

## EXPLANATORY STATEMENT

### *NATIONAL HEALTH ACT 1953*

#### ***National Health (Take Home Naloxone Pilot) Special Arrangement 2019*** **PB 97 of 2019**

#### **Authority**

Subsection 100(1) of the *National Health Act 1953* (the Act) enables the Minister to make special arrangements for the supply of pharmaceutical benefits.

Subsection 100(3) of the Act provides that Part VII of the Act, and instruments made for the purposes of Part VII, have effect subject to a special arrangement made under subsection 100(1).

#### **Purpose**

This is the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019* (the Arrangement). The purpose of the Arrangement is to establish a special arrangement under s 100(1) of the Act to support the implementation of the PBS subsidised Take Home Naloxone Pilot (the Pilot), which will operate from 1 December 2019 to 28 February 2021 in New South Wales (NSW), Western Australia (WA), and South Australia (SA).

The Pilot aims to trial the supply of naloxone to persons who are at risk of an opioid overdose, and persons who are likely to be able to assist such persons. The Arrangement will allow for naloxone to be supplied under the Pilot outside of the normal PBS supply regime. Naloxone will be supplied free of charge and without a prescription by hospitals, pharmacists, certain medical practitioners, and other authorised persons or organisations such as needle and syringe programs, alcohol drug treatment centres or correctional release programs.

The Arrangement also sets out the requirements in relation to payments for supplies of naloxone and administrative matters relating to the Pilot.

A provision-by-provision description of the Arrangement is contained in the [Attachment](#).

#### **Consultation**

The design of the Pilot established as a result of this Arrangement has occurred in close consultation with the NSW Ministry of Health, the WA Mental Health Commission and SA Health. This Arrangement was circulated to the relevant state agencies for comment and no significant comment on the nature of the Arrangement was received.

In relation to the listing of naloxone, and selection of brands, forms and strengths for inclusion within the Pilot advice was sought from the Pharmaceutical Benefits Advisory Committee (PBAC).

The PBAC is an independent expert body established by section 100A of the Act, which makes recommendations to the Minister for Health about which drugs and medicinal preparations should be available as pharmaceutical benefits and the circumstances in which they should be available. Part VII of the Act only applies to drugs or medicinal preparations recommended by the PBAC.

PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of these interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC.

This Arrangement has been prepared by the Office of Parliamentary Counsel.

The Arrangement commences on 1 December 2019.

The Arrangement is a legislative instrument for the purposes of the *Legislation Act 2003*.

## ***DETAILS OF THE NATIONAL HEALTH (TAKE HOME NALOXONE PILOT) SPECIAL ARRANGEMENT 2019***

### **Part 1 - Preliminary**

#### **Section 1 Name**

This section provides that the Arrangement is the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019*. It can also be cited as PB 97 of 2019.

#### **Section 2 Commencement**

This section provides that the Arrangement commences on 1 December 2019.

#### **Section 3 Authority**

This section provides that the Arrangement is made under section 100 of the *National Health Act 1953*.

#### **Section 4 Repeal of this instrument**

This section provides that the Arrangement is repealed on 1 May 2021.

#### **Section 5 Simplified outline of this instrument**

This section provides a summary of the Pilot and explains the purpose of the Arrangement. It states that:

- The purpose of the Arrangement is to make a special arrangement that will allow for a trial of the supply of naloxone to persons who are at risk of an opioid overdose and persons who are likely to be able to assist such persons.
- Through the Pilot, naloxone will be supplied from 1 December 2019 to 28 February 2021 in NSW, WA and SA free of charge and without a prescription by hospitals, pharmacists, certain medical practitioners and other authorised persons and organisations.
- The Arrangement will set out payment arrangements and administrative matters relating to the supply of naloxone as part of the Pilot.

The note to Section 5 clarifies that Part VII of the Act, and regulations or other instruments made for the purposes of that Part, have effect subject to this Arrangement (see subsection 100(3) of the Act).

