

# Take Home Naloxone non-government and private services procedures

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## REVISION HISTORY

Version	Approved by	Amendment notes
November-2021	Executive Director, Centre for Alcohol & Other Drugs	Amendments reflect the addition of an online education intervention and postal method of supplying take home naloxone medicines. A reference to the National COVID-19 Clinical Evidence Taskforce advice regarding basic life support was added. Client eligibility now includes people who use other illicit drugs that may be adulterated with opioids.
August-2020	Deputy Secretary, Population and Public Health	Initial Document

## 1 BACKGROUND

### 1.1 About this document

#### 1.1.1 Purpose of the Procedures

The Take Home Naloxone Intervention aims to prevent opioid overdose-related mortality and morbidity by increasing access to naloxone for people who are likely to experience or witness an overdose, but who may experience barriers (such as stigma, discrimination or physical access issues) to accessing naloxone from a pharmacy or doctor.

These Take Home Naloxone Procedures support participating non-government and private health/welfare service providers (see Definitions, section 1.3) to provide Take Home Naloxone Interventions, including the supply of naloxone, for clients at risk of experiencing or witnessing opioid overdose.

*Where the Authority – Supply of the Schedule 3 substance naloxone for injection or intranasal spray by a credentialed health/welfare worker to a person using the Take Home Naloxone intervention and these Take Home Naloxone Procedures are complied with, naloxone can be supplied to clients by means of a structured education and supply intervention, without a pharmacist or medical practitioner being present.*

These Procedures describe the conditions and process by which health/welfare workers employed or engaged at participating services can be trained, credentialed and authorised to supply take home naloxone medication as part of a structured overdose response intervention to prevent opioid overdose-related mortality and morbidity. They also describe processes for governance, medication handling (including ordering, storing and supplying naloxone for take home use) and workforce credentialing by non-government organisations (NGOs); private, for-profit service providers; and sole traders that have been confirmed as participating services.

These Procedures are relevant to the supply of naloxone to clients for later use. These Procedures do not apply to health/welfare workers directly administering naloxone and other emergency procedures in response to a suspected patient overdose in a health/welfare service setting.

### **1.1.2 Reducing opioid overdose mortality and morbidity**

People who use illicit opioids have a mortality rate of 10-20 times greater than non-opioid users in the community. Pharmaceutical opioids also pose a considerable overdose risk, especially when not used as prescribed.

The *National Drug Strategy 2017-2026*<sup>1</sup> identifies increasing access to naloxone as an evidence-based strategy for preventing and responding to opioid overdoses.

The World Health Organization<sup>2</sup> recommends that people likely to witness an opioid overdose should have access to naloxone and be instructed in its administration to enable them to use it for the emergency management of suspected opioid overdose.

### **1.1.3 Naloxone medication**

Naloxone is a short-acting opioid antagonist registered in Australia for the reversal of opioid overdose. It is available in several formulations for injected (intravenous, intramuscular and subcutaneous) use, and for administration by intranasal spray. Naloxone is a relatively safe medication, with few precautions, contraindications or adverse events.

Naloxone when used for the treatment of opioid overdose is scheduled in Australia as a Schedule 3 medication, enabling over the counter supply by a pharmacist directly and, with appropriate education to the client, in addition to supply by or on the prescription of a doctor.

### **1.1.4 Making take home naloxone accessible in NSW**

Take home naloxone programs have been established in Australia and internationally to reduce mortality and morbidity for people who use opioids, are at risk of relapsing to opioid use or are likely to witness an opioid overdose. Take home naloxone programs provide overdose response interventions, including guidance for the supply of take home naloxone for administration by community members such as peers and carers in the event of an opioid overdose.

Uptake of take home naloxone where supplied on prescription, or over the counter purchase in a community pharmacy, has been limited until recently. Barriers include:

- over the counter cost;
- some people may be reluctant to ask a doctor or pharmacist about naloxone due to experiences of stigma; and/or

<sup>1</sup> Commonwealth of Australia Department of Health (2017), *National Drug Strategy 2017-2026*.

<sup>2</sup> World Health Organization (2014), *Community management of opioid overdose*.

- people may prefer to get naloxone from a service they already know and trust.

In 2017-18, an Overdose Response Take Home Naloxone (ORTHN) trial developed, piloted and evaluated an intervention delivered by trained and credentialed health/welfare workers in some NSW Health drug and alcohol and needle and syringe program services. Credentialed workers supplied naloxone to clients and trained them to administer the medicine appropriately. The procedures piloted and evaluated by South Eastern Sydney Local Health District and partner services (including the NSW Users and AIDS Association) in that trial<sup>3</sup> form the basis of these Procedures.

