



**PB 61 of 2023**

# **National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023**

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I, David Laffan, as delegate of the Minister for Health and Aged Care, make the following special arrangement.

Dated                    28 June 2023

David Laffan  
Assistant Secretary  
Pharmacy Branch  
Technology Assessment and Access Division  
Department of Health and Aged Care

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## Part 1—Preliminary

### 1 Name

- (1) This instrument is the *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023*.
- (2) This instrument may also be cited as PB 61 of 2023.

### 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 July 2023.	1 July 2023

Note: This table relates only to the provisions of this instrument as originally made.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 Repeal of this instrument

This instrument is repealed at the start of 1 March 2024.

### 4 Authority

This instrument is made under paragraph 85(7)(b) and section 100 of the *National Health Act 1953*.

### 5 Simplified outline of this instrument

This instrument makes a special arrangement for the supply of certain pharmaceutical benefits for the purpose of treating opioid dependence, including for detoxification (withdrawal) and maintenance of withdrawal, by authorised suppliers between 1 July 2023 and 30 November 2023.

The pharmaceutical benefits will be supplied to persons who are receiving treatment by medical practitioners and authorised nurse practitioners.

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The authorised suppliers will be persons and organisations who are not approved suppliers but are authorised by States and Territories to supply these pharmaceutical benefits.

This instrument also deals with payments for these supplies of pharmaceutical benefits, payments for other supplies of these pharmaceutical benefits made before 1 July 2023, and administrative matters.

Note 1: 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).

Note 2: For supplies of these pharmaceutical benefits by approved suppliers, see the Listing Instrument and the HSD Special Arrangement.

### 6 Definitions

Note 1: A number of expressions used in this instrument are defined in the Act, including the following:

- (a) premises;
- (b) Secretary.

Note 2: Under subsection 4(1A) of the Act, a word or phrase defined for the purposes of the *Health Insurance Act 1973* has the meaning that it would have if used in that Act. Expressions used in this instrument that are defined in that Act include the following:

- (a) eligible person;
- (b) medical practitioner.

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

*authorised nurse practitioner* has the same meaning as in Part VII of the Act.

*authorised supplier* means a person or organisation:

- (a) that has premises in a State or Territory; and
- (b) that is authorised (however described) by an authority of the State or Territory for the purposes of supplying ODT pharmaceutical benefits in accordance with this instrument; and
- (c) that is not an approved supplier; and
- (d) that is not an HSD hospital authority (within the meaning of the HSD Special Arrangement).

*eligible patient* means a person who:

- (a) is, or is to be treated as, an eligible person; and
- (b) is receiving:
  - (i) medical treatment by a medical practitioner; or
  - (ii) nurse practitioner treatment by an authorised nurse practitioner.

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**HSD Special Arrangement** means the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021*.

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

**Listing Instrument** means the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*.

**medication for the treatment of opioid dependence** has the same meaning as in the HSD Special Arrangement.

**nurse practitioner treatment** has the same meaning as in Part VII of the Act.

**ODT pharmaceutical benefit** has the same meaning as in the HSD Special Arrangement.

**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.

**pre-commencement benefit** has the same meaning as in Division 2 of Part 6 of the HSD Special Arrangement.

**pre-commencement prescription** has the same meaning as in Division 2 of Part 6 of the HSD Special Arrangement.

**pre-commencement supplier** means a person who was, before 1 July 2023, permitted (however described) by a State or Territory to supply an opiate treatment drug to a patient in that State or Territory.

**responsible person** for a brand of a pharmaceutical item has the same meaning as in Part VII of the Act.

**special arrangement supply**: see section 7.

## **Part 2—Special arrangement supplies of ODT pharmaceutical benefits**

### **Division 1—Preliminary**

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

*Supplies on the basis of prescriptions written on or after 1 July 2023*

- (1) A supply of an ODT pharmaceutical benefit is a ***special arrangement supply*** of the benefit if the benefit is supplied:
- (a) on or after 1 July 2023 and before 1 December 2023; and
  - (b) to an eligible patient; and
  - (c) by an authorised supplier; and
  - (d) on the basis of a prescription written:
    - (i) on or after 1 July 2023; and
    - (ii) in the circumstance that the prescription was for the treatment of opioid dependence.