The simplified outline is included to assist readers to understand the substantive provisions, and is not intended to be comprehensive. It is intended that readers should rely on the substantive provisions of the Arrangement.

#### **Section 6 Definitions**

A number of expressions used in the Arrangement are defined in section 6.

These generally provide that terms have the same meaning as in the Act. The terms approved supplier, approved hospital authority, approved medical practitioner and approved pharmacist have the same meanings as in Part VII of the Act (see s 84 of the Act, as well as ss 90, 92 and 94, which deal further with the terms approved pharmacist, approved hospital authority and approved medical practitioner).

Section 6 defines an ‘authorised alternative supplier’ as being a person or organisation that has premises located within a participating jurisdiction; has been authorised by an authority of the participating jurisdiction for the purposes of supplying a designated pharmaceutical benefit. To be authorised, the state authority must have provided a written notice to the Secretary of the Department of Health that states that the person or organisation is authorised to participate and includes their name and contact details.. Authorised alternative suppliers may include, but are not limited to, organisations such as needle and syringe programs, alcohol and drug treatment centres, homeless shelters and custodial release services.

The term ‘day admitted patient’ is defined as being a person who is on a particular day admitted to the hospital for treatment and discharged on that same day.

Section 6 defines a ‘designated person’ as somebody who is at risk of an opioid overdose or somebody who is likely to be able to assist somebody experiencing an opioid overdose. As a guide, the following are some non-exhaustive examples of people who would be included in the definition:

- persons who take prescription opioid medications,
- persons who use opioid substances illicitly, or
- a friend, family member or support person of either of the above category of persons, who is likely to witness an opioid overdose.

## **Part 2 – Special Arrangement supplies of designated pharmaceutical benefits**

### **Division 1 – Preliminary**

#### **Section 7 Definition of *special arrangement supply***

This section sets out the criteria that must be met by different types of suppliers in order for their supply of a designated pharmaceutical benefit (defined in s 6 as the drug naloxone in the forms and strengths set out in the table included at Schedule 1 of the Arrangement) to be a ‘special arrangement supply’.

For approved hospital authorities, approved medical practitioners, and approved pharmacists, ss 7(1)-(3) provide that a supply of a designated pharmaceutical benefit will be a special arrangement supply if the benefit is supplied:

- on or after 1 December 2019, and before 1 March 2021;
- within a participating jurisdiction (defined in section 6 as being New South Wales, South Australia or Western Australia);
- to a person meeting the definition of a designated person;
- without a prescription; and
- by a hospital authority, approved medical practitioner or approved pharmacist that has not been notified as an ‘excluded approved supplier’ by their participating jurisdiction (‘excluded approved supplier’ is defined in s 6).

Subsection 7(1) sets out additional criteria for approved hospital authorities to make a supply of a designated pharmaceutical benefit under the special arrangement. Supply by a designated hospital authority will only be a special arrangement supply if it is supplied to designated persons who, at the time of supply, are:

- a day admitted patient of the hospital; or
- a patient on discharge; or

- a non-admitted patient; or
- somebody who is not a patient receiving treatment in or at the hospital.

The following scenarios are provided as examples to assist in interpreting the types of situations where a supply of naloxone will be a special arrangement supply capable of being supplied and claimed under the special arrangement from an approved hospital authority.

- a patient is discharged from hospital after being an in-patient or day admitted patient for a surgical event with prescription opioids and is provided naloxone at point of discharge;
- a patient attends a drug and alcohol clinic as an outpatient (considered to be a non-admitted patient) and is provided naloxone as part of their attendance;
- a patient is brought to emergency experiencing an opioid overdose and is treated within emergency then discharged or released later that same day and provided naloxone at point of discharge;
- a patient is brought to emergency experiencing an opioid overdose and is treated and then transferred to a ward as an admitted patient. The patient is discharged several days later and provided naloxone at point of discharge;
- a friend, family member or support person of the patient in any of the above scenarios may access naloxone from an approved hospital authority.

This list of examples is provided as a guide only and is not meant to be exhaustive.

