

PB 87 of 2015

National Health (Botulinum Toxin Program) Special Arrangement 2015

*National Health Act 1953*

I, STEVE DUNLOP, Acting Assistant Secretary, Pharmaceutical Access Branch, Pharmaceutical Benefits Division, Department of Health, delegate of the Minister for Health, make this instrument under subsections 100(1) and (2) of the *National Health Act 1953*.

Dated 27 AUGUST 2015

STEVE DUNLOP

Acting Assistant Secretary

Pharmaceutical Access Branch

Department of Health

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Part 1—Preliminary

1 Name of Special Arrangement

 (1) This Special Arrangement is the *National Health (Botulinum Toxin Program) Special Arrangement 2015*.

 (2) This Special Arrangement may also be cited as PB 87 of 2015.

2 Commencement

 This Special Arrangement commences on 1 September 2015.

3 Revocation

 The *National Health (Botulinum Toxin Program) Special Arrangement 2011* (PB 89 of 2011) is revoked.

4 Definitions

 In this Special Arrangement:

***Act*** means the *National Health Act 1953*.

***approved hospital*** means a hospital in respect of which the hospital authority is approved under section 94 of the Act.

***approved hospital authority*** has the meaning given by subsection 84(1) of the Act.

***approved pharmacist*** has the meaning given by subsection 84(1) of the Act.

***eligible medical practitioner*** has the meaning given by section 11.

***eligible patient*** means a person who, under subsection 8(1), is eligible to receive a pharmaceutical benefit.

***medical practitioner*** has the same meaning as in subsection 3(1) of the *Health Insurance Act 1973*.

***other Special Arrangement*** means another Special Arrangement under section 100 of the Act.

***provider number*** has the meaning given by regulation 2 of the *Health Insurance Regulations 1975*.

***registered practice location*** has the meaning given by section 12.

***Regulations*** means the *National Health (Pharmaceutical Benefits) Regulations 1960*.

Note: Terms used in this Special Arrangement have the same meaning as in the Act—see section 13 of the *Legislative Instruments Act 2003*. These terms include:

• pharmaceutical benefit

• public hospital

Part 2 – Pharmaceutical benefits covered by this Special Arrangement

5 Pharmaceutical benefits covered by this Special Arrangement

 (1) This Special Arrangement applies to each pharmaceutical benefit mentioned in Schedule 1.

 (2) Each pharmaceutical benefit is a brand of a listed drug mentioned in Schedule 1:

 (a) in the form mentioned in Schedule 1 for the listed drug; and

 (b) with the manner of administration mentioned in Schedule 1 for the form of the listed drug.

Note: Each listed drug mentioned in Schedule 1 has been declared by the Minister under subsection 85(2) of the Act. The form, manner of administration and brand mentioned in Schedule 1 have been determined by the Minister under subsections 85(3), (5) and (6) of the Act respectively.

6 Application of Part VII of the Act

 (1) Each pharmaceutical benefit supplied in accordance with this Special Arrangement is supplied under Part VII of the Act.

 (2) A provision of Part VII of the Act, or of regulations or other instruments made for Part VII of the Act, applies, subject to this Special Arrangement.

Note: See subsection 100(3) of the Act.

 (3) If a pharmaceutical benefit is supplied in accordance with this Special Arrangement, regulations 22, 24 and 28 of the Regulations do not apply to the supply.

7 Section 100 only supply

 (1) If the letter ‘D(100)’ is mentioned in the column in Schedule 1 headed ‘Section 100 only’ for a listed drug, the listed drug may be supplied only in accordance with this Special Arrangement and any other Special Arrangement relating to the listed drug.

 (2) A pharmaceutical benefit that has a drug mentioned in subsection (1) is not available for general supply on the Pharmaceutical Benefits Scheme.

Note: The Minister has declared, under subsection 85(2A) of the Act, that the listed drug can only be supplied under a section 100 Special Arrangement.