*Supplies on the basis of pre-commencement prescriptions*

- (2) A supply of an ODT pharmaceutical benefit is a ***special arrangement supply*** of the benefit if the benefit is supplied:
- (a) on or after 1 July 2023 and before 1 December 2023; and
  - (b) to an eligible patient; and
  - (c) by an authorised supplier; and
  - (d) on the basis of a pre-commencement prescription.



## **Division 2—Prescribing for special arrangement supplies**

### **8 Prescription circumstances (Act s 85(7)(b))**

- (1) For the purposes of paragraph 85(7)(b) of the Act, the circumstances in which a prescription for a special arrangement supply of an ODT pharmaceutical benefit may be written are that the prescription is for the treatment of opioid dependence.
- (2) This section applies in addition to section 10 of the Listing Instrument.

Note 1: For the determination of ODT pharmaceutical benefits as relevant pharmaceutical benefits for the purposes of section 88A of the Act, see paragraph 85(7)(a) of the Act and subsection 15(1) of the HSD Special Arrangement.

Note 2: For the authorisation of authorised nurse practitioners and medical practitioners to write prescriptions for the supply of ODT pharmaceutical benefits, see section 88 of the Act, section 9 of the Listing Instrument and section 14 of the HSD Special Arrangement.

### **9 Determinations under section 85A of the Act do not apply**

Determinations under section 85A of the Act do not apply to a prescription for a special arrangement supply of an ODT pharmaceutical benefit.

### **10 Section 39 of the Regulations does not apply**

Section 39 of the *National Health (Pharmaceutical Benefits) Regulations 2017* does not apply to a prescription for a special arrangement supply of an ODT pharmaceutical benefit.

## **Division 3—Supplying special arrangement supplies**

### **11 Definition of *value for safety net purposes***

- (1) The *value for safety net purposes* for a special arrangement supply of an ODT pharmaceutical benefit is zero.
- (2) This section has effect despite the definition of *value for safety net purposes* in subsection 84(1) of the Act.

### **12 Charges to patients not limited**

Section 86 of the Act does not apply to a special arrangement supply of an ODT pharmaceutical benefit.

### **13 Entitlement to receive supplies from authorised suppliers**

- (1) An eligible patient is entitled to receive a special arrangement supply of an ODT pharmaceutical benefit from an authorised supplier on the basis of a prescription written by an authorised nurse practitioner or medical practitioner from whom the eligible patient is receiving medical treatment or nurse practitioner treatment.
- (2) This section has effect despite section 89 of the Act.

### **14 Pre-commencement prescriptions directing supply of methadone**

- (1) This section applies if a pre-commencement prescription is for the supply of methadone.
- (2) On the basis of the prescription, the person for whom the prescription was written is entitled to receive, and an authorised supplier may supply to the person, any of the pharmaceutical benefits with the drug methadone mentioned in Schedule 1 to the HSD Special Arrangement.
- (3) This section has effect despite section 89 and paragraph 103(2)(a) of the Act.

### **15 Repeated supplies of pharmaceutical benefits**

Section 51 of the *National Health (Pharmaceutical Benefits) Regulations 2017* does not apply to a special arrangement supply of an ODT pharmaceutical benefit.

### **16 Authorised suppliers not entitled to payment by the Commonwealth**

An authorised supplier who has made a special arrangement supply of an ODT pharmaceutical benefit is not entitled to be paid by the Commonwealth in relation to the supply of the benefit.

## **Division 4—Payment for supplies to authorised suppliers**

### **17 Responsible persons entitled to payment by the Commonwealth**

#### *Application*

- (1) This section applies if, on or after 1 July 2023 and before 1 December 2023, a responsible person for a brand of a pharmaceutical item of an ODT pharmaceutical benefit supplies the benefit to an authorised supplier.

#### *Entitlement to payment*

- (2) Subject to this section, the responsible person is entitled to payment from the Commonwealth.

#### *Amount of payment*

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

#### *Claims for payment*

- (4) If a responsible 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 (5).
- (5) A claim for payment must:
  - (a) be made, in writing, to the Secretary; and
  - (b) relate to a calendar month; and
  - (c) include the following information for each ODT pharmaceutical benefit supplied to an authorised supplier in the calendar month:
    - (i) the ODT pharmaceutical benefit;
    - (ii) the name and address of the authorised supplier;
    - (iii) the date of supply; and
  - (d) include a certification by the responsible person that:
    - (i) the information included in the claim is true and correct; and
    - (ii) the supplies of ODT pharmaceutical benefits covered by the claim were made for the purpose of special arrangement supplies of the benefits; and
    - (iii) the responsible person understands that giving false or misleading information is a serious offence under section 137.1 of the *Criminal Code*.

