On June 24, 2016, the National Association of Pharmacy Regulatory Authorities (NAPRA) finalized the scheduling change for naloxone hydrochloride injection ("naloxone"). Naloxone, when indicated for emergency use for opioid overdose outside hospital settings, is now classified as a Schedule II drug in the NAPRA’s National Drug Schedule (NDS).

As a result, effective June 24, 2016, naloxone no longer requires a prescription to be sold in Ontario pharmacies if indicated for emergency use for opioid overdose outside hospital settings.

Effective June 24, 2016, all pharmacies may receive reimbursement for providing naloxone emergency kits by submitting claims through the Health Network System (HNS).

If you have any questions, please contact the ministry by email at PublicDrugPrgrms.moh@ontario.ca or the Ontario Drug Benefit (ODB) Help Desk at 1-800-668-6641.

Background

On June 3, 2016, the Ministry of Health and Long-Term Care’s (ministry) new Ontario Naloxone Program for Pharmacies (ONPP) made publicly-funded naloxone available in pharmacies that dispense opioid agonist maintenance therapy (methadone/Suboxone) under a prescription order from the Chief Medical Officer of Health (CMOH) for Ontario. The CMOH’s prescription order required this prior to NAPRA’s decision has expired, effective June 24, 2016.

In addition, completion of the “2016 Naloxone Training Module” respecting the preparation and administration of emergency naloxone kits is no longer required. Completion of a signed Attestation for Participation in the Ontario Naloxone Pharmacy Program (ONPP) is also no longer required.
**Pharmacy Compliance**

This notice and the accompanying Frequently Asked Questions (FAQs) constitute a ministry policy that pharmacy operators must comply with when submitting claims through the HNS for providing naloxone kits. Compliance with the ministry policy is required under section 3.2 of the HNS Subscription Agreement for Pharmacy Operators.

**Eligibility**

As of June 24, 2016, all pharmacies are eligible to provide naloxone emergency kits at no cost to eligible persons, if certain terms and conditions are met. Criteria for an “eligible person” includes:

- a person who is either currently using opioids or is a past opioid user who is at risk of returning to opioid use, or
- a family member, friend or other person in a position to assist a person at risk of overdose from opioids.

**Procedures for Providing and Billing**

Pharmacists must be trained prior to providing naloxone kits. The Ontario Pharmacists Association (OPA) has developed an online education module available on their website. There may be other resources available to pharmacists. The OCP has developed a guidance document for the providing or selling of naloxone available on their website.

The trained pharmacist who provides the publicly funded naloxone emergency kit must be identified in the pharmacist field on the claim submitted for payment through the HNS using the proper PIN that was provided.

For eligible persons, who are first time users and do not have training with the naloxone kit, the Initial Naloxone Emergency Kit (which includes a professional training component) will be provided by the pharmacist. For eligible persons, who do have training with the naloxone kit, the Replacement Naloxone Emergency Kit (excludes the professional training) can be provided by the pharmacist.

Pharmacists must ensure that the eligible person’s name, date of birth, and Ontario health card number are entered accurately as part of the HNS claims submission.

Pharmacists, where possible, must ensure that the quarterly report-back form (available at: [www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/eo_communiq.aspx](http://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/eo_communiq.aspx)) relating to outcomes for individuals who were provided a naloxone emergency kit, be completed.
and returned to the ministry by 30 days after end of each quarter in a fiscal year. Please refer to the FAQs for details on the reporting schedule.

Pharmacies will procure naloxone and the required supplies to assemble the naloxone kit through usual suppliers (i.e., pharmacy-assembled naloxone kits). The emergency kit shall be assembled by a pharmacist, or a person under the supervision of a pharmacist and contain the follow:

- Two 1 ml naloxone hydrochloride 0.4 mg/ml by injection;
- Two safety engineered syringes with 25 g one inch needles attached;
- Two safe ampoules opening devices (also known as “breakers”, “snappers”, or “openers”) as applicable;
- One pair of non-latex gloves; and
- One naloxone identifier card.

