EXPLANATORY STATEMENT

National Health Act 1953

National Health (Botulinum Toxin Program) Special Arrangement 2015

PB 87 of 2015

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 *National Health (Botulinum Toxin Program) Special Arrangement 2015* repeals and replaces the *National Health (Botulinum Toxin Program) Special Arrangement 2011* (PB 89 of 2011).

The old Special Arrangement allowed the pharmaceutical benefits specified in Schedule 1 of that arrangement, being Botulinum Toxin pharmaceutical benefits, to be administered to patients outside of the normal Pharmaceutical Benefits Scheme (PBS) supply regime.

Eligible patients were entitled to receive the Botulinum Toxin pharmaceutical benefits, specified in the Schedule, from authorised medical practitioners at registered practice locations. Authorisation to prescribe the pharmaceutical benefit and registration of the practice location had to be obtained from the Department of Human Services – Medicare (DHS-Medicare). The medical practitioners had to order the Botulinum Toxin through DHS-Medicare and it was delivered to the registered practice location. The medical practitioners were not required to write a prescription for the benefits, and patients were not charged the normal PBS co-payment by the Australian Government. The authorised medical practitioner received the Botulinum Toxin pharmaceutical benefits from the manufacturers of the medicines. The manufacturers then claimed from the Australian Government and, if the claims were allowed, were paid for the supply.

The Australian Government has decided to more closely align the access, supply and claiming of these pharmaceutical benefits with those of normal pharmaceutical benefits. This will save costs in the administration and program delivery of Botulinum Toxin pharmaceutical benefits within the Department of Health and DHS-Medicare. This is why the *National Health (Botulinum Toxin Program) Special Arrangement 2011* (PB 89 of 2011) is being repealed and replaced with a new scheme.

On and from 1 September 2015, Botulinum Toxin pharmaceutical benefits will be available, like other pharmaceutical benefits, under the general PBS supply regime. Amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012 (*PB 71 of 2012*)* will give effect to these listing changes. The amendments will commence operation on 1 September 2015.

On and from 1 July 2015, a PBS prescriber will be required to write a prescription for a patient for a Botulinum Toxin pharmaceutical benefit, if the patient meets the conditions for the administration of that medicine under the PBS.

Supply of that pharmaceutical benefit will occur through approved suppliers, being hospital authorities approved under section 94 of the Act. Administration of the benefit can occur by medical practitioners at those same hospital authorities, or by medical practitioners approved under section 92 of the Act, who are operating out of registered practice locations.

A supplier can claim for reimbursement from the Commonwealth for the supply of the pharmaceutical benefit.

Unlike general supply pharmaceutical benefits, community pharmacies will not be able to supply the Botulinum Toxin pharmaceutical benefits, given the toxic nature of the drug, which means that it should not be handled by patients, as is the usual practice in pharmacies.

On and from 1 September 2015, patients prescribed a Botulinum Toxin pharmaceutical benefit will be required to pay the usual co-payment for the pharmaceutical benefit. Standard patient eligibility criteria and entitlement rules will also apply, enabling patients to use the Safety Net and patient refund arrangements.

A section 100 Special Arrangement is still needed for the supply of these Botulinum Toxin pharmaceutical benefits, because the payments made will not be the same amounts as for general supply. Instead, the payments will reflect amounts paid under the *National Health (Highly Specialised Drugs Program for Hospitals) Special Arrangement 2010* (PB 116 of 2010).

Consultation

The amendments made by this instrument accord with recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC) and agreement by Government to align the process for prescribing and dispensing of Botulinum Toxin pharmaceutical benefits closer to that of other PBS medicines.

An ongoing and formal process of consultation in relation to matters relevant to the Special Arrangement includes the involvement of interested parties through the membership of the PBAC.

Consultations have also occurred with representatives of specialist colleges, DHS-Medicare, Medical Benefits Division and Pharmaceutical companies in relation to these changes.

This Instrument commences on 1 September 2015.

Details of the Instrument are set out in the Attachment.