**Part 2** Special arrangement supplies of ODT pharmaceutical benefits

**Division 4** Payment for supplies to authorised suppliers

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*Responsible persons not to demand or receive payment from authorised suppliers*

- (6) The responsible person must not demand or receive any payment or other valuable consideration from an authorised supplier in respect of a supply of an ODT pharmaceutical benefit.

**18 Secretary to determine and pay claims**

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

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## Part 3—Payment for pre-commencement supplies

### 19 Application of this Part

This Part applies if, before 1 July 2023:

- (a) a pre-commencement benefit was supplied, by the responsible person for the brand of the pharmaceutical item of the benefit, to a pre-commencement supplier; and
- (b) the responsible person had not received payment for the supply from the Commonwealth; and
- (c) the responsible person had neither demanded nor received any payment or other valuable consideration from the pre-commencement supplier for the supply.

### 20 Responsible persons entitled to payment by the Commonwealth

#### *Entitlement to payment*

- (1) Subject to this section, the responsible person 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 benefit that was applicable on the day the responsible person supplied the benefit to the pre-commencement supplier.

#### *Claims for payment*

- (3) If a responsible 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) A claim for payment must:
  - (a) be made, in writing, to the Secretary; and
  - (b) relate to a calendar month; and
  - (c) specify the following:
    - (i) the name and address of each pre-commencement supplier to whom pre-commencement benefits were supplied in the month;
    - (ii) the number of packs of each pre-commencement benefit supplied to each pre-commencement supplier in the month;
    - (iii) the number of packs of each pre-commencement benefit supplied in each State and Territory in the month and the amount claimed for the supply of each benefit in each State and Territory in the month;
    - (iv) the number of packs of all pre-commencement benefits supplied in each State and Territory in the month and the amount claimed for the supply of all of those benefits in each State and Territory in the month;

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- (v) the total number of packs of each pre-commencement benefit supplied in Australia in the month and the amount claimed for the supply of each benefit in Australia in the month;
- (vi) the total number of packs of all pre-commencement benefits supplied in Australia in the month and the amount claimed for the supply of all of those benefits in Australia in the month.

*Responsible persons not to demand or receive payment from pre-commencement suppliers*

- (5) The responsible person must not demand or receive any payment or other valuable consideration from a pre-commencement supplier in respect of a supply of a pre-commencement benefit.

**21 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.

## **Part 4—Administration**

### **22 Secretary may request information from responsible persons**

#### *Supplies of ODT pharmaceutical benefits*

- (1) The Secretary may, in writing, ask a responsible person for a brand of a pharmaceutical item of an ODT pharmaceutical benefit to give the Secretary further information in relation to any supply of the benefit by the responsible person to an authorised supplier.

#### *Supplies of pre-commencement benefits*

- (2) The Secretary may, in writing, ask a responsible person for a brand of a pharmaceutical item of a pre-commencement benefit to give the Secretary further information in relation to any supply of the benefit by the responsible person to a pre-commencement supplier.
- (3) 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.

### **23 Responsible persons to supply information on request**

If a responsible person receives a request for information under section 22, the responsible person must comply with the request by the day specified in the request.

### **24 Internal review of decisions**

#### *Application for review*

- (1) A person who is affected by a decision of the Secretary under this instrument may apply to the Secretary for review of the decision.
- (2) An application for review must:
  - (a) be in writing; and
  - (b) be made within:
    - (i) 28 days after the day the decision first came to the notice of the applicant; or
    - (ii) if the Secretary allows a longer period (whether before or after the end of the 28-day period referred to in subparagraph (i))—that longer period.

#### *Review of decision*

- (3) On receiving an application, the Secretary must:
  - (a) review the decision; and

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- (b) affirm, vary or set aside the decision; and
  - (c) if the Secretary sets aside the decision—make a new decision in substitution for the decision set aside.
- (4) The decision (the *decision on review*) of the Secretary takes effect:
- (a) on the day specified in the decision on review; or
  - (b) if a day is not specified—on the day the decision on review was made.

*Notice of decision*

- (5) After the Secretary makes a decision under this section, the Secretary must give the applicant a written notice stating the following:
- (a) the terms of the decision;
  - (b) the reasons for the decision.