



# CCENDU Bulletin

## The Availability of Take-Home Naloxone in Canada

### Summary

In response to increasing numbers of fatal and non-fatal opioid poisonings in Canada, there has been a great deal of effort invested in increasing the availability of naloxone, a drug that temporarily reverses the effects of opioids and can save lives in opioid overdose situations. Efforts to increase the availability of naloxone have followed several different trajectories:

- Establishing take-home naloxone programs to increase access to naloxone among people who use opioids and their friends or family;
- Encouraging or permitting accessibility and use of naloxone by first responders (e.g., paramedics, firefighters, law enforcement, etc.); and
- Encouraging authorities to change the prescription-only status of naloxone to increase availability, and encouraging reimbursement of naloxone through publicly funded drug plans across Canada, particularly for people with low incomes.<sup>i</sup>

As of the release of this bulletin, there are take-home naloxone programs in seven of the 13 provinces and territories in Canada. Increased access to naloxone is only one part of a comprehensive overdose prevention strategy that also includes improved overdose prevention education, training and services, and enhanced surveillance and utilization of overdose data.<sup>1</sup>

On March 22, 2016, Health Canada removed naloxone from the Prescription Drug List. However, there are still several steps necessary before naloxone becomes available to the Canadian general public in pharmacies. Best estimates provided by those involved suggest availability could be achieved as early as July 2016, provided that evidence reviews and public consultations support this change.

### Background

Naloxone is a drug used to temporarily reverse the effects of opioid overdose and can save lives in overdose situations. In Canada, take-home naloxone kits commonly contain two one-mL single dose ampoules of naloxone, 0.4 mg/mL solution for intra-muscular injection.<sup>ii</sup> Other formulations exist (e.g., nasal, auto-injector), but the injectable form of naloxone is the only one currently approved in Canada. While naloxone has been available as a prescription drug for many years, it has not been widely prescribed or widely dispensed in community pharmacies to date. Its main use has been in the hospital setting. Increasing numbers of fatal and non-fatal overdoses related to opioid use in Canada<sup>2</sup> have lead many jurisdictions across Canada to take steps to increase public access to the drug.

<sup>i</sup> According to a Canadian Agency for Drugs and Technologies in Health (CADTH) environmental scan, *Prescribing and Dispensing Policies to Address Harms Associated with Prescription Drug Abuse*, naloxone is currently only reimbursed by the Canadian Armed Forces drug plan: [www.cadth.ca/prescribing-and-dispensing-policies-address-harms-associated-prescription-drug-abuse](http://www.cadth.ca/prescribing-and-dispensing-policies-address-harms-associated-prescription-drug-abuse).

<sup>ii</sup> In Canada, naloxone is also available in other strengths and volumes. Please see Health Canada's Drug Product Database at [www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php) for further information.



In response to many questions about the availability of naloxone and the changes that have occurred and are expected to occur in the future, members of the Canadian Community Epidemiology Network on Drug Use (CCENDU) and the First Do No Harm (FDNH) Overdose and Overdose Death Prevention project team decided it was important to exchange information on the availability naloxone and the steps being taken to increase access to it. This information will permit those working in public health to better plan overdose prevention strategies.

The following bulletin is broken into two parts. Part I provides a snapshot of existing take-home naloxone programs in Canada to facilitate understanding and sharing of information. Part II provides an overview of the steps required to make naloxone available without a prescription in Canada.

## Part I: Take-Home Naloxone Programs in Canada

Initiatives have been taken in seven of the 13 provinces and territories in Canada to increase accessibility to and use of naloxone by providing take-home naloxone kits through community programs. These programs also offer training to families and friends on how to best respond to an opioid overdoses and how to use naloxone most effectively.

