PB 97 of 2019

National Health (Take Home Naloxone Pilot) Special Arrangement 2019

I, Penny Shakespeare, as delegate of the Minister for Health, make the following special arrangement.

Dated 29 November 2019

Penny Shakespeare
Deputy Secretary, Health Financing Group
Department of Health

OPC64207 - A

Contents

Part 1—Preliminary

1 Name

(1) This instrument is the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019*.

(2) This instrument may also be cited as PB 97 of 2019.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	1 December 2019.	1 December 2019

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 100 of the *National Health Act 1953*.

4 Repeal of this instrument

This instrument is repealed at the start of 1 May 2021.

5 Simplified outline of this instrument

This instrument makes a special arrangement 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.

Naloxone will be supplied from 1 December 2019 to 28 February 2021 in New South Wales, Western Australia and South Australia.

Naloxone will be supplied free of charge and without a prescription by hospitals, pharmacists, certain medical practitioners and other authorised persons and organisations.

This instrument also deals with payments for supplies of naloxone and administrative matters.

Note: Part VII of the Act, and regulations or other instruments made for the purposes of that Part, have effect subject to this instrument (see subsection 100(3) of the Act).

6 Definitions

Note: A number of expressions used in this instrument are defined in the Act, including the following:
(a) hospital;
(b) premises;
(c) Secretary.

In this instrument:

Act means the *National Health Act 1953*.

approved ex-manufacturer price of a listed brand of a pharmaceutical item has the same meaning as in Part VII of the Act.

approved hospital authority has the same meaning as in Part VII of the Act.

approved medical practitioner has the same meaning as in Part VII of the Act.

approved pharmacist has the same meaning as in Part VII of the Act.

approved supplier has the same meaning as in Part VII of the Act.

authorised alternative supplier means a person or organisation:
(a) that has premises in a participating jurisdiction; and
(b) that is authorised (however described) by an authority of the jurisdiction for the purposes of supplying designated pharmaceutical benefits in accordance with this instrument; and
(c) in relation to which the authority has given the Secretary a written notice stating:
(i) that the person or organisation is so authorised; and
(ii) the name and contact details of the person or organisation.

day admitted patient: a person is a ***day admitted patient*** of a hospital on a day if, on that day, the person:
(a) is admitted to the hospital (other than through the hospital's emergency department); and
(b) receives treatment; and
(c) is discharged from the hospital;
in accordance with a pre-existing plan for the person's treatment.

designated person means:
(a) a person who is at risk of an opioid overdose; or
(b) a person who is likely to be able to assist such a person.

designated pharmaceutical benefit means a pharmaceutical benefit mentioned in Schedule 1.

excluded approved supplier means an approved supplier in a participating jurisdiction in relation to which there is in force a notice given by an authority of the jurisdiction to the Secretary and the supplier to the effect that the authority wants the supplier not to be able to supply designated pharmaceutical benefits in accordance with this instrument.

listed brand of a pharmaceutical item has the same meaning as in Part VII of the Act.

participating jurisdiction: each of the following is a ***participating jurisdiction***:

(a) New South Wales;
(b) Western Australia;
(c) South Australia.

pharmaceutical benefit has the same meaning as in Part VII of the Act.

pharmaceutical item has the same meaning as in Part VII of the Act.

special arrangement supply has the meaning given by section 7.

Part 2—Special arrangement supplies of designated pharmaceutical benefits

Division 1—Preliminary

7 Definition of *special arrangement supply*

Supplies by approved hospital authorities

(1) A supply of a designated pharmaceutical benefit is a ***special arrangement supply*** of the benefit if the benefit is supplied:
  (a) on or after 1 December 2019 and before 1 March 2021; and
  (b) in a participating jurisdiction; and
  (c) by an approved hospital authority that is not an excluded approved supplier; and
  (d) to a designated person who, at the time of the supply, is:
    (i) a day admitted patient of a hospital of which the approved hospital authority is the governing body or proprietor; or
    (ii) a patient on discharge from such a hospital; or
    (iii) a non-admitted patient of such a hospital; or
    (iv) not a patient receiving treatment in or at such a hospital; and
  (e) without a prescription.