The ORTHN pilot was the precursor to the Take Home Naloxone Intervention that is now being delivered in alcohol and other drugs services and needle and syringe programs in NSW public health facilities and the Medically Supervised Injecting Centre in NSW, under NSW Health policy and procedures specific to their settings.

Outside of the credentialed health/welfare worker delivery model, efforts are also underway to increase supply of naloxone at no cost to consumers in NSW through other channels, including some community pharmacies, emergency departments and other hospital units.

### 1.2 Health/welfare worker delivered Take Home Naloxone Intervention

*The Authority – Supply of the Schedule 3 substance naloxone for injection or intranasal spray by a credentialed health/welfare worker to a person using the Take Home Naloxone intervention* legal authority authorises appropriately trained and credentialed health/welfare workers in participating private or non-government health/welfare services to supply naloxone to eligible people.

The Procedures outline a structured opioid overdose response intervention (Take Home Naloxone Intervention). The Procedures must be complied with if naloxone is to be supplied by workers not otherwise authorised to supply Schedule 3 medications (refer to definition of ‘Credentialed health/welfare worker’ below for the full list of worker designations that can supply naloxone under these Procedures).

Medical practitioners may be guided by this client intervention but are exempted from the training and credentialing requirements. If medical practitioners, nurse practitioners and pharmacists wish to supply naloxone outside of these Procedures, existing regulations and models for prescribing/supply of scheduled medicines are to be followed. Adherence with this procedure does not change the usual supervision arrangements for enrolled nurses.

Key features of the Take Home Naloxone Intervention include:

- Identification and assessment of the client against clear eligibility criteria.

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<sup>3</sup> Lintzeris, N, Monds, LA, Bravo, M, Read, P, Harrod, ME, Gilliver, R, Wood, W, Nielsen, S, Dietze, PM, Lenton, S, Shanahan, M, Jauncey, M, Jefferies, M, Hazelwood, S, Dunlop, AJ, Greenaway, M, Haber, P, Ezard, N, Malcolm, A (2020), ‘Designing, implementing and evaluating the overdose response with take-home naloxone model of care: An evaluation of client outcomes and perspectives’, *Drug and Alcohol Review*, Jan, 39, pp. 55-65.

- If client inclusion criteria are not met, or there are concerns regarding the suitability of an individual client for take home naloxone supply under the Procedures (e.g. due to impaired cognition or severe intoxication), the worker is required to revert to “usual care”, which may include providing urgent care, or referring the client to an appropriate service for further assessment and intervention.
- If the client’s care can be provided through the Take Home Naloxone Intervention, the worker manages the episode of care using specified:
  - Take Home Naloxone Procedures, including documentation using the Take Home Naloxone Intervention Form; and
  - Consumer Information Sheets.

### 1.3 Key definitions

Client	A person being considered for the Take Home Naloxone Intervention. The person may be at risk of opioid overdose, or they may be a family member, carer or significant other who is likely to witness an opioid overdose.
Credentialed health/welfare worker	<p>A <i>credentialed health/welfare worker</i> is:</p> <p>(1) a person who:</p> <ul style="list-style-type: none"> <li>○ is a health/welfare worker (registered nurse, enrolled nurse, registered midwife, nurse practitioner, psychologist, social worker, counsellor, occupational therapist, manager, director, alcohol and other drugs worker, health education officer, community support worker, Aboriginal and Torres Strait Islander worker, Aboriginal health worker, Aboriginal health practitioner, AOD bilingual clinician, outreach officer, needle syringe program worker/coordinator/manager, case manager/worker, project officer, consumer worker, peer support worker/coordinator, transitional drug and alcohol worker, women’s transition worker, transition worker, pharmacist, medical practitioner – including any of the above designations with “Aboriginal” or “multicultural” as a preface); and</li> <li>○ is employed in a participating private or non-government health/welfare service; and</li> <li>○ has satisfactorily completed the Take Home Naloxone Worker Training Program and been assessed as meeting the credentialing criteria as identified in the Take Home Naloxone Training and Credentialing Framework.</li> </ul> <p>Note: A nurse practitioner who seeks to supply naloxone outside</p>