Jurisdictions across Canada have used a variety of systems to grant community programs permission to dispense naloxone:

- In British Columbia, the Decision Support Tool allowed nurses to dispense naloxone without a prescription from a medical doctor or nurse practitioner.<sup>3</sup> However, as of March 24, 2016, naloxone is available in British Columbia without a prescription.
- In Alberta, a Ministerial Order passed on December 10, 2015, allows registered nurses and registered psychiatric nurses to prescribe as well as dispense naloxone.<sup>4</sup> Kits are now available at over 500 pharmacies free of charge with a valid prescription.
- In Saskatchewan, the College of Physicians and Surgeons in 2016 granted permission to physicians to prescribe naloxone directly to associates of people (e.g., friends, family) who use opioids. Paramedics in Saskatchewan have carried naloxone for years, but fire department first responders have yet to receive permission.
- In Manitoba, the College of Physicians and Surgeons granted an exemption permitting medical doctors to prescribe naloxone without seeing the patient.
- The College of Physicians and Surgeons of Ontario has recently amended its Prescribing Drugs policy to allow for physicians to prescribe naloxone through medical directives for inclusion in opioid overdose emergency kits distributed through public health units and harm programs.<sup>5</sup>
- In Quebec, a medical directive signed by a regional public health director allows a pharmacist to dispense take-home naloxone kits to individuals who have been trained through a certified training program.
- In Nova Scotia, the College of Physicians and Surgeons endorsed a medical directive for the duration of the demonstration community-based naloxone project scheduled to end September 2016. The directive permits both regulated and non-regulated healthcare providers to dispense naloxone. To fully endorse the demonstration project, the College additionally had to grant a temporary exemption from the *Prescribing in the Absence of Direct Patient Contact* policy, similar to what was done in Manitoba, to allow project staff to be able to dispense naloxone kits without requiring each participant to see a physician. Pending the results of an implementation evaluation, the College will consider making this exemption long term.



- In the Northwest Territories (N.W.T.), naloxone is on the N.W.T. Health Centre Formulary as a “must stock” item. This requirement means that a community health nurse can give one dose of it before needing to contact a physician or nurse practitioner for an order. This allowance applies to communities where there are no medical clinics, which includes the majority of communities. In Yellowknife, Inuvik, Hay River and Fort Smith, where there are clinics, a medical prescription is required to access naloxone.

In addition, some provinces have allowed a wider range of professionals, such as paramedics and first responders, to administer naloxone:

- In Alberta, the Ministerial Order of December 2015 expanded the scope of practice for emergency medical services, so that all classifications of paramedics can now administer naloxone.
- In British Columbia, all ambulance paramedics throughout the province carry and can administer naloxone. Following collaborative agreement between municipalities and firefighters, once training is completed and a firefighter’s license is updated, he or she can carry and administer naloxone.<sup>6</sup>
- In Ontario, all Advanced Care Paramedics (ACPs) are authorized under physicians’ orders (medical directives) to administer naloxone to patients who are experiencing symptoms of opioid toxicity. Naloxone is currently listed as a mandatory medication for all ACP vehicles, with a specified minimum quantity as directed by the Provincial Equipment Standards for Ontario Ambulance Services. In response to the increase of reported fentanyl overdose cases, pre-hospital naloxone administration was reviewed in 2014. As a result of the review, it was decided that the scope of practice would be expanded for all Primary Care Paramedics (PCPs) to also be able to administer the medication under physician’s orders. As of February 1, 2016, naloxone became a mandatory medication for all PCP vehicles, when a revised version of the Provincial Equipment Standards came into force.
- In Quebec, naloxone is available in ambulances in most health regions.

The following table overviews the state of take-home naloxone programs in Canada. Given the public health burden associated with opioid poisonings, provincial policy and naloxone availability is changing rapidly. Therefore, the information in the table is likely to quickly become out of date.