1. If the code ‘PB(100)’ is mentioned in the column in Schedule 1, headed ‘Section 100 only’ for a pharmaceutical benefit, the pharmaceutical benefit may be supplied only in accordance with this Special Arrangement and with any other Special Arrangement relating to the pharmaceutical benefit.
2. A pharmaceutical benefit mentioned in subsection (3) is not available for general supply on the Pharmaceutical benefits Scheme.

Note: The Minister has declared, under paragraph 85(8)(a) of the Act, that this pharmaceutical benefit can only be supplied under a section 100 Special Arrangement.

1. If the code ‘C(100)’ is mentioned in the column in Schedule 1, headed ‘Section 100 only’ for a pharmaceutical benefit, and a circumstances code is mentioned for the pharmaceutical benefit in the column headed ‘Circumstances’, 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.
2. A pharmaceutical benefit mentioned in subsection (5) is not available for general supply on the Pharmaceutical Benefits Scheme.

Note: The Minister has declared, under paragraph 85(8)(b) of the Act, that 1 or more of the circumstances in which a prescription for the supply of the pharmaceutical benefit may be written are circumstances in which the benefit can only be supplied under a section 100 Special Arrangement.

Part 3—Entitlement to pharmaceutical benefits

8 Eligible persons

 (1) A person is eligible to receive a pharmaceutical benefit under this Special Arrangement if:

 (a) the person is an eligible person within the meaning of section 86 of the Act;

 (b) the person meets the requirements specified in the circumstances code, purposes code and conditions code (if any) mentioned for the pharmaceutical benefit, as declared by the Minister under subsection 85(2) of the Act; and

 (c) either;

(i) the person is being treated in or at a private hospital; or

(ii) the person is being treated in or at a public hospital as a non-admitted patient, a day-admitted patient, or an in-patient admitted for less than 24 hours; or

(iii) the person is being treated at a registered practice location.

 (2) In this section:

***private hospital*** has the same meaning as in the *Health Insurance Act 1973*.

Part 4—Supply of pharmaceutical benefits

9 Who can supply pharmaceutical benefits

 (1) Under this Special Arrangement a pharmaceutical benefit can only be supplied by an approved hospital authority for a private hospital or public hospital on receipt of a valid prescription for an eligible patient.

 (2) To avoid doubt, this section modifies section 94 of the Act in that an approved hospital authority may supply pharmaceutical benefits that are subject to this Special Arrangement for an eligible patient receiving treatment in or at the hospital of which it is the governing body or proprietor, or outside of the hospital of which it is the governing body or proprietor.

 (3) To avoid doubt, an approved pharmacist or an approved medical practitioner cannot supply pharmaceutical benefits under this Special Arrangement.

 (4) Under this Special Arrangement, the supplier of a pharmaceutical benefit cannot physically supply or hand over the pharmaceutical benefit directly to an eligible patient.

Part 5—Administration of pharmaceutical benefits

10 Requirements for administering pharmaceutical benefits under this Special Arrangement

 (1) A pharmaceutical benefit to which this Special Arrangement applies may only be administered:

 (a) to an eligible patient;

 (b) by a medical practitioner who is a eligible medical practitioner under section 11;

 (c) in accordance with the eligible medical practitioner’s prescription; and

 (d) in or at a public hospital, a private hospital or a registered practice location.

11 Eligible medical practitioner

 For this Special Arrangement:

 a medical practitioner is an ***eligible medical practitioner*** for administering a pharmaceutical benefit to an eligible patient, if the medical practitioner holds the specialist qualification required in the circumstances code declared by the Minister under subsection 85(2) of the Act, for treatment of that eligible patient with that pharmaceutical benefit.

12 Registered practice location

 (1) For this Special Arrangement:

***registered practice location***, for an eligible medical practitioner, means a business at an address for which the eligible medical practitioner has a provider number.

 (2) An eligible medical practitioner may have more than one registered practice location.

Part 6— Payment amounts

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

**13 Payments to approved hospital authorities for public hospitals**

 (1) An approved hospital authority for a public hospital is entitled to be paid by the Commonwealth the amount, if any, by which the dispensed price for its supply of the pharmaceutical benefit is greater than the amount that the approved hospital authority was entitled to charge under subsection 22(2).

