

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Indigenous Chronic Disease – PBS Co-payment Measure) Special Arrangement 2016

PB 9 of 2016

Authority

Subsection 100(1) of the *National Health Act 1953* (the Act) enables the Minister to make special arrangements for the supply of pharmaceutical benefits.

Subsection 100(2) of the Act provides that the Minister may vary or revoke a special arrangement made under subsection 100(1).

Purpose

The purpose of this legislative instrument is to revoke and remake the *National Health (Indigenous Chronic Disease – PBS Co-payment Measure) Special Arrangement 2015* to make consequential changes associated with amendments to the *National Health Amendment (Pharmaceutical Benefits) Act 2015*.

These amendments resulted from the Pharmaceutical Benefits Scheme (PBS) Access and Sustainability Package (the Package) of measures announced recently, particularly the optional one dollar patient co-payment discount on PBS prescriptions, announced by the Australian Government in May 2015. Community pharmacies are currently required by the Act to charge no less than the legislated amount as the co-payment for a PBS supply. From 1 January 2016, pharmacists will be able to reduce co-payment amounts by up to one dollar for each dispensed PBS medicine. Pharmacists can choose whether to offer a reduction, and the amount up to the one dollar maximum. There will be no change to the reimbursement from the Commonwealth for the supply of PBS medicines for any supply where the pharmacist elects to offer a discount on the relevant co-payment.

The Special Arrangement assists eligible Aboriginal and Torres Strait Islander peoples to access PBS and Repatriation PBS (RPBS) medicines with reduced patient co-payments under the PBS.

The Special Arrangement continues to benefit Aboriginal and Torres Strait Islander peoples who present with an existing chronic disease or are at risk of chronic disease, and in the opinion of the prescriber:

- would experience setbacks in the prevention or ongoing management of chronic disease if the person did not take the prescribed medicine; and
- are unlikely to adhere to their medicines regimen without assistance through the Special Arrangement.

The Special Arrangement continues to provide for the usual PBS co-payment (\$38.30 per medicine) to be reduced to the concessional rate (\$6.20 per medicine less any allowable discount (*allowable discount* has the meaning given by subsection 87 (2AAAA) of the Act)). Those patients who would normally pay the concessional rate will receive their PBS medicines without making a patient co-payment. Mandatory

premiums for a small number of medicines may still need to be paid by the patient. The amount of the PBS co-payment is indexed annually under the Act, and appears on the Department of Health website at:

<http://www.pbs.gov.au/info/healthpro/explanatory-notes/front/fee>

Consultation

A wide range of stakeholders from pharmacy, the pharmaceutical industry, and consumer groups were consulted during the development of the Package. The Department of Health consulted with the Department of Human Services regarding consequential amendments required to implement these changes. Consultation with pharmacy software providers has occurred as part of the implementation.

General

Details of the instrument are set out in the Attachment.

This instrument commences 1 February 2016.

This instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

Details of the *National Health (Indigenous Chronic Disease – PBS Co-payment Measure) Special Arrangement 2016*

Section 1 Name of Instrument

This section provides that the Special Arrangement is the *National Health (Indigenous Chronic Disease – PBS Co-payment Measure) Special Arrangement 2016* and that it may also be cited as PB 9 of 2016.

Section 2 Commencement

This section provides that the Special Arrangement commences on 1 February 2016.

Section 3 Revocation

This section provides the *National Health (Indigenous Chronic Disease – PBS Co-payment Measure) Special Arrangements Instrument 2015* (PB 23 of 2015) is revoked.

Section 4 Definitions

A number of expressions are defined in section 4, including ‘Aboriginal Community Controlled Health Service’, ‘chronic disease’, ‘Indigenous Health Service’, medication chart prescription, ‘RACGP,’ ‘referred’, and ‘specialist’. The definition ‘allowable discount’ is added, and has the same meaning as in the Act.

Section 5 Pharmaceutical benefits covered by this Special Arrangement

This section provides that the pharmaceutical benefits covered by this Special Arrangement are all those pharmaceutical benefits generally available for supply under Part VII of the Act. It does not apply to those pharmaceutical benefits which can only be supplied under another special arrangement under section 100 of the Act, or under the prescriber bag supply provisions of the Act.

For example, pharmaceutical benefits that can only be supplied under the special arrangement for Highly Specialised Drugs, the special arrangement for Efficient Funding of Chemotherapy, or the special arrangement for Human Growth Hormone are not covered by this Special Arrangement.

