

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment (Safety Net) Regulations 2018

By authority of the Minister for Health

The Pharmaceutical Benefits Scheme (PBS) is established under the *National Health Act 1953* (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.

Section 140 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which are required or permitted to be prescribed, or which are necessary or convenient to be prescribed, for carrying out or giving effect to the Act.

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

The *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations) prescribe matters and set out details in relation to the operation of the PBS. The *National Health (Pharmaceutical Benefits) Amendment (Safety Net) Regulations 2018* (the Regulations) amends the Principal Regulations to set the amount which can be tallied toward the general patient or concessional patient safety net. This includes the amount where the cost of the pharmaceutical benefit exceeds the maximum patient co-payment (over co-payment pharmaceutical benefits) and where the cost of the pharmaceutical benefit is equal to or less than the maximum patient co-payment (under co-payment pharmaceutical benefits).

Where the cost is greater than the patient co-payment amount, the amount which can be tallied towards the patient safety net is the co-payment amount charged to the patient, not including any additional charges such as brand premiums.

Where the cost is less than the patient co-payment amount, the amount which can be tallied towards the patient safety net is the lesser of:

- the sum of the price of the pharmaceutical benefit worked out under a determination under subsection 84C(7) of the Act, minus any *additional patient charge*;
- and
- the amount charged for the supply.

The Regulations also insert a definition for '*additional patient charge*'. This term has the same meaning as the further additional patient charge referred to in the Sixth Community Pharmacy Agreement, as in force on 1 June 2018 – the commencement date of the Regulations.

A determination made under subsection 84C(7) of the Act which also has effect from 1 June 2018 includes the same definition for *additional patient charge* and includes this charge in the manner for calculating the price of pharmaceutical benefits. The Regulations, together with the subsection 84C(7) determination, clarify the legislative basis for existing

administrative practice for calculating the maximum patient charge for under co-payment pharmaceutical benefits and the amount which is the value for safety net purposes.

Consultation regarding the safety net provisions has been undertaken previously with the Pharmacy Guild of Australia, Medicines Australia, the Generic and Biosimilar Medicines Association, the National Pharmaceutical Services Association, the Medical Software Industry Association and the Consumers Health Forum of Australia. No specific consultation was undertaken in relation to the Regulations as it is a technical requirement for implementation.

Details of the Regulations are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the Regulations is exercised.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on 1 June 2018. The Sixth Community Pharmacy Agreement is referenced as being the version in force on this date, consistent with the requirements outlined in the *Legislation Act 2003*. Nominating a specific commencement date enables the Regulations and the determination made under section 84C(7) of the Act to have effect from the same day.

Authority: Section 140 of the
National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment (Safety Net) Regulations 2018

1 - Name

This section provides that the title of the instrument is *National Health (Pharmaceutical Benefits) Amendment (Safety Net) Regulations 2018*.

2 - Commencement

This section provides that the instrument commences on 1 June 2018.

3 - Authority

This section provides that the instrument is made under the *National Health Act 1953* (the Act).

4 - Schedules

This section provides that each instrument that is specified in a schedule to this instrument is amended or repealed as set out in the applicable items in the schedule concerned, and any other item in a schedule to this instrument has effect according to its terms.

Schedule 1 – Amendments

National Health (Pharmaceutical Benefits) Regulations 2017

Items [1], [2] and [3] – subsection 5(1)

Item 1 inserts a new definition ‘*additional patient charge*’ to mean the further additional patient charge referred to in paragraphs 5.2.2(c) and 5.2.3(c) of the Sixth Community Pharmacy Agreement as in force on 1 June 2018. The clauses containing those paragraphs are as follows:

5.2.2 For Ready-Prepared Pharmaceutical Benefits that are priced below the maximum co-payment (other than Admixed Ready-Prepared Pharmaceutical Benefits), approved pharmacists can charge the sum of:

- (a) the Commonwealth price;
- (b) \$1.17; and
- (c) a further additional patient charge amounting to 10% of the maximum co-payment plus 50 cents,

provided that such a sum does not exceed the maximum co-payment.

5.2.3 For Extemporaneously-Prepared Pharmaceutical Benefits and Admixed Ready-Prepared Pharmaceutical Benefits that are priced below the maximum co-payment, approved pharmacists can charge the sum of:

- (a) the Commonwealth price;
- (b) \$1.53; and
- (c) a further additional patient charge amounting to 10% of the maximum co-payment plus 50 cents,

provided that such a sum does not exceed the maximum co-payment.