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

ATTACHMENT

Details of the *National Health (Botulinum Toxin Program) Special Arrangement 2015*

Part 1 – Preliminary

Section 1 Name of Instrument
This section provides that the name of this instrument is the *National Health (Botulinum Toxin Program) Special Arrangement 2015*. It can also be cited as PB 87 of 2015.

Section 2 Commencement
This section provides that this instrument commences on 1 September 2015.

Section 3 Revocation
This section provides that this instrument revokes the *National Health (Botulinum Toxin Program) Special Arrangement 2011 (PB 89 of 2011).*

Section 4 Definitions
A number of expressions used in the Special Arrangement are defined in section 4.

Part 2 – Pharmaceutical benefits covered by this Special Arrangement

Section 5 Pharmaceutical benefits covered by this Special Arrangement
This section provides for the pharmaceutical benefits that are covered by this Arrangement. They are the pharmaceutical benefits set out in Schedule 1 to the Arrangement. Each pharmaceutical benefit is a brand of a listed drug in the form and with the manner of administration set out in Schedule 1.

Section 6 Application of Part VII of the Act
Subsection 100(3) of the Act provides that Part VII of the Act, and regulations or other instruments made for the purposes of Part VII, have effect subject to a special arrangement made under subsection 100(1).

Subsection 6(1) provides that the pharmaceutical benefits supplied under this Arrangement are supplied under Part VII. This is the situation under the Act and the subsection confirms that this is not intended to be modified by the Special Arrangement.

Subsection 6(2) confirms that the provisions of Part VII, and regulations and other instruments made for Part VII apply subject to the Special Arrangement.

Subsection 6(3) sets out the provision of the Regulations which do not apply to the pharmaceutical benefits in this Special Arrangement.

Section 7 Section 100 only supply
This section provides for matters relating to section 100 only supply of the pharmaceutical benefits covered by this Arrangement. These matters have been determined by the Minister, under relevant provisions of the Act, in another legislative instrument and are included in this Arrangement for transparency. The matters concern section 100 only drugs, declared under subsection 85(2A) of the Act.

The letter 'D' in the 'Section 100 only' column in Schedule 1 indicates that the drug is a section 100 only drug, and that all pharmaceutical benefits that have that drug may only be supplied under this or another special arrangement under section 100. These drugs are not available for general supply on the PBS.

The letters 'PB' in the 'Section 100 only' column in Schedule 1 indicates that the pharmaceutical benefit is a section 100 only pharmaceutical benefit and that pharmaceutical benefit may only be supplied under this or another special arrangement under section 100. These drugs are not available for general supply on the PBS.

The letters 'C' in the 'Section 100 only' column in Schedule 1 indicates the pharmaceutical benefit can only be supplied in the circumstances identified in the instrument made under section 85A of the Act and in accordance with this Special Arrangement.

Part 3 –Entitlement to pharmaceutical benefits

Section 8 Eligible persons
A person is eligible to receive a Botulinum Toxin pharmaceutical benefit, under the Special Arrangement, if they meet the criteria set out in this section.

In summary, the person must meet requirements specified in the Act, the circumstances, purposes and conditions set out in the subsection 85(2) declaration (currently the *National Health (Listing of pharmaceutical benefits) Instrument 2012*), and must be being treated at a registered practice location, at a private hospital or at a public hospital (as a certain type of patient).

Part 4 –Supply of pharmaceutical benefits

Section 9 Who can supply pharmaceutical benefits
Under this section, the supply of a Botulinum Toxin pharmaceutical benefit can only occur from an approved hospital authority of a public or private hospital. In all cases, a valid prescription must be received by the hospital authority.

The supply of the Botulinum Toxin pharmaceutical benefit cannot be given to the patient. This is due to the potency of the drug.

Part 5 –Administration of pharmaceutical benefits

Section 10 Requirements for administering pharmaceutical benefits under this Special Arrangement

Under this section, administration of a Botulinum Toxin pharmaceutical benefit can only occur:

(a) to an eligible patien;t
(b) by an eligible medical practitioner;
(c) in accordance with a prescription; and
(d) in or at a public hospital, a private hospital or a registered practice location.