	<p>the lawful practice of their profession for prescribing/supply of scheduled medicines must undertake Take Home Naloxone training and credentialing.</p> <p>Note: Medical practitioners are exempted from the training requirements.</p>
Non-Government Organisation (NGO)	<p>A non-profit organisation that is independent from government. A non-profit organisation is one that is not operating for the profit or gain of its individual members, whether these gains would have been direct or indirect. A non-profit organisation can still make a profit, but this profit must be used to carry out its purposes and must not be distributed to owners, members or other private people. NGOs must be registered with the Australian Charities and Not-for-profits Commission.</p> <p>In order to become a participating service that supplies naloxone, the NGO must:</p> <ul style="list-style-type: none"> <li>• employ or engage eligible health/welfare workers (designations are listed in the definition of ‘credentialed health/welfare worker’ above, and other pre-requisites are in Section 4.4 of these Procedures); and</li> <li>• provide health/welfare services to people at risk of witnessing or experiencing opioid overdose.</li> </ul> <p>Note: Non-government entities that operate for private profit are defined under ‘Private service provider’.</p>
Participating service (also known as a ‘participating private or non-government health/welfare service’)	<p>A health/welfare service provider that is registered with NSW Health to supply naloxone under the model set out in these Procedures. A participating service may be either an NGO or a private service provider including a sole trader. The participating service must first enter into an Agreement with the NSW Ministry of Health, to acknowledge agreement to the terms and conditions of participation in the NSW Take Home Naloxone Program.</p>
Private service provider	<p>A privately owned and operated organisation or sole trader that provides health/welfare services.</p> <p>In order to become a participating service that supplies naloxone, the private service provider must:</p> <ul style="list-style-type: none"> <li>• employ or engage eligible health/welfare workers (designations are listed in the definition of ‘credentialed health/welfare worker’ above, and other pre-requisites are in Section 4.4 of these Procedures); and</li> <li>• provide health/welfare services to people at risk of witnessing or experiencing opioid overdose.</li> </ul>



Responsible Person	<p>A key role within an organisational governance framework responsible for ensuring that the participating service complies with these Procedures regarding staff eligibility for training and credentialing; and medication handling (including procurement, storage, stock control, compliance with regulatory requirements and record-keeping).</p> <p>The Responsible Person is the manager/director nominated as responsible for the Take Home Naloxone Program when the entity is approved by NSW Health as a participating service.</p> <p>The Responsible Person must be trained and credentialed i.e. also be a credentialed health/welfare worker.</p>
Supply	<p>In the Take Home Naloxone Intervention, 'supply' relates to provision of naloxone to clients for use at a later time.</p> <p>To provide to or for a specific client. Supply also includes medication selection, labelling, handover to client/carer, verbal counselling and provision of information sheets and/or Consumer Medicines Information as described in these Procedures.</p> <p>These Procedures do not refer to the 'on-site' administration of naloxone by health/welfare workers. These procedures do not permit supply to other organisations (see Section 3.1 for more information about supply).</p>
Take Home Naloxone Intervention	<p>An intervention that includes identification and assessment, client education and the supply of naloxone (as pre-filled syringes or intranasal preparations), which aims to prevent and respond to opioid-related overdoses to reduce overdose related morbidity and mortality.</p>
Take Home Naloxone Procedures	<p>These Procedures describe the delivery of overdose response interventions by credentialed health/welfare workers, including the identification and assessment of clients, the provision of client education, supply of take home naloxone (as pre-filled syringes or intranasal preparations) to clients and relevant documentation.</p>



## 2 PROCEDURES

### 2.1 What to do

The Procedures outline the delivery of the Take Home Naloxone Intervention by a credentialed health/welfare worker in an individual (one to one) session. The Take Home Naloxone Intervention takes approximately 10-20 minutes to deliver (subject to the setting, client and credentialed health/welfare worker characteristics), and has five core elements:

- i. *Client identification and assessment:* Clients must be assessed for contraindications and eligibility for the intervention by the credentialed health/welfare worker. Specific eligibility criteria are described in Section 2.2.
- ii. *Client education:* Client education is a mandatory component of the intervention, delivered by credentialed health/welfare worker, and is described in Section 2.3.
- iii. *Client Consent:* Signed consent by the client that they understand the risk factors for opioid overdose, how to identify an opioid overdose, and what to do in the event of a suspected opioid overdose, including the use of naloxone pre-filled syringe or nasal spray; and have been supplied with naloxone and relevant Consumer Information Sheet. Client consent is documented on the Take Home Naloxone Intervention Form.
- iv. *Supply of 'take home' naloxone:* Naloxone (as pre-filled syringes or intranasal preparations only) is supplied under the conditions of the Take Home Naloxone Procedures and requires appropriate medication labelling.
- v. *Documentation:* Credentialed health/welfare workers must complete documentation regarding the intervention. The Take Home Naloxone Intervention Form includes the necessary documentation, client consent for signature, and record of supply.

Alternatively, the five core elements may be delivered by means of a Take Home Naloxone online education intervention and postal supply model. This model is delivered by means of an online brief training video and a telephone consultation with client if required, with postal naloxone supply. Participating services require NSW Health approval to provide take home naloxone via the Take Home Naloxone online education intervention and postal supply model.

