

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Subsection 84C(7)) Amendment Determination 2018 (No. 1)

PB 47 of 2018

Section 84C of the *National Health Act 1953* (Act) provides the circumstances where a person or a person and their family become eligible for a safety net concession card or a pharmaceutical benefits entitlement card.

Subsection 84C(7) of 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 and repatriation benefits is to be ascertained for the purposes of subparagraph 84C(4)(e)(i) of the Act.

Subparagraph 84C(4)(e)(i) of the Act deals with eligibility for safety net of supplies of pharmaceutical benefits which fall under subsections 99(2A), (2AB) or (2B) of the Act, that is, where the Commonwealth price of the benefit is less than the general or concessional co-payment amount (often referred to as under co-payment supplies). It provides that an under co-payment prescription counts to safety net only if the amount charged to the patient is not more than the amount worked out in accordance with a determination made under subsection 84C(7) of the Act. If the charge is more, the prescription is excluded from safety net and no portion of the amount paid accrues to the safety net tally.

The *National Health (Subsection 84C(7)) Amendment Determination 2018 (No. 1)* (the determination) amends the *National Health (Subsection 84C(7)) Determination 2010* (the principal determination) to insert a definition for ‘additional patient charge’ and include this charge in the manner for calculating the price of under co-payment pharmaceutical benefits and repatriation benefits.

The additional patient charge is included in the Sixth Community Pharmacy Agreement as an amount agreed by the Australian Government and the Pharmacy Guild of Australia that approved pharmacists can include (in full, in part or not at all) in the price charged to consumers for pharmaceutical benefits priced below the general patient co-payment. The ability to include the additional patient charge is capped as the addition of the charge (or part thereof) must not result in the total charge exceeding the maximum co-payment amount. The Sixth Community Pharmacy Agreement states that the additional patient charge is equal to ten per cent of the general patient co-payment amount plus 50 cents and does not count to the safety net. The amount of the additional patient charge currently equates to \$4.45.

The changes made by the determination are necessary because although it has been agreed by the Government in the Sixth and previous Community Pharmacy Agreements that an additional patient charge can be charged for an under co payment prescription, the charge is not mentioned in the method for working out the maximum patient charge in the subsection 84C(7) determination. In addition, it is not clear that where the additional patient charge is included in the price charged for an under co-payment prescription, the prescription is eligible for safety net and would not be excluded due to the effect of subparagraph 84C(4)(e)(i).

The amendments provide the legislative basis for including the additional patient charge in the calculation of the maximum charge for an under co-payment pharmaceutical benefit or

repatriation benefit. The additional patient charge becomes an amount determined by the Minister for the purposes of paragraph 84C(8)(d) of the Act and agreed with the Pharmacy Guild of Australia in accordance with subsection 84C(9) of the Act.

Whether the additional patient charge can be added in full, in part, or not at all, depends on the Commonwealth dispensed price of the benefit. The principal determination provides that the calculation of the charge is capped such that the total charge must not be more than the amount that may be charged for the supply under subsection 87(2) or (3) of the Act (that is, the calculated amount is capped to be no more than the co-payment amount). This provision continues to limit the total charge, including any allowable additional amounts, to the amount of the co-payment. (Special patient contribution amounts can be added to the total worked out under the subsection 84C(7) determination.)

Subsection 84C(1E) of the Act provides that regulations made for the purpose of working out the 'value for safety net purposes' of a supply of a pharmaceutical benefit must take into account the amount charged for the supply, but may make adjustments to the value such as excluding certain components of the amount charged or setting a maximum limit on the value.

Amendments to the *National Health (Pharmaceutical Benefits) Regulations 2017* which come into force on the same day as the determination, 1 June 2018, exclude the additional patient charge or any part thereof from the value for safety net of an under co-payment prescription. They provide for the safety net value to be the total worked out under subsection 84C(7) determination minus the additional patient charge component, or the amount charged, if less. The effect is that under co payment prescriptions can be discounted to any amount less than the subsection 84C(7) determination total and remain eligible for safety net.

