

PROGRAM RULES

Take Home Naloxone

July 2022

Not in Use



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TAKE HOME NALOXONE

1 INTRODUCTION

This document outlines the Program Rules governing the Take Home Naloxone (THN) Program for Approved Providers. This document must be read in conjunction with the Pharmacy Programs Administrator (PPA) General Terms and Conditions (General Terms).

Definitions in the General Terms apply in these Program Rules.

2 BACKGROUND

Naloxone is a medicine that rapidly reverses the effects of an opioid overdose. It can be administered by injection or through a nasal spray. Under the THN Program, naloxone is available free, in all Australian States and Territories, to people who are at risk of or who may witness an opioid overdose or adverse reaction. A prescription is not required for supply.

Following the evaluation of the Take Home Naloxone Pilot Program, which ran from 1 December 2019 to 30 June 2022, the 2022-23 Federal Budget included \$19.6 million (over four years) for a National, THN Program commencing from 1 July 2022.

More information about the Take Home Naloxone Pilot can be found [here](#).

3 PARTICIPATION

Under the THN Program, each State or Territory will identify where naloxone will be made available. Participating sites providing naloxone to individuals are defined as either an [Approved Provider](#) or an [Authorised Alternative Supplier](#).

Approved Providers include community pharmacies, hospital-based pharmacies and approved medical practitioners. Approved providers will supply naloxone and be reimbursed by the Pharmacy Programs Administrator (PPA).

Organisations such as alcohol and other drug treatment services, injecting centres, and homelessness/outreach services in certain states can also supply naloxone by first becoming an Authorised Alternative Supplier (AAS). Information about registering to become an AAS can be found by contacting relevant State or Territory health departments. An AAS can supply naloxone to an individual but does not receive reimbursement from the PPA.

3.1 Approved Providers: Community (s90) pharmacies, hospital (s94) pharmacies and approved (s92) medical practitioners

To be eligible to participate in the THN Program, and supply naloxone, Approved Providers must:

- Be approved under sections 90, 92 or 94 of the *National Health Act 1953*
- Register for the THN Program via the [PPA Portal](#)
- Confirm that they are registered for GST
- Agree that the pharmacy/practice trading name and location may be listed on the Department of Health's website and/or provided to participating State/Territory health departments for communications relating to the Program

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- Agree to provide services in accordance with these THN Program Rules, including the collection of required **supply claim** data.

Pharmacies and approved medical practitioners are required to source naloxone through their usual supply channel (e.g. pharmaceutical wholesaler). Once naloxone has been supplied free of charge to an individual under the THN Program, a claim for payment can be made via the PPA Portal.

Claiming processes for naloxone dispensed over the counter, on PBS or private script do not change and cannot be claimed for under the THN Program.

3.2 Authorised Alternative Suppliers

To be eligible to participate in the THN Program, and supply naloxone, an Approved Alternative Supplier (AAS) must:

- Be approved by the relevant State/Territory authority in the relevant jurisdiction (most commonly the Health Department) to provide naloxone under the THN Program
- Agree to provide services in accordance with these THN Program Rules, including the collection of required **supply claim** data.

Some AASs will also be required to register for the THN Program via the PPA [Portal](#) and provide supply claims data directly to the PPA. These AASs are:

- AASs in New South Wales (this includes both Government and Non-Government Organisations)
- Certain AASs in South Australia.

AASs are required to source naloxone through a variety of mechanisms, depending on their location and should discuss these arrangements with their relevant state health authority. Information on who to contact can be found on the Department of Health website.

Please note: As at 1 July 2022 only AASs in NSW, WA and SA can participate in the THN Program. Consultation is currently being undertaken with other States and Territories to confirm the participation requirements for AASs in each jurisdiction. Further information will be provided once available.

3.3 Wholesalers

In certain states a wholesaler may provide naloxone to an AAS for distribution to individuals.