Subsection 7(4) outlines the criteria that must be met for an ‘authorised alternative supplier’ to make a supply of a designated pharmaceutical benefit under the special arrangement.

As for approved suppliers, authorised alternative suppliers may only supply a designated pharmaceutical benefit where the supply is made on or after 1 December 2019 and before 1 March 2021 and that the supply is made in a participating jurisdiction to a designated person.

Subsection 7(5) clarifies that the policy intent of the Arrangement is not to extend access to state funded ambulance services for the purposes of treating somebody who is experiencing an opioid overdose. The intention is that this will be funded as part of normal state funding responsibilities.

## **Division 2—Special arrangement supplies of designated pharmaceutical benefits**

### **Section 8 Definition of value for safety net purposes for supplies**

Section 8(1) provides that the ‘value for safety net purposes’ of a special arrangement supply of a designated pharmaceutical benefit is zero. Section 8(2) provides that the definition in s 8 applies despite the definition in s 84(1) of the Act.

Subsection 84(1) of the Act relevantly defines the term ‘value of safety net purpose’ for the supply of a pharmaceutical benefit to be the amount prescribed by regulations made for the purposes of subsection 84C(1E) of the Act.

The purpose of s 8 of the Arrangement is to set out that despite the definition in the Act, there will be no value attributed towards a person’s safety net for a supply allowed through this Arrangement. That is, because there is no patient contribution charged to the patient, there is correspondingly no financial amount that can be counted towards the patient’s safety net benefit when receiving a supply of naloxone through this Arrangement.

## **Section 9 Designated persons entitled to receive supplies free of charge**

Subsection 9(1) provides that a designated person is entitled to receive a special arrangement supply of a designated pharmaceutical benefit without payment or provision of money or other consideration. Subsection 9(2) provides that s 9(1) has effect in addition to s 86 of the Act.

Section 86 of the Act states that an eligible person who is receiving certain kinds of treatment is entitled to receive a pharmaceutical benefit without payment or provision of money or other consideration, other than a charge made in accordance with s 87. Section 87 sets out the fees that an approved supplier may charge to a person receiving a pharmaceutical benefit in certain circumstances.

The purpose of s 9 of the Arrangement is to set out that, in addition to what is set out in s 86 of the Act, a designated person is entitled to receive a special arrangement supply of a designated pharmaceutical benefit without payment. It is intended that a person receiving naloxone supplied under the Arrangement will not be charged the fees specified in s 87 for supplies made under the Arrangement.

## **Section 10 Suppliers not to demand or receive payment for supplies or services**

Subsection 10(1) sets out that an approved supplier may not demand or receive a payment, or other valuable consideration, for the special arrangement supply of a designated pharmaceutical benefit (i.e. naloxone) other than the payment from the Commonwealth. Subsection 10(3) provides that s 10(1) has effect despite s 87 of the Act. (Section 87 of the Act sets out the fees that an approved supplier may charge to a person receiving a pharmaceutical benefit).

Subsection 10(2) provides that an approved supplier must not demand or receive a payment, or other valuable consideration, for a service associated with the supply of the designated pharmaceutical benefit.

Similarly, subsection 10(4) specifies that an authorised alternative supplier must not demand or receive a payment, or other valuable consideration, for the supply, or service associated with the supply, of a designated pharmaceutical benefit.

## **Section 11 Supplies by approved hospital authorities**

Subsection 11(1) sets out the requirements that must be met for a designated person to receive a special arrangement supply of a designated pharmaceutical benefit from an approved hospital authority. These requirements are that the person must be:

- a day admitted patient of the hospital; or
- a patient on discharge from the hospital; or
- a non-admitted patient of the hospital; or
- not a patient receiving treatment in or at the hospital.

The last requirement is intended to ensure that an approved hospital authority can, for instance, supply naloxone to a person who walks into the hospital off the street seeking access to naloxone, or to a friend or family member of a patient in the hospital. Subsection 11(1)(b) ensures that a designated person may only access a supply of a designated pharmaceutical benefit from an approved hospital authority that has not been subject to a notification excluding the hospital from making supplies under the Arrangement.

