

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Continued Dispensing – Emergency Measure) Determination 2025 (No.2)

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) Determination 2025 (No.2)* (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*. The Instrument is primarily intended to support patients affected by the flooding disaster in New South Wales 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. However, these arrangements will apply across Australia, including in areas not affected by the flooding disaster in New South Wales.

The eligible pharmaceutical benefits that can be provided as a Continued Dispensing supply under this Instrument are those contained in Schedule 1 of the Instrument.

The Instrument does not apply to the supply of pharmaceutical benefits in accordance with special arrangements made under section 100 of the Act or supplies made under 'prescriber bag' arrangements.

The Instrument will 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 2025 are \$7.70 for concessional patients and \$31.60 for general patients.

The Instrument will be repealed at the end of 30 June 2025.

Authority

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

The Instrument does not override state and territory legislation, and does not apply in the external territories.

This instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

Commencement

Parts 1 to 3 and Schedule 1 of the Instrument commence immediately after this Instrument is registered on the Federal Register of Legislation. Schedule 2 of the Instrument, which provides for its repeal, commences at the end of 30 June 2025.

Consultation

The Instrument affects approved pharmacists who are supplying pharmaceutical benefits at or from premises in respect of which the pharmacist is for the time being approved. Prior to commencement of the *National Health (Continued Dispensing) Determination 2022*, consultation was undertaken with relevant peak bodies including the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia. The Department also undertook direct consultation with Services Australia, and consulted with state and territory Departments of Health about implementation for the *National Health (Continued Dispensing) Determination 2022*.

It was considered that further consultation for this instrument was unnecessary due to the nature of the consultation that had already taken place and the nature and urgency of the flooding disaster in New South Wales.

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

This 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**.

National Health (Continued Dispensing – Emergency Measure) Determination 2025 (No.2)

Part 1—Preliminary

Section 1.01 – Name

Section 1.01 provides that the name of the Instrument is the *National Health (Continued Dispensing – Emergency Measure) Determination 2025 (No.2)* and specifies the PB number as PB 66 of 2025.

Section 1.02 – Commencement

Section 1.02 provides that the Instrument commences as follows:

- Parts 1 to 3 and Schedule 1 - immediately after the Instrument is registered;
- Schedule 2 – at the end of 30 June 2025.

Section 1.03 – Authority

Section 1.03 provides that the Instrument is made under subsection 89A(3) of the *National Health Act 1953 (Act)*.

Section 1.04 – Schedules

Section 1.04 provides that each instrument specified in Schedule to the Instrument is amended or repealed as set out in the relevant item in the Schedule concerned, and any other item in a Schedule has effect according to its terms. Schedule 2 provides for the repeal of the Instrument at the end of 30 June 2025.

Section 1.05 – Definitions

Subsection 1.05(1) defines key terms used in the Instrument, including:

- ‘Act’ – this means the *National Health Act 1953*;
- ‘electronic prescription’ – this term has the same meaning as in the *National Health (Pharmaceutical Benefits) Regulations 2017 (Regulations)*;
- ‘increased maximum quantity’ - an increased maximum quantity of a pharmaceutical benefit is defined as the maximum quantity or number of units of the benefit, or the pharmaceutical item in the benefit, that may be prescribed for supply on the one occasion, for a relevant purpose. These quantities are determined under subsection 85A(2) of the Act. Increased maximum quantities are quantities equivalent to 60-days’ supply;
- ‘relevant purpose’ – a relevant purpose, for a pharmaceutical benefit, is defined to mean a specified purpose for which the benefit can be prescribed that includes the phrase “The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient”. This phrase is included in all purposes that enable the prescribing of a maximum quantity or number of units

equivalent to 60 days' supply. Purposes are specified in Schedule 4 to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (Listing Instrument) by the use of 'purposes codes'; and

- 'patient' and 'requested supply' – both definitions point readers to subsection 3.01(1) of the Instrument.

Definitions incorporated by reference from the Listing Instrument and the Regulations are incorporated as in force from time to time. Both legislative instruments are available free of charge on the Federal Register of Legislation.

Subsection 1.05(2) provides that a reference to a pharmaceutical benefit having a drug is a reference to the benefit having the declared drug or medicinal preparation in relation to the pharmaceutical benefit, as that term is defined in the Act.