## Existing Take-Home Naloxone Programs in Canada

Naloxone Program Profile	Prescribed by:	Dispensed by:	Trained by:	Target Population	No. of Sites	No. of Kits Dispensed	No. of Kits Used
<b>British Columbia<sup>iii</sup></b> (entry accurate as of March 23, 2016; on March 24 naloxone became available without a prescription in BC)							
<b>Agency Operating Program</b> BCCDC enrolled 120 sites/agencies in THN program throughout BC <b>Oversight</b> BC Harm Reduction Program (based at BCCDC) <b>Program Operational Since:</b> 2012 <b>Locations:</b> 4 emergency departments; piloted at 2 provincial prisons; inpatient units; First Nations communities	MD, NP	MD, NP, RN, pharmacist	Anyone at participating THN sites	PWUO at risk of overdose in the community	120	6,389	488
<b>Alberta<sup>iv</sup></b>							
<b>Agency Operating Program:</b> Streetworks (Edmonton) <b>Oversight:</b> Streetworks <b>Program Operational Since:</b> 2005 <b>Locations:</b> Streetworks site & mobile van	RN (delegation)	RN	RN	PWUO illicitly	3	418	46
<b>Agency Operating Program:</b> Member Organizations of the Alberta Community Council on HIV <b>Oversight:</b> AHS <sup>v</sup> <b>Program Operational Since:</b> 2015 <b>Locations:</b> Central Alberta AIDS Network (Red Deer); HIV Community Link (Medicine Hat); HIV North Society (Grand Prairie & Fort McMurray); HIV West Yellowhead (Jasper)	MD, NP, RN, pharmacist with prescribing authority	NP, RN	Anyone at participating THN sites	PWUO illicitly	8	966	75
<b>Agency Operating Program:</b> Sites registered with AHS (includes AHS facilities, clinics, primary care networks, emergency departments, residential treatment, corrections, First Nations health centres, community organizations, etc.) <b>Oversight:</b> Alberta Health Services <b>Program Operational Since:</b> 2016 <b>Locations:</b> Lethbridge HIV Connection; Safeworks (Calgary); Streetworks (Edmonton).	physician, RN, NP, prescribing pharmacist, RPN	physician, RN, NP, prescribing pharmacist, RPN	counsellor, licenced practical nurse, RN, NP, physician	PWUO, illicit or not	88 (Feb. 2016)	N/A or not available	Not available
<b>Agency Operating Program:</b> N/A, community pharmacies <b>Oversight:</b> AHS <b>Program Operational Since:</b> 2016 <b>Locations:</b> Throughout Alberta; see website <sup>vi</sup>	pharmacist with prescribing authority	pharmacist with prescribing authority	pharmacist with prescribing authority	PWUO, illicit or not.	360	Not available	Not available

<sup>iii</sup> More information on the British Columbia naloxone program can be found at [towardtheheart.com/assets/naloxone/evaluation-of-bc-thn-sep15\\_181.pdf](http://towardtheheart.com/assets/naloxone/evaluation-of-bc-thn-sep15_181.pdf) and [www.cmajopen.ca/content/2/3/E153.full](http://www.cmajopen.ca/content/2/3/E153.full).

<sup>iv</sup> More information about the Alberta naloxone program can be found at [www.albertahealthservices.ca/info/page12491.aspx](http://www.albertahealthservices.ca/info/page12491.aspx) and [www.health.alberta.ca/health-info/AMH-Naloxone-Take-home.html](http://www.health.alberta.ca/health-info/AMH-Naloxone-Take-home.html).

<sup>v</sup> More information on naloxone programs operated by Alberta Health Services can be found at [www.albertahealthservices.ca/info/page12491.aspx](http://www.albertahealthservices.ca/info/page12491.aspx).

<sup>vi</sup> For a list of community pharmacies that have naloxone see [www.albertahealthservices.ca/assets/healthinfo/mh/hi-amh-thn-pharmacies.pdf](http://www.albertahealthservices.ca/assets/healthinfo/mh/hi-amh-thn-pharmacies.pdf).