### 2.2 When to use Take Home Naloxone Intervention

Clients attending or contacting a service may be eligible for the Take Home Naloxone Intervention and should be assessed by a credentialed health/welfare worker to confirm that the client meets eligibility criteria.

*Client eligibility criteria* for the intervention are:

- Clients at risk of opioid overdose as evidenced by current or recent (including prescribed) opioid use, use of other illicit drugs that may be adulterated with opioids, or at risk of relapse to opioid use following a period of abstinence (due to withdrawal episode, rehabilitation program, hospital admission, incarceration or any other reason); and/or

- Potential witnesses to an opioid overdose (for example family, friend or carer of someone at risk of opioid overdose); and
- Aged 16 years and over; and
- Able to give informed consent (i.e. not affected by *severe* intoxication, *severe* cognitive impairment, or *severe* active psychological or physical medical condition that impairs informed consent).

Contraindications for naloxone (hypersensitivity to naloxone<sup>4</sup>) and precautions (pregnancy and breastfeeding) must also be assessed before determining client suitability for the Take Home Naloxone Intervention.

If eligibility criteria are not met or there are concerns regarding whether the Take Home Naloxone Intervention is appropriate for an individual client (e.g. due to hypersensitivity to naloxone), it is recommended that the credentialed health/welfare worker seek additional assistance or advice (e.g. discuss with a colleague or supervisor who is experienced in delivering the Take Home Naloxone Intervention), and document on the Take Home Naloxone Intervention Form. If the client is deemed to be not suitable for the Take Home Naloxone Intervention, the credentialed health/welfare worker is required to revert to “usual care”, which may include referring the client to an appropriate worker (e.g. medical officer) or service for further assessment and intervention.

In AOD treatment settings, Take Home Naloxone Interventions should be considered as part of the care planning process, and included in care plans, treatment plans and discharge plans. In non-AOD treatment settings, Take Home Naloxone Interventions may serve to increase interest in engaging in AOD treatment, and appropriate referrals should be made either in accordance with local practice, or with assistance from the Alcohol & Drug Information Service ([ADIS](#)).

### 2.3 How to deliver the Take Home Naloxone Intervention

The key steps for the Take Home Naloxone Intervention are summarised in the Take Home Naloxone Intervention Form, to be completed when each Take Home Naloxone Intervention is delivered, for each client.

#### 2.3.1 Introduce the intervention

The credentialed health/welfare worker providing the Take Home Naloxone Intervention should describe the purpose of the intervention (‘to help people respond to suspected opioid overdoses and prevent overdose death or harm’), that it usually takes between 10 and 20 minutes to complete, and involves the supply of ‘take home naloxone’ medication.

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<sup>4</sup> Hypersensitivity to naloxone is characterised as an anaphylactic reaction to naloxone and is extremely rare. Many people who use opioids may experience a withdrawal-like reaction following use of naloxone, but this is not hypersensitivity.

### 2.3.2 Assess what the client already knows

A key principle of brief interventions is to assess the person's existing knowledge and attitudes, which allows more efficient tailoring of the educational intervention. To assess existing knowledge and attitudes use:

- an unstructured assessment (e.g. discussion using the Take Home Naloxone Consumer Information Sheet as a prompt); or
- a structured assessment (e.g. Take Home Naloxone Client Questionnaire).

The Take Home Naloxone Client Questionnaire examines client understanding of opioid overdose risk, how to recognise an opioid overdose and what to do in response to a suspected opioid overdose. The Take Home Naloxone Client Questionnaire focusses on essential knowledge and can be completed in 2-3 minutes.

Clients with literacy issues or some cognitive challenges may need assistance in completing the questionnaire or may be better suited to an unstructured assessment.

It is not necessary to retain a copy of the client's Take Home Naloxone Client Questionnaire responses in clinical documentation.

### 2.3.3 Provide feedback, information and resources to client

#### *Provide feedback*

Examine client's responses in the Take Home Naloxone Client Questionnaire, or to their understanding of overdose from the unstructured assessment. Provide positive feedback to correct responses and address any incorrect responses with client. It is recommended that the Consumer Information Sheet relevant to the naloxone product be used when providing feedback.

#### *Reinforce information on key messages regarding overdose prevention and response*

Use the Consumer Information Sheet to discuss the key education messages with the client, specifically:

- Identifying opioid overdose risks;
- How to recognise an opioid overdose; and
- What to do in response to a suspected overdose. These steps are highlighted in **Table 1** below.

#### *Discuss with client the resources provided*

Assist the client to determine whether the pre-filled syringe product or intranasal naloxone is more appropriate for their needs and discuss the Take Home Naloxone Consumer Information Sheet and naloxone medication supplied. This may include information on how to assemble and use the naloxone pre-filled syringe and how to administer an intramuscular injection; or how to administer intranasal naloxone.