The ministry is aware that some of supplies (e.g., ampoule openers/snappers/breakers) listed can be ordered from Canadian based suppliers such as Pharmasystem, Canadian Safety Supplies, and Kohl and Frisch. The Ontario Pharmacists Association has also compiled a list of the required kit components as well as some suppliers for these items, in the event that pharmacists are unable to procure some or all of the elements through their usual suppliers. This list can be found at [www.opatoday.com/professional/naloxone_kit_tools](http://www.opatoday.com/professional/naloxone_kit_tools). Types of containers that have been reportedly used to contain all the components include sunglasses cases, eyeglass cases, pencil cases, or a variation of a compact, portable container resembling a case or box. Pharmacies are encouraged to seek out these and/or other local suppliers for obtaining components required for pharmacy-assembled naloxone kits.

**Pharmacy Eligibility**

All pharmacies that comply with the requirements of this ministry policy are able to provide emergency naloxone kits, and bill the cost of those kits to the ministry through the HNS.

Prior to providing naloxone kits to eligible persons, pharmacies must ensure that their pharmacists are trained to provide the necessary training to eligible persons who are to receive the naloxone kits.
Pharmacy Record Requirements

Standard record keeping requirements under current standards of practice apply. Pharmacies must keep a record when the naloxone kit (see table below) is provided to the eligible person.

For billing purposes, pharmacy records must be maintained in a readily available format for the purpose of a ministry audit of billing for a minimum of 2 years.

Pharmacists shall keep records consistent with their obligations under the Pharmacy Act, 1991, the Drug and Pharmacies Regulation Act and any instructions provided by the Ontario College of Pharmacists or the ministry. These records must include, at a minimum:

- Full instructions for use of drug; and
- The drug’s material risks, including material side-effects, contradictions or precautions were discussed with the eligible person to ensure that they provide appropriate training to individuals receiving naloxone emergency kits.

Pharmacy billing procedure

Naloxone emergency kits will be reimbursed by the Ontario Government, effective June 24, 2016, in accordance with this ministry policy. The PINs listed in Table 1 below are to be used whenever an emergency naloxone kit is supplied to an eligible person, regardless of the person’s eligibility under the Ontario Drug Benefit (ODB) Program.

Table 1: PINs to support reimbursement of Naloxone emergency kits

<table>
<thead>
<tr>
<th>PIN</th>
<th>Description</th>
<th>Total Amount Reimbursed</th>
</tr>
</thead>
<tbody>
<tr>
<td>93877251</td>
<td>Initial Naloxone Emergency Kit (reimbursed amount includes naloxone kit at $35, plus professional fee at $10, plus professional training at $25)</td>
<td>$70.00</td>
</tr>
<tr>
<td>93877252</td>
<td>Replacement Naloxone Emergency Kit (reimbursed amount includes naloxone kit at $35 plus professional fee at $10)</td>
<td>$45.00</td>
</tr>
</tbody>
</table>

Claims must be submitted using the ministry-assigned PIN associated with the naloxone
emergency kit and service provided. Do not use the Drug Identification Number (DIN) of the naloxone that is contained in the naloxone kit.

**For ODB-eligible recipients:**

The claim submission follows the normal process for submitting claims on the HNS with the following additional information:

- Intervention code ‘PS’: (Professional Care Services)
- Product Identification Number (PIN): see table above for list of PINs
- Valid Pharmacist ID
- Professional Fee: see table above for “Total Amount Reimbursed” for each kit

**For Non-ODB eligible recipients:**

When submitting a claim for an eligible person who does not have ODB coverage, pharmacists must submit the following information:

- Person’s Gender: ‘F’ = female; ‘M’ = male
- Person’s Date of Birth: Valid YYYYMMDD
- Person’s Ontario Health Card number
- Intervention codes:
  - PS: Professional Care Services
  - ML: Established eligibility coverage (i.e., 1 day of the Plan ‘S’ coverage)
- Carrier ID: ‘S’
- Product Identification Number (PIN): see table above for list of PINs
- Valid Pharmacist ID
- Professional Fee: see table above for “Total Amount Reimbursed” for each kit

**Restrictions:**

A maximum of one (1) naloxone kit may be provided to an eligible person at one time.