

## EXPLANATORY STATEMENT

### *NATIONAL HEALTH ACT 1953*

#### *NATIONAL HEALTH (SUPPLIES OF OUT-PATIENT MEDICATION) DETERMINATION 2019 (No. 2)*

#### **PB 110 of 2019**

#### **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 purposes of the PBS patient safety net threshold.

#### **Purpose**

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 Pharmaceutical Benefits Scheme (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) defines out-patient medication as a drug or medicinal preparation that is 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 safety net concession card or a safety net 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,
  - ii. holders of a concession card; and
  - iii. general patients (other than holders of a concession card).

This instrument differs from the instrument made under subsection 84BA(2) for the previous entitlement period because the maximum value of the supply of out-patient medication to a person who is a general patient and who is not the holder of a concession card has changed from \$32.20 to \$32.80. This instrument, among other things, determines different amounts in respect of the supply of out-patient medication by public hospitals depending on whether the public hospital is participating in Pharmaceutical Reform Arrangements within the meaning of the National Health Reform Agreement.

The *Federal Financial Relations Act 2009* refers to the National Health Reform Agreement as agreed to by the Council of Australian Governments on 2 August 2011 as amended from time to time. A copy of the National Health Reform Agreement can be obtained at the Council of Australian Governments (“COAG”) website at <http://www.coag.gov.au>.

Details of this instrument are set out in the Attachment.

This instrument commences on 1 January 2020.

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

### **Consultation**

Historically, the Department of Health has consulted with the 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 Australian Government. 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.

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

**1 Name of Instrument**

This section provides that the name of this Determination is the *National Health (Supplies of out-patient medication) Determination 2019 (No. 2)* and that it can also be cited as PB 110 of 2019.

**2 Commencement**

This section provides that this Determination commences on 1 January 2020.

**3 Authority**

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

**4 Repeal**

This section repeals and replaces the previous determination made under subsection 84BA(2), being the *National Health (Supplies of out-patient medication) Determination 2019 (PB 8 of 2019)*.

**5 Interpretation**

This section provides for the meaning of certain words and phrases appearing in the Determination, and also states that unless the contrary intention appears, a word or expression that is defined in the Act shall be taken to have the same meaning as in the Act.

**6 Amount taken to have been paid to a public hospital for the supply of out-patient medication**

This section provides that the amount, for the purposes of Part VII of the Act, taken to have been paid to a public hospital for the supply of out-patient medication is the lesser of either:

- the maximum value of the supply of out-patient medication; or
- the amount charged.

The term *out-patient medication* is defined in subsection 84(1) of the Act to mean a drug or medicinal preparation supplied through the out-patient department of a public hospital. The maximum value of the supply of out-patient medication is the amount specified in section 7, 8, 9 or 10 of the Determination, as appropriate based on the circumstances of supply.

**7 Maximum value of the supply of out-patient medication to a person who is a concessional beneficiary, a dependant of a concessional beneficiary or a holder of a concession card**

This section provides that the maximum value of the supply of out-patient medication to a person who is a concessional beneficiary, a dependant of a concessional beneficiary or the

holder of a concession card is an amount that is equivalent to the amount referred to in paragraph 87(2)(a) of the Act for the supply of a pharmaceutical benefit by an approved pharmacist or approved medical practitioner.

The terms *concessional beneficiary*, *dependant* and *concession card* are defined in subsection 84(1) of the Act.

The relevant charge under paragraph 87(2)(a) of the Act will be \$6.60 when this instrument commences on 1 January 2020. These charges are periodically adjusted under section 99G of the Act.

## **8 Maximum value of the supply of out-patient medication to a person who is a general patient and who is not a holder of a concession card**

Subsection 7(1) provides that the maximum value of the supply of out-patient medication to a person who is a general patient and who is not the holder of a concession card is \$32.80.

Subsection 7(2) provides that this section does not apply to supplies of out-patient medication made by a public hospital located in Queensland or a public hospital that is participating in Pharmaceutical Reform Arrangements within the meaning of the National Health Reform Agreement. The National Health Reform Agreement is defined in section 4 of this Determination.

## **9 Maximum value of the supply of out-patient medication by a Queensland public hospital to person who is a general patient and who is not the holder of a concession card**

This section provides for the maximum value of a supply of out-patient medication to a person who is a general patient and who is not the holder of a concession card for supplies of out-patient medication made by public hospitals located in Queensland.

Paragraph 8(2)(a) specifies that where the medication is a pharmaceutical benefit and the Commonwealth price for that pharmaceutical benefit exceeds the amount referred to in paragraph 87(2)(e) of the Act, the maximum value is an amount equivalent to the amount referred to in paragraph 87(2)(e) of the Act for the supply of a pharmaceutical benefit by an approved pharmacist or an approved medical practitioner.

The relevant amount under paragraph 87(2)(e) of the Act will be \$41.00 when this instrument commences on 1 January 2020. These charges are periodically adjusted under section 99G of the Act.

Paragraph 8(2)(b) specifies that where the medication is a pharmaceutical benefit and the Commonwealth price for that pharmaceutical benefit does not exceed the amount referred to in paragraph 87(2)(e) of the Act, the maximum value is the price for that pharmaceutical benefit ascertained in accordance with the determination made under subsection 84C(7) of the Act as in force from time to time.

Paragraph 8(2)(c) specifies that where the medication is a drug or medicinal preparation that is not a pharmaceutical benefit, the maximum value is the amount ascertained by taking as a basis the cost to the hospital of that drug or medicinal preparation and applying, as if that cost

were the approved ex-manufacturer price or proportional ex-manufacturer price, the determination under subsection 84C(7) of the Act as in force from time to time.

**10 Maximum value of the supply of out-patient medication by a participating public hospital to a person who is a general patient and who is not a holder of a concession card**

This section provides for the maximum value of a supply of out-patient medication to a person who is a general patient and who is not the holder of a concession card for supplies of out-patient medication made by public hospitals that are participating in Pharmaceutical Reform Arrangements within the meaning of the National Health Reform Agreement, except if the public hospital is located in the State of Queensland.

Paragraph 9(2)(a) specifies that where the medication is a pharmaceutical benefit, the maximum value of the pharmaceutical benefit shall be the maximum value of the pharmaceutical benefit ascertained in accordance with regulation 17A of the *National Health (Pharmaceutical Benefits) Regulations 2017* as if the pharmaceutical benefit had been supplied by an approved pharmacist or an approved medical practitioner.

Paragraph 9(2)(b) specifies that where the medication is a drug or medicinal preparation that is not a pharmaceutical benefit, the maximum value is the amount ascertained by taking as a basis the cost to the hospital of that drug or medicinal preparation and applying, as if that cost were the approved ex-manufacturer price or proportional ex-manufacturer price, the determination under subsection 84C(7) of the Act as in force from time to time.

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

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

### ***National Health (Supplies of out-patient medication) Determination 2019 (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**

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

This instrument differs from the instrument made under subsection 84BA(2) for the previous entitlement period because the maximum value of the supply of out-patient medication to a person who is a general patient and who is not the holder of a concession card has changed from \$32.20 to \$32.80. The maximum value of the supply of out-patient medication to a person who is a general patient at a hospital in Queensland or participating in the Pharmaceutical Reform Arrangements is \$41.00. This is in line with section 99G of the Act which refers to indexation under the Consumer Price Index (CPI) as it should be applied to the remuneration prices for the medications under 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 sets out 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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