Discuss precautions for naloxone use with the client and check they understand them.

Illustrate using demonstration pack and/or instructional tools.

**Table 1: Responding to a suspected opioid overdose: key messages to reinforce when providing the intervention to clients**

(Note: these steps are specific to the Take Home Naloxone Intervention. They differ from standard first aid procedures followed by people trained in CPR for other contexts such as a cardiovascular emergency)

<p><b>1. Danger</b></p>	<p>Check the environment that you and others are not in danger.</p> <p>Call for help from others if you are alone.</p>
<p><b>2. Response: Is it a possible opioid overdose?</b></p>	<p>Assess response to verbal and physical stimuli, breathing, skin/lip colour, pupil size and evidence of recent substance use.</p>
<p><b>3. Call an ambulance</b></p>	<p>Dial 000 and follow the operator’s instructions. Tell them that you think this may be an opioid overdose, and that you have access to naloxone.</p>
<p><b>4. Administer naloxone</b></p>	<p><b>Naloxone pre-filled injection (Prenoxad®)</b></p> <p>Lie the person on their side in the recovery position. Assemble Prenoxad® pre-filled needle and syringe. Insert the needle into the person’s outer thigh or upper arm, through clothing if necessary, and inject the first dose (0.4ml), to the first black line. Withdraw the needle and syringe after the dose. Note the time given.</p> <p><b>OR</b></p> <p><b>Naloxone intranasal spray (Nyxoid®)</b></p> <p>Lie the person on their back and check the nose is clear. Hold Nyxoid® device with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle. Do not prime or test the device before you give the dose. Insert nozzle in one nostril. Press firmly on the plunger until it clicks to give the dose.</p>
<p><b>5. Clear airways and perform rescue breathing if you know how</b></p>	<p>Lie person on their back, tilt head back, open mouth, and clear any obstruction. Exhale two times into the person’s mouth.</p> <p>Refer to the National COVID-19 Clinical Evidence Taskforce clinical flowchart that provides <a href="#">guidance on basic life support for adults in the community during the COVID-19 pandemic</a>.</p>

<p><b>6. Put person in the recovery position &amp; wait for ambulance to arrive.</b></p> <p><b>If no improvement after 2 to 3 minutes: repeat naloxone dose/s.</b></p> <p><b>After further doses, perform rescue breathing if you know how, or else put person in recovery position and wait for ambulance to arrive.</b></p>	<p>Put person in recovery position and stay with them until the ambulance arrives. Monitor person to see whether they have recovered (awake, breathing normally).</p> <p><b>Naloxone pre-filled injection</b></p> <p>Give further intramuscular injections of 0.4ml Prenoxad® Injection (to next black line) into the outer thigh or upper arm muscle every 2 to 3 minutes until the ambulance arrives or the person regains consciousness.</p> <p><b>OR</b></p> <p><b>Naloxone intranasal spray</b></p> <p>Give the second dose of Nyxoid®, using the second Nyxoid® device. Insert nozzle into the other nostril. Press firmly on the plunger until it clicks to give the second dose. If available, further doses may be given every 2 to 3 minutes if needed until ambulance arrives.</p>
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**2.3.4 Assess client competence with intervention**

The credentialed health/welfare worker delivering the intervention should be confident that the client understands the key aspects of an effective overdose response, and the rationale and instructions for naloxone use. The credentialed health/welfare worker is to complete the relevant section in the Take Home Naloxone Intervention Form to indicate client competence.

**2.3.5 Seek client informed consent**

The client is asked to provide written informed consent on the Take Home Naloxone Intervention Form, documenting that they consent to receiving the intervention, and they understand when and how to use the naloxone product that they have been supplied with.

**2.3.6 Supply labelled naloxone and provide Consumer Information Sheet**

*Take Home Naloxone Intervention Form*

Finalise and sign the Take Home Naloxone Intervention Form, documenting the number and type of naloxone packs provided.

Up to two packs of naloxone can be provided at each intervention. This may be two packs of Prenoxad®; or two packs of Nyxoid®; or one pack of each product, in accordance with client preference. No time restrictions apply to clients returning to the service to be re-supplied with naloxone.

### *Access stock and record stock movements*

Access naloxone stock (as pre-filled syringes or intranasal preparations only), and complete necessary record of supply. Each participating service will maintain a record of naloxone supply, documenting each time medication is moved in or out of stock, with the credentialed health/welfare worker recording their name and date of supply and remaining stock balance.

Credentialed health/welfare workers in the participating service will access stock procured by the Responsible Person at the agency.

### *Packaging*

Naloxone must be supplied to the client in the manufacturer's original packaging.