Item 2 repeals the definition for ‘*maximum value for safety net purposes*’ from subsection 5(1) as it is no longer be required.

Item 3 inserts a new definition for *value for safety net purposes* to have the same meaning as in Part VII of the Act.

Item [4] – section 6

Item 4 repeals section 6 of the Principal Regulations which sets out the ‘*maximum value for safety net purposes*’, that is, for the purposes of recording the safety net value on a prescription record form. The section is no longer be required as the new provision under section 17A (item 5 refers) provides the value for safety net purposes.

Item [5] – Before division 1 of part 3

Item 5 inserts new section 17A to define the value for safety net purposes of the supply of a pharmaceutical benefit for the purposes of subsection 84C(1E) of the Act.

Subsection 17A(2) provides the value for safety net purposes for the supply of a pharmaceutical benefit to which subsection 99(2A), (2AB) or (2B) of the Act applies. That is, the Commonwealth price for the supply is equal to or less than the patient co-payment amount. In such cases, the value for safety net purposes is the lesser of: the price of the pharmaceutical benefit worked out in accordance with a determination in force under subsection 84C(7) of the Act at the time of the supply, minus any additional patient charge (or part thereof) included in the amount charged for the supply; and the amount charged for the supply.

Subsection 17A(3) provides the value for safety net purposes for the supply of a pharmaceutical benefit where subsection (2) does not apply. That is, the Commonwealth price for the supply is greater than the patient co-payment amount. In such cases, the value for safety net purposes is the amount charged under whichever of paragraphs 87(2)(a), (b) or (e) of the Act applies, not including any amount charged under other subsections of section 87.

Subsection 17A(4) provides that the value for safety net purposes is zero in cases where the amount charged for the supply is not in accordance with the Act.

Item [6] – sections 18, 19 and 21

Item 6 omits the word ‘maximum’ from sections 18, 19 and 21. The effect is that what was previously described as the ‘*maximum value for safety net purposes*’ with regard to prescription record forms, becomes ‘*value for safety net purposes*’ (refer to items 1, 2 and 4).

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits) Amendment (Safety Net) Regulations 2018

The *National Health (Pharmaceutical Benefits) Amendment (Safety Net) Regulations 2018* (the Regulations) are 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 Regulations amend the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations) to support amendments to the *National Health Act 1953* (the Act) made by the *National Health Amendment (Pharmaceutical Benefits – Budget and Other Measures) Act 2018*.

The Pharmaceutical Benefits Scheme (PBS) provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The PBS operates under Part VII of the Act which regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits. The Principal Regulations prescribe matters and set out details in relation to the operation of the PBS.

The Regulations make amendments to PBS safety net provisions to set values for safety net purposes. The value for safety net is the amount of the patient charge for a PBS prescription which can be counted toward the general or concessional patient safety net threshold for the purposes of issuing a safety net card. The Regulations set safety net values for pharmaceutical benefits where the government price of a PBS medicine is greater than the maximum patient co-payment (ie. over co-payment) and where it is less (under co-payment).

The new provisions also include a definition for ‘additional patient charge’, a charge provided for under the Sixth Community Pharmacy Agreement, and which can be included in full or in part in the patient charge for an under co-payment PBS prescription. The changes provide expressly for the safety net value of an under co-payment prescription to be the price calculated according to a determination under subsection 84C(7) of the Act minus any amount due to the additional patient charge, or the amount paid, whichever is less. These provisions introduce the additional patient charge into legislation.

The amendments are required to ensure that where the additional patient charge is included in the patient charge for a PBS prescription, the prescription can be counted towards the safety net and at the correct value.

Human rights implications

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 International Covenant on Economic, Social and Cultural Rights (ICESCR), as it is a positive step towards attaining the highest standard of health for all Australians, and it 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 Principal Regulations are compatible with Articles 2 and 12 of the ICESCR as they contribute to the efficient operation and effective administration of the scheme.

The Regulations make no practical change to the calculation of patient charges or safety net amounts. The purpose is to ensure legislative clarity for established policy and administrative practice. There is no effect on the listing, pricing, prescribing, subsidy or cost to consumers of PBS medicines. There is no change to PBS safety net thresholds, or the operation of and benefits provided by, the PBS safety net.

Conclusion

The Regulations are compatible with human rights as they do not raise any human rights issues or impinge on any applicable rights or freedoms.

The Hon. Greg Hunt MP, Minister for Health