EXPLANATORY STATEMENT

National Health Act 1953

National Health (Continued Dispensing) Determination 2022

Purpose and operation

Continued Dispensing enables community pharmacists to supply a single standard pack of an eligible medicine to a patient at the usual PBS price, under specific circumstances. The person must have previously been supplied the medicine on the basis of a PBS prescription and, the pharmacist may supply the medicine to the patient under Continued Dispensing arrangements once in a 12-month period.

The *National Health (Continued Dispensing) Determination 2012* (2012 Determination) was made under subsection 89A(3) of the Act and specifies the pharmaceutical benefits that may be supplied, and the conditions that must be satisfied when those pharmaceutical benefits are supplied by an approved pharmacist without a current prescription, but on the basis of a previous prescription from a PBS prescriber. Only certain medicines for the treatment of high cholesterol levels (statins) and oral contraceptives were available through the 2012 Determination.

The *National Health (Continued Dispensing – Emergency Measures) Determination 2020* (Emergency Determination) was made in response to the bushfire crisis and the COVID pandemic to temporarily expand the range of medicines available under Continued Dispensing to include most Pharmaceutical Benefits Scheme (PBS) medicines. The Continued Dispensing Emergency arrangements under the Emergency Determination were extended until 30 June 2022, at which time they will be replaced from 1 July 2022 with the Continued Dispensing arrangements under the *National Health (Continued Dispensing) Determination 2022*. These temporary arrangements under the Emergency Determination provided another option to support continuity of therapy for consumers across Australia who may have been unable to make an appointment with their medical practitioner for a new prescription in a timely manner during the COVID-19 crisis. These arrangements complement emergency supply provisions available under state and territory legislation.

The purpose of the *National Health (Continued Dispensing) Determination 2022* (instrument) is to remake the 2012 Determination and expand the list of eligible medicines that can be obtained under Continued Dispensing arrangements, as recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) at its November 2021 meeting. This is to ensure that patients will still be able to obtain PBS subsidised access to their medicines if the usual prescriber is unable to be contacted and/or is unable to provide an e-prescription or owing prescription.

At its November 2021 meeting, the PBAC recommended the inclusion of additional medicines to be provided under the instrument on the basis that they would be safe and well-tolerated for the treatment of chronic and stable disease. The additional medicines recommended by the PBAC are predominantly chronic disease medicines supplied under the PBS General Schedule and Special arrangements under section 100 of the Act.

The PBAC is an independent expert body established under section 100A of the Act and consists of doctors, health professionals, health economists and consumer representatives.

The eligible pharmaceutical benefits that can be provided as a continued dispensing supply will be limited to those contained in Schedule 1 of this instrument.

This instrument will allow people to obtain their usual PBS medicines without a prescription from their doctor, for the PBS price. The PBS co-payment as at 1 January 2022 is $6.80 for concessional persons and up to $42.50 for general persons.

The instrument also repeals the Emergency Determination. However, the Emergency Determination will continue to have effect on and after 1 July 2022 for the purposes of the *National Health (Supply of Pharmaceutical Benefits – Under Co-payment Data and Claims for Payment) Rules 2022* for pharmaceutical benefits that are provided under the Emergency Determination, which are not available in Schedule 1 of this instrument.

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 to their own legislation to allow access to the eligible medicines.

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.

Reliance on subsection 33(3) of the *Acts Interpretation Act 1901*

Under subsection 33(3) of the Acts Interpretation Act 1901, 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.

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

Commencement

This instrument commences 1 July 2022.

Consultation

This instrument affects approved pharmacists supplying a pharmaceutical benefit.

The Department of Health consulted 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 of Health has also consulted with

Central Agencies, including Services Australia, and State and Territory Departments of Health about implementation of this instrument.

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**.

ATTACHMENT A

National Health (Continued Dispensing) Determination 2022

Part 1—Preliminary

Section 1.01 – Name

Section 1.01 provides that the name of this instrument is the *National Health (Continued Dispensing) Amendment Determination 2022* and specifies the PB number as 59 of 2022.

Section 1.02 – Commencement

Section 1.02 provides that the instrument commences on 1 July 2022.

Section 1.03 – Authority

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

Section 1.04 – Repeal

Section 1.04 provides that each instrument specified in Schedule 2 is repealed as set out in that Schedule, and any other item in Schedule 2 has effect according to its terms.

Section 1.05 – Definitions

Section 1.05 sets out the definition of 'Act' as meaning the *National Health Act 1953* and 'Regulations' as meaning the *National Health (Pharmaceutical Benefits) Regulations 2017*. This section also defines 'electronic prescription' as having the meaning given by subsection 5(1) of the Regulations and that the definitions of 'patient' and 'requested' supply are set out in subsection 3.01(1) of this instrument.

This section also provides that certain expressions used in this instrument has the same meaning as the expressions used in Part VII of the Act.

Section 1.06 – Purpose

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

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 the pharmaceutical benefits specified in Schedule 1 of the instrument are pharmaceutical benefits that may be supplied without a prescription for the purposes of paragraph 89A(3)(a) of the Act.

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 for a pharmaceutical benefit to a person requesting a supply without a prescription in accordance with subsection 89A(1) of the Act, the conditions specified in Part 3 must be satisfied.

