**EXPLANATORY STATEMENT**

*National Health Act 1953*

***National Health (Growth Hormone Program) Special Arrangement 2015***

**PB 85 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 (Growth Hormone Program) Special Arrangement 2015* repeals and replaces the *National Health (Growth Hormone Program) Special Arrangement 2011* (PB 88 of 2011). The repealed Special Arrangement is referred to in this Arrangement as the old Arrangement.

The old Arrangement allowed the pharmaceutical benefits specified in Schedule 1 of that arrangement (growth hormone pharmaceutical benefits) to be administered to patients under supply arrangements outside of the normal Pharmaceutical Benefits Scheme (PBS) supply regime.

Eligible patients were entitled to receive the growth hormone pharmaceutical benefits, specified in the Schedule, for the treatment of nine separate conditions. Authorised prescribers were required to apply to the Department of Health (the Department) for authority to prescribe the benefits, and patients were not charged the normal PBS

co-payment by the Australian Government.

The Program was fully administered by the Department with assistance from the Growth Hormone Advisory Committee (GHAC), a panel of paediatric endocrinologists. When the Department had approved an application to prescribe a growth hormone pharmaceutical benefit, departmental officers would order growth hormone from the relevant supplier for prescribing by the authorised prescriber, and dispensing to the patient at a pre-arranged pharmacy location. These orders were processed by the Department four times per year for each patient.

The Australian Government has decided to align the access, supply and claiming processes for these pharmaceutical benefits with those of other pharmaceutical benefits. Alignment is anticipated to improve the efficiency of the efficiency of the Program administration, and result in savings to Government. In order to give effect to the alignment, the old Special Arrangement is being repealed and replaced with a new Special Arrangement.

On and from 1 September 2015, growth hormone pharmaceutical benefits will be available, like other pharmaceutical benefits, under the general PBS supply arrangements. Amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012 (*PB 71 of 2012*)* will give effect to these listing changes.

On and from 1 September 2015, an authorised prescriber will be required to submit an application to the Department of Human Services – Medicare for authority to prescribe a growth hormone pharmaceutical benefit. Patients must meet the conditions for eligibility for that medicine under the PBS. If approval is granted by the Department of Human Services – Medicare, supply of that pharmaceutical benefit will occur through approved suppliers, being community pharmacies approved under section 90 of the Act, hospital authorities approved under section 94 of the Act and medical practitioners approved under section 92 of the Act. These suppliers will then claim for reimbursement from the Commonwealth.

On and from 1 September 2015, most patients prescribed a growth hormone 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.

While patient conditions for eligibility will be contained within the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012 (*PB 71 of 2012*),* a section 100 Special Arrangement is still needed for the supply of these pharmaceutical benefits because of the complexity of dosing arrangements, and the introduction of pharmacist remuneration which will not be the same as for PBS general supply. The pharmacist remuneration will be the same amounts paid under the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010).

This instrument also inserts a new brand of growth hormone into Schedule 1 of the *National Health (Growth Hormone Program) Special Arrangement 2015.*

**Consultation**

The amendments made by this Instrument accord with recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC), as agreed to by Government to align the process for prescribing and dispensing of growth hormone pharmaceutical benefits more closely 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 the GHAC, Department of Human Services -Medicare, Medical Benefits Division, Pharmaceutical companies and clinicians 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 (Growth Hormone 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 (Growth Hormone Program) Special Arrangement 2015.* It can also be citied as PB 85 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 (Growth Hormone Program) Special Arrangement 2011* (PB 88 of 2011)

**Section 4 Definitions**

A number of terms used in the Special Arrangement are defined in section 4.

**Part 2 – Pharmaceutical benefits covered by this Special Arrangement**

***Division 1 General***

**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 Arrangement.

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

***Division 2 Prescriptions for pharmaceutical benefits***

**Section 8  Prescription – Maximum quantity**

This section details the maximum quantity or number of units of the pharmaceutical benefit that may be supplied for the different treatment phases.

**Section 9  Prescription – Maximum number of repeats**

This section details the maximum number of repeats of the pharmaceutical benefit that may be included on the prescription for the different treatment phases.

**Part 3 –Treatment dose**

***Division 1 General***

**Section 10 Definitions**

This section defines a number of terms relating specifically to dose.

**Section 11 Assessment of dosage of pharmaceutical benefit**

Section 11 details the dose restrictions that authorised prescribers must comply with when prescribing the pharmaceutical benefit for each condition during the initial and continuing treatment phases.

***Division 2 Reclassification***

**Section 12 Dose for change of treatment category (reclassification)**

Section 12 details the dose restrictions that authorised prescribers must comply with when prescribing the pharmaceutical benefit for a patient that is reclassified to a different condition.

***Division 3 Recommencement treatment***

**Section 13 Dose for recommencement treatment**

Section 13 details the dose restrictions that authorised prescribers must comply with when prescribing the pharmaceutical benefit for a patient that is recommencing treatment for the same condition.

**Part 4 – Payment amounts**

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

**Section 14  Payments to approved hospital authorities for public hospitals**

Subsection 14(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 section 16.