The amendments to the principal determination do not change the way patient charges or safety net amounts are calculated in practice. The same effect has been achieved administratively for many years using a combination of the legislative provisions and relevant clauses of successive Community Pharmacy Agreements. The changes provide legislative clarity to support agreed policy and practice.

It should be noted that at the time of commencement of the determination, there are no repatriation benefits for which the Commonwealth price for a supply is less than the concessional co-payment amount.

Consultation has occurred with the Department of Human Services. Public consultation was not considered necessary as the amendments provide legislative force for established administrative practice and are consistent with provisions agreed by the Government and the Pharmacy Guild of Australia in the Sixth Community Pharmacy Agreement.

A provision by provision description of the determination is contained in the Attachment.

The determination commences immediately after the commencement of the *National Health (Pharmaceutical Benefits) Amendment (Safety Net) Regulations 2018*.

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

Provision by provision description of the *National Health (Subsection 84C(7)) Amendment Determination 2018 (No. 1)*

Section 1 Name

This section provides that the determination is the *National Health (Subsection 84C(7)) Amendment Determination 2018 (No. 1)* and may also be cited as PB 47 of 2018.

Section 2 Commencement

This section provides that the determination commences immediately after the commencement of the *National Health (Pharmaceutical Benefits) Amendment (Safety Net) Regulations 2018*.

Section 3 Authority

This section provides that the determination is made under subsection 84C(7) of the *National Health Act 1953*.

Section 4 Amendments

This section provides that each schedule in the instrument is amended or repealed as set out in the applicable items in that Schedule.

Schedule 1 Amendments

Item 1 Section 4 – After definition of Act

This item inserts the new term ‘additional patient charge’ and defines it as having the same meaning as in the *National Health (Pharmaceutical Benefits) Regulations 2017*.

Item 2 Subsection 6(1)

This item repeals subsection 6(1) and substitutes new subsection 6(1) which specifies the additional amounts which may be included when ascertaining a price for pharmaceutical benefits and repatriation pharmaceutical benefits. For a ready-prepared pharmaceutical benefit, the amount is the sum of \$1.21 and the additional patient charge; for an extemporaneously prepared pharmaceutical benefit, the amount is the sum of \$1.57 and the additional patient charge.

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 determination 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 Determination

The *National Health (Subsection 84C(7)) Amendment Determination 2018 (No. 1)* (the determination) amends the *National Health (Subsection 84C(7)) Determination 2010* (the principal determination).

The purpose of the determination is to provide a legislative basis for including the ‘additional patient charge’ negotiated as part of the Sixth Pharmacy Community Agreement (the Agreement) in the method used to calculate the patient charge for a pharmaceutical benefit where the Commonwealth price is not more than the maximum co-payment amount (an under co-payment prescription). The determination as amended allows the additional patient charge to be included in full or in part to the extent that the resulting total patient charge for a prescription supplied under the Pharmaceutical Benefits Scheme (PBS) is not more than the applicable co-payment amount.

Human rights implications

The principal determination engages Article 7 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) which is in place to facilitate favourable conditions of work and to ensure remuneration for workers with fair wages. The determination adds a definition for ‘additional patient charge’ and amends the manner of ascertaining the price for pharmaceutical benefits and repatriation benefits to include the additional patient charge. This change does not affect the extent to which Article 7 is engaged because, in practice, there is no change to the way the price is calculated for under co-payment prescriptions. Previously, a price was worked out using the method in the subsection 84C(7) determination and the additional patient charge was added to that price based on the provisions in the Agreement. The method in the determination as amended incorporates the full calculation and provides an identical pricing outcome. There will be no change to the maximum patient charge for any under co-payment PBS medicine as a result of the amendment.

More broadly, the PBS is a benefit scheme which assists with providing subsidised access to medicines for people in the community. It engages Articles 2 and 12 of the ICESCR, as it is a positive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for the PBS support effective administration of the scheme. In addition, it also 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 determination has no net effect on the Articles engaged by the principal determination; its effect is to ensure that legislative provisions reflect existing arrangements as agreed by Government.

Conclusion

The determination is compatible with human rights, as they apply to Australia, as it does not raise any human rights issues and does not impinge on any rights or freedoms.

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