

UPDATED Executive Officer Notice: Ontario Naloxone Program for Pharmacies

Effective October 28, 2024

This is an update to an earlier Executive Officer ("EO") Notice dated August 23, 2024.

This notice provides 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 and other authorized pharmacy staff (acting under the supervision of a pharmacist who is physically present), 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 Part A pharmacists and other authorized pharmacy staff are trained to provide the necessary training to eligible persons who are to receive the naloxone kits.

Overview of Changes

Under the ONPP, pharmacies are paid a fixed dollar amount for dispensing a naloxone kit to eligible individuals. The dollar amount is based on the PIN used to submit the claim for payment through the Health Network System. This dollar amount includes the drug cost of the naloxone product included in a kit, and this drug cost is based on the list price of the naloxone product in the marketplace.

In the case of intra-nasal naloxone spray, the drug cost paid to pharmacies for PINs: 93877255 and 93877256 is based on the list price of Narcan® nasal spray. Effective October 28, 2024, a generic version of intra-nasal naloxone spray will become eligible for funding under the ONPP (Teva-Naloxone nasal spray 4mg/0.1mL, DIN: 02511568) at a list price that is lower than the list price of Narcan® nasal spray. Accordingly, effective October 28, 2024, new PINs will be introduced for claim submissions for intra-nasal naloxone spray kits with updated dollar amounts that reflect the list price of Teva-Naloxone nasal spray (PINs: 93877261 and 93877262). These PINs must be used if a pharmacy is dispensing kits containing Teva-Naloxone nasal spray.



Pharmacies will still be eligible to submit claims for dispensing kits containing Narcan[®] nasal spray using existing PINs 93877255 and 93877256 (for reimbursement based on the list price of Narcan[®]) until end of day on December 1, 2024. As of December 2, 2024, ONPP will only cover the cost of generic intra-nasal naloxone spray as listed below in Table 1, subject to one exception (see last bullet below).

Therefore, effective December 2, 2024 updates to the ONPP are as follows:

- Deactivation of the existing intra-nasal naloxone spray PINs 93877255 and 93877256 that reflect the list price of Narcan[®] nasal spray.
- A requirement that pharmacies use PINs 93877261 and 93877262 that reflect
 the list price of Teva-Naloxone nasal spray when dispensing publicly funded kits
 containing naloxone nasal spray, <u>regardless</u> of which naloxone nasal spray
 product (i.e., Narcan[®] or Teva-Naloxone) is dispensed.
- Rules that allow pharmacies to charge other payors the difference between the
 dollar amounts for a naloxone kit with Narcan[®] and a naloxone kit with TevaNaloxone nasal spray where an eligible individual specifically requests a
 naloxone kit containing Narcan[®] nasal spray and there is no shortage of TevaNaloxone nasal spray.
- An "exception" rule that allows pharmacies to charge the ministry the list price of Narcan[®] nasal spray, but only where there is a product shortage of Teva-Naloxone nasal spray and Narcan[®] must be dispensed instead. In this scenario, a Special Service Code (SSC) must be used during claim submission in order for the price of Narcan[®] nasal spray to be reimbursed.

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 has not required 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, unless otherwise specified in this Notice.

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 other authorized pharmacy staff acting 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

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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 individual 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	\$105



PIN	Naloxone Kit Type and Description	Total Amount Paid
	\$25 – training fee	
93877258	Two Injectable Kits (two replacement kits with one professional fee only)	\$80
	 \$70 – cost of two kits \$10 – professional fee 	
93877261	One Intra-Nasal Kit	
	 \$82 – cost of one kit \$10 – professional fee 	\$92
93877262	Two Intra-Nasal Kits	
	 \$164 – cost of two kits \$10 – professional fee 	\$174

Notes

- **Do not** use the Drug Identification Number (DIN) of the naloxone product that is contained in the naloxone kit for claim submission.
- Effective **October 28, 2024**, pharmacies must submit claims for <u>generic</u> intra-nasal naloxone sprays using the appropriate PINs in Table 1 above.
- Until end of day on December 1, 2024, pharmacies are eligible to submit claims for Narcan[®] nasal spray using the current PINs below. As of December 2, 2024, the PINs below will be deactivated.
 - PIN: 93877255 for One Intra-Nasal Kit with a Total Dollar Amount of \$120
 - o PIN: 93877256 for Two Intra-Nasal Kits with a Total Dollar Amount of \$230
- Effective **December 2, 2024**:
 - Pharmacies must submit claims for <u>all</u> intra-nasal naloxone sprays using the PINs in Table 1 above.
 - In the event of a shortage of Teva-Naloxone nasal spray that requires a pharmacy to include Narcan[®] nasal spray in a naloxone kit, the pharmacy may claim a higher dollar amount that corresponds to the list price of Narcan[®] nasal spray by using the PINs below and including Special Service Code (SSC) "N" (Short Term Dispense Modified Fee) in the SSC field of the claim.
 - PIN: 93877261 for One Intra-Nasal Kit with a Total Dollar Amount of \$120



- PIN: 93877262 for Two Intra-Nasal Kits with a Total Dollar Amount of \$230
- Where there is no shortage of Teva-Naloxone nasal spray and an eligible individual specifically requests Narcan[®] nasal spray, despite being informed by the pharmacy that Teva-Naloxone nasal spray is available at no cost under the ONPP, the pharmacy may dispense Narcan[®] nasal spray and charge the eligible individual or another payor the following amounts (do not use SSC "N" in the claim submission):

PIN: 93877261 for One Intra-Nasal Kit: \$28

PIN: 93877262 for Two Intra-Nasal Kits: \$56

 Overpayments due to inappropriate use of SSC "N" are subject to recovery through claim validation. See documentation requirements below.

Pharmacy documentation requirements

Part A pharmacists, other authorized 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 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, unless otherwise noted below.

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

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Effective December 2, 2024, in the event of a shortage of Teva-Naloxone nasal spray that requires a pharmacy to include Narcan® nasal spray in a naloxone kit and use SSC "N" to claim the higher dollar amount that corresponds to the list price of Narcan® nasal spray, supporting documentation (manufacturer or wholesaler's invoice), which clearly indicates that the Teva-Naloxone nasal spray had been ordered and was unavailable during the appropriate time period, must be maintained on file for at least two years from the day the invoice was received.

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 for an eligible individual not at the pharmacy, the Part A pharmacist or other authorized pharmacy staff must offer real-time virtual training on the use of the naloxone kit, if required. Training consisting solely of instructional videos or websites is 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 submitted twice in a day for an eligible individual as two kits.
- Claims submitted with SSC "N" for Narcan® nasal spray when there is no actual shortage of the Teva-Naloxone nasal spray.

In addition:

- Only the cost of the kit (without a professional fee) is eligible for payment for kits
 provided to residents of long-term care homes (but training must still be provided
 when the kits are supplied to long-term care home residents).
- 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.

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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 naloxone hydrochloride intra-nasal spray 4 mg/0.1 mL (DIN 02511568, or DIN 02458187)
- 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 02453258, 02455935, or 02458578)
- Two (2) safety engineered syringes with 25g x 1" (one inch) needles attached, as applicable
- Two (2) safe ampoule-opening devices (also known as breakers, snappers, or openers), as applicable
- Two (2) alcohol swabs
- 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>)