### *Labelling*

In participating services, a label must be attached to product packaging providing the name and address of the service supplying naloxone. If the client requests it, client name can also be included on the label. The label should not obstruct existing information on the packaging (Appendix A). In addition, the participating private or non-government health/welfare service must ensure that the existing label from the manufacturer remains visible on the medicine.

### *Consumer Information Sheet*

When naloxone is supplied to the client, it should be provided with the Consumer Information Sheet for that product.

## **2.3.7 Document the Take Home Naloxone Intervention**

### *If client has a client record or file*

Where the client has a client record or file (paper or electronic), the completed paperwork (Take Home Naloxone Intervention Form) is to be filed and an entry is to be made by the credentialed health/welfare worker into the client's clinical notes regarding the Take Home Naloxone Intervention.

### *If client does not have a client record or file*

Where the client does not have a client or file record (such as at an outreach setting, or if the client is a carer or family member likely to witness an overdose) the completed Take Home Naloxone Intervention Form should be filed in a Take Home Naloxone Intervention Folder, specific for each site, and retained in accordance with the relevant legislation or authority. The Responsible Person at the health/welfare facility must ensure these records are kept and audited.

### *Naloxone record of stock*

The credentialed health/welfare worker should follow usual practice to record stock movements. In services that do not supply other medicines, the worker should ensure completion of the Naloxone stock control sheet (Appendix B).



### *Data reporting*

Participating services must report data about each intervention they provide, in accordance with instructions provided by NSW Health.

### *Renewing clients' naloxone supply*

Naloxone medications have a limited shelf life, and if possible, attempts should be made to contact clients when their naloxone medication supply is approaching the expiry date and offer to renew their supply. The credentialed health/welfare worker should provide a 'refresher' repeat of the Take Home Naloxone Intervention using this procedure when renewing naloxone supplies.

Note: All the procedures described here are summarised in a Quick Guide to Delivering Take Home Naloxone Interventions.

In services that are approved to provide take home naloxone via a Take Home Naloxone online education intervention and postal supply model, the steps set out in Section 2.3 may be undertaken via an agreed alternative method.



## 3 REGULATION AND GOVERNANCE FOR TAKE HOME NALOXONE

### 3.1 Legal and legislative framework

Under Clauses 17, 170 and 171 of the *Poisons and Therapeutic Goods Regulation 2008* (Regulation) the Secretary of Health has authorised (for the purposes of the Act) a participating service, via its credentialed health/welfare workers, to supply naloxone for injection or nasal spray to clients. The authorisation applies only to naloxone supplied under the intervention described in these Procedures.

Participating services (defined in section 1.3 of this document) fit the definition of 'authorised alternative supplier' in the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019*.

*Important points for complying with legal and regulatory requirements*

- A participating service must legally obtain naloxone from a wholesaler licensed to supply Schedule 3 medicines.
- The Responsible Person must provide a written purchase order to the wholesaler.
- Private or non-government health/welfare services must be confirmed by NSW Health as a participating service before the Responsible Person will be able to establish an account with the pharmaceutical wholesaler to order naloxone products.
- Participating services cannot legally obtain naloxone from a community pharmacy to supply to patients under the Take Home Naloxone model. Also, community pharmacists cannot legally supply naloxone to participating services.
- A credentialed health/welfare worker at a participating service must not supply naloxone to another agency or worker. The credentialed health/welfare worker can only supply the naloxone directly to clients of the participating service or the client of another service.
- The naloxone for injection or intranasal spray must be in the form of Prenoxad® pre-filled syringe or Nyxoid® single-dose intranasal spray.
- The participating private or non-government health/welfare service must:
  - obtain the *Prenoxad®* pre-filled syringe or *Nyxoid®* intranasal spray from a pharmaceutical wholesaler licensed to supply Schedule 3 naloxone under the *Poisons and Therapeutic Goods Act 1966 and Poisons and Therapeutic Goods Regulation 2008*,
  - attach a label to the product packaging providing the name and address of the service supplying *Prenoxad®* pre-filled syringe or *Nyxoid®* intranasal spray. In addition, the participating private or non-government health/welfare service must ensure that the existing label from the manufacturer remains visible on the medicine, and

- ensure a credentialed health/welfare worker completes the Take Home Naloxone Intervention Form and retain this record in accordance with Section 2.3.7 of the Take Home Naloxone Procedures.
- The Responsible Person at the participating service must ensure that the credentialed health/welfare worker files a completed Take Home Naloxone Intervention Form:
  - in the Client Record; or
  - if the client does not have a record, in the entity's Take Home Naloxone Intervention Folder for filing of completed Take Home Naloxone Intervention Forms.