Supplies by approved medical practitioners

(2) A supply of a designated pharmaceutical benefit is also a ***special arrangement supply*** of the benefit if:
  (a) the benefit is supplied:
    (i) on or after 1 December 2019 and before 1 March 2021; and
    (ii) in a participating jurisdiction; and
    (iii) to a designated person; and
    (iv) without a prescription; and
    (v) by an approved medical practitioner who is not an excluded approved supplier; and
  (b) the benefit was not obtained by the approved medical practitioner under section 93 of the Act (prescriber bag supplies).

Supplies by approved pharmacists

(3) A supply of a designated pharmaceutical benefit is also a ***special arrangement supply*** of the benefit if the benefit is supplied:
  (a) on or after 1 December 2019 and before 1 March 2021; and
  (b) in a participating jurisdiction; and
  (c) to a designated person; and
  (d) without a prescription; and
  (e) by an approved pharmacist who is not an excluded approved supplier.

Supplies by authorised alternative suppliers

(4) A supply of a designated pharmaceutical benefit is also a ***special arrangement supply*** of the benefit if the benefit is supplied:
  (a) on or after 1 December 2019 and before 1 March 2021; and
  (b) in a participating jurisdiction; and
  (c) to a designated person; and
  (d) by an authorised alternative supplier.

(5) However, a supply of a designated pharmaceutical benefit mentioned in subsection (4) is not a ***special arrangement supply*** of the benefit if:
  (a) the authorised alternative supplier is the ambulance service of the participating jurisdiction; and
  (b) the benefit supplied is administered to the designated person by an ambulance officer to treat the person for an opioid overdose.

Division 2—Special arrangement supplies of designated pharmaceutical benefits

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

(1) The ***value for safety net purposes*** for a special arrangement supply of a designated pharmaceutical benefit is zero.

(2) This section applies despite the definition of ***value for safety net purposes*** in subsection 84(1) of the Act.

9 Designated persons entitled to receive supplies free of charge

(1) A designated person is entitled to receive a special arrangement supply of a designated pharmaceutical benefit without the payment or provision of money or other consideration.

(2) This section has effect in addition to section 86 of the Act.

10 Suppliers not to demand or receive payment for supplies or services

Approved suppliers

(1) An approved supplier must not demand or receive a payment (other than a payment from the Commonwealth) or other valuable consideration in respect of a special arrangement supply of a designated pharmaceutical benefit.

(2) An approved supplier must not demand or receive a payment or other valuable consideration in respect of any other service relating to a special arrangement supply of a designated pharmaceutical benefit.

(3) Subsection (1) has effect despite section 87 of the Act.

Authorised alternative suppliers

(4) An authorised alternative supplier must not demand or receive a payment or other valuable consideration in respect of:
  (a) a special arrangement supply of a designated pharmaceutical benefit; or
  (b) any other service relating to a special arrangement supply of a designated pharmaceutical benefit.

11 Supplies by approved hospital authorities

(1) A designated person is entitled to receive a special arrangement supply of a designated pharmaceutical benefit by an approved hospital authority if:
  (a) at the time of the supply, the designated person is:
    (i) a day admitted patient of a hospital of which the approved hospital authority is the governing body or proprietor; or
    (ii) a patient on discharge from such a hospital; or
    (iii) a non-admitted patient of such a hospital; or

(iv) not a patient receiving treatment in or at such a hospital; and

(b) the approved hospital authority is not an excluded approved supplier.

(2) Subsection (1) has effect despite sections 89 and 94 of the Act.

(3) A designated person is entitled to receive a special arrangement supply of a designated pharmaceutical benefit by an approved hospital authority as mentioned in subsection (1) without a prescription.

(4) Subsection (3) has effect despite the Act and the *National Health (Pharmaceutical Benefits) Regulations 2017*.