 (2) The dispensed price for the supply of a pharmaceutical benefit by an approved hospital authority for a public hospital is to be worked out under Division 1 of Part 7.

 (3) No mark-ups may be added to the cost of a pharmaceutical benefit for which payment is claimed by an approved hospital authority for a public hospital.

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

14 Payments to approved hospital authorities for private hospitals

 (1) An approved hospital authority for a private hospital is entitled to be paid by the Commonwealth the amount, if any, by which the dispensed price for its supply of the pharmaceutical benefit is greater than the amount that the approved hospital authority was entitled to charge under subsection 22(2).

 (2) The dispensed price for the supply of a pharmaceutical benefit by an approved hospital authority for a private hospital is to be worked out under Division 2 of Part 7.

Part 7 – Dispensed price

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

15 The dispensed price—supply by public hospital

 (1) 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 quantity of the benefit—the sum of the approved ex-manufacturer price or of the proportional ex-manufacturer price for each pack quantity; or

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

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

1. the approved ex-manufacturer price or the proportional ex-manufacturer price for each pack quantity; and
2. the amount calculated in accordance with section 16 for the remainder of the quantity supplied that is less than a pack quantity.

16 Where quantity is less than a pack quantity

 (1) If the quantity of a pharmaceutical benefit that is ordered and supplied is less than a pack quantity of the benefit (a broken quantity), the amount mentioned in paragraph 15(1)(b) and subparagraph 15(1)(c)(ii) is to be calculated by:

 (a) dividing the quantity or number of units in the broken quantity by the pack quantity, expressed as a percentage to 2 decimal places; and

 (b) applying that percentage to the approved ex-manufacturer price or proportional ex-manufacturer price for the pack quantity.

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

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

 (1) The dispensed price for the supply of a pharmaceutical benefit by an approved hospital authority for a private 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 quantity, the sum of:

1. the approved ex-manufacturer price or of the proportional ex-manufacturer price for each pack quantity, plus the mark-up mentioned in section 18, taken to the nearest cent, with one half cent being rounded up to 1 cent; and
2. a dispensing fee equal to the dispensing fee for the supply of a ready prepared pharmaceutical benefit, mentioned in the determination made under paragraph 98B(1)(a) of the Act, as in force at the time of the supply of the pharmaceutical benefit; or

 (b) if a quantity of the pharmaceutical benefit that is ordered and supplied is less than a pack quantity, the sum of:

1. the amount calculated in accordance with section 19; and
2. a dispensing fee equal to the dispensing fee for the supply of a ready prepared pharmaceutical benefit, mentioned in the determination made under paragraph 98B(1)(a) of the Act, as in force at the time of the supply of the pharmaceutical benefit; or

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

1. for each pack quantity, the approved ex-manufacturer price or the proportional ex-manufacturer price for the pack quantity, plus the mark-up mentioned in section 18, taken to the nearest cent, with one half cent being counted as one cent; and
2. the amount calculated in accordance with section 19 for the remainder of the quantity supplied that is less than a pack quantity; and
3. a dispensing fee equal to the dispensing fee for the supply of a ready prepared pharmaceutical benefit, mentioned in the determination made under paragraph 98B(1)(a) of the Act, as in force at the time of the supply of the pharmaceutical benefit.

18 Mark-up

For subparagraphs 17(1)(a)(i) and 17(1)(c)(i) and for paragraph 19(1)(a), the mark-up for a pack quantity of a ready-prepared pharmaceutical benefit is:

1. if the pack quantity for which a mark-up is to be calculated under this section is equal to a maximum quantity of the pharmaceutical benefit, the mark-up is the amount mentioned in the table below for the approved ex-manufacturer price (AEMP) or for the proportional ex-manufacturer price (PEMP) for that quantity.