Subsection 3.02(2) clarifies that any reference to 'PBS prescriber' in Part 3 means the PBS prescriber who most recently prescribed the supply of pharmaceutical benefit to the patient, and any reference to 'the pharmaceutical benefit' in sections 3.03, 3.05, 3.06 and 3.07 of the instrument refers to a pharmaceutical benefit in Schedule 1.

Section 3.02 – Condition—unable to obtain prescription

Section 3.02 specifies the condition that the approved pharmacist must be satisfied that the PBS prescriber is unable to be contacted and/or is unable to provide an electronic prescription. This condition is consistent with the language reflected in the updated Continued Dispensing Principles.

Section 3.03 - Condition—previous supply of pharmaceutical benefit

Section 3.03 specifies the condition that the approved pharmacist must be satisfied that the patient has previously been supplied the pharmaceutical benefit based on a prescription from a PBS prescriber and that the supply was made by the authorised writing of a prescription in the circumstances determined in the instrument.

Section 3.04 - Condition—stability of therapy

Section 3.04 specifies the condition that the approved pharmacist must be satisfied that the patient's therapy is stable.

Section 3.05 - Condition—prior clinical review by PBS prescriber

Section 3.05 specifies the condition that the approved pharmacist must be satisfied that the patient has been taking the pharmaceutical benefit regularly for an uninterrupted period during which the PBS prescriber has 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 specifies the condition that the approved pharmacist is 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 specifies the condition that the approved pharmacist must be satisfied that the patient was not supplied with the pharmaceutical benefit in the 12 months prior to requesting a supply under Continued Dispensing arrangements.

Section 3.08 - Condition—declaration for supply of pharmaceutical benefit

Section 3.08 specifies the condition that the approved pharmacist must 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.

Section 3.09 - Condition—maximum quantity of supply

Section 3.09 specifies the condition that the approved pharmacist must supply a maximum quantity or number of units of the pharmaceutical benefit.

Section 3.10 - Condition—preparing and recording information

Section 3.10 specifies that when an approved pharmacist supplies a pharmaceutical benefit, 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. This section also sets out the type of information that the pharmacist must record and prepare as being: a statement that the pharmaceutical benefit being supplied is a pharmaceutical benefit covered by Schedule 1 of this instrument; a statement that the conditions in sections 3.02 to 3.05 are satisfied; and a statement that the approved pharmacist is satisfied the patient needs the pharmaceutical benefit to facilitate continuity of treatment.

Section 4.01 – Application of this instrument

Section 4.01 is an application provision that provides that despite the repeal of the *National Health (Continued Dispensing – Emergency Measures) Determination 2020* (Emergency Determination), as specified in Schedule 2 Item 1 of this instrument, the Emergency Determination will continue to have effect on or after 1 July 2022 to allow claims to be made by approved pharmacists under the *National Health (Supply of Pharmaceutical Benefits — Under Co-payment Data and Claims for Payment) Rules 2022* for supplies of pharmaceutical benefits made pursuant to the Emergency Determination on or before 30 June 2022.

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

Item 1 of Schedule 1 sets out a list of pharmaceutical benefits that may be supplied without a prescription by an approved pharmacist for the purposes of paragraph 89A(3)(a) of the Act. The list includes medicines recommended by the PBAC at its November 2021 meeting including medicines for HIV, which are available under the section 100 Highly Specialised

Drugs Program under the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021*.

Schedule 2—Repeals

National Health (Continued Dispensing) Determination 2012

Item 1 of Schedule 2 repeals the *National Health (Continued Dispensing) Determination 2012* in its entirety.

National Health (Continued Dispensing – Emergency Measures) Determination 2020

Item 2 of Schedule 2 repeals the *National Health (Continued Dispensing – Emergency Measures) Determination 2020* in its entirety.

ATTACHMENT B

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 2022

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) Determination 2022* (instrument) is a remake of the *National Health (Continued Dispensing) Determination 2012* and expands the list of pharmaceutical benefits that may be supplied by an approved pharmacist to a patient without a prescription on the basis of a previous prescription from a PBS prescriber.

This instrument also specifies the conditions that must be satisfied when requesting and making a supply of a listed pharmaceutical benefit to a patient by an approved pharmacist.

This instrument repeals the *National Health (Continued Dispensing – Emergency Measures) Determination 2020* (Emergency Determination), however retains its effect on and after 1 July 2022 to allow for claims to be validly made by pharmacists under the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment Rules 2022*) in relation to the supply of pharmaceutical benefits under the Emergency Determination on or before 30 June 2022.

Human rights implications

The overarching purpose of the instrument is to allow appropriate access to health goods, including essential drugs and services and to ensure effective delivery of medical treatment to patients, especially to vulnerable or marginalised groups.

This supports Article 12(1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by promoting the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access for people to medicines. Continued Dispensing arrangements further promotes this right by ensuring continued access for patients to prescribed medication in circumstances where it they are unable to obtain a prescription. This is a positive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for the PBS support effective administration of the Scheme.

Conclusion

The legislative instrument is compatible with human rights as it does not raise any human rights issues.