Subsection 14(2) provides that the dispensed price must be determined in accordance with Division 1 of Part 5.

Subsection 14(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, approved pharmacies or approved medical practitioners***

**Section 15  Payments to certain suppliers of pharmaceutical benefits**

This section sets out the amount that may be claimed by an approved pharmacist, an approved medical practitioner or an approved hospital authority for a private hospital that makes a claim for payment for the supply of a pharmaceutical benefit.

Subsection 15(1) provides that an approved hospital authority for a private 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 section 18.

Subsection 15(2) provides that an approved pharmacist or approved medical practitioner is entitled to be paid the dispensed price for the supply of the pharmaceutical benefit less any amount that the approved pharmacist or approved medical practitioner was entitled to charge under section 18.

Subsection 15(3) provides that the dispensed price must be determined in accordance with Division 2 of Part 5.

**Part 5 –Dispensed price**

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

This Division sets out the manner in which the dispensed price for the supply of a pharmaceutical benefit by a hospital authority for a public hospital is calculated.

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

**Section 16       The dispensed price – supply by public hospital**

Section 16 provides the methods for calculating dispensed price for the supply of a pharmaceutical benefit by a hospital authority for a public hospital when the quantity of the pharmaceutical benefit ordered and supplied is equal to a multiple of a pack, less than a pack quantity, or more than a multiple of a pack quantity.

**Section 17     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 the quantity contained in the manufacturer’s pack.

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

This Division sets out the manner in which the dispensed price for the supply of a pharmaceutical benefit by a hospital authority for a private hospital, an approved pharmacist or an approved medical practitioner is calculated.

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

**Section 18     The dispensed price – supply by an approved hospital authority for a private hospital, an approved pharmacist or an approved medical practitioner** Section 18 provides the methods for calculating dispensed price for the supply of a pharmaceutical benefit by a hospital authority for a private hospital when the quantity of the pharmaceutical benefit ordered and supplied is equal to a multiple of a pack, less than a pack quantity, or more than a multiple of a pack quantity.

**Section 19     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, or an approved pharmacist or an approved medical practitioner.

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.

Section 20 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 21 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.

***Division 3        Dispensed price – other matters***

**Section 22      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 rounded up to one cent.

**Part 6 –Patient contributions**

Part 6 sets out the amounts which a patient may be charged for the supply of a pharmaceutical benefit under this Special Arrangement.

**Section 23 Patient contributions**

This section sets out the amount that an approved hospital authority for a private or public hospital, an approved medical practitioner or an approved pharmacist may charge a patient for the supply of a pharmaceutical benefit, where a claim for payment is made.

In these circumstances, the patient may be charged 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 7 – Approved Hospital Authorities**

This section makes changes to section 94 approved hospital authorities for the supply of Growth Hormone pharmaceutical benefits on presentation of a valid PBS prescription.

**Section 24 Modified application of section 94 approved hospital authorities**

This supports section 94 approved hospital authorities to supply pharmaceutical benefits following presentation of a valid PBS prescription for a medicine for a patient regardless of where that patient is receiving treatment.

**Part 8 –Transitional arrangements**

Part 8 provides for transitional arrangements for the supply of a pharmaceutical benefit in Schedule 1 under this Arrangement.

Section 25 Definitions

This section defines what ‘old arrangement’ and ‘growth hormone treatment’ is for the purposes of the transitional provisions.

**Section 26 Pending applications under the old Arrangement**

This section defines when pending applications cease to be valid applications under the old Arrangement.

**Section 27 Treatment of patients under the old Arrangement**

This section allows patients that have been approved to receive growth hormone treatment under the old Arrangement to continue to be treated for that treatment period under the old Arrangement. At the end of that treatment period applications for that patient must be made in accordance with this Special Arrangement.

Section 28 Claims for payment 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 Arrangement is taken to be a claim made, and may be processed, under the old Arrangement.

**Section 29 Supplies made but not claimed for under the 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.

**Statement of Compatibility with Human Rights**

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

***National Health (Growth Hormone 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 (Growth Hormone Program) Special Arrangement 2015* (PB 85 of 2015) repeals the *National Health (Growth Hormone Program) Special Arrangement 2011* (PB 88 of 2011).

On and from 1 September 2015, the Special Arrangement will provide for the availability of the pharmaceutical benefits listed in Schedule 1 in a manner more closely aligned with normal medicine supply under the Pharmaceutical Benefits Scheme (PBS). On 1 September 2015 an authorised prescriber will be able to submit an application to the Department of Human Services - Medicare to prescribe the pharmaceutical benefits set out in the Schedule. If approval is granted by the Department of Human Services – Medicare, supply of the pharmaceutical benefit will occur through suppliers - approved hospital authorities and approved pharmacists - who can claim for a reimbursement from the Commonwealth in the usual way.

Most 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.

The Special Arrangement also includes a new brand of growth hormone in

Schedule 1.

**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. This Special Arrangement will more closely align growth hormone pharmaceutical benefits supply arrangements with normal medicines supplied under the PBS.

**Conclusion**

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

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