Section 11 Eligible medical practitioner
This section defines an ***eligible medical practitioner.***

Section 12 Registered practice location
This section defines a ***registered practice location***.

Part 6 – Payment amounts

Division 1 – Payments to suppliers that are approved hospital authorities for public hospitals

Section 13 Payments to approved hospital authorities for public hospitals
Subsection 13(1) provides that an approved hospital authority for a public hospital is entitled to be paid the dispensed price for the supply of the pharmaceutical benefit, less any amount that the approved hospital authority was entitled to charge under subsection 22(2).

Subsection 13(2) provides that the dispensed price is to be worked out in accordance with Division 1 of Part 7.

Subsection 13(3) provides there are no mark-ups to be added to the costs of a pharmaceutical benefit for approved hospital authorities of a public hospital.

Division 2 Payments to suppliers that are approved hospital authorities for private hospitals

Section 14 Payments to approved hospital authorities for private hospitals
This section sets out the amount that may be paid by the Commonwealth to an approved hospital authority for a private hospital that makes a claim for payment for the supply of a pharmaceutical benefit. The authority is entitled to the amount by which the dispensed price for the supply of the pharmaceutical benefit is greater than the amount the authority could charge under subsection 22(2).

Part 7 –Dispensed price

Part 7 sets out the manner in which the dispensed price for the supply of a pharmaceutical benefit, by a hospital authority for a public or private hospital, is worked out.

The dispensed price is the basis for calculating the amount that a hospital authority may claim for supplying a pharmaceutical benefit under the Arrangement.

Division 1—Dispensed price for supply of a pharmaceutical benefit by a hospital authority for a public hospital

Section 15 The dispensed price – supply by public hospital

Section 15 provides that the dispensed price for the supply of a pharmaceutical benefit by a hospital authority, for a public hospital, is as follows:

(a) if the quantity of the pharmaceutical benefit that is ordered and supplied is equal to a multiple of a pack - the sum of the approved ex-manufacturer price or the proportional ex-manufacturer price for each pack quantity;

(b) if the quantity of the pharmaceutical benefit that is ordered and supplied is less than a pack quantity - the amount calculated in accordance with section 16;

(c) if the quantity of the pharmaceutical benefit that is ordered and supplied is more than a multiple of a pack quantity – the sum of:

- the approved ex-manufacturer price or the proportional ex-manufacturer price for each complete pack contained in the quantity supplied; and
- the amount calculated in accordance with section 16 for the quantity left over.

Section 16 Where quantity is less than a pack quantity

This section sets out the manner in which to calculate the dispensed price where the quantity of a pharmaceutical benefit that is ordered and supplied is less than a pack quantity of the benefit.

Division 2—Dispensed price for supply of a pharmaceutical benefit by certain suppliers

Section 17 The dispensed price – supply by an approved hospital authority for a private hospital

Paragraph 17(1)(a) provides that, where the quantity of a pharmaceutical benefit that is ordered and supplied by an approved hospital authority for a private hospital is equal to a multiple of a pack quantity, the dispensed price is the sum of:

- the approved ex-manufacturer or proportional ex-manufacturer price for each pack quantity; and
- the mark-up mentioned in section 18; and
- a dispensing fee.

Paragraph 17(1)(b) provides that, where the quantity of a pharmaceutical benefit that is ordered and supplied is less than a pack quantity, the dispensed price is the sum of:

- the amount calculated in accordance with section 19; and
- a dispensing fee.

Paragraph 17(1)(c) provides that where the quantity of a pharmaceutical benefit that is ordered and supplied is more than a pack quantity, the dispensed price is the sum of:

- the approved ex-manufacturer price or the proportional ex-manufacturer price for each pack quantity; and

- the mark-up mentioned in section 18 for each complete manufacturer's pack contained in the quantity supplied; and
- the amount calculated in accordance with section 19 for the quantity left over; and
- a dispensing fee.