Subsection 1.05(3) provides that where an expression is used in the Instrument and also in Part VII of the Act, the expression has the same meaning in the Instrument as in Part VII.

Section 1.06 – Purpose

Section 1.06 provides that the purpose of the Instrument is to determine pharmaceutical benefits that may be supplied by an approved pharmacist without a prescription, and the conditions that must be satisfied for this to occur.

Section 1.07 – Operation of this instrument

Subsection 1.07(1) provides that the Instrument does not apply to the supply of pharmaceutical benefits that are not generally available for supply under Part VII of the Act, supplies that are made in accordance with special arrangements under section 100 of Act or the supply of pharmaceutical benefits under the prescriber bag provisions under Part VII of the Act.

Subsection 1.07(2) defines when a pharmaceutical benefit is not generally available for supply under Part VII of the Act, being when any of the following apply:

- the benefit contains a drug that is subject to a declaration under subsection 85(2A) of the Act, the result of which is that the benefit can only be supplied under a special arrangement;
- the benefit is subject to a determination under paragraph 85(8)(a) of the Act that the benefit can only be supplied under a special arrangement;
- the supply of the benefit is made in circumstances that have been determined under paragraph 85(8)(b) of the Act as circumstances in which the benefit can only be supplied under a special arrangement.

Part 2—Pharmaceutical benefits that may be supplied without a prescription

Section 2.01 – Pharmaceutical benefits covered by this instrument

Section 2.01 provides that each pharmaceutical benefit that has a drug mentioned in an item in Schedule 1 is determined to be a pharmaceutical benefit that may be supplied by an approved pharmacist without a prescription for the purposes of paragraph 89A(3)(a) of the Act. This means that where a drug is mentioned in an item in Schedule 1, any pharmaceutical benefit having that drug is determined for paragraph 89A(3)(a), irrespective of the form, manner of administration or brand.

Part 3—Specified conditions for supplying pharmaceutical benefits without a prescription

Section 3.01 – General

Subsection 3.01(1) provides that when making a supply of a pharmaceutical benefit to a person requesting a supply without a prescription in accordance with subsection 89A(1) of the Act, in other words a Continued Dispensing supply, the conditions specified in Part 3 must be satisfied.

Paragraph 3.01(2)(a) clarifies that any reference to ‘the PBS prescriber’ in Part 3 of the Instrument means the PBS prescriber who most recently prescribed the supply of the pharmaceutical benefit to the patient.

Paragraph 3.01(2)(b) clarifies that any reference to ‘the pharmaceutical benefit’ in sections 3.03, 3.05, 3.06 and 3.07 of the Instrument includes a reference to a pharmaceutical benefit that is ‘Schedule equivalent’ to the pharmaceutical benefit. ‘Schedule equivalent’ pharmaceutical benefits can be expected to be interchanged without any difference in clinical effect. Sections 3.03, 3.05, 3.06 and 3.07 include conditions relating to whether the patient seeking supply of a pharmaceutical benefit without prescription has previously been supplied with the benefit. The effect of paragraph 3.01(2)(b) is that the previous supply of a different, but Schedule equivalent, pharmaceutical benefit can be taken into account for meeting the conditions in sections 3.03, 3.05, 3.06 and 3.07.

Section 3.02 – Condition—unable to obtain prescription

Section 3.02 requires the approved pharmacist making the supply of the pharmaceutical benefit without prescription to be satisfied that either or both of the following apply:

- the patient’s PBS prescriber is unable to be contacted;
- the PBS prescriber is unable to provide an electronic prescription.

This may include, for example, where the patient’s PBS prescriber has been displaced by flooding.

Section 3.03 - Condition—previous supply of pharmaceutical benefit

Section 3.03 requires the approved pharmacist to be satisfied that 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.

Section 3.04 - Condition—stability of therapy

Section 3.04 requires the approved pharmacist to be satisfied that the patient's therapy is stable.

Section 3.05 - Condition—prior clinical review by PBS prescriber

Section 3.05 requires the approved pharmacist to be satisfied that 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.

Section 3.06 - Condition—prescription for last supply of pharmaceutical benefit

Section 3.06 requires the approved pharmacist to be satisfied that the patient had a valid prescription for the last supply of the pharmaceutical benefit prior to requesting a supply under Continued Dispensing arrangements.

