-time, and not in group settings. Training
 consisting solely of instructional videos or websites are not permitted, but realtime virtual training may be provided.

Pharmacists are expected to use their professional judgement when distributing naloxone kits and providing training as appropriate.

Naloxone Kits Contents

The ministry does **not** procure naloxone kits and/or supplies for participating pharmacies but does mandate required kit contents.

Participating pharmacies can procure pre-made naloxone kits and/or the required supplies to assemble the naloxone kits (i.e., injectable and intra-nasal naloxone products) from their usual pharmacy suppliers and/or distributors.

For pharmacy-assembled naloxone kits, these shall be assembled by a Part A pharmacist, or a pharmacy staff member under the supervision of a Part A pharmacist. Appendix A to this EO Notice lists the required items in a naloxone kit, with each kit containing 2 doses of naloxone.

The Ontario Pharmacists Association (OPA) has developed resources relating to naloxone kits, including a listing of kit contents (https://opatoday.com/naloxone-kit-supplies-list), on their website at https://opatoday.com/naloxone.



Billing Procedure

Pharmacies must submit claims for payment using the individual's valid Ontario health card number (if available), on the same day the naloxone kit(s) and training are provided. Reasonable efforts must be made to obtain the eligible individual's Ontario health card number.

If the eligible individual is an ODB program recipient:

- Intervention code 'PS': Professional Care Services
- Product Identification Number (PIN): see Table 1 below for list of PINs

If the eligible individual is **not** an ODB program recipient and **has an Ontario health** card number:

- Patient Gender: 'F' = female; 'M' = male
- Patient Date of Birth: Valid YYYYMMDD
- Patient's Ontario Health number
- Intervention codes:
 - 'PS': Professional Care Services
 - o 'ML': Established eligibility coverage (i.e., 1 day of the Plan 'S' coverage)
- Carrier ID: 'S'
- Product Identification Number (PIN): see Table 1 below for list of PINs

If the eligible individual is **not** an ODB program recipient and **does not have an Ontario health card number**, pharmacists must submit claims using a Proxy ID for payment:

- First Name: HARM
- Last Name: REDUCTION
- Patient Gender: 'F' = female; 'M' = male; (or) Blank
- Patient Date of Birth: Valid YYYYMMDD (if known) or 20000101
- Proxy patient ID: 89999 999 91
- Intervention codes:
 - 'PS': Professional Care Services
- Product Identification Number (PIN): see Table 1 below for list of PINs
- A valid Pharmacist ID is required in the prescriber field for all claim submission, this
 is the license number of the Part A pharmacist who provides or supervises the
 provision of naloxone kits.
- **Table 1** lists the claim submission PINs and the total amount payable for naloxone kits provided to each eligible individuals by participating pharmacies. The amount associated with each PIN is payment for providing the kit(s) and providing training on how to use the kit(s).
- A maximum of two (2) naloxone kits (i.e., total 4 doses) may be provided to an
 eligible individual per day and should be submitted as a single claim for payment.



Table 1: Naloxone kits funded under the ONPP

| PIN | Naloxone Kit Type and Description | Total Amount Paid |
|----------|--|-------------------|
| 93877251 | One Injectable Kit \$35 – cost of one kit \$10 – professional fee \$25 – training fee | \$70 |
| 93877252 | One Injectable Kit (replacement kit with no training) • \$35 – cost of one kit • \$10 – professional fee | \$45 |
| 93877257 | Two Injectable Kits (one initial and one replacement kit with one professional fee and one training fee only) • \$70 – cost of two kits • \$10 – professional fee • \$25 – training fee | \$105 |
| 93877258 | Two Injectable Kits (two replacement kits with one professional fee only) • \$70 – cost of two kits • \$10 – professional fee | \$80 |
| 93877255 | One Intra-Nasal Kit • \$110 – cost of one kit • \$10 – professional fee | \$120 |
| 93877256 | Two Intra-Nasal Kits (one professional fee only) • \$220 – cost of two kits • \$10 – professional fee | \$230 |

Notes

 Do not use the Drug Identification Number (DIN) of the naloxone product that is contained in the naloxone kit for claim submission.

Pharmacy documentation requirements

Pharmacists, pharmacy staff and pharmacies shall keep records consistent with their obligations under the *Pharmacy Act*, 1991, the *Drug and Pharmacies Regulation Act*, and any instructions or guidelines provided by the Ontario College of Pharmacists or the ministry.