Section 18 Mark-up
This section sets out the mark-up that is included in the dispensed price for the supply of a pharmaceutical benefit by an approved hospital authority for a private hospital.

The section uses the expressions ***pack quantity*** and ***approved ex-manufacturer price*** or ***proportional ex-manufacturer price***. It provides for a mark-up based on the price for the maximum quantity of the pharmaceutical benefit. The maximum quantity is the maximum for prescribing purposes determined under paragraph 85A(2)(a) of the Act.

The section reflects the way mark-ups are calculated in practice.

Section 19 Where quantity is less than a pack quantity
This section determines how to work out the dispensed price for a part of a pack quantity – ***a broken quantity***.

Section 20 Dispensing fee
This section provides that where an eligible medical practitioner, instead of directing a repeated supply of a pharmaceutical benefit, directs the supply on one occasion, of a quantity or number of units of the drug, the dispensed price of the pharmaceutical benefit will only include one dispensing fee.

Section 21 Rounding up of dispensed price
This section provides that the dispensed price for the supply of a pharmaceutical benefit is rounded to the nearest cent, with one half cent being counted as one cent.

Part 8 –Patient contributions

Part 8 sets out the amounts which a patient may be charged for the supply of a pharmaceutical benefit under this Arrangement.

Section 22 Patient contributions in relation to approved hospital authorities
This section sets out the amount that an approved hospital authority for a private or public hospital may charge a patient for the supply of a pharmaceutical benefit where a claim for payment is made.
In these circumstances, an approved hospital authority may charge the patient an amount equivalent to the amount that may be charged under section 87 of the Act for the supply of a pharmaceutical benefit to a patient.

Part 9 –Transitional arrangements

Part 9 provides for transitional arrangements for the supply of a pharmaceutical benefit in Schedule 1 under this Arrangement.

Section 23 Old Arrangement
This section defines what an old Arrangement is, for the purposes of the transitional provisions.

Section 24 Claims lodged but not determined under the old Arrangement
This section provides for transitional arrangements, which have the effect that a claim that was lodged, but not finally determined under the old arrangements, is taken to be a claim made, and may be processed, under the old Arrangement.

Section 25 Supply made but not claimed for under old Arrangement
This section provides for transitional arrangements, which have the effect that, if a supply was made under the old Arrangement but no claim was lodged, the claim will be processed under the old Arrangement.

Section 26 Stock on hand as at 1 September 2015
This section provides for transitional arrangements where a supplier holds stock of the pharmaceutical benefits listed in Schedule 1, as at 1 September 2015.

This supplier may continue to supply that stock until 31 December 2015 under the old Arrangement.

All claims for this stock must be lodged by 31 December 2015 and, if valid, will be processed under the old Arrangement.

Section 27 Registered practice locations under old Arrangement
This section provides that registered practice location under the old Arrangement is taken to be a registered practice location for this Special Arrangement.

Statement of Compatibility with Human Rights

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

National Health (Botulinum Toxin Program) Special Arrangement 2015

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 *National Health (Botulinum Toxin Program) Special Arrangement 2015* (PB 87 of 2015) repeals the *National Health (Botulinum Toxin Program) Special Arrangement 2011* (PB 89 of 2011).

On and from 1 September 2015, the Special Arrangement will provide for the availability of the pharmaceutical benefits listed in Schedule 1 of the old Special Arrangement, in a manner more closely aligned with the general PBS supply regime. This means that, like other PBS subsidised medicines, a PBS prescriber can, if a patient meets certain conditions, write a prescription for the patient for a Botulinum Toxin pharmaceutical benefit. Supply of the pharmaceutical benefit will occur through approved suppliers, being approved hospital authorities, who claim for a reimbursement from the Commonwealth in the usual way.

Patients prescribed a pharmaceutical benefit listed in Schedule 1 will be required to pay the usual co-payment for the pharmaceutical benefit, and standard patient eligibility criteria and entitlement rules will apply.

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 the advancement of these human rights by providing for subsidised access to medicines. The change to the supply regime introduced by these amendments more closely aligns to the general PBS supply regime.

Conclusion

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

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