

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Amendment (Extension) Special Arrangement 2024

PB 106 of 2024

The *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Amendment (Extension) Special Arrangement 2024 (Extension Instrument)* extends the self-repeal date of the *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023 (Instrument)* from the start of 1 October 2024 to the end of 31 January 2025. The extension will allow time to settle existing invoices for payments to responsible persons (pharmaceutical companies) of opioid dependence treatment (**ODT**) medicines.

The Instrument remains time-limited, and only applies to supplies of ODT medicines made by responsible persons until 30 June 2024. After 1 July 2024, existing patients transitioned to Pharmaceutical Benefits Scheme (**PBS**) Approved Suppliers, or other arrangements as determined by their respective jurisdictions.

Background

On 1 July 2023, the Instrument implemented arrangements to temporarily provide for responsible persons of ODT medicines to continue to supply certain non-PBS dosing sites directly, and for responsible persons to claim payment directly from the Commonwealth for those supplies before 1 July 2024. Responsible persons submit claims for payment to the Department of Health and Aged Care and are paid the approved ex-manufacturer price of ODT medicines supplied to authorised suppliers.

The Instrument did not displace the individual ODT programs operated by state and territory governments in their respective jurisdictions.

Under the arrangements in the Instrument, patients do not make a PBS contribution for the cost of the medicine (PBS co-payment), as authorised suppliers are not able to submit claims for payment through Services Australia in the same way as approved suppliers do for other PBS medicines and are supplied ODT medicines for free. The amount that contributes to a patient's PBS Safety Net is zero because there is no requirement to make a PBS co-payment. It is understood that some dosing sites may continue to charge patients dispensing or dosing fees for the supply of their ODT medicines during this transition period until patients can be transitioned to receiving their supplies under the Section 100 Highly Specialised Drugs Program and pay the PBS co-payment.

The amendments made under the Extension Instrument do not alter the arrangements provided for under the Instrument.

Authority

Subsection 100(1) of the *National Health Act 1953 (Act)* provides that the Minister may make special arrangements for, or in relation to, the adequate supply of pharmaceutical benefits:

- to certain persons living in isolated areas or who are receiving treatment in circumstances in which pharmaceutical benefits are inadequate for that treatment; or
- where the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

Subsection 100(2) of the Act provides that the Minister may vary or revoke an arrangement made under subsection 100(1) of the Act.

Consultation

No consultation was undertaken as the amendments made under the Extension Instrument do not alter the arrangements provided for under the Instrument.

Commencement

The Extension Instrument will commence the day after it is registered on the Federal Register of Legislation.

General

The Act specifies no conditions that need to be satisfied before the power to make the Extension Instrument may be exercised. This Extension Instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

Details of this instrument are set out in **Attachment A**.

This Extension Instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

Details of the *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Amendment (Extension) Special Arrangement 2024*

Part 1 – Preliminary

Section 1 – Name

This section provides that the title of the instrument is the *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Amendment (Extension) Special Arrangement 2024* (the **Extension Instrument**).

The instrument can also be cited as PB 106 of 2024.

Section 2 – Commencement

This section provides that the instrument commences the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the instrument is made under subsection 100(2) of the *National Health Act 1953*.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Extension Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Extension Instrument has effect according to its terms.

Schedule 1 – Amendments

Item 1 – Section 3

Item 1 amends section 3 of the *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023 (Instrument)* to extend the date of its repeal from the start of 1 October 2024 to the end of 31 January 2025.

The extension of the date of repeal will allow time to settle existing invoices for payments to responsible persons under sections 18 and/or 21 of the Instrument.

Statement of Compatibility with Human Rights

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011
National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines)
Amendment (Extension) Special Arrangement 2024*

PB 106 of 2024

This Disallowable Legislative Instrument 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 Disallowable Legislative Instrument

The Instrument implemented arrangements to temporarily provide for responsible persons of ODT medicines to continue to supply certain non-PBS dosing sites directly, and for responsible persons to claim payment directly from the Commonwealth for those supplies before 1 July 2024.

The Extension Instrument amends the *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023* to extend the date on which the Instrument will self-repeal from the start of 1 October 2024 to the end of 31 January 2025.

This extension to the period of operation of the Instrument will allow time to settle existing invoices for payments to responsible persons under sections 18 and/or 21 of the Instrument.

Human rights implications

As the Extension Instrument does not modify any entitlements or the access to benefits under the Instrument, the Extension Instrument does not engage any of the applicable rights or freedoms.

Conclusion

This Extension Instrument is compatible with human rights as it does not raise any human rights issues.

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