Section 6 Application of Part VII of the Act

This section provides that each pharmaceutical benefit supplied in accordance with this Special Arrangement is supplied under Part VII of the Act.

A provision of Part VII of the Act, the Regulations and other instruments made under the Act apply subject to this Special Arrangement.

The reduced co-payment provided for under this Special Arrangement is not available when continued dispensing occurs under subsection 89A(1) of the Act. (Continued dispensing is a term used to describe the situation when a pharmaceutical benefit may be supplied by an approved pharmacist without a prescription.)

Section 7 Prescribing

Subsection 7(1) provides that a pharmaceutical benefit is prescribed for supply under this Special Arrangement in accordance with Part VII of the Act, and instruments made for Part VII of the Act, with the modification set out in section 7.

Subsection 7(2) provides that the prescription must be written for supply to a patient registered under subsection 10(2) of this Special Arrangement.

Subsection 7(3) provides that the PBS prescriber must be a member, employee or contractor of a general practice that meets the requirements of section 8, or an Indigenous Health Service that meets the requirements of section 9.

In addition, subsection 7(3) provides that a specialist treating a patient who is registered under subsection 10(2), and who is referred to the specialist by a medical practitioner who is a member, employee or contractor of a general practice that meets the requirements of section 8, or an Indigenous Health Service that meets the requirements of section 9, may also prescribe under this Special Arrangement. The terms 'specialist' and 'referred' are defined in section 4.

Effectively, unlike other PBS prescribers, to prescribe under this Special Arrangement, a specialist is not required to be a member, employee or contractor of a section 9 general practice or Indigenous Health Service.

Subsection 7(4) provides that the PBS prescriber must annotate the prescription with an indicator that the prescription is being written for the supply of a pharmaceutical benefit under this Special Arrangement.

Subsection 7(5) provides that the Special Arrangement does not apply to a medication chart prescription, unless the person for whom the pharmaceutical benefit is prescribed is receiving treatment in or at a residential care service at which that person is receiving residential care. This maintains the existing access to PBS/RPBS medication chart prescriptions.

Section 8 General Practices

The requirements that must be met by a general practice for the purposes of this Special Arrangement are set out in section 8. The term 'RACGP' is defined in section 4.

Section 9 Indigenous Health Services

The requirements that must be met by an Indigenous Health Service for the purposes of this Special Arrangement are set out in section 9. The term 'Aboriginal Community Controlled Health Service' or ACCHS is defined in section 4.

Section 10 Registering patients

The requirements that must be met by in order to register a patient for the purposes of this Special Arrangement are set out in section 10. The terms 'general practitioner', and 'chronic disease' are defined in section 4.

Section 11 Co-payment reduction

Subsection 11(1) provides that section 87 of the Act applies to the supply of a pharmaceutical benefit under this Special Arrangement, but with the modifications set out in section 11.

Co-payment of nil

Paragraph 11(2)(a) has the effect that if the amount that the patient would normally pay the approved supplier for the supply of the medicine (the patient co-payment) is the concessional beneficiary charge or the general patient reduced charge (i.e. \$6.20

per medicine), an approved supplier is not to charge the patient. In other words the co-payment for an eligible Aboriginal and Torres Strait Islander person is nil.

Paragraph 11(2)(b) refers to a situation that would be under an under co-payment situation (where subsection 99(2AB) or (2B) of the Act applies). In these under co-payment situations, the patient co-payment is the same or greater than the rate of Commonwealth payment, so the approved supplier receives payment from the patient and no PBS payment is made to the approved supplier.

Paragraph 11(2)(b) has the effect that if these under co-payment situations arise, the approved supplier is not to charge the patient.

Co-payment for general patients

Paragraph 11(3)(a) has the effect that if the patient co-payment would normally be the general patient charge (i.e. \$38.30), that amount is reduced to the concessional beneficiary charge (i.e. \$6.20, less any allowable discount to the co-payment of up to \$1.00).

Paragraph 11(3)(b) refers to a situation that would be an under co-payment situation (where subsection 99(2A) of the Act applies). In this under co-payment situation, the patient co-payment is the same or greater than the rate of Commonwealth payment, so the approved supplier receives payment from the patient and no PBS payment is made to the approved supplier.

Paragraph 11(3)(b) has the effect that if this under co-payment situation arises, the approved supplier charges the patient the concessional beneficiary charge (i.e. \$6.20).

