

EXPLANATORY STATEMENT

Approved by the Department of Health

National Health Act 1953

National Health (Subsection 84C(7)) Amendment Determination 2019

PB 50 of 2019

Authority

Subsection 84C(7) of the *National Health Act 1953* (the Act) provides that the Minister may determine the manner in which the price for all or any pharmaceutical benefits and repatriation pharmaceutical benefits is to be ascertained for the purpose of the Safety Net. Paragraph 84C(8)(d) of the Act provides for the addition of fees or amounts as determined by the Minister in accordance with subsection 84C(9) of the Act which requires the agreement in writing of the Pharmacy Guild of Australia.

This price is determined in the *National Health (Subsection 84C(7)) Determination 2010* (the Principal Determination), as being the sum of the Commonwealth price for a pharmaceutical benefit, calculated in accordance with the determination by the Pharmaceutical Benefits Remuneration Tribunal under paragraph 98B(1)(a) of the Act, and an additional amount for paragraph 84C(8)(d).

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.

Purpose

The *National Health (Subsection 84C(7)) Amendment Determination* (the Amending Determination) amends the *National Health (Subsection 84C(7)) Determination 2010* (the Primary 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, consistent with the requirements under the Sixth Community Pharmacy Agreement (the Sixth Agreement), with effect from 1 July 2019. The amendments relate to the additional fee for ready prepared pharmaceutical benefits and for extemporaneously prepared pharmaceutical benefits.

Overview of the instrument

Part VII of the Act is the legislative basis of the Pharmaceutical Benefits Scheme (PBS) by which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

Division 1A of Part VII of the Act provides for the Safety Net arrangements for the PBS and Repatriation Pharmaceutical Benefits Scheme (RPBS). 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 receive 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 PBS or RPBS medicines at a reduced rate or free of charge for the remainder of the entitlement period. An entitlement period for the Safety Net is a calendar year from 1 January to 31 December.

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 medicine 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, subsection 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 or repatriation 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 or repatriation 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 (7) shall accord with the requirements set out in subsection (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 under paragraph 98B(1)(a) of the Act, and an additional amount determined by the Minister for paragraph 84C(8)(d) of the Act (the additional fee). A different amount applies for ready prepared and extemporaneously prepared pharmaceutical benefits.

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 can be included, in full or in part, only where the price is up to a maximum of the patient co-payment.

A component of the Sixth Agreement is that the additional fee is indexed annually by Wage Cost Index 9 (WCI9) on 1 July. The fee for 2015/16 was set as part of the Sixth Agreement negotiations and indexation is applied annually from 1 July 2017.

The Amending Determination indexes the additional fee for ready prepared pharmaceutical benefits from \$1.23 to **\$1.25** and for extemporaneously prepared pharmaceutical benefits from \$1.59 to **\$1.61**, with effect from 1 July 2019.

Consultation

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

The Guild has agreed, in writing, to the revised values of the additional amounts for ready prepared and extemporaneously prepared pharmaceutical benefits.

The Amendment Determination commences on 1 July 2019.

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

Regulatory impact assessment

Indexation involving the PBS is considered to be part of the standing exemption dated 26 May 2011 (OBPR reference number 12116) therefore no Regulation Impact Statement is required.

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

The purpose of this legislative instrument, made under subsection 84C(7) of the *National Health Act 1953* (the Act), is to give effect to the execution of the Sixth Pharmacy Community Agreement. It amends the *National Health (Subsection 84C(7)) Determination 2010* (the Primary 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 includes 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 legislative instrument increases the additional amount for ready prepared pharmaceutical benefits from \$1.23 to **\$1.25** and for extemporaneously prepared pharmaceutical benefits from \$1.59 to **\$1.61**, with effect from 1 July 2019.

Human rights implications

The Primary Determination engages Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). The Primary Determination assists in 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 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.

The amendments made by the legislative instrument is only in relation to the additional amounts described above. It does not change the protection of human rights to health by all Australians under the PBS implemented under the Primary Determination.

Conclusion

The legislative instrument is compatible with human rights because it maintain the protection of human rights to health.

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