Naloxone Program Profile	Prescribed by:	Dispensed by:	Trained by:	Target Population	No. of Sites	No. of Kits Dispensed	No. of Kits Used
<b>Saskatchewan<sup>vii</sup></b>							
<b>Agency Operating Program:</b> Saskatoon Health Region <b>Oversight:</b> Saskatchewan Ministry of Health <b>Program Operational Since:</b> 2015 <b>Locations:</b> Mayfair Medical Clinic (Saskatoon)	MD, NP	pharmacist	registered psychiatric nurse	PWUO illicitly	1	17	Not available
<b>Manitoba<sup>viii</sup></b>							
<b>Agency Operating Program:</b> Winnipeg Regional Health Authority Street Connections <b>Oversight:</b> Winnipeg Regional Health Authority <b>Program Operational Since:</b> 2015 <b>Locations:</b> Public Health Centralized Services Office (Winnipeg)	MD, RN, (shared competency agreement)	pharmacist, RN (shared competency agreement)	RN.	PWUO illicitly; family, friends & other lower risk groups are eligible for training, but not THN	1	Not available	Not available
<b>Ontario</b>							
<b>Agency Operating Program:</b> MOHLTC has approved 22 eligible organizations (out of a possible 52) to participate in the Ontario Naloxone Program <sup>ix</sup> <b>Oversight:</b> MOHLTC's AIDS & Hepatitis C Secretariat <b>Program Operational Since:</b> 2013 <b>Locations:</b> Eligible organizations include: <ul style="list-style-type: none"> <li>• PHUs that manage a core NEP)</li> <li>• Community-based organizations that have been contracted by their local PHU to manage a core NEP</li> <li>• Ministry-funded Hepatitis C Teams</li> </ul>	MD, NP	MD, NP, RN, outreach workers; any front line staff who are named in the relevant medical directive	identified staff at the participating organization	PWUO illicitly.	22	2,734	496 clients reported administering naloxone 65 clients reported receiving naloxone
<b>Quebec (Island of Montreal)<sup>x</sup></b>							
<b>Agency Operating Program:</b> Direction régionale de santé publique de Montréal <b>Oversight:</b> Santé publique de Montréal <b>Program Operational Since:</b> 2015 <b>Locations:</b> 2 training sites (as of Nov. 23, 2015)	regional public health director	pharmacist	peers with RN support; public health RN; public health agent (for community workers)	PWUO illicitly; family, friends & community workers	2	155 (as of Dec. 31, 2015); trained 215 persons	11

<sup>vii</sup> More information about the Saskatchewan naloxone program can be found at [www.saskatchewan.ca/government/news-and-media/2015/november/04/naloxone-kits](http://www.saskatchewan.ca/government/news-and-media/2015/november/04/naloxone-kits).

<sup>viii</sup> More information about the Manitoba naloxone program can be found at [cpsm.mb.ca/cji39alckF30a/wp-content/uploads/St805.pdf](http://cpsm.mb.ca/cji39alckF30a/wp-content/uploads/St805.pdf).

<sup>ix</sup> Among these organizations are early adoptors of the Works Needle Exchange and Oasis Opioid Substitution Treatment, each initiated with private funding.

<sup>x</sup> More information about the Montreal naloxone program can be found at [www.dsp.santemontreal.qc.ca/naloxone](http://www.dsp.santemontreal.qc.ca/naloxone).



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<b>Nova Scotia</b>							
<p><b>Agency Operating Program:</b> Two demonstration sites:            Cape Breton: Health Promotion &amp; Prevention, Mental Health &amp; Addictions, NSHA partnering with the Ally Centre of Cape Breton            Halifax: Direction 180</p> <p><b>Oversight:</b> Nova Scotia Department of Health &amp; Wellness &amp; College of Physicians &amp; Surgeons, NS</p> <p><b>Program Operational Since:</b> Feb 16, 2016</p> <p><b>Locations:</b> Cape Breton: 2 primary locations / sites where people access safer drug using equipment.            Halifax: Direction 180, Mainline Needle Exchange &amp; allied community agencies</p>	MD at each demo site	regulated & non-regulated care providers (health promotion specialists, RN, outreach workers, needle syringe program staff)	regulated & non-regulated care providers; (health promotion specialists, RN's outreach workers, needle syringe program staff)	PWUO (current or past use); family, friends & other lower risk groups are eligible for training, but not THN	3 total	As of March 22, 2016: 33 kits in Cape Breton, 37 in Halifax	Not available

