

## **EXPLANATORY STATEMENT**

### *National Health Act 1953*

#### *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Amendment (General Co-payment) Rules 2022*

#### **Purpose**

The *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022* (the Principal Rules) define the procedures to be followed and set out the details regarding the information required to be provided by approved suppliers when making claims for payment for pharmaceutical benefits or providing information on supplies of pharmaceutical benefits where there is no claim to be made. The purpose of the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Amendment (General Co-payment) Rules 2022* (Amending Instrument) is to make consequential amendments to the Principal Rules to support the *National Health Amendment (General Co-payment) Act 2022* (the Amendment Act). The Amendment Act amends the *National Health Act 1953* (the Act), to reduce the Pharmaceutical Benefits Scheme (PBS) general co-payment (general patient charge) from \$42.50 to \$30 (indexed annually) commencing on 1 January 2023.

The Amendment Act also enables approved pharmacists and medical practitioners to apply an optional discount to certain PBS medicines with a Commonwealth price between the new co-payment of \$30 and the current co-payment of \$42.50, to ensure that patients will not be inadvertently worse off after the general patient charge is reduced. The Amending Instrument ensures information about supplies that are eligible for increased discounting and have had the discount applied is able to be submitted by pharmacists and collected by Services Australia.

#### *Option to discount the price by more than one dollar*

From 1 January 2023, approved pharmacists and approved medical practitioners will be able to apply an increased discount to certain PBS medicines. Approved pharmacists and approved medical practitioners can choose whether to offer this discount, if the supply is 'eligible for increased discounting'. A supply is 'eligible for increased discounting' if it is a general patient supply, is not an early supply and is between \$42.50 and \$30. A supply that is eligible for increased discounting and has had a discount applied, will count for safety net purposes and the amount accruing to the safety net threshold is the discounted co-payment amount charged.

The entitlement for the approved pharmacist or medical practitioner to be paid by the Commonwealth for the supply of the pharmaceutical benefit does not apply to a supply that is eligible for increased discounting and has had a discount applied.

#### *Expanded definition of 'contribution discount'*

The existing term 'contribution discount' has been expanded to include supplies eligible for increased discounting, that have an increased discount applied. The amount is worked out by reducing the general patient charge amount by the amount charged for the supply under paragraph 87(2)(e) of the Act.

This information is required to be provided by the approved pharmacist or medical practitioner when providing information on a general patient supply with no claim for payment, to the Commonwealth. The collection of data on these types of supplies is by operation of section 98AC of the Act.

### **Authority**

The Amending Instrument is made pursuant to subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953* (the Act).

### **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.

### **Background**

The Pharmaceutical Benefits Scheme (PBS) is established under 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 supply of drugs and medicinal preparations as pharmaceutical benefits.

Subsections 98AC(4) and 99AAA(8) of the Act provides that the Minister must, by legislative instrument, make rules defining the procedures to be followed by approved suppliers and by the Secretary, and specifying the information to be given to the Secretary by approved suppliers, in relation to the supply of pharmaceutical benefits, including a claim for payment. These rules are the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022*.

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

### **Commencement**

The Amending Instrument will commence on 1 January 2023.

### **Consultation**

There has been broad consultation with various stakeholders, including the clinical software industry and Services Australia. These industries welcome the Amending Instrument, noting that the Amending Instrument supports prescribers in correctly collecting, recording and submitting information about supplies where the option to apply increased discounting has been exercised, to Services Australia.

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

## ATTACHMENT

### Details of the National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Amendment (General Co-payment) Rules 2022

#### **Section 1 – Name**

Section 1 provides that the name of the amending instrument is the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Amendment (General Co-payment) Rules 2022* (the Amending Instrument). The instrument may also be cited as PB 108 of 2022.

#### **Section 2 – Commencement**

Section 2 provides that the Amending Instrument commences on 1 January 2023.

#### **Section 3 – Authority**

Section 3 provides that the Amending Instrument is made under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953* (the Act).

#### **Section 4 – Schedules**

Section 4 provides that each instrument specified in a Schedule to the Amending Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in that Schedule has effect according to its terms.

#### **Schedule 1—Amendments**

##### **Items 1 - 3— Subsection 5(1) - Definitions**

Items 1 to 3 amend subsection 5(1) by:

- adding a note at the end of the definition of ‘allowable discount’ as the note previously appeared with the definition of ‘contribution discount’ which has also been amended.
- substituting the definition of ‘contribution discount’ to include supplies eligible for increased discounting, that have an increased discount applied. The amount is worked out by reducing the general patient charge amount by the amount charged for the supply under paragraph 87(2)(e) of the Act.
- Insert the definition for ‘eligible for increased discounting’, which has the meaning given by section 87AA of the Act. Section 87AA is inserted by the *National Health Amendment (General Co-payment) Act 2022* which commences on 1 January 2023.

