

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) (Subsection 84C(7) Price) Amendment Determination 2023

PB 52 of 2023

Authority

Subsection 84C(7) of the *National Health Act 1953* (the Act) provides that the Minister may determine, by legislative instrument, the manner in which the price for particular quantities or numbers of units of all or any pharmaceutical benefits is to be ascertained for safety net purposes. Paragraph 84C(8)(d) of the Act provides for the addition of fees or amounts as determined by the Minister with the agreement in writing of the Pharmacy Guild of Australia (the Guild), as required by subsection 84C(9) of the Act.

The manner for ascertaining the price for particular quantities or numbers of units of all or any pharmaceutical benefits is determined in the *National Health (Pharmaceutical Benefits) (Subsection 84C(7) Price) Determination 2019* (PB 113 of 2019) (the Principal Determination).

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

The Principal Determination provides that the subsection 84C(7) price for a pharmaceutical benefit must not exceed the patient co-payment amount. This means that the additional fee (the safety net recording fee) can be included, in full or in part, only where the price is up to a maximum of the patient co-payment.

The *National Health (Pharmaceutical Benefits) (Subsection 84C(7) Price) Amendment Determination 2023* (the Amendment Determination) amends the Principal Determination to increase the safety net recording fee that an approved pharmacist may charge a patient in respect of the supply of certain pharmaceutical benefits, consistent with the requirements under the Seventh Community Pharmacy Agreement, with effect from 1 July 2023. A copy of the Seventh Community Pharmacy Agreement can be found at the Department of Health and Aged Care's website at: <https://www.health.gov.au/topics/primary-care/what-we-do/7cpa>.

The Amending Determination increases the additional fee (safety net recording fee) for ready prepared pharmaceutical benefits from \$1.31 to **\$1.40** and for extemporaneously prepared pharmaceutical benefits from \$1.68 to **\$1.80**, with effect from 1 July 2023. These amendments have been agreed with the Guild in writing for the purposes of subsection 84C(9) of the Act.

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.

Division 1A of Part VII of the Act provides for the safety net arrangements for the PBS. The safety net reduces the cost of medicines for individuals and families who require a large number of pharmaceutical benefits.

Section 84C of the Act provides that a person is eligible to be issued with a safety net concession card or entitlement card when expenditure on pharmaceutical benefits for the person or the person and their family

during an entitlement period reaches a certain amount (the safety net amount). A safety net concession card or entitlement card enables access to pharmaceutical benefits at a lower price or free of charge during the relevant entitlement period, once the relevant thresholds are met.

Section 84C also sets out the supplies and amounts which can be taken into account for the purpose of the safety net. Where the Commonwealth price for a pharmaceutical benefit is equal to or greater than the maximum amount the patient may be charged (the patient co-payment), the amount for safety net purposes is the amount charged as the patient co-payment. Where the Commonwealth price for a pharmaceutical benefit is less than the patient co-payment, paragraph 84C(4)(e) of the Act provides that the supply cannot be taken into account for safety net purposes unless the amount charged does not exceed the sum of the subsection 84C(7) price for the pharmaceutical benefit and any charges (where applicable) for supplying the pharmaceutical benefit outside of normal trading hours and/or by delivery to premises other than the approved pharmacy.

Subsection 84C(7) of the Act provides that the Minister may determine the manner in which the price for all or any pharmaceutical benefits (including those referred to in paragraph 84C(4)(e)) is to be ascertained for the purpose of the safety net. Subsection 87C(8) provides that the manner determined under subsection 84C(7) shall align with the requirements set out in subsection 84C(8).

The price of a pharmaceutical benefit for subsection 84C(7) of the Act is determined in the Principal Determination to be the sum of the Commonwealth price, calculated in accordance with a determination by the Pharmaceutical Benefits Remuneration Tribunal made under paragraph 98B(1)(a) of the Act, the additional patient charge and an additional amount determined by the Minister for paragraph 84C(8)(d) of the Act (the additional fee). Different amounts apply for the additional fee for ready prepared and extemporaneously prepared pharmaceutical benefits.

Commencement

The Amendment Determination commences on 1 July 2023.