Note 1: Sections 84AAA, 84D, 99 and 134 of the Act deal with the supply of pharmaceutical benefits by approved hospital authorities on prescription.

Note 2: Sections 18, 30, 41, 44, 45, 52 and 53 of the *National Health (Pharmaceutical Benefits) Regulations 2017* deal with the supply of pharmaceutical benefits by approved hospital authorities on prescription.

12 Supplies by approved medical practitioners

(1) 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.

(2) This section has effect despite the *National Health (Pharmaceutical Benefits) Regulations 2017*.

Note: Sections 44, 48, 52 and 53 of the *National Health (Pharmaceutical Benefits) Regulations 2017* deal with the supply of pharmaceutical benefits by approved medical practitioners on prescription.

13 Supplies by approved pharmacists

(1) A designated person is entitled to receive a special arrangement supply of a designated pharmaceutical benefit by an approved pharmacist who is not an excluded approved supplier without a prescription.

(2) This section has effect despite section 89 of the Act.

14 Supplies by authorised alternative suppliers

(1) A designated person is entitled to receive a special arrangement supply of a designated pharmaceutical benefit by an authorised alternative supplier.

(2) This section has effect despite section 89 of the Act.

15 Maximum quantity or number of units for supplies

The maximum quantity or number of units of the pharmaceutical item of a designated pharmaceutical benefit that may be supplied to a designated person in a special arrangement supply of the benefit on any one occasion is the quantity or number of units specified in the column headed "Maximum quantity or number of units" of the item of the table in clause 1 of Schedule 1 for the pharmaceutical benefit.

Section 16

16 No limit on number of occasions for supplies

There is no limit on the number of occasions on which a designated person is entitled to receive a special arrangement supply of a designated pharmaceutical benefit.

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

17 Supplies by approved hospital authorities to certain patients

(1) An approved hospital authority that wants to receive payment from the Commonwealth in relation to a special arrangement supply by the approved hospital authority of a designated pharmaceutical benefit to any of the following must make a claim for payment in accordance with section 20:

(a) a day admitted patient of a hospital of which the approved hospital authority is the governing body or proprietor;

(b) a patient on discharge from such a hospital;

(c) a non-admitted patient of such a hospital.

Note: See subsection 99(4) of the Act for the entitlement of an approved hospital authority to payment for the supply of pharmaceutical benefits to patients receiving treatment in or at a hospital in respect of which the authority is approved.

(2) This section has effect despite section 99AAA of the Act.

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

Entitlement to payment

(1) Subject to this section, an approved hospital authority is entitled to payment from the Commonwealth in respect of a special arrangement supply by the approved hospital authority of a designated pharmaceutical benefit to a person who is not a patient receiving treatment in or at a hospital in respect of which the authority is approved.

Rates and conditions for payment

(2) The payment is at the rates and subject to the conditions determined by the Minister under subsection 99(4) of the Act in respect of the supply of designated pharmaceutical benefits.

Claims for payment

(3) If an approved hospital authority wants to receive a payment to which it is entitled under this section, the authority must make a claim for payment in accordance with section 20.

19 Supplies by approved medical practitioners and approved pharmacists

(1) An approved medical practitioner or an approved pharmacist who wants to receive payment from the Commonwealth in relation to a special arrangement supply by the approved medical practitioner or approved pharmacist of a designated pharmaceutical benefit must make a claim for payment in accordance with section 20.

Note: See section 99 of the Act for the entitlement of approved medical practitioners and approved pharmacists to payment for the supply of pharmaceutical benefits.

(2) This section has effect despite section 99AAA of the Act.

