

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Amendment (Extension) Special Arrangement 2023

PB 124 of 2023

Purpose and operation

The *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Amendment (Extension) Special Arrangement 2023 (Extension Instrument)* amends the *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023 (Instrument)* to extend the period of operation of the Instrument so that responsible persons (pharmaceutical companies) of opioid dependence treatment (ODT) medicines can continue to supply certain dosing sites directly, and for the Commonwealth to continue paying responsible persons for ODT medicines supplied on or before 1 July 2024.

The Extension Instrument is intended to support dosing sites to transition patients to usual Pharmaceutical Benefits Scheme (PBS) arrangements for the supply of ODT medicines under the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021 (HSD Special Arrangement)*.

Although responsible persons will not be entitled to Commonwealth payment for supplies of ODT made to authorised suppliers on or after 1 July 2024, the Extension Instrument extends the date of repeal of the Instrument to 1 October 2024. This will allow responsible persons time to submit their final claims for supplies made before 1 July 2024. It will also ensure there is sufficient time for any requests for internal merits review made under section 24 of the Instrument to be finalised before the Instrument is repealed.

After 1 July 2024, existing patients will have transitioned to PBS Approved Suppliers, or other arrangements as determined by their respective jurisdictions.

State and territory governments will continue to operate ODT programs in their respective jurisdictions. The operation of state and territory ODT programs will continue to be governed by the respective policies, guidelines, and regulations within each of those jurisdictions.

The Instrument remains time-limited, and only applies to supplies of ODT medicines made by responsible persons until the end of June 2024.

Background

On 1 July 2023, the Instrument implemented arrangements to temporarily provide for responsible persons (pharmaceutical companies) 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 until 30 November 2023. 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 HSD 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)* enables the Minister to make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to certain persons:

- living in isolated areas or who are receiving treatment in circumstances in which pharmaceutical benefits are inadequate for that treatment;
- 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.

Commencement

The Extension Instrument will commence on 1 December 2023.

Consultation

The Extension Instrument extends the period of operation of the Instrument in response to ongoing stakeholder concerns regarding continuity of care for patients receiving treatment at non-PBS dosing sites and requests from states and territories for a transition period, until all supply of ODT medicines under the PBS can occur under the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021*. While no formal process of public consultation was undertaken, the Extension Instrument was made in response to ongoing engagement with states and territories on the progress of transitioning supply of ODT medicines to the Highly Specialised Drugs Program. Most states and territories are supportive of the extension.

Regulatory Impact

The Office of Impact Analysis was consulted, and it advised that an Impact Analysis was not required to be prepared in relation to the Extension Instrument (OIA ref: OIA23-06024).

General

This Extension Instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

Details of this Extension 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 2023*

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Amendment (Extension) Special Arrangement 2023*.

The instrument can also be cited as PB 124 of 2023.

Section 2 – Commencement

Section 2 provides that the instrument commences on 1 December 2023.

Section 3 – Authority

Section 3 provides that the instrument is made under subsection 100(2) of the *National Health Act 1953*.

Section 4 – Schedules

Section 4 provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms. Schedule 1 amends the *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023*.

Schedule 1 – Amendments

Item 1 – Section 3

This item 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 March 2024 to the start of 1 October 2024.

The extension of the date of repeal allows time for responsible persons to submit their final claims for supplies made before 1 July 2024.

Item 2 – Section 5

This item amends the simplified outline in section 5 to reflect that a responsible person can now claim payment from the Commonwealth for supplies made under the Instrument until the end of 30 June 2024, rather than the end of 30 November 2023.

Items 3 and 4 – Paragraphs 7(1)(a) and 7(2)(a)

Section 7 of the Instrument defines a ‘special arrangement supply’ of an ODT medicine and currently requires that supplies are made to eligible patients on or after 1 July 2023 and before 1 December 2023. Items 3 and 4 amend section 7 to ensure a special arrangement supply includes supplies made on or after 1 July 2023 and *before 1 July 2024*. This is applicable for both supplies made on prescriptions written on or after 1 July 2023 (see subsection 7(1)) and pre-commencement prescriptions written before 1 July 2023 (see subsection 7(2)).

Item 5 – Subsection 17(1)

Section 17 sets out arrangements for a responsible person to receive payment from the Commonwealth for the supply of an ODT medicine to an authorised supplier. Section 17 currently only applies where the responsible person for a listed brand of ODT medicine supplies the benefit to an authorised supplier on or after 1 July 2023 and before 1 December 2023. Item 5 amends subsection 17(1) to enable payment for supplies made on or after 1 July 2023 and *before 1 July 2024*.

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 2023*

PB 124 of 2023

The *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Amendment (Extension) Special Arrangement 2023 (Extension 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 Extension Instrument amends the *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023* to:

- Extend the end date for ‘special arrangement supplies’ of Opioid Dependence Treatment (**ODT**) medicines for the treatment of Opioid Dependence to private clinics and non-Pharmaceutical Benefits Scheme (PBS) approved pharmacies from supplies made before 1 December 2023 to supplies made before 1 July 2024.
- Provide that the Commonwealth will pay responsible persons (drug companies) for supplying ODT medicines to authorised suppliers (entities which are not PBS approved suppliers and which are approved by their relevant state or territory for the purposes of supply of ODT medicines under the Instrument) for supplies made before 1 July 2024, extended from 1 December 2023.
- Extend the date on which the Instrument will self-repeal from 1 March 2024 to 1 October 2024.

This extension to the period of operation of the Instrument is to ensure patients can be safely transitioned over to PBS approved community or hospital pharmacies for their supplies of ODT medicines.

This complements a recommendation made by the Pharmaceutical Benefits Advisory Committee (**PBAC**) out-of-session in March 2023 to include ODT medicines in the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021*, which was implemented on 1 July 2023. This change to supply under the Highly Specialised Drugs Program is intended to address the core issues of patient affordability and equitable access to ODT medicines through the PBS, such that access to PBS subsidised ODT medicines aligns with usual PBS arrangements including the PBS co-payment and safety net arrangements.

Human rights implications

The Instrument engages Articles 9 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), specifically the rights to social security and health.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation. The UN Committee on Economic Social and Cultural Rights reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health. The Committee reports that the 'highest attainable standard of health' takes into account the country's available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

The extension of these transitional arrangements will have a positive effect on the rights to health and social security because they will ensure patients can still access Commonwealth subsidised ODT medicines from their current non-PBS dosing sites while the states and territory governments transition patients to a PBS approved supplier where the patient will pay the PBS co-payment. In the absence of this Extension Instrument, affected patients may have been required to pay the full private cost of their ODT medicines.

The PBS is a benefit scheme which assists with the advancement of these human rights by providing for subsidised access by patients to medicines. The recommendatory role of the PBAC ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

Conclusion

This Extension Instrument is compatible with human rights because it advances the protection of human rights.

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