Section 3.07 - Condition—no continued dispensing in previous 12 months

Section 3.07 requires the approved pharmacist to be satisfied that the patient was not supplied with the pharmaceutical benefit under Continued Dispensing arrangements in the 12 months prior to requesting this supply.

Section 3.08 - Condition—declaration for supply of pharmaceutical benefit

Section 3.08 requires the approved pharmacist to ensure the patient, or an agent of the patient who is not the approved pharmacist, signs a declaration acknowledging they are being supplied with the pharmaceutical benefit without a valid prescription under Part VII of the Act.

Section 3.09 - Condition—maximum quantity of supply

Section 3.09 requires the approved pharmacist to supply a maximum quantity or number of units of the pharmaceutical benefit. Maximum quantities or number of units of a pharmaceutical benefit that may, in one prescription, be directed to be supplied on any one occasion are determined under paragraph 85A(2)(a) of the Act.

Subsection 3.09(2) is relevant where an increased maximum quantity has been determined for the pharmaceutical item in the pharmaceutical benefit. The approved pharmacist may only supply that larger increased maximum quantity as a Continued Dispensing supply if the last supply to the patient of the pharmaceutical benefit, or a pharmaceutical benefit that is Schedule equivalent, was on the basis of a prescription written for a relevant purpose (ie a purpose enabling prescribing of an increased maximum quantity amount).

Section 3.10 - Condition—preparing and recording information

Subsection 3.10(1) specifies that when an approved pharmacist supplies a pharmaceutical benefit under these Continued Dispensing arrangements, the pharmacist must record the information used to support the pharmacist's decision to supply the pharmaceutical benefit, and prepare information relating to the supply which the pharmacist will send to the PBS prescriber.

Subsection 3.10(2) sets out the types of information that the pharmacist must record and prepare as the following statements:

- that the pharmaceutical benefit being supplied is a pharmaceutical benefit covered by Schedule 1 of the Instrument;
- that the conditions in sections 3.02 to 3.05 are satisfied; and
- that the approved pharmacist is satisfied the patient needs the pharmaceutical benefit to facilitate continuity of treatment.

Schedule 1—Pharmaceutical benefits that may be supplied without a prescription

Item 1 of Schedule 1 sets out a list of drugs for the purposes of section 2.01. A pharmaceutical benefit that has a drug listed in Schedule 1 may be supplied without a prescription by an approved pharmacist as a Continued Dispensing supply, irrespective of the form, manner of administration or brand.

Schedule 2—Repeals

Schedule 2 repeals the Instrument with effect from the end of 30 June 2025. This reflects that the Instrument is intended to be a temporary measure to allow expanded access to Continued Dispensing arrangements while patients and prescribers may be affected by the flooding disaster in New South Wales.

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) Determination 2025
(No.2)***

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) Determination 2025 (No.2)* (Instrument) temporarily expands the list of pharmaceutical benefits that may be supplied by an approved pharmacist to a patient who is unable to present a prescription to the pharmacist, where a number of conditions are met (Continued Dispensing). These conditions include 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.

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

This Instrument advances the right to health and the right to social security by temporarily expanding the Commonwealth subsidised pharmaceutical benefits that patients can access under Continued Dispensing arrangements without a prescription, in response to the flooding disaster in New South Wales.

This is to ensure that patients affected by the flooding disaster in New South Wales who need a new prescription for their medicine and are practically unable to access a PBS prescriber, or their prescriber cannot provide a prescription electronically, can obtain a one-off supply from an approved pharmacist, subsidised under the PBS, even without a prescription.

As with ongoing Continued Dispensing arrangements, the approved pharmacist may only make a Continued Dispensing supply where satisfied of a range of matters intended to maintain patient safety, including that the patient has previously been prescribed the medicine, that the patient’s therapy is stable and the PBS prescriber who previously prescribed the medicine had reviewed the patient’s treatment and decided that ongoing therapy with the medicine was necessary.

The Instrument will cease at the end of 30 June 2025. It is appropriate to limit the operation of the Instrument as it is intended to be a temporary measure in response to the flooding disaster in New South Wales.

Conclusion

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

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