**Note:** Circumstances are changing rapidly; this chart is accurate as of March 2016.

**Abbreviations Used in Table:** AHS = Alberta Health Services; AIDS = acquired immune deficiency syndrome; BCCDC = British Columbia Centre for Disease Control; HCV = hepatitis C virus; HIV = human immunodeficiency virus; MD = medical doctor; MOHLTC = Ministry of Health and Long-Term Care (Ontario); NEP = Needle Exchange Program; NP= nurse practitioner; NX = naloxone; PHU = Public Health Unit; PWUO = people who use opioids; OHRDP = Ontario Harm Reduction Distribution Program; RN = registered nurse; RPN = registered practical nurse; THN = Take-home naloxone



## Part II: Process to Permit the Sale of Naloxone without a Prescription in Pharmacies across Canada

In spite of progress at the jurisdictional level, widespread access to naloxone across Canada is still limited. Allowing the sale of naloxone without a prescription in pharmacies across Canada would greatly increase accessibility of the drug and could contribute to preventing opioid-related overdose deaths or harms associated with non-fatal overdoses.

Several steps have already been taken to change federal regulations to make naloxone available as a non-prescription drug. Additional actions will be required at the provincial-territorial level.

### Removal of Naloxone from Health Canada's Prescription Drug List

(Achieved March 22, 2016)

The Prescription Drug List (PDL) lists drugs that require a prescription and is established at the federal level by the Minister of Health. For the public to have access to naloxone as a non-prescription drug through pharmacies across Canada, naloxone had to first be removed from this list.

On January 14, 2016, Health Canada put forward a proposed amendment to the PDL to allow non-prescription use of naloxone specifically for emergency use for opioid overdose outside of hospital settings.<sup>7</sup> According to Health Canada's published process, notice of this proposed amendment must be followed by a 75-day public consultation through the Health Canada website. The consultation period was shortened to 65 days to expedite access to naloxone. The consultation period closed on March 19, 2016.

After the consultation, Health Canada evaluated the comments received. Based on overwhelming support, on March 22 Health Canada amended the PDL to exempt from prescription status the emergency use of naloxone outside hospital settings for opioid overdose. The exemption became effective immediately, forgoing the usual six-month delayed implementation period.<sup>8</sup>

### Rescheduling at the Provincial and Territorial Levels to Make Naloxone Available in Pharmacies

Provincial and territorial drug schedules describe the legal conditions required for the sale of a drug. Each drug schedule describes certain conditions required for sale and includes a list of drugs for which those conditions apply.

Once naloxone is removed from the federal PDL, its provincial or territorial drug scheduling must be determined. The National Association of Pharmacy Regulatory Authorities (NAPRA) provides a common final recommendation on drug scheduling to all provinces and territories except Quebec. The national scheduling model used by NAPRA consists of three schedules (Schedules I–III) and one category (Unscheduled):

- Schedule I: prescription required for sale
- Schedule II: pharmacist intervention required for sale
- Schedule III: option to consult pharmacist required for sale
- Unscheduled: no professional supervision required for sale<sup>9</sup>

The usual process to initiate a NAPRA review is for a drug manufacturer to make a submission to NAPRA that provides information and justification for a placement of the drug in a specific schedule



or category. A fee is required to initiate the review. NAPRA, rather than a manufacturer, can also initiate a review, if it is deemed to be in the public interest.<sup>10</sup> Federal or provincial/territorial governments also have some opportunity to make submissions.

After a submission is received, NAPRA publishes a meeting notice on its website and coordinates the activities of the National Drug Scheduling Advisory Committee (NDSAC), an eight-member expert committee that deliberates on the submission and makes the scheduling recommendation. NDSAC usually meets four times per year or as required. After the meeting, NDSAC formulates its recommendation to list the drug in a particular schedule or category. The recommendation is posted for consultation for 30 days. NAPRA then releases its final recommendation.

Many jurisdictions (Sask., Man., Ont., N.S., N.B., P.E.I., N.W.T., Y.T., Nvt.) have adopted “scheduling by reference,” meaning that they immediately implement all NAPRA recommendations on drug scheduling. Other jurisdictions (B.C., Alta., N.L.) have additional or different approval processes. These provinces generally follow NAPRA’s final recommendations, but there might be exceptions in certain cases based on needs specific to a province. Implementation of a NAPRA final recommendation in these provinces can be immediate or can take up to three months. Quebec, which does not participate in the NAPRA process, follows its own rules about scheduling when a drug is removed from the PDL. Therefore, by three months after the NAPRA final recommendation, all jurisdictional decisions should be completed. Depending on NAPRA’s final recommendation, naloxone could then be available in pharmacies across Canada.