Subsection 11(2) provides that s 11(1) has effect despite ss 89 and 94 of the Act. Section 89 of the Act relevantly provides that an eligible person cannot receive a pharmaceutical benefit unless it is supplied by an approved pharmacist, at or from the pharmacist's approved premises, on the presentation of a prescription. Section 94 provides that hospital authority can be approved by the Minister to supply pharmaceutical benefits to patients receiving treatment in or at the hospital.

Subsection 11(3) provides that a designated person is entitled to receive a special arrangement supply of a designated pharmaceutical benefit by an approved hospital authority without a prescription. Subsection 11(4) provides that s 11(3) has effect despite the Act and the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations). The note to s 11(4) lists the sections of the Act and the Regulations which deal with the supply of pharmaceutical benefits by approved hospital authorities on prescription.

### **Section 12 Supplies by approved medical practitioners**

Section 12 provides that a designated person is entitled to receive a special arrangement supply of a designated pharmaceutical benefit by an approved medical practitioner who is not an excluded approved supplier, without a prescription. Subsection 13(2) specifies that s 13 has effect despite the Regulations.

The Regulations, specifically sections 44, 48, 52 and 53, set out the circumstances that must be met for the supply of a pharmaceutical benefit by an approved medical practitioner on prescription in various circumstances (for example, on first presentation of a prescription, supplies in cases of urgency, authority prescriptions, repeat authorisations and situations where deferred supply is required).

Section 12 ensures that a designated person is entitled to receive a supply of a designated pharmaceutical benefit under the Arrangement by an approved medical practitioner, despite the requirements set out in the Regulations.

### **Section 13 Supplies by approved pharmacists**

Under s 13 a designated person is entitled to receive a supply of a designated pharmaceutical benefit under this Arrangement by an approved pharmacist without a prescription, as long as the pharmacist is not an excluded approved supplier.

Section 13(2) further clarifies that s 13 has effect despite section 89 of the Act which only permits supply by an approved pharmacist, on presentation of a prescription, to occur at or from the premises at which the pharmacist holds an approval.

### **Section 14 Supplies by authorised alternative suppliers**

Section 14 provides that a designated person is entitled to receive a special arrangement supply of a designated pharmaceutical benefit by an authorised alternative supplier. Section 14(2) provides that this supply is allowed despite the provisions of section 89 of the Act which, relevantly, only permit the supply of a pharmaceutical benefit by an approved pharmacist, on presentation of a prescription, to occur at or from the premises at which the pharmacist holds an approval.

For example, a needle and syringe program, authorised by written notice to the Secretary by their participating state authority in accordance with the definition of an 'authorised approved supplier' under s6, would under s 14 be able to supply naloxone in accordance with the Arrangement to a person at risk of opioid overdose (or their family or friend).

### **Section 15 Maximum quantity or number of units for supplies**

This section sets out that the maximum quantity or number of units of a designated pharmaceutical benefit that may be supplied to a designated person on any one occasion is the number specified within the table included in clause 1 of Schedule 1 in the column headed 'Maximum Quantity or number of units'.

### **Section 16 No limit on number of occasions for supplies**

This section specifies that there is no time limit imposed on the number of occasions on which a designated person may receive a designated pharmaceutical benefit supplied in accordance with the Arrangement. For example, a designated person may be supplied with naloxone in accordance with the Arrangement twice on the same day or on subsequent days if needed.

## **Division 3—Payment for special arrangement supplies of designated pharmaceutical benefits**

### **Section 17 Supplies by approved hospital authorities to certain patients**

Subsection 17(1) provides that an approved hospital authority is entitled to payment from the Commonwealth for a supply of a designated pharmaceutical benefit under this Arrangement where the approved hospital authority makes the supply to the following categories of patients of a hospital of which the approved hospital authority is the governing body or proprietor:

- day admitted patients
- patients on discharge, and
- non admitted patients.