Consultation

Subsection 84C(9) of the Act provides that the Minister must not determine an additional amount unless the Guild has agreed in writing to the making of that determination.

The Seventh Community Pharmacy Agreement includes an agreement between the Commonwealth and the Guild for the purposes of subsection 84C(9) of the Act. The Department of Health and Aged Care consulted with the Guild and the Guild has agreed to the proposed changes.

The Amendment Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the *National Health (Pharmaceutical Benefits) (Subsection 84C(7) Price) Amendment Determination 2023*

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Pharmaceutical Benefits) (Subsection 84C(7) Price) Amendment Determination 2023*. It also provides that the instrument may also be cited as PB 52 of 2023.

Section 2 – Commencement

Section 2 provides that the instrument commences on 1 July 2023.

Section 3 – Authority

Section 3 provides that the instrument is made under subsection 84C(7) of the *National Health Act 1953*.

Section 4 – Schedules

Section 4 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 (Pharmaceutical Benefits) (Subsection 84C(7) Price) Determination 2019 (PB 113 of 2019)

Item 1 omits subparagraphs 6(1)(c)(i) and 6(1)(c)(ii) and substitutes new subparagraphs 6(1)(c)(i) and 6(1)(c)(ii). New subparagraph 6(1)(c)(i) provides that the additional fee (safety net recording fee) for ready prepared pharmaceutical benefits is \$1.40. New subparagraph 6(1)(c)(ii) provides that the additional fee (safety net recording fee) for extemporaneously prepared pharmaceutical benefits is \$1.80.

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits)(Subsection 84C(7) Price) Amendment Determination 2023

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This Disallowable 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 Disallowable Legislative Instrument

The purpose of the *National Health (Pharmaceutical Benefits)(Subsection 84C(7) Price) Amendment Determination 2023* (the Amendment Determination), made under subsection 84C(7) of the *National Health Act 1953* (the Act), is to amend the *National Health (Pharmaceutical Benefits) (Subsection 84C(7) Price) Determination 2019* (the Principal Determination) to adjust the additional amount (also known as the safety net recording fee) used in the calculation of the price of pharmaceutical benefits for safety net purposes. The supply of pharmaceutical benefits by approved pharmacists can include recording patient payments for safety net purposes. The additional amount forms part of the price that can be charged to the patient for a pharmaceutical benefit where the Commonwealth price is less than the patient co-payment amount. It is included in full or in part such that the patient payment is not more than the co-payment amount.

The Amendment Determination increases the additional amount for ready prepared pharmaceutical benefits from \$1.31 to **\$1.40** and for extemporaneously prepared pharmaceutical benefits from \$1.68 to **\$1.80**, with effect from 1 July 2023. The amounts were agreed with the Pharmacy Guild of Australia for the purposes of subsection 84C(9) of the Act in the Seventh Community Pharmacy Agreement. A copy of the Seventh Community Pharmacy Agreement can be found at the Department of Health and Aged Care's website at: <https://www.health.gov.au/topics/primary-care/what-we-do/7cpa>.

Human rights implications

The Principal Determination engages Articles 9 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). The Principal Determination assists in the progressive realisation by all appropriate means of the right of everyone to social security, and the enjoyment of the highest attainable standard of physical and mental health.

The Pharmaceutical Benefits Scheme (PBS) is a statutory benefit scheme which assists with providing subsidised access for people to medicines. This is a positive and supportive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for PBS support effective administration of the scheme.

Further, the safety net scheme under the PBS is a social security measure which is designed to provide financial protection for patients and families who require a large number of PBS medicines. Increasing the safety net recording fee is consistent with the right to social security as it incentivises the recording of information for the purposes of the PBS. Further, this fee is only payable when the patient payment is not more than the co-payment amount, creating no additional burden for patients whose medicines are more than the co-payment amount.

The amendment made by the Amendment Determination is only in relation to the additional amounts described above. It does not change the protection of human rights to health and social security by all Australians under the PBS implemented under the Principal Determination.

Conclusion

This Disallowable Legislative Instrument is compatible with human rights because it maintains the protection of human rights to health.

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