To be eligible to participate in the THN Program, and receive payments for naloxone supplied, the wholesaler must:

- Have an arrangement in place with the Commonwealth Government and/or the relevant State/Territory Government to supply naloxone to AASs under the THN Program.
- Register for the THN Program via the PPA [Portal](#)
- Confirm that it is registered for GST

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- Agree to provide services in accordance with these THN Program Rules, including the collection of required bulk supply data.
 - Note: where costs incurred are associated with distribution from a wholesaler the arrangement and payment of these costs are the responsibility of the relevant State or Territory entering into the arrangement.

3.4 Western Australia Mental Health Commission (WA MHC)

The WA MHC has an agreement with the Commonwealth Government to supply naloxone to Western Australia AASs under the THN Program and has agreed to provide services in accordance with these THN Program Rules, including the collection of required bulk supply data.

3.5 Individuals receiving naloxone

Any person across Australia is able to access free naloxone, without prescription, under the THN Program.

Specifically, the THN Program aims to make naloxone free and easily available for:

- People who are at risk of an opioid overdose, or adverse reaction, which includes illicit drug users and people who use prescription opioid medications
- Carers, friends, family and the community.

4 DATA SUBMISSION

All sites participating in the THN Program are required to submit data, in most instances to the PPA.

The data collected is used to:

- Enable the PPA to make payment (where applicable)
- Allow the Commonwealth Government and the relevant State Health Departments to monitor the supply of naloxone under the THN Program.

Data collected relates to supplies of both naloxone to individuals (known as individual supply claims), as well as the supply of bulk quantities of naloxone to AASs (known as bulk supply claims).

The data your organisation must collect depends on the type of supply (individual or bulk). The requirements for the submission of eligible claims are shown at:

- **Appendix A – Individual supply claims**, relevant for:
 - Community (s90) pharmacies
 - Public and Private Hospital (s94) pharmacies
 - Approved medical practitioners (s92)
 - AASs.
- **Appendix B – Bulk supply claims**, relevant for:
 - Wholesalers and WA MHC
 - Some (s94) hospital pharmacies.

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5 PORTAL REGISTRATION

To become an Approved Provider under the THN Program, pharmacies and approved medical practitioners must first register via the PPA [Portal](#).

Registration will not be complete until the Provider receives email notification from the PPA confirming that registration has been successful.

After approval by the relevant States or Territories, some AASs may also be required to register via the PPA Portal to submit data.

6 FUNDING AVAILABILITY

The 2022-23 Federal Budget included \$19.6 million (over four years) for a National Take Home Naloxone Program, commencing from 1 July 2022.

7 FEES

The following tables contain the fees (including dispensing fee, where applicable) that are payable by the PPA to each applicable Approved Provider for eligible claims made in relation to the supply of naloxone, under the THN Program from 1 July 2022. GST is added to all supplies.

The fees payable for supplies provided under the Take Home Naloxone Pilot, which ran between 1 December 2019 and 30 June 2022 can be found [here](#).

Alternative Approved Suppliers do not receive fees for supplying naloxone to an individual.

Table 7-1: Naloxone supply fees: Community (S90) Pharmacies

Individual Supply (ex GST)	Product
\$49.08	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)
\$36.11	Prenoxad (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)
\$39.31	Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)
\$39.31	Naloxone Hydrochloride (DBL) (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)

Table 7-2: Naloxone supply fees: Public Hospital (S94) Pharmacies

Individual Supply (ex GST)	Bulk Supply (ex GST)	Product
\$36.94	\$34.36	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)



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Individual Supply (ex GST)	Bulk Supply (ex GST)	Product
\$23.97	\$22.29	Prenoxad (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)
\$27.17	\$25.27	Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)
\$27.17	\$25.27	Naloxone Hydrochloride (DBL) (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)

Table 7-3: Naloxone supply fees: Private Hospital (S94) Pharmacies

Individual Supply (ex GST)	Bulk Supply (ex GST)	Product
\$45.28	\$34.36	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)
\$32.13	\$22.29	Prenoxad (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)
\$35.37	\$25.27	Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)
\$35.37	\$25.27	Naloxone Hydrochloride (DBL) (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)