The general patient safety net or concessional beneficiary safety net

Subsection 11(4) has the effect that the amount that would have accumulated towards PBS Safety Net for the benefit of patients and their families is the same amount (i.e. the legislated PBS co-payment) that would have accumulated if this Special Arrangement had not applied. If an allowable discount is given, it is ignored.

Section 12 Eligibility for concession and entitlement cards under the Act

Section 12 has the effect that the eligibility criteria for concessional and entitlement cards under section 84C of the Act are applied as if the legislated PBS co-payment had been paid by the patient.

Section 13 Payment by Commonwealth

Subsection 13(1) provides that section 99 of the Act applies, but with the modifications set out in section 13. Section 99 of the Act deals with an approved supplier's entitlement to payment by the Commonwealth for supply of a pharmaceutical benefit. Section 13 provides for additional reimbursement of approved suppliers due to the lower amount (ignoring any allowable discount to co-payment given) they are charging patients when this Special Arrangement applies.

If the co-payment is nil under paragraph 11(2)(a)

Subsection 13(2) provides that if the approved supplier must not charge the patient due to paragraph 11(2)(a) of this Special Arrangement, the supplier is entitled to be paid by the Commonwealth an amount equivalent to the concessional benefit charge or the general patient reduced charge (i.e. \$6.20) in addition to what the supplier is otherwise entitled to be paid under subsection 99(2) or 99(4) of the Act for supply of the medicine to the patient.

If the co-payment is nil under paragraph 11(2)(b)

Subsection 13(3) provides that if the approved supplier must not charge the patient due to paragraph 11(2)(b) of this Special Arrangement, the supplier is entitled to be paid by the Commonwealth the price of the pharmaceutical benefit under subsection 84C(7) of the Act. This is an amount worked out in accordance with an instrument under subsection 84C(7) of the Act and is the amount that can count towards PBS Safety Net.

If the co-payment is for a general patient under paragraph 11(3)(a)

Subsection 13(4) provides that if the approved supplier charges the patient the concessional beneficiary charge due to paragraph 11(3)(a) of this Special Arrangement (including if any allowable discount is given), the supplier is entitled to be paid by the Commonwealth the difference between the concessional beneficiary charge and the general patient charge, ignoring any allowable discount given (i.e. the supplier is not paid for the discount given) in addition to what the supplier is entitled to be paid under subsection 99(2) or 99(4) of the Act for supply of the medicine to the patient.

If the co-payment is for a general patient under paragraph 11(3)(b)

Subsection 13(5) provides that if the approved supplier charges the patient the concessional beneficiary charge due to paragraph 11(3)(b) of this Special Arrangement, the supplier is entitled to be paid by the Commonwealth the difference (if any) between the price of the pharmaceutical benefit under subsection 84C(7) of the Act and the amount charged by the approved supplier.

Section 14 Claim for payment

Subsection 14(1) provides that an approved supplier who wants to receive payment from the Commonwealth for the supply of a pharmaceutical benefit under this Special Arrangement, must make a claim for payment to the Chief Executive Medicare on behalf of the Secretary.

Subsection 14(2) provides that the claim must be made in accordance with the National Health (Claims and under co-payment data) Rules with the following modifications. The modifications are:

- the claim must include an indicator that the Special Arrangement applies (unless manual system claim is made – in a manual system claim the indicator will appear on the prescription); and
- the rules are modified to allow payment in accordance with the Special Arrangement in the under co-payment situations where a claim is not usually payable.

Statement of Compatibility with Human Rights

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

National Health (Indigenous Chronic Disease – PBS Co-payment Measure) Special Arrangement 2016

This 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 Instrument

The purpose of this legislative instrument, made under subsections 100(1) and 100(2) of the Act, is to revoke and remake the *National Health (Indigenous Chronic Disease – PBS Co-payment Measure) Special Arrangements Instrument 2015* (PB 23 of 2015) to make consequential changes associated with amendments to the *National Health Amendment (Pharmaceutical Benefits) Act 2015* on 1 February 2016.

The Special Arrangement continues to provide, for the benefit of eligible Aboriginal and Torres Strait Islander peoples, for a reduction in the PBS co-payment to nil, or if the full PBS co-payment would otherwise apply, a reduction to the concessional PBS co-payment. The co-payment amount (prior to reduction) continues to count towards PBS safety net.

Human rights implications

This instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights by assisting with 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 PBS assists with advancement of these human rights by providing for subsidised access to medicines. This instrument ensures more ready and equitable access to PBS medicines for eligible Aboriginal and Torres Strait Islander peoples and is part of the Australian Government's Closing the Gap reform agenda.

Conclusion

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

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