EXPLANATORY STATEMENT

Issued by Authority of the Minister for Health and Ageing

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM FOR HOSPITALS) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2010 (No. 1)

PB 122 of 2010

Purpose

This legislative instrument is made under subsections 100(1) and 100(2) of the *National Health Act 1953* (the Act) and amends the *National Health (Highly Specialised Drugs Program for Hospitals) Special Arrangements 2010*, also known as PB 116 of 2010 (the Special Arrangement), with respect (among other things) to the circumstances in which certain highly specialised drugs are available under the Special Arrangement.

The medicines supplied under the Special Arrangement are for the treatment of chronic conditions which, because of their clinical use or other special features, may only be supplied to patients receiving treatment at or from a public or private hospitals having access to appropriate specialised facilities.

Subsection 100(1) enables the Minister to make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to persons:

(a) who are living in isolated areas: or

(b) who are receiving treatment in circumstances in which generally available pharmaceutical benefits are inadequate for that treatment; or

(c) if the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

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

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

The Pharmaceutical Benefits Scheme and Section 100 Special Arrangements

- **Overview**

  Part VII of the Act is the legislative basis for the Pharmaceutical Benefits Scheme (PBS) under which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

  Subsection 85(1) provides that benefits are to be provided by the Commonwealth in accordance with Part VII in respect of pharmaceutical benefits.

  All pharmaceutical benefits are supplied under Part VII of the Act. The pharmaceutical benefits supplied under Part VII may be:

  - pharmaceutical benefits available for general supply only;
  - pharmaceutical benefits available both for general supply and for supply under special arrangements made under section 100 (ie, dual supply pharmaceutical benefits); or

- pharmaceutical benefits available, or available in specified circumstances, only under special arrangements made under section 100 (ie, section 100 only supply).

- **Pharmaceutical benefits available under section 100 special arrangements**

  The pharmaceutical benefits available under section 100 special arrangements may thus be dual supply or section 100 only supply. The section 100 only supply, which is provided for in section 85AA of the Act, may relate to:

  - section 100 only drugs (ie, drugs declared under subsection 85(2A);
  - section 100 only pharmaceutical benefits (ie, pharmaceutical benefits determined under paragraph 85(8)(a); or
  - section 100 only circumstances for prescribing a pharmaceutical benefit (ie, circumstances determined under paragraph 85(8)(b) in relation to the pharmaceutical benefit).

- **Amendments to the Act commencing 1 December 2010**

  Amendments to the Act which commenced on 1 December 2010 streamlined and simplified the process for listing section 100 medicines on the PBS. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2010* (the new listing instrument) which commenced on 1 December 2010 contains a number of declarations and determinations made under the new provisions. Amendments to section 100 of the Act also commenced on 1 December 2010. This Amendment Instrument is being made under the amended section 100 and in reliance on the declarations and determinations in the new listing instrument, as amended for 1 January 2011.

- **Section 100 special arrangements and Part VII of the Act**

  Special arrangements are made under section 100 to ensure an adequate supply of pharmaceutical benefits is available to persons in the situations set out in subsection 100(1) when supply under Part VII, the regulations and other instruments made for the purposes of Part VII is not appropriate. Part VII of the Act, the regulations and other instruments made for the purposes of Part VII have effect subject to a special arrangement (subsection 100(3)). A section 100 arrangement may thus modify the operation of Part VII, the regulations and other relevant instruments.

The Special Arrangement

The Special Arrangement provides for the supply of certain medicines to eligible patients, who are required to be receiving medical treatment by a medical practitioner at, or from, a hospital as a non-admitted patient, a day admitted patient or a patient on discharge. The relevant medicines are referred to throughout the Special Arrangement as "HSD pharmaceutical benefits". The relevant HSD pharmaceutical benefits covered by the Special Arrangement are set out in Schedule 1 to the Special Arrangement. Each HSD pharmaceutical benefit is a brand of a highly specialised drug in a specified form and with a specified manner of administration.

There are two categories of HSD pharmaceutical benefits – those that have a "complex Authority Required" (CAR drugs) and those that have a "Non-complex Authority Required" (Non-CAR drugs). The list of CAR drugs is set out in the definitions section of the Special Arrangement. A non-CAR drug is any highly specialised drug that is not a CAR drug. HSD pharmaceutical benefits that have a CAR drug require a higher level of authorisation to prescribe in certain circumstances.

Under the Special Arrangement, HSD pharmaceutical benefits may be supplied by hospital authorities for public and private hospitals to an eligible patient receiving treatment at or from the hospital. If the eligible patient is receiving treatment at or from a private hospital, the HSD pharmaceutical benefits may also be supplied by an approved pharmacist. An approved pharmacist may also supply an HSD pharmaceutical benefit to an eligible patient receiving treatment at or from a public hospital if the HSD pharmaceutical benefit has a CAR drug.