20 Claims for payment by approved suppliers

For the purposes of subsections 17(1), 18(3) and 19(1), a claim for payment by an approved supplier in relation to a special arrangement supply of a designated pharmaceutical benefit must:

(a) be made, in writing, to the Secretary; and

(b) include the following information:

(i) the benefit supplied;

(ii) the date the benefit was supplied;

(iii) the postcode in which the benefit was supplied;

(iv) the title of the individual who interacted with the person to whom the benefit was supplied;

(v) whether the person to whom the benefit was supplied was given a participant information sheet;

(vi) 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 this instrument; and

(c) if the person to whom the benefit was supplied consented as mentioned in subparagraph (b)(vi)—include the following information:

(i) whether the person is at risk of an opioid overdose, or is likely to be able to assist such a person;

(ii) for a person at risk of an opioid overdose—whether the opioids concerned are prescribed for the person;

(iii) whether the person had previously received a supply of a designated pharmaceutical benefit;

(iv) if the person had previously received a supply of a designated pharmaceutical benefit—the reason for receiving a further supply of a designated pharmaceutical benefit;

(v) whether educative information or advice was provided to the person with the supply of the benefit;

(vi) the person's gender.

21 Supplies to authorised alternative suppliers

Entitlement to payment

(1) Subject to this section, a person who supplies a designated pharmaceutical benefit to an authorised alternative supplier is entitled to payment from the Commonwealth.

Amount of payment

(2) The amount of the payment is the approved ex-manufacturer price of the listed brand of the pharmaceutical item of the designated pharmaceutical benefit that was applicable on the day the person supplied the benefit to the authorised alternative supplier.

Claims for payment

(3) If a person wants to receive a payment to which the person is entitled under this section, the person must make a claim for payment in accordance with subsection (4).

(4) The claim must:
  (a) be made, in writing, to the Secretary; and
  (b) include the name of the authorised alternative supplier; and
  (c) include, for each day covered by the claim on which the person supplied a designated pharmaceutical benefit to the authorised alternative supplier, the volume of each designated pharmaceutical benefit supplied on the day.

22 Secretary to determine and pay claims

The Secretary must determine the amount payable for a claim made under this Part and make any payment relating to the claim.

Division 4—Administration

23 Secretary may request information from authorised alternative suppliers

(1) The Secretary may, in writing, ask an authorised alternative supplier to give the Secretary the information mentioned in paragraphs 20(b) and (c) in relation to any special arrangement supply of a designated pharmaceutical benefit made by the supplier.

(2) A request for information must:
  (a) be in writing; and
  (b) specify a day for complying with the request which is at least 28 days after the day of the request.

24 Authorised alternative suppliers to supply information on request

If an authorised alternative supplier receives a request for information under section 23, the supplier must comply with the request by the day specified in the request.

25 Secretary may authorise persons to perform functions or exercise powers

(1) The Secretary may, in writing, authorise persons having suitable qualifications and experience to perform any of the Secretary's functions, or exercise any of the Secretary's powers, under this instrument on behalf of the Secretary.

(2) Without limiting subsection (1), an authorisation under this section may be in the form of a contract entered into by the Secretary on behalf of the Commonwealth.

(3) A person who is authorised under this section must comply with any directions of the Secretary in the performance of the functions or exercise of the powers specified in the authorisation.

Schedule 1—Designated pharmaceutical benefits and maximum quantities or numbers of units

Note: See the definition of ***designated pharmaceutical benefit*** in section 6, and section 15.

1 Designated pharmaceutical benefits

Each pharmaceutical benefit specified in the following table is a designated pharmaceutical benefit.

Designated pharmaceutical benefits

Item	Drug	Form	Manner of administration	Brand	Maximum quantity or number of units
1	Naloxone	Injection containing naloxone hydrochloride 400 micrograms in 1 mL ampoule	Injection	Naloxone Hydrochloride (DBL)	10
2	Naloxone	Injection containing naloxone hydrochloride 400 micrograms in 1 mL ampoule	Injection	Naloxone Juno	10
3	Naloxone	Injection containing naloxone hydrochloride 2 mg in 2 mL pre-filled syringe	Injection	Prenoxad	2
4	Naloxone	Nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2	Nasal	Nyxoid	2

Note: The drug mentioned in the table has been declared by the Minister under subsection 85(2) of the Act. The forms, manners of administration and brands mentioned in the table have been determined by the Minister under subsections 85(3), (5) and (6) of the Act respectively.