*Important points for eligibility for the free PBS subsidised naloxone*

- If a participating service obtains PBS subsidised naloxone, it cannot legally charge customers for the naloxone it supplies to them.
- Reimbursement can only be claimed if naloxone is *supplied* to a client for later use. If a credentialed health/welfare worker *administers* naloxone directly to a client in response to a suspected patient overdose, reimbursement cannot legally be obtained.
- NSW Health requires participating services to report naloxone intervention de-identified data monthly via the online 'PPA portal' established by the Australian Government.
- The Take Home Naloxone Intervention Form includes all data collection fields required for the PPA portal. All participating services must use the form (which can be downloaded from the NSW Health website).

### **3.2 Summary of responsibilities**

*Employees, Sole traders:*

- Act in accordance with these Procedures
- Implement the Take Home Naloxone Intervention only if trained and credentialed

*Line Managers, Supervisors:*

- Ensure these Procedures are followed by all relevant employees
- Ensure only credentialed staff deliver the Take Home Naloxone Intervention

*Service Managers, Directors, Sole traders:*

- Ensure governance structures are established and maintained
- Nominated 'Responsible Person' performs key Take Home Naloxone compliance roles
- Support employee implementation of the Take Home Naloxone Intervention

- Ensure compliance with these Procedures

*NSW Ministry of Health:*

- Review applications to become participating services
- Enable participating services to procure naloxone
- Legally enable naloxone supply by credentialed health/welfare workers
- Facilitate access to training and credentialing for eligible workers at participating services
- Facilitate access to a portal for reporting intervention data

### **3.3 Implementation pre-requisites**

Key pre-requisites for the implementation of the Take Home Naloxone Procedures include:

*Governance*

- NGOs and private service providers must complete and submit an Expression of Interest to NSW Ministry of Health to become a participating service, nominate a Responsible Person, and sign a Letter of Agreement to comply with these Procedures.
- Each participating service is responsible for establishment and maintenance of a local governance structure regarding compliance with these Take Home Naloxone Procedures.
- Participating service status must be renewed periodically via a Letter of Agreement signed by NSW Health and the CEO (or equivalent) of the NGO or private service provider.

*Worker training and credentialing*

- Take Home Naloxone worker training: Training is delivered via a Ministry of Health-approved structured Take Home Naloxone Worker Training Program.
- Credentialing of health/welfare workers: Upon completion of training, each health/welfare worker will complete a post-training assessment of their knowledge, skills and competencies regarding the delivery of the Take Home Naloxone Intervention. Successful completion of the assessment will result in credentialing of the worker to supply naloxone in compliance with the Take Home Naloxone Procedures. The Responsible Person in the participating service will ensure records of workers who have successfully completed worker training and credentialing, are maintained and stored in an accessible location, and are able to be provided to NSW Health authorities on request.

### 3.4 Implementation of Take Home Naloxone Procedures

In implementing these Procedures, service managers and directors, and the designated Responsible Person, must ensure that:

- A health/welfare worker operating under these Procedures is aware of their responsibility to: Comply with the requirements of the Take Home Naloxone Procedures and Take Home Naloxone Training and Credentialing Framework as outlined in section 2.3 How to deliver the Take Home Naloxone Intervention.
- Health/welfare workers at participating services who are not otherwise authorised to supply Schedule 3 medications must have successfully completed the Take Home Naloxone training and credentialing requirements as set out in these Take Home Naloxone Procedures in order to supply naloxone using this model.
- Credentialed health/welfare workers must only provide naloxone interventions while working in their role at the participating service (including in an outreach capacity). Credentialed health/welfare workers cannot supply naloxone in a private capacity, or when employed by an agency that is not a participating service.
- Naloxone must be procured from a licensed wholesaler by the Responsible Person, who should be the manager/director responsible for the Take Home Naloxone program at the facility.
- The Responsible Person must order the naloxone in writing from the wholesaler. The Responsible Person will not be able to order naloxone until NSW Health has approved the service as a participating service and has confirmed this in writing for the licensed pharmaceutical wholesaler.
- Naloxone obtained through this method can only be made available for credentialed health/welfare workers at the participating service to supply directly to eligible clients. It cannot legally be supplied to another service for distribution.
- Naloxone storage and labelling meets requirements: Naloxone is stored in locked cupboards with restricted access by credentialed health/welfare workers and the Responsible Person only. The manufacturer's original packaging is used. Additional labelling requirements are described further in Section 2.3.6 of this document.
- Relevant information is supplied: including the Take Home Naloxone Consumer Information Sheet appropriate to the supplied naloxone product.
- All records relating to the supply of medication are retained in accordance with the *Health Records and Information Privacy Act 2002* and the authority from NSW Health.

