

# EXPLANATORY STATEMENT

## *National Health Act 1953*

### *National Health (Supplies of out-patient medication) Amendment Determination 2020*

PB 41 of 2020

#### **Authority**

Subsection 84BA(2) of the *National Health Act 1953* (the Act) provides that the Minister must determine the amount that will be taken to have been paid to a public hospital for supplies of out-patient medication for the relevant entitlement period for the purposes of the Pharmaceutical Benefits Scheme (PBS) patient safety net threshold.

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.

#### **Purpose**

This instrument makes minor amendments to the *National Health (Supplies of out-patient medication) Determination 2019 (No. 2)* (PB 110 of 2019) (the determination). In particular, this instrument clarifies the definition of Pharmaceutical Reform Arrangements in the determination. It also consequently, repeals the use of the term National Health Reform Agreement from the determination (at sections 5, 8 and 10 of the determination).

#### **Background**

Part VII of the Act regulates when benefits will be paid by the Commonwealth in respect of drugs and medicinal preparations that are listed on the PBS. As such, it is the legislative basis by which the Commonwealth provides reliable, timely and affordable access to a wide range of medicines to Australians.

Division 1A of Part VII of the Act provides for a safety net scheme in relation to pharmaceutical benefits. The safety net scheme is designed to provide financial protection for those patients and their families who require a large number of pharmaceutical benefits.

Subsection 84(1) of the Act defines *out-patient medication* as a drug or medicinal preparation supplied through the out-patient department of a public hospital. A drug or medicinal preparation that is supplied by a public hospital as out-patient medication may or may not be a pharmaceutical benefit under Part VII of the Act.

Subsection 84BA(1) of the Act provides that the purpose of section 84BA is to make provision so that account may be taken of payments made by a person to a public hospital authority for supplies of out-patient medication, when it is being ascertained, for the purpose of Part VII of the Act, whether the person is eligible to be issued with a concession card or an entitlement card.

Subsection 84BA(2) of the Act provides that prior to the commencement of the relevant entitlement period (a calendar year), the Minister must determine in writing the amounts that will be taken to have been paid to a public hospital for supplies of out-patient medication made by a hospital during the relevant entitlement period.

Subsection 84BA(3) of the Act provides that, in making a determination, the Minister may determine:

- a) different amounts in respect of a supply of out-patient medication, having regard to the State or Territory in which the hospital supplying the medication is situated; and
- b) different amounts in respect of supplies made to:
  - i. concessional beneficiaries and their dependants (within the meaning of subsection 84(4) or (7) of the Act),
  - ii. holders of a concession card; and
  - iii. general patients (other than holders of a concession card).

Generally, the parties to Pharmaceutical Reform Arrangements are the Commonwealth and a State or Territory. The National Health Reform Agreement at paragraph G5, page 56 provides that ‘States which have signed bilateral agreements for Pharmaceutical Reform Arrangements may charge the PBS for pharmaceuticals for specific categories of patients as provided for in the Arrangements’

([http://www.federalfinancialrelations.gov.au/content/npa/health/\\_archive/national-agreement.pdf](http://www.federalfinancialrelations.gov.au/content/npa/health/_archive/national-agreement.pdf)).

## **Consultation**

Historically, the Department of Health has consulted with state and territory health departments through the Highly Specialised Drugs Working Party (HSDWP). The HSDWP was a working party of the Australian Health Ministers’ Advisory Council (AHMAC) and was made up of representatives from each state and territory health department and the Commonwealth. This Working Party has now been discontinued as a second tier committee of the Hospitals Principal Committee on recommendations endorsed by AHMAC.

Through the HSDWP, the state and territory health departments agreed to the value of out-patient medication being 80% of the general co-payment each year, excluding hospitals which are in Queensland or participating in the Pharmaceutical Reform Arrangements.

Further consultation was unnecessary given the nature of this minor change was to clarify a definition in the instrument.

## **Commencement**

This instrument commences the day after registration.

Details of the instrument are set out in the **Attachment**.

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

**Details of the *National Health (Supplies of out-patient medication) Amendment Determination 2020***

**1 Name**

This section provides that the name of this instrument is the *National Health (Supplies of out-patient medication) Amendment Determination 2020*. The instrument can also be cited as PB 41 of 2020.

**2 Commencement**

This section provides that this instrument commences the day after registration.

**3 Authority**

This section provides that the instrument is made under section 84BA of the *National Health Act 1953*.

**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 concerned, and any other item in a Schedule to the instrument has effect according to its terms.

Schedule 1—Amendments

*National Health (Supplies of out-patient medication) Determination 2019 (No 2)* (the determination)

**Item 1 – Section 5(1), after the definition of approved ex-manufacturer price**

This item repeals the definition of National Health Reform Agreement from the determination.

**Item 2 – Section 5(1), after the definition of out-patient medication**

This item inserts a definition of Pharmaceutical Reform Arrangements in the determination. The item defines Pharmaceutical Reform Arrangements as:

Arrangements which provide for public hospitals that are Approved Hospital Authorities under Section 94 of the *National Health Act 1953* to supply pharmaceuticals funded by the PBS for specific categories of patients including:

- admitted patients on separation;
- non-admitted patients; and
- same day admitted patients for a range of drugs made available by specific delivery arrangements under Section 100 of the *National Health Act 1953*.

**Item 3 – Subsection 8(2)(b)**

This item removes the reference to the National Health Reform Agreement from the paragraph and instead refers to the Pharmaceutical Reform Arrangements.

**Item 4 – Subsection 10(1)**

This section removes reference to the National Health Reform Agreement from the paragraph and instead refers to the Pharmaceutical Reform Arrangements.

## **Statement of Compatibility with Human Rights**

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

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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**

This legislative instrument is made pursuant to subsection 84BA(2) of the *National Health Act 1953*, which determines the amounts that will be taken to have been paid to a public hospital for supplies of out-patient medication.

This instrument clarifies the definition of Pharmaceutical Reform Arrangements in the *National Health (Supplies of out-patient medication) Determination 2019 (No. 2)* PB 110 of 2019 (the determination). It consequently, repeals the use of the term National Health Reform Agreement from the determination.

### **Human rights implications**

This legislative instrument engages Articles 2 and 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 (PBS) is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines.

This legislative instrument specifies what will be taken to have been paid to a public hospital for supplies of out-patient medication for the purposes of the PBS patient safety net threshold.

The safety net scheme is designed to provide financial protection for those patients and their families who require a large number of pharmaceutical benefits.

### **Conclusion**

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

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