##### **Item 4 – Subsection 5(2) - Definitions**

Item 4 inserts the expression ‘general patient charge amount’ that is used in the instrument and in Part VII of the Act that has the same meaning in the instrument as it has in that Part.

##### **Item 5 – Subsections 6(1) and 7(1)**

Item 5 omits ‘(under co-payment data) and 99AAA(8)(a) (claims for payment)’ and substitutes ‘and 99AAA(8)(a)’, in order to remove the unnecessary references to ‘under co-payment data’ and ‘claims for payment’. This removal of the term ‘under co-payment data’ which previously followed references to section 98AC clarifies that the power under section 98AC of the Act is not limited to under co-payment supply.

**Item 6 – Subsection 8(1)**

Item 6 omits ‘(under co-payment data) and 99AAA(8)(c) (claims for payment)’ and substitutes ‘and 99AAA(8)(c)’, in order to remove the unnecessary references to ‘under co-payment data’ and ‘claims for payment’. This removal of the term ‘under co-payment data’ which previously followed references to section 98AC clarifies that the power under section 98AC of the Act is not limited to under co-payment supply.

**Item 7 – Subsection 9(1)**

Item 7 omits ‘(under co-payment data) and 99AAA(8)(b) (claims for payment)’ and substitutes ‘and 99AAA(8)(b)’, in order to remove the unnecessary references to ‘under co-payment data’ and ‘claims for payment’. This removal of the term ‘under co-payment data’ which previously followed references to section 98AC clarifies that the power under section 98AC of the Act is not limited to under co-payment supply.

**Item 8 – Clause 1, Schedule 1 (note 1)**

Item 8 omits ‘under co-payment data’ in Note 1 and substitutes ‘information about supplies.’ This removes the reference to ‘under co-payment data’ as the power under section 98AC of the Act is not limited to under co-payment supply.

**Item 9 – Clause 1, Schedule 1 (item 38, column 2)**

Item 9 omits ‘submitted (whether by way of claim or under co payment data)’ in item 38, column 2 of the table and substitutes ‘given (whether under section 98AC or section 99AAA of the Act)’. This removes the references to ‘claim’ and ‘under co-payment data’ as the powers to collect information about supplies are not limited to claims for payment or under co-payment supplies.

**Item 10 – Subclause 2(1) of Schedule 1**

Item 10 omits ‘under co-payment data’ in Note 1 and inserts ‘information about supplies.’ This removes the reference to ‘under co-payment data’ as the power under section 98AC of the Act is not limited to under co-payment supply.

## Statement of Compatibility with Human Rights

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

### *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Amendment (General Co-payment) Rules 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 Amending Instrument**

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

The *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022* (the Principal Rules) define the procedures to be followed and set out the details regarding the information required to be provided by approved suppliers when making claims for payment for pharmaceutical benefits or providing information on supplies of pharmaceutical benefits where there is no claim to be made.

The purpose of the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Amendment (General Co-payment) Rules 2022* (Amending Instrument) is to make consequential amendments to the Principal Rules to support the *National Health Amendment (General Co-payment) Act 2022* (the Amendment Act). The Amendment Act amends the *National Health Act 1953* (the Act), to reduce the PBS general patient charge from \$42.50 to \$30 (indexed annually) commencing on 1 January 2023.

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#### **Human rights implications**

The Amending Instrument engages Articles 2 and 12 of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR), by supporting the right to health and assisting in realisation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The UN Committee on Economic Social and Cultural Rights (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

The Amending Instrument does this by supporting the efficient operation and effective administration of the PBS scheme, which provides Australians with subsidised access to medicines.

The Rules also engage the right to privacy contained in Article 17 of the *International Covenant on Civil and Political Rights* (ICCPR), by providing for the collection and transmission of personal information. There is no incompatibility with the right to privacy, as the data collections and transmissions provided for by the Rules are neither arbitrary nor an unlawful interference with the privacy of PBS clients. The data will be collected and disclosed in accordance with the *Privacy Act 1988* and the secrecy provisions of the Act.

### **Conclusion**

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

**Nikolai Tsyganov, delegate of the Minister for Health and Aged Care**