## 4 TRAINING AND CREDENTIALING HEALTH/WELFARE WORKERS

### 4.1 Purpose of the Take Home Naloxone Training & Credentialing Framework

The Take Home Naloxone Training & Credentialing Framework identifies the necessary prerequisites, training, competencies and assessment criteria required for a health/welfare worker to become credentialed to provide Take Home Naloxone Interventions and supply naloxone under these Procedures. Training will be delivered via a Ministry of Health-approved structured Take Home Naloxone Worker Training Program.

### 4.2 Who the training is for

Health/welfare workers of the following designations may be eligible to be credentialed: registered nurse, enrolled nurse, registered midwife, nurse practitioner, psychologist, social worker, counsellor, occupational therapist, manager, director, alcohol and other drugs worker, health education officer, community support worker, Aboriginal and Torres Strait Islander worker, Aboriginal health worker/practitioner, AOD bilingual clinician, outreach officer, needle syringe program worker/coordinator/manager, case manager/worker, project officer, consumer worker, peer support worker/coordinator, transitional drug and alcohol worker, women's transition worker, transition worker, pharmacist, medical practitioner – including any of the above designations with "Aboriginal" or "multicultural" as a preface, employed in participating services in NSW.

The service manager or service director who is the Responsible Person at the participating service must undertake the training and credentialing.

Medical practitioners are exempted from these training and credentialing requirements but are welcome to undertake training and credentialing if they wish to.

### 4.3 Core components of the training program

The core components of the training program include:

- Overview of overdose in opioid drug users: epidemiology, risk factors, overview of interventions aimed at reducing overdose;
- Overview of naloxone, including pharmacology, formulations;
- Overview of medication handling requirements and documentation;
- Outline of medico-legal requirements for delivering Take Home Naloxone interventions;
- Training on delivering brief interventions targeting overdose prevention and response including naloxone provision. This includes training on assessing client eligibility, contraindications and existing knowledge and attitudes; providing feedback, information and resources for responding to a suspected overdose; assessing client competence and seeking their consent; how to administer naloxone products; and the supply, labelling and documentation of naloxone medication;

- Overview of available resources for clients (client questionnaires, Consumer Information Sheets) and workers (Take Home Naloxone Intervention Form, Quick Guide to Delivering Take Home Naloxone Interventions).

#### 4.4 Pre-requisites and assessment

The necessary pre-requisites, methods of assessment and competencies for a health/welfare worker to be credentialed to deliver the Take Home Naloxone Intervention are shown in **Table 2**.

**Table 2: Pre-requisites and assessment criteria for credentialing**

Pre-requisites	How assessed
Employed or engaged as a health/welfare worker in a participating service	a. Site at which worker is employed or engaged appears on the NSW Health list of 'Participating services' and b. Worker is employed or engaged or is a sole trader within the site in a relevant role (role designation appears in the definition of 'credentialed health/welfare worker' in Key Definitions).
Experience providing health/welfare-related interventions to people who use opioids	>3 months experience in position providing such interventions
Current Certificate in basic life support/CPR	Evidence of satisfactory completion of an accredited basic life support/CPR course (e.g. <i>Provide cardiopulmonary resuscitation</i> (Australian course code HLTAID001)).
Assessment criteria	How assessed
Appropriate knowledge, skills and competencies required to deliver the Take Home Naloxone Intervention	Assessment of knowledge, skills and competence by NSW Health-approved training provider.

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## **4.5 Credentialing**

Upon completion of training, each health/welfare worker will complete a post-training assessment of their knowledge, skills and competencies regarding delivery of the Take Home Naloxone intervention. Successful completion of the assessment will result in being credentialed to supply naloxone in compliance with the Take Home Naloxone Procedures. The Responsible Person in the participating service will ensure records of workers who have successfully completed the Take Home Naloxone Worker Training Program and been credentialed are maintained and stored in an accessible location. Participating services must be able to provide evidence of workers' credentialing if requested by NSW Health.



## 5 DOCUMENTATION

Take Home Naloxone trained and credentialed health/welfare workers in participating services must use the following list of forms required for the implementation of this Procedure:

- Take Home Naloxone Intervention Form
- Take Home Naloxone Client Questionnaire
- Consumer Information Sheet: Responding to an opioid overdose – Prenoxad®
- Consumer Information Sheet: Responding to an opioid overdose – Nyxoid®
- Quick Guide to Delivering Take Home Naloxone Interventions
- Training and Credentialing Framework for the NSW Implementation of the Take Home Naloxone Program

These forms are available to order or download from the NSW Health website: <https://www.health.nsw.gov.au/aod/programs/Pages/naloxone.aspx>

Appendix A	Sample naloxone package label
Appendix B	Sample naloxone stock control sheet

## 6 AUDIT

A quarterly self-audit of implementation of this Procedure will be conducted at each participating service, overseen by the Responsible Person, and provided to NSW Health.