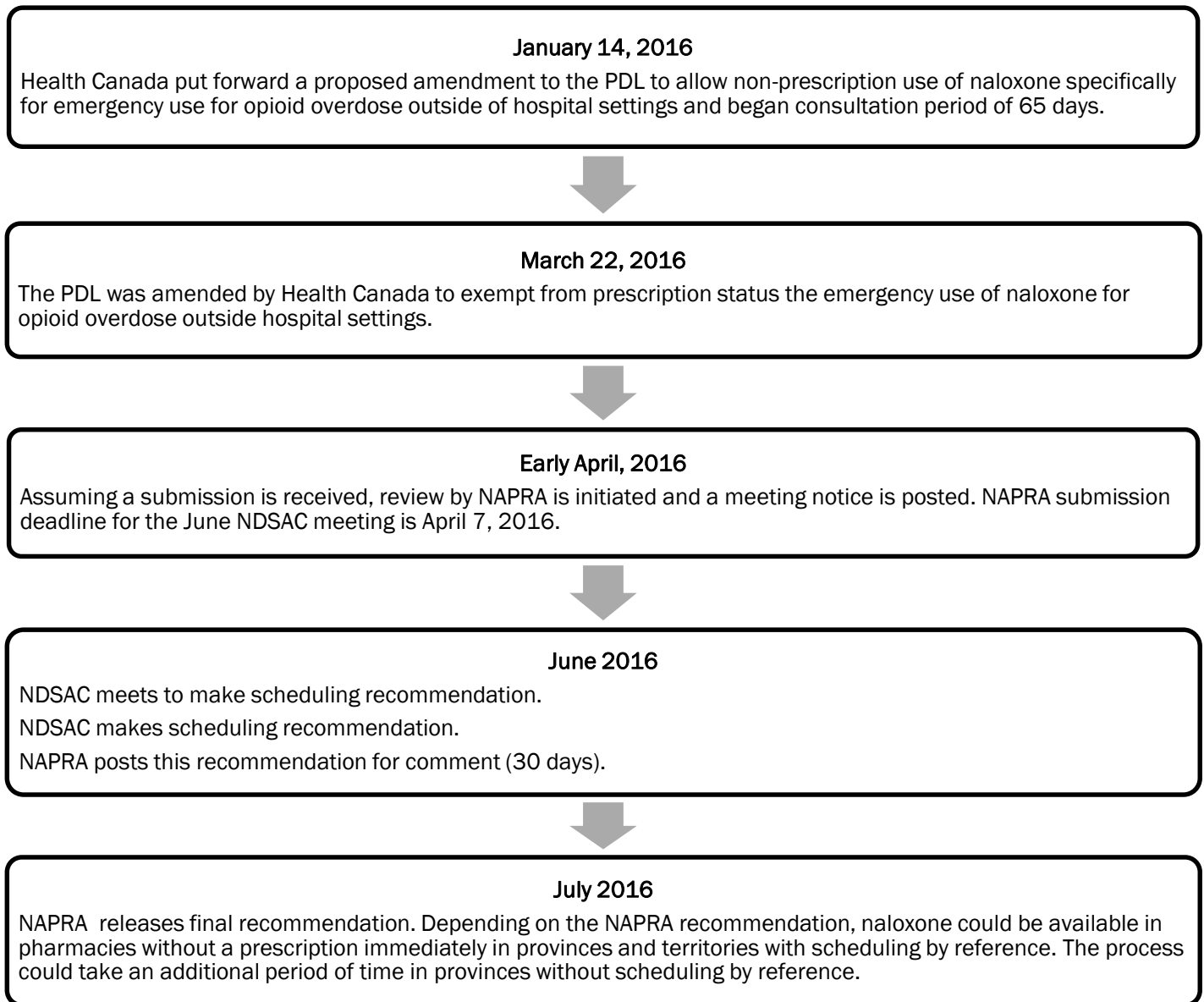
According to NAPRA’s Policy for Drugs Not Reviewed, if a drug is removed from the Health Canada PDL and NAPRA does not receive a scheduling submission, the drug will be placed in Schedule I (prescription required for sale) until such time as a submission is received.<sup>11</sup>