For purposes of post-payment verification, pharmacy records related to claims for naloxone distribution must be maintained in a readily available format for the purpose of ministry inspection for a minimum of 10 years from the last recorded pharmacy service

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Ministry of Health Health Programs and Delivery Division

provided to the patient, or until 10 years after the day on which the patient reached or would have reached the age of 18 years, whichever is longer.

For every naloxone kit distributed to eligible individuals and submitted for payment to the ministry, participating pharmacies must keep a record of service provision, including:

- Type of naloxone kit(s) provided and details of the training provided;
- Name and address of pharmacy where services were provided, signature of authorized pharmacy staff who provided the naloxone kit; and
- Date of service (and delivery date, if applicable)

In addition, reasonable efforts must be made to obtain the eligible individual's identity and contact information, including:

- Name, date of birth, and address of eligible individual,
- Ontario health card number of eligible individual

Exclusions and Restrictions under the ONPP

Naloxone kits must be provided to eligible individuals at the physical premises of the pharmacy location. This requirement does not apply if:

- the eligible individual is unable to physically attend the pharmacy and requires the naloxone kit to be delivered to them at an address in Ontario; and
- the eligible individual is already receiving care from the pharmacy.

In the case of service provision is for an eligible individual not at the pharmacy, the authorized pharmacy member must offer real-time virtual training on the use of the naloxone kit, if required, Training consisting solely of instructional videos or websites are not permitted.

All other requirements in this Notice must be met by the pharmacy (e.g., quantity limit, and pharmacy documentation of service).

The following are **not** eligible for payment under the ONPP:

- Naloxone kits provided to businesses and/or organizations.
- Naloxone kits provided by in-patient hospital pharmacies.
- Claims for one (single) naloxone kit (injectable PIN 93877251 or PIN 93877252, or intra-nasal spray PIN 93877255) submitted twice in a day for an eligible person as two kits.

In addition:

 Only the cost of the kit (without professional fee) is eligible payment for residents of long-term care homes.



- A claim under the Pharmaceutical Opinion Program may not be made for the recommendation for, and/or provision of naloxone kits.
- Overpayments due to inappropriate claim submissions are subject to recovery.

Additional Information:

For pharmacy billing:

Please call ODB Pharmacy Help Desk at: 1-800-668-6641

For inquiries relating to ONPP:

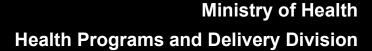
Please email the ministry at: PublicDrugPrgrms.moh@ontario.ca

For Ministry webpages relating to naloxone:

Please access this website

For all other Health Care Providers and the Public:

Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282.





APPENDIX A:

Contents of the naloxone kits (both injectable and intra-nasal spray) are outlined below.

Each intra-nasal spray naloxone kit must include:

- One (1) hard case (preferably, a zippered hard black case with red "naloxone" cross)
- Two (2) doses of Narcan[®] (naloxone hydrochloride) intra-nasal spray 4 mg/0.1 mL (DIN 02458187)¹
- One (1) rescue breathing barrier
- One (1) pair of non-latex gloves
- One (1) card that identifies the person trained to give the naloxone
- One (1) updated instructional insert (English and French)

Each injectable naloxone kit **must** include:

- One (1) hard case (preferably, a zippered hard black case with red "naloxone" cross)
- Two (2) 1 mL ampoules or vials of naloxone hydrochloride injection 0.4 mg/mL (DIN 02455935, 02458578, or 02453258)
- Two (2) safety engineered syringes with 25g x 1" (one inch) needles attached
- Two (2) alcohol swabs
- Two (2) safe ampoule-opening devices (also known as breakers, snappers, or openers), as applicable
- One (1) rescue breathing barrier
- One (1) pair of non-latex gloves
- One (1) card that identifies the person trained to give the naloxone
- One (1) updated instructional insert (<u>English</u> and <u>French</u>)

¹Intra-nasal naloxone kits may include two (2) doses of any Health Canada approved naloxone hydrochloride intra-nasal spray 4 mg/0.1 mL drug product until September 2, 2024; after this date, intra-nasal naloxone kits will only be funded under the ONPP if they contain two (2) doses of Narcan[®].