To receive payment, the approved hospital authority must make a claim in accordance with the requirements of section 20 of the Arrangement.

The note to s 17 clarifies that payment under s 17 will be in accordance with the rates determined by the Minister under subsection 99(4) of the Act. At the time of making this Arrangement, the relevant determinations are:

- the *National Health (Pharmaceutical benefits supplied by private hospitals) Determination 2010*, and
- the *National Health (Commonwealth Price—Pharmaceutical Benefits Supplied by Public Hospitals) Determination 2017*.

Subsection 17(2) ensures that the claim for payment arrangements relating to the supply of pharmaceutical benefits determined under s 99AAA of the Act do not apply to the claiming requirements for approved hospital authorities established under this Arrangement.

### **Section 18 Supplies by approved hospital authorities to persons who are not patients**

Section 18 sets out the arrangements for an approved hospital authority to receive payment in respect of special arrangement supplies to a person who is not a patient of a hospital in respect of which the authority is approved. Specifically, this section sets out that:

- the approved hospital authority is entitled to payment from the Commonwealth in respect of a supply of a designated pharmaceutical benefit where the person is not a



patient receiving treatment in or at a hospital in respect of which the authority is approved.

- the rate of payment that will be made by the Commonwealth is consistent with the conditions determined by the Minister under subsection 99(4) of the Act (the relevant determinations are noted above against s 17); and
- the approved hospital authority must make a claim for payment in accordance with the requirements of section 20 of the Arrangement in order to receive a payment for the supply of a designated pharmaceutical benefit.

### **Section 19 Supplies by approved medical practitioners and approved pharmacists**

This section states that where an approved medical practitioner or approved pharmacist wants to receive payment from the Commonwealth for a supply made under the Arrangement, they must lodge a claim in accordance with s 20. The note clarifies that such payment will be in accordance with s 99 of the Act (see also the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015*, which at the time of making this Arrangement, relevantly determines the Commonwealth price for pharmaceutical benefits).

Subsection 19(2) clarifies that the claim for payment requirements specific to this Arrangement operate despite the claim for payment arrangements set out within section 99AAA of the Act.

### **Section 20 Claims for payment by approved suppliers**

Section 20 sets out the claim for payment requirements for the purposes of subsections 17(1), 18(3) and 19(1). It provides that an approved supplier must undertake the following in order to make a claim for payment:

- submit a claim in writing to the Secretary;
- include the following mandatory information:
  - the benefit supplied;
  - the date the benefit was supplied;
  - the postcode in which the benefit was supplied;
  - the title of the individual who interacted with the person to whom the benefit was supplied;
  - whether the person to whom the benefit was supplied was given a patient information sheet;
  - whether the person to whom the benefit was supplied consented to the use of their de-identified data for evaluation of the supply of designated pharmaceutical benefits in accordance with the Arrangement; and
- where such consent is provided:
  - whether the person is at risk of an opioid overdose, or is likely to be able to assist such a person;
  - for a person at risk of an opioid overdose—whether the opioids concerned are prescribed for the person;
  - whether the person had previously received a supply of a designated pharmaceutical benefit;
  - if the person had previously received a supply of a designated pharmaceutical benefit—the reason for receiving a further supply of the benefit;

- whether educative information or advice was provided to the person with the supply of the benefit; and
- the person's gender.

### **Section 21 Supplies to authorised alternative suppliers**

This section sets out arrangements for a person to receive payment from the Commonwealth for supplying designated pharmaceutical benefits to authorised alternative suppliers.

Subsection 21(1) establishes an entitlement to payment from the Commonwealth for persons making such a supply. These persons may be, for example, a responsible person (pharmaceutical company), a wholesale distributor, a State or Territory government department or a public hospital (who is an approved hospital authority).

Subsection 21(2) states that the amount paid for supplies to authorised alternative suppliers will be the equivalent of the approved ex-manufacturer price of the listed brand of the pharmaceutical item of the designated pharmaceutical benefit. 'Approved ex-manufacturer price' is given the same meaning as in Part VII of the Act (s 6).