The Special Arrangement provides for matters relating to the prescribing and supplying of HSD pharmaceutical benefits to eligible patients. The Special Arrangement also specifies how claims for payment for the supply of HSD pharmaceutical benefits may be made, the amount of reimbursement that the relevant supplier is entitled to receive from the Commonwealth for each supply and the amount the patient may be required to pay for each supply of a HSD pharmaceutical benefit.

Changes to the Special Arrangement Effected by this Instrument

This Amendment Instrument provides for amended circumstances in which a prescription for the supply of certain HSD pharmaceutical benefits may be written. The amendments accord with recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC). For most HSD pharmaceutical benefits, the amended circumstances have been determined by the Minister under subsection 85(7) of the Act in the new listing instrument and are included in this Amendment Instrument for transparency. However, for some drugs, including CAR drugs, the prescribing circumstances are set out in the Special Arrangement. This Amendment Instrument amends the prescribing circumstances for the CAR drug, infliximab.

This Amendment instrument also amends the reference to two determinations referred to in PB 116 of 2010 and corrects an error in the responsible person schedule.

A provision by provision description of this Amendment Instrument is contained in the Attachment.

Consultation

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. PBAC is an independent expert body established by section 100A of the Act which makes recommendations to the Minister about which drugs and medicinal preparations should be available as pharmaceutical benefits. PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of PBAC, and that would enable them to contribute meaningfully to the deliberations of PBAC. When recommending the listing of a medicine on the PBS, PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Pharmaceutical companies were consulted throughout the process of changes to the prescribing circumstances for listings on the PBS and for this amendment Instrument. This includes consultation through the PBAC process, and agreement to final listing details.

This Amendment Instrument commences on 1 January 2011.

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

ATTACHMENT

PROVISION BY PROVISION DESCRIPTION OF THE *NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM FOR HOSPITALS) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2010 (No.1)*

Section 1 Name of Amendment Instrument

This section provides that this Amendment Instrument is the *National Health (Highly Specialised Drugs Program For Hospitals) Special Arrangement Amendment Instrument 2010 (No. 1)* and that it may also be cited as PB 122 of 2010.

Section 2 Commencement

This section provides that this Amendment Instrument commences on 1 January 2011.

Section 3 Amendments to PB 116 of 2010

Schedule 1 amends the *National Health (Highly Specialised Drugs Program for Hospitals) Special Arrangement 2010 (PB 116 of 2010)* which was made on 28 November 2010 and commenced on 1 December 2010. A summary of the changes provided for in Schedule 1 is set out below.

SUMMARY OF CHANGES

Reference to *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2010*

Items [1] – [2] amend four references to the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2010* so that the reference is to the more general 'determination made under paragraph 98B(1)(a) of the Act'. These references occur in sections 4 and 39 of PB 116 of 2010.

Reference to *Determination made pursuant to subsection* 84BA(2) *of the National Health Act 1953*

Item [3] amends the reference in section 45 of PB 116 of 2010 to the *Determination made pursuant to subsection* 84BA(2) *of the National Health Act 1953* so that the reference is to the more general 'determination made under subsection 84BA(2) of the Act'

Responsible person Schedule

Item [32] amends Schedule 2 of PB 116 of 2010 to correct an error.

Amendment of Circumstances

Items [4] – [31] and [33] – [59] amend Schedules 1 and 3 of PB 116 of 2010 with respect to the circumstances in which HSD pharmaceutical benefits that have the listed drugs below may be prescribed under this Special arrangement. Please see the table below for details:

Listed Drug	Alteration
Abacavir	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Abacavir with Lamivudine	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents in a patient over 12 years of age, weighing 40 kg or more
Abacavir with Lamivudine and Zidovudine	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents in a patient over 12 years of age, weighing 40 kg or more
Atazanavir	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Darunavir	circumstances amended for the treatment of HIV infection
Didanosine	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Efavirenz	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Emtricitabine	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Enfuvirtide	circumstances amended for the treatment of HIV infection
Etravirine	circumstances amended for the treatment of HIV infection
Fosamprenavir	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Infliximab	circumstances amended for the initial treatment of Crohn disease in a paediatric patient
Indinavir	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Lamivudine	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Lamivudine with Zidovudine	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antretroviral agents
Lopinavir	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Maraviroc	circumstances amended for the treatment of HIV infection
Nevirapine	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Raltegravir	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antretroviral agents
Ritonavir	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Saquinavir	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents

Stavudine	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Tenofovir	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Tenofovir with Emtricitabine	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Tenofovir with emtricitabine and efavirenz	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents
Tipranavir	circumstances amended for the treatment of HIV infection
Zidovudine	circumstances amended for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents