

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Continued Dispensing – Emergency Measure) Amendment Determination (No. 1) 2024

Purpose and operation

Continued Dispensing enables community pharmacists to supply a single standard pack of an eligible medicine to a patient at the usual Pharmaceutical Benefits Scheme (PBS) price without the presentation of a prescription, where specific conditions are met. These include that the pharmacist is satisfied that the patient has previously been supplied the medicine on the basis of a PBS prescription, that the patient's therapy is stable and that the patient has not already been supplied with the medicine under Continued Dispensing arrangements in the previous 12-month period.

The *National Health (Continued Dispensing – Emergency Measure) Amendment Determination (No. 1) 2024* (Amending Instrument) extends the operation of the *National Health (Continued Dispensing – Emergency Measure) Determination 2023* (Principal Instrument) until the end of 31 March 2024.

The Principal Instrument provides for temporary access under Continued Dispensing arrangements to a wider range of medicines than those available under ongoing arrangements under the *National Health (Continued Dispensing) Determination 2022*. It is primarily intended to support patients affected by the flooding disaster in Far North Queensland to continue to access their PBS subsidised medicines, where there is an immediate need for the medicine but the PBS prescriber is unable to be contacted and/or is unable to provide an electronic PBS prescription or owing prescription.

The extension to the operation of the Principal Instrument is in response to the continuation of the flooding disaster in Far North Queensland.

The Amending Instrument amends section 1.02 of the Principal Instrument with the effect that the Principal Instrument is repealed at the end of 31 March 2024, rather than the beginning of 1 March 2024. It makes no other changes to the operation of the Principal Instrument, meaning:

- the Principal Instrument continues to provide patients across Australia access to these arrangements, even those that are not in the flood-affected areas in Queensland;
- the Principal Instrument continues not to apply to the supply of pharmaceutical benefits in accordance with special arrangements made under section 100 of Act or supplies made under 'prescriber bag' arrangements; and
- the Principal Instrument will continue to allow people to obtain their usual PBS medicines without a prescription from their doctor, for the PBS price. The PBS co-payment amounts as at 1 January 2024 are \$7.70 for concessional patients and \$31.60 for general patients.

Authority

The Amending Instrument is made under subsection 89A(3) of the *National Health Act 1953* (Act) and subsection 33(3) of the *Acts Interpretation Act 1901* (AIA). Subsection 89A(3) of the Act determines pharmaceutical benefits that can be supplied by an approved pharmacist without presentation of a prescription where the conditions in the Instrument are met.

Subsection 33(3) of the AIA provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Commencement

The Amending Instrument commences the day after it is registered on the Federal Register of Legislation.

Consultation

The Amending Instrument extends the operation of the Principal Instrument for one month. It makes no other changes to the operation of the Principal Instrument, including to when a patient is eligible for a Continued Dispensing supply under the Principal Instrument, the pharmaceutical benefits covered by the Principal Instrument or requirements for approved pharmacists when making a Continued Dispensing supply. It was therefore considered that consultation on the Amending Instrument was unnecessary.

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

The Amending 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 A**.

Statement of Compatibility with Human Rights

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

National Health (Continued Dispensing – Emergency Measure) Amendment Determination (No. 1) 2024

(PB 20 of 2024)

This 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 legislative instrument

The *National Health (Continued Dispensing – Emergency Measure) Amendment Determination (No. 1) 2024* (Amending Instrument) extends the operation of the *National Health (Continued Dispensing – Emergency Measure) Determination 2023* (Principal Instrument) from the start of 1 March 2024 to the end of 31 March 2024.

The Principal Instrument provides for temporary access under Continued Dispensing arrangements to a wider range of medicines than those available under ongoing Continued Dispensing arrangements. It was made in December 2023 in response to the flooding disaster in Far North Queensland, although it is open to patients across Australia. The Principal Instrument enables an approved pharmacist to supply certain pharmaceutical benefits to a patient who is unable to present a prescription to the pharmacist, where a number of conditions are met. These conditions include (but are not limited to) that the approved pharmacist is satisfied that:

- the patient's PBS prescriber cannot be contacted and/or is unable to provide an electronic prescription for the patient;
- the patient has previously been supplied the pharmaceutical benefit based on a prescription from a PBS prescriber and that the patient was prescribed the benefit in at least one of the circumstances determined under paragraph 85(7)(b) of the Act as an authorised circumstance for prescribing the benefit under the PBS;
- the patient's therapy is stable;
- the patient has been taking the pharmaceutical benefit regularly for an uninterrupted period during which the relevant PBS prescriber assessed the patient's condition and decided a need for ongoing treatment with the particular pharmaceutical benefit.

The extension to the Principal Instrument was made in response to the ongoing flooding in Far North Queensland.

Human rights implications

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

The Right to Social Security

The right to social security is contained in Article 9 of the International Covenant on Economic Social and Cultural Rights (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 (the Committee) 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.

Analysis

The PBS serves as a crucial social security measure that facilitates subsidised access to medicines thereby assisting in the advancement of the right to health and the right to social security. In response to the continuation of the flooding disaster in Far North Queensland, the Amending Instrument extends the period of operation of the *National Health (Continued Dispensing – Emergency Measure) Determination 2023*. The Instrument advances the right to health and the right to social security by continuing to support patients, primarily those affected by the flooding, to access PBS-subsidised medicines under the Continued Dispensing arrangements. Continuing the operation of the expanded range of pharmaceutical benefits that may be supplied by approved pharmacists to patients that are unable to access authorised PBS prescribers and are without prescriptions and consequently advancing both the right to health and the right to social security.

The Amending Instrument will cease at the end of 31 March 2024. It is appropriate to limit the operation of the Instrument because as it is intended to be a temporary measure in response to the flooding emergency in Far North Queensland.

Conclusion

The legislative instrument is compatible with human rights as it advances the rights to health and social security.

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