Subsections 21(3) and 21(4) state that if a person wishes to receive a payment for a supply of a designated pharmaceutical benefit to an authorised alternative supplier, they must lodge a claim with the Commonwealth, which must:

- be made in writing to the Secretary; and
- include:
  - the name and address of the authorised alternative supplier; and
  - for each day covered by the claim, the volume of each designated pharmaceutical benefit supplied.

### **Section 22 Secretary to determine and pay claims**

This section confers the functions of determining the amount payable for claims made under Part 2 of the Arrangement, and making any payment relating to the claim, on the Secretary.

The Secretary may authorise third parties to perform these functions in accordance with s 25 of the Arrangement.

## **Division 4—Administration**

### **Section 23 Secretary may request information from authorised alternative suppliers**

Under s 23 the Secretary may request an authorised alternative supplier to provide the information mentioned in ss 20(b) and (c) in relation to supplies that they have made of designated pharmaceutical benefits to designated persons under the Arrangement. The Secretary's request must be made in writing, and must specify a day for complying with the request which is a minimum of 28 days after the day of the request.

### **Section 24 Authorised alternative suppliers to supply information on request**

Section 24 requires an authorised alternative supplier to comply with any written request for information made by the Secretary under s 23. The authorised alternative supplier must comply with the request by the date specified within the request.

**Section 25 Secretary may authorise persons to perform functions or exercise powers**

Subsection 25(1) empowers the Secretary to authorise a third party, with suitable qualifications and experience, to perform any of the Secretary's functions or exercise any of the Secretary's powers under the Arrangement. This authorisation must be in writing.

Subsection 25(2) provides that the authorisation may be in the form of a contract entered into by the Secretary on behalf of the Commonwealth.

A person authorised under s 25 must comply with any directions issued by the Secretary in relation to the performance of the functions or exercise of the powers specified in the authorisation (s 25(3)).

**Schedule 1 – Designated pharmaceutical benefits and maximum quantities or numbers of units****Clause 1 Designated pharmaceutical benefits**

The table in this clause sets out each pharmaceutical benefit that is a designated pharmaceutical benefit for the purposes of this Arrangement. The table sets out that naloxone in the forms and of the brands specified, administered in the manners specified, and to the maximum quantity specified, will be a designated pharmaceutical benefit.

## Statement of Compatibility with Human Rights

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

### ***National Health (Take Home Naloxone Pilot) Special Arrangement 2019***

This *National Health (Take Home Naloxone Pilot) Special Arrangement 2019* (the Arrangement) is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

#### **Overview of the Legislative Instrument**

The purpose of this Arrangement, made under subsection 100 of the *National Health Act 1953* (the Act), is to establish the requirements of supply of a pharmaceutical benefit, naloxone, through a PBS subsidised Take Home Naloxone Pilot (the Pilot).

The Pilot seeks to address a growing rate of deaths from accidental overdose due to opioid use, both via illicit drugs and prescription medications. Through this Arrangement, naloxone will be made available for free to a person at risk of or likely to witness an opioid overdose. The person will not be required to obtain or present a prescription to access naloxone. This Arrangement will enable supply of naloxone to occur through a wide variety of settings outside of the normal supply mechanisms established through the Act. It will be possible to obtain naloxone from pharmacy settings in addition to a number of other access points such as needle and syringe programs, alcohol and drug treatment centres and on release from custodial settings. Where a supply of naloxone is made in accordance with this Arrangement the Commonwealth will pay a PBS equivalent subsidy for that supply.

#### **Human Rights Implications**

This Arrangement engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

This Arrangement assists with the advancement of this right by increasing access to PBS subsidised naloxone through a variety of settings, free of charge, to persons at risk of or likely to witness an opioid overdose.

#### **Conclusion**

This Arrangement is compatible with human rights because it promotes the right to health in Articles 2 and 12 of ICESCR.

**Penny Shakespeare**  
**Deputy Secretary, Health Financing Group**  
**Department of Health**