Table 7-4: Naloxone supply fees: Approved Medical Practitioners (S92)

Individual Supply (ex GST)	Product
\$49.08	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)
\$36.11	Prenoxad (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)
\$39.31	Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)
\$39.31	Naloxone Hydrochloride (DBL) (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)

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Table 7-5: Naloxone supply fees: WA MHC and Wholesalers

Bulk Supply (ex GST)	Product
\$34.36	Nyxoïd (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)
\$22.29	Prenoxad (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)
\$25.27	Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)
\$25.27	Naloxone Hydrochloride (DBL) (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)

8 AUDIT REQUIREMENTS

By participating in the THN Program, organisations recognise that providing false or misleading information is a serious offence and auditing of claims made under the THN Program may occur. Your organisation should therefore appropriately maintain all records (such as invoices and other supporting documents) related to the THN Program for seven years.

9 REVIEW OF DECISIONS

If you have any questions or do not agree with a decision made by the PPA in administering your claim for payment, please contact us at support@ppaonline.com.au or on 1800 951 285. We'll check the decision, explain why we made the decision and ensure there aren't any errors. We aim to resolve matters quickly in line with the Program Rules set out in this document. A discussion explaining a decision is not a formal review.

Formal review

If you still disagree with the outcome, you can ask for a review of the decision. The review will be undertaken by the Department of Health, not the PPA, in accordance with the requirements set out in the *National Health (Take Home Naloxone Pilot) Special Arrangement Amendment (2022 Measures No. 1) Instrument 2022*. An application for review must be in writing to the Secretary of the Department of Health and importantly, in most circumstances the request for review must be made within 28 days after the decision came to your notice unless a longer period of time is allowed for by the Department of Health.

You can submit your formal request for a review by mail (GPO Box 9848, Canberra ACT 2601, Australia) or by email to s100programs@health.gov.au.

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APPENDIX A DATA COLLECTION FOR THE SUPPLY OF NALOXONE TO INDIVIDUALS

The following table indicates which organisations should collect the individual supply data outlined in Appendix A and confirms the method by which this data should be captured and reported.

Organisation	Data capture method	Submit data to:
Community (s90) pharmacies	PPA Portal	PPA
Public and Private Hospital (s94) pharmacies	PPA Portal	PPA
Approved (s92) Medical Practitioners	PPA Portal	PPA
Certain AASs in SA	PPA Portal	PPA
AASs in WA	Information about required data capture will be provided to AASs by WA MHC	WA MHC
AASs in NSW	PPA Portal	PPA

The required data set for each supply is:

- Date of naloxone supply
- Formulations and quantities of naloxone supplied (maximum of two)
- Staff designation (e.g. Pharmacist, Social Worker)
- Whether the individual consents to the collection of de-identified information for program monitoring purposes
- If yes, whether the naloxone supplied was an initial supply or refill
- If refill, was the reason for refill:
 - My THN was used on me
 - My THN was used on someone else
 - My THN was given to someone else to keep
 - My THN is lost, damaged or expired.

This data is used to determine the appropriate payment rates for S90, S94 pharmacies, and s92 approved medical practitioners.

It is also used to allow the Commonwealth Government and State and Territory health departments to monitor the supply of naloxone under the Program.



CONTACT THE SUPPORT CENTRE: 1800 951 285 | support@ppaonline.com.au

APPENDIX B DATA COLLECTION FOR THE BULK SUPPLY OF NALOXONE TO AAS

Wholesalers, WA MHC and hospital (s94) pharmacies providing bulk supply of naloxone to AASs must supply to the PPA via the PPA Portal the following information for payment:

- Name of AAS naloxone supplied to
- Address of AAS naloxone supplied to
- Date of naloxone supply
- Staff designation (e.g. Pharmacist, Social Worker)
- Formulations and quantities of naloxone supplied
- Invoice/Supporting evidence.

Please note the invoice/evidence uploaded must show all of the above information (other than the Staff Designation).

Rates of payment vary by organisation type and are summarised at *Section 7, Fees*.

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