

## EXPLANATORY STATEMENT

### *National Health Act 1953*

#### *National Health (Pharmaceutical Benefits) Amendment (Eighth Community Pharmacy Agreement) Regulations 2024*

#### **Purpose and operation**

The *National Health (Pharmaceutical Benefits) Amendment (Eighth Community Pharmacy Agreement) Regulations 2024* amends the *National Health (Pharmaceutical Benefits) Regulations 2017* to remove the reference to the Seventh Community Pharmacy agreement in the definition of “additional patient charge” and substitute this with a reference to the Eighth Community Pharmacy Agreement with effect from 1 July 2024.

#### **Background**

The Pharmaceutical Benefits Scheme (PBS) is established under the *National Health Act 1953* (the Act) and provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The Act regulates the listing, prescribing, pricing, charging and payment of subsidies for the supply of drugs and medicinal preparations as pharmaceutical benefits.

#### **Authority**

Section 140 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by the Act are required or permitted or are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Subsection 84C(1E) of the Act provides that the regulations may prescribe the “value for safety net purposes” of a supply of a pharmaceutical benefit. Subsection 84C(1F) of the Act provides that the “value for safety net purposes” must take into account the amount charged for the supply but may make adjustments to the value for safety net purposes such as excluding certain components of the amount charged or setting a maximum limit on the value.

The *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations) prescribe, among other things, the calculation of the “value for safety net purposes” to determine whether a person is entitled to be issued with a safety net concession card or pharmaceutical benefit entitlement card under Division 1A of Part VII of the Act. Section 87 of the Act provides that the holder of a safety net concession card or a pharmaceutical benefit entitlement card is entitled to be supplied pharmaceutical benefits at a lower price or free of charge during the relevant entitlement period where the relevant thresholds are met.

Section 17A of the Principal Regulations prescribes the “value for safety net purposes” of the supply of a pharmaceutical benefit for the purposes of the Act. Section 17A provides that where the supply is one to which subsections 99(2A), (2AB) or (2B) of the Act applies (an under co-payment supply), the value for safety net purposes is the lesser of:

- the price of the pharmaceutical benefit worked out under a determination made under subsection 84C(7) of the Act, less any additional patient charge (or part thereof) that an approved pharmacist charges a patient in respect of the supply of the pharmaceutical benefit; and
- the amount charged by the approved pharmacist.

Subsection 5(1) of the Principal Regulations defines “additional patient charge” by reference to clause 4.2.1(c) or 4.2.2(c) of the Seventh Community Pharmacy Agreement, as in force on 1 July 2020. The Seventh Community Pharmacy Agreement is an agreement between the Commonwealth, through the Minister for Health and Aged Care and the Pharmacy Guild of Australia.

On 3 June 2020, the Commonwealth, through the Minister for Health and Aged Care and the Pharmacy Guild of Australia signed the Eighth Community Pharmacy Agreement, which replaces the Seventh Community Pharmacy Agreement with effect from 1 July 2024. The Eighth Community Pharmacy Agreement includes clauses that set the additional patient charge that an approved pharmacist may charge a patient in respect of the supply of pharmaceutical benefits.

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

Subsection 33(3) of the *Acts Interpretation Act 1901* 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**

This instrument commences on 1 July 2024.

### **Consultation**

The additional patient charge was negotiated with the Pharmacy Guild of Australia as a part of the Eighth Community Pharmacy Agreement. No specific consultation was undertaken in relation to these Regulations as they provide for a technical amendment related to the implementation of the Eighth Community Pharmacy Agreement.

### **General**

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

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**.

**Details of the *National Health (Pharmaceutical Benefits) Amendment (Eighth Community Pharmacy Agreement) Regulations 2024***

Section 1 - Name

This section provides that the title of the instrument is the *National Health (Pharmaceutical Benefits) Amendment (Eighth Community Pharmacy Agreement) Regulations 2024*.

Section 2 - Commencement

This section provides for the instrument to commence on 1 July 2024.

Section 3 - Authority

This section provides that the instrument is made under the *National Health Act 1953*.

Section 4 - Schedules

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

Schedule 1 - Amendments

**Item 1 - subsection 5(1)**

The instrument amends the existing definition for “additional patient charge” in subsection 5(1) of the *National Health (Pharmaceutical Benefits) Regulations 2017*.

Subsection 5(1) sets out that 'additional patient charge' means the further additional patient charge referred to in clause 4.2.1(c) or 4.2.2(c) of the Seventh Community Pharmacy Agreement, as in force on 1 July 2020. This item amends subsection 5(1) to reference the newly agreed consolidated clause 6.2.1(c) of the Eighth Community Pharmacy Agreement, as in force on 1 July 2024.

A copy of the Eighth Community Pharmacy Agreement will be made available free of charge on the Department of Health and Aged Care’s website (<https://www.health.gov.au>).

## Statement of Compatibility with Human Rights

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

*National Health (Pharmaceutical Benefits) Amendment (Eighth Community Pharmacy Agreement) Regulations 2024*

The *National Health (Pharmaceutical Benefits) Amendment (Eighth Community Pharmacy Agreement) Regulations 2020* (the Amendment Regulations) are 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 Regulations

The Amendment Regulations are made under section 140 of the *National Health Act 1953* (the Act). Section 140 provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which are required or permitted to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act. Subsection 84C(1E) of the Act further provides that regulations may prescribe the “value for safety net purposes” of the supply of a pharmaceutical benefit.

The Amendment Regulations amend the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations). The Amendment Regulations establish the amounts for the purposes of determining the “additional patient charge” for the purpose of calculating the value for safety net purposes in order to determine if a person is entitled to be issued with a safety net concession card or a pharmaceutical benefit entitlement card under the Act. The holder of a safety net concession card or a pharmaceutical benefit entitlement card is entitled to be supplied pharmaceutical benefits at a lower price or free of charge during an entitlement period once the relevant thresholds are met.

The amount of the additional patient charge has been agreed between the Commonwealth, through the Minister for Health and Aged Care and the Pharmacy Guild of Australia in the Eighth Community Pharmacy Agreement to commence from 1 July 2024.

The Amendment Regulations are required to ensure that approved pharmacists can continue to record the correct value for the purposes of determining the price of a pharmaceutical benefit for safety net purposes, where approved pharmacists charge patients an additional patient charge. Section 17A of the Principal Regulations provides that the value of any “additional patient charge (or part thereof)” that an approved pharmacist charges a patient in respect of the supply of a pharmaceutical benefit is not to be counted towards determining the value for safety net purposes. The Amendment Regulations update the amount of the additional patient charge that must be deducted from the value calculated for safety net purposes to reflect the amount of the additional patient charge agreed between the Commonwealth, through the Minister for Health and Aged Care, and the Pharmacy Guild of Australia in the Seventh Community Pharmacy Agreement.

## **Human rights implications**

The Amendment Regulations engage Article 2 and Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The Pharmaceutical Benefits Scheme and the safety net scheme under the Act are benefit schemes which assist with the advancement of these human rights by providing patients with subsidised access to medicines.

## **Conclusion**

The Amendment Regulations are compatible with human rights as they do not raise any human rights issues or impinge on any applicable rights or freedoms. Human rights continue to be protected by ensuring access to affordable medicines for Australians.

**The Hon Mark Butler MP**  
**Minister for Health and Aged Care**