

EXPLANATORY STATEMENT

National Health Act 1953

NATIONAL HEALTH (CONTINUED DISPENSING) AMENDMENT DETERMINATION 2023 (No. 3)

PB 115 of 2023

Purpose

The purpose of this legislative instrument, made under subsection 89A(3) of the *National Health Act 1953* (the Act), is to amend the *National Health (Continued Dispensing) Determination 2022* to make changes to the pharmaceutical benefits eligible to be provided as a Continued Dispensing supply.

The *National Health (Continued Dispensing) Determination 2022* (the Principal Instrument) lists the pharmaceutical benefits that can be supplied by an approved pharmacist under Part VII of the Act without a prescription, and provides the conditions for such a supply (a 'Continued Dispensing' supply).

The amendments made by this instrument clarify the conditions under which a patient can be dispensed, under Continued Dispensing arrangements, a quantity of pharmaceutical benefits equivalent to 60 days' supply.

Authority

Subsection 89A(3) of the *National Health Act 1953* (the Act) provides that the Minister may determine the pharmaceutical benefits that can be supplied by an approved pharmacist under Part VII of the Act without a prescription, and the conditions for such a supply ('Continued Dispensing').

This instrument does not override state and territory legislation and does not apply in the external territories. States and territories have been informed of the intended Commonwealth changes and asked to consider amendments that may be required to their law to allow access to the eligible medicines.

Amendments made by this Instrument

Continued Dispensing arrangements enable approved pharmacists to supply pharmaceutical benefits without the presentation of a prescription. The Principal Instrument specifies the pharmaceutical benefits that can be supplied under Continued Dispensing arrangements and the conditions that must be met before an approved pharmacist can make a Continued Dispensing supply, which include that there is an immediate need for the supply and the PBS prescriber cannot be contacted or cannot provide a prescription for the patient electronically. Where an approved pharmacist makes a Continued Dispensing supply, they are required to dispense a maximum quantity of the pharmaceutical benefit.

Schedule 1 to this instrument clarifies the conditions under which a patient may be dispensed, under Continued Dispensing arrangements, a maximum quantity of a pharmaceutical benefit equivalent to 60 days' supply. These amendments are required as a result of a provision, from 1 September 2023, that PBS prescriptions may be written for 60 days' supply of certain pharmaceutical benefits in certain circumstances. The amendments also involve the addition of new definitions of 'increased maximum quantity', 'purposes code' and 'relevant purpose'.

These changes are summarised, by subject matter, in the Attachment.

Consultation

This instrument affects approved pharmacists, at or from premises in respect of which the pharmacist is for the time being approved, supplying a pharmaceutical benefit. Prior to commencement of the Principal Instrument, consultation was undertaken with relevant peak bodies including the

Pharmaceutical Society of Australia, Australian Medical Association, Royal Australian College of General Practitioners, Consumers Health Forum, the Australian Federation of AIDS Organisations, and the Pharmacy Guild of Australia. The Department has also undertaken direct consultation with Services Australia, and has consulted with state and territory Departments of Health about implementation.

General

A provision-by-provision description of this instrument is contained in the Attachment.

This instrument commences on 1 December 2023.

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

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (CONTINUED DISPENSING) AMENDMENT DETERMINATION 2023 (No. 3)*

Section 1 Name

This section provides that the Instrument is the *National Health (Continued Dispensing) Amendment Determination 2023 (No. 3)* (Determination) and may also be cited as PB 115 of 2023.

Section 2 Commencement

This section provides that the Determination commences on 1 December 2023.

Section 3 Authority

This section states that this Determination is made under subsection 89A(3) of the of the *National Health Act 1953*.

Section 4 Schedules

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

Schedule 1 amends the *National Health (Continued Dispensing) Determination 2022* (Principal Determination).

Schedule 1 - Amendments

National Health (Continued Dispensing) Determination 2022

Item 1 – Subsection 1.05(1)

Section 1.05 defines certain terms used in the Principal Determination.

Item 1 amends subsection 1.05(1) of the Principal Determination to insert the following definitions:

- increased maximum quantity;
- purposes code;
- relevant purpose.

An increased maximum quantity, for a pharmaceutical item, means a quantity or number of units that has been determined under paragraph 85A(2)(a) of the Act as the maximum quantity or number of units of the pharmaceutical item in the pharmaceutical benefit that may, for a relevant purpose, be directed in a prescription to be supplied on any one occasion. Increased maximum quantities are quantities equivalent to 60-days supply.

A purposes code is defined to have the same meaning as in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (the Listing Instrument). Purposes codes are used in the Listing Instrument to indicate the purposes for which a maximum quantity or number of units of a pharmaceutical item may be prescribed for PBS supply.

A relevant purpose, for a pharmaceutical benefit, means a purpose mentioned in Schedule 4 of the Listing Instrument for a purposes code specified in Schedule 1 of that instrument for the pharmaceutical benefit, and which 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.

The Listing Instrument is incorporated by reference as in force from time to time, and can be accessed free of charge on the Federal Register of Legislation at www.legislation.gov.au.

Item 2 – Section 3.09

Item 2 repeals and replaces section 3.09 of the Principal Determination, which specifies conditions relating to the maximum quantity or number of units of a pharmaceutical benefit to be dispensed in a continued dispensing supply.

Subsection 3.09(1) retains the previous condition that when making a continued dispensing supply, an approved pharmacist must supply a maximum quantity or number of units of the pharmaceutical benefit.

New 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.

Statement of Compatibility with Human Rights

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

National Health (Continued Dispensing) Amendment Determination 2023 (No. 3) **(PB 115 of 2023)**

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) Amendment Determination 2023 (No. 2)* (the Instrument) amends the *National Health (Continued Dispensing) Determination 2022* (the Principal Instrument) which specifies the pharmaceutical benefits that can be supplied by an approved pharmacist under Part VII of the *National Health Act 1953* without a prescription, and the conditions for such a supply ('Continued Dispensing').

Continued Dispensing arrangements enable approved pharmacists to supply pharmaceutical benefits without the presentation of a prescription. The Principal Instrument specifies the pharmaceutical benefits that can be supplied under Continued Dispensing arrangements and the conditions that must be met before an approved pharmacist can make a Continued Dispensing supply, which include that there is an immediate need for the supply and the PBS prescriber cannot be contacted or cannot provide a prescription for the patient electronically. Where an approved pharmacist makes a Continued Dispensing supply, they are required to dispense a maximum quantity of the pharmaceutical benefit.

Schedule 1 to this instrument clarifies the conditions under which a patient may be dispensed, under Continued Dispensing arrangements, a maximum quantity of a pharmaceutical benefit equivalent to 60 days' supply. These amendments are required as a result of a provision, from 1 September 2023, that PBS prescriptions may be written for 60 days' supply of certain pharmaceutical benefits in certain circumstances. The 60 days' supply can only be dispensed under Continued Dispensing arrangements where the patient's last prescription was written for a purpose for which a 60 days' supply could be prescribed. This relevantly includes that the prescriber considered the patient's condition was stable and that the 60 days' quantity was suitable.

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 ensuring that amendments to the *National Health (Pharmaceutical benefits—early supply) Instrument 2015*, that affect the pharmaceutical benefits that may be supplied as a Continued Dispensing supply, are also made in the Principal Instrument (*National Health (Continued Dispensing) Determination 2022*).

Conclusion

This legislative instrument is compatible with human rights because it advances the protection of human rights.

Nikolai Tsyganov
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health