Figure 1 outlines the expected timeline for the remaining process steps required to permit the sale of naloxone without a prescription in pharmacies across Canada according to the usual process. Exceptions to this process are rare, but can happen depending on jurisdictional need. For example, the government of British Columbia and the BC College of Pharmacists worked together to classify non-prescription naloxone as a Schedule II drug in the province, effective March 24, 2016.”<sup>12</sup>





**Figure 1. Projected timeline for the remaining process steps required to permit the sale of naloxone without a prescription in pharmacies across Canada, according to the usual process**





## Discussion

If naloxone becomes available in pharmacies without a prescription in Canada there are a number of issues that will need to be addressed. These issues are discussed below.

**Training.** Training is a critical component of ensuring effective use of naloxone in preventing opioid overdose deaths. It is unclear how this training will take place if naloxone becomes available in pharmacies without a prescription.

**Role of pharmacists.** Depending on the NAPRA scheduling recommendation and as decided by each province, pharmacists might have a key role in providing education to individuals on the use of naloxone and on the treatment of opioid-overdose in general. The College of Pharmacists of BC have some useful resources available on their website, including a patient educational handout, Naloxone FAQs, and a checklist for naloxone training.<sup>13</sup> In addition, pharmacists could play an important role in providing referrals to individuals who might be looking for treatment options. Partners from the Canadian Pharmacists Association have indicated that they are prepared to work with provincial and territorial counterparts to provide training for pharmacists so that they will be knowledgeable about the use of this drug in treating overdose, and are prepared to educate individuals (i.e., patients and caregivers) on the appropriate administration of naloxone.

**Formulation of naloxone and naloxone kit components.** Although pre-packaged naloxone auto-injectors and nasal formulations are available for sale in the United States, at the time of this bulletin these formulations were not available in Canada. Currently, take-home naloxone kits in Canada usually contain two naloxone vials, needles, syringes and instructions, as well as alcohol swabs, one-way breathing mask and carrying cases in some circumstances. It is unclear how naloxone kits will be assembled and priced in pharmacies, and what kit components in addition to naloxone, needles and syringes will be included.

**Payment.** If naloxone becomes available in pharmacies without a prescription, individuals wishing to obtain the drug could be required to pay the retail costs for the drug, as well as the costs for other components, such as syringes and needles, required for use of naloxone. The cost of a take-home naloxone kit is approximately \$35, but the cost varies across the provinces and territories in Canada and across different distributors. Based on current pricing in the U.S., the auto-injector and nasal formulations are expected to be much more expensive, if they become available in Canada. It is unclear whether publicly funded and private drug plans would provide reimbursement for naloxone and naloxone kit components, and whether pharmacists who provide education on the use of naloxone would require a professional fee.

## Next Steps

The FDNH Overdose and Overdose Death Prevention project team is developing a briefing note and associated costing tool on naloxone and reimbursement for naloxone. Based on the literature, the team has identified criteria for those at high risk of opioid overdose who would therefore benefit from access to the drug.

- For further information on the work being conducted under FDNH, please contact [info@ccsa.ca](mailto:info@ccsa.ca).
- If you have any questions, comments, information to contribute or corrections to the information contained in this bulletin, or wish to subscribe and receive updates as new information becomes available, please contact [CCENDU@ccsa.ca](mailto:CCENDU@ccsa.ca).
- For more information on CCENDU and to review previous CCENDU Alerts and Bulletins please visit [www.CCENDU.ca](http://www.CCENDU.ca).



## Acknowledgements

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The Canadian Community Epidemiology Network on Drug Use (CCENDU) is a nation-wide network of community level partners who share information about local trends and emerging issues in substance use and exchange knowledge and tools to support more effective data collection.

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