 (b) if the pack quantity for which a mark-up is to be calculated under this section is not equal to a maximum quantity of the pharmaceutical benefit, the mark-up is worked out as follows:

1. if the mark-up that would apply to the maximum quantity is shown in the table in paragraph (a) as a monetary amount—the mark-up for the pack quantity is that monetary amount, reduced proportionately for the relative quantities; and
2. if the mark-up that would apply to the maximum quantity is shown in the table in paragraph (a) as a percentage of AEMP or PEMP—the mark-up for the pack quantity is that percentage of the AEMP or PEMP for the pack quantity.

19 Where quantity is less than a pack quantity

 (1) If the quantity of a pharmaceutical benefit that is ordered and supplied is less than a pack quantity of the benefit (a **broken quantity**), the amount mentioned in subparagraphs 17(1)(b)(i) and 17(1)(c)(ii) is to be calculated by:

 (i) adding the mark-up mentioned in section 18 to the approved ex-manufacturer price or to the proportional ex-manufacturer price for the pack quantity, taking the result to the nearest cent, with one half cent being counted as 1 cent; and

 (ii) dividing the quantity or number of units in the broken quantity by the pack quantity, expressed as a percentage to 2 decimal places; and

 (iii) applying the percentage worked out under subparagraph (b) to the amount worked out under subparagraph (a).

20 Dispensing fee

 If 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, not exceeding the total quantity or number of units that could be prescribed, if the eligible medical practitioner directed a repeated supply, the dispensed price for the supply of the pharmaceutical benefit will include only one dispensing fee.

21 Rounding up of dispensed price

The dispensed price for the supply of a pharmaceutical benefit will in each case be taken to the nearest cent, one half cent being counted as one cent.

Part 8 – Patient contributions

22 Patient contributions in relation to approved hospital authorities

 (1) This section applies to an approved hospital authority for a public hospital or to a private hospital that supplies a pharmaceutical benefit.

 (2) The 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 the patient.

Part 9—Transitional arrangements

23 Definitions

In this part:

***old Arrangement*** means the National Health *(Botulinum Toxin Program) Special Arrangement 2011 (PB 89 of 2011*), as in force immediately before 1 September  2015.

24 Claims lodged but not determined under the old Arrangement

A claim for payment that was lodged, but a decision on whether or not to pay the claim was not made, under the old Arrangement is, after the commencement of this Special Arrangement, to be processed, under the old Arrangement as in force immediately before 1 September 2015.

25 Supply made but not claimed for under old Arrangement

A supply of a pharmaceutical benefit that was made under the old Arrangement, but for which no claim has been lodged, prior to the commencement of this Special Arrangement, is after the commencement of this Special Arrangement, taken to be a supply made under the old Arrangement and a claim for payment must be lodged prior to the close of business on 31 December 2015 and, if valid, processed under the old Arrangement as in force immediately before 1 September 2015.

26 Stock on hand as at 1 September 2015

(1) Where a supplier of pharmaceutical benefits under the old Arrangement holds stock, being pharmaceutical benefits listed in Schedule 1, as at 1 September 2015, that supplier may continue to supply that stock under the old Arrangement until 31 December 2015.

(2) All claims for supply under this section must be lodged prior to the close of business on 31 December 2015 and, if valid, paid for under the old Arrangement.

27 Registered practice locations under old Arrangement

A location that is a registered practice location for the old Arrangement is taken to be a registered practice location for this Special Arrangement.

Schedule 1—Pharmaceutical benefits to which this Special Arrangement applies

(sections 5, and 7)

| Listed Drug | Form | Manner of Administration | Brand | Section 100 only |
| --- | --- | --- | --- | --- |
| Botulinum Toxin Type A Purified Neurotoxin Complex | Lyophilised powder for injection 100 units | Injection | Botox | D(100) |
| Clostridium Botulinum Type A Toxin‑Haemagglutinin Complex | Lyophilised powder for I.M. injection 300 units | Injection | Dysport | D(100) |
| Clostridium Botulinum Type A Toxin–Haemagglutinin Complex | Lyophilised powder for I.M.injection 500 units | Injection | Dysport | D(100) |
| Incobotulinumtoxin A | Lyophilised powder for injection 100 units | Injection | Xeomin | D(100) |