#### EXPLANATORY STATEMENT

#### *National Health Act 1953*

#### *National Health (Remote Aboriginal Health Services Program) Special Arrangements Amendment Instrument 2012 (No. 2)*

#### PB 87 of 2012

**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).

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

**Purpose**

The purpose of this Amendment Instrument, made under subsections 100(1) and 100(2) of the Act, is to amend the *National Health (Remote Aboriginal Health Services Program) Special Arrangements Instrument 2010* (PB 65 of 2010) (the Special Arrangement), to reflect amendments to the Act made by the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2012*, which commence on 1 October 2012.

The amendments to the Act which are reflected in this Instrument are:

* the removal of the concept of an *approved price to pharmacists* and its replacement with an *approved ex-manufacturer price* as the base price for medicines under the Pharmaceutical Benefits Scheme (PBS). The *approved ex‑manufacturer price* of a brand of a pharmaceutical item is the price agreed or determined under the Act as the appropriate maximum price for the purposes of Part VII of the Act. The price for each brand of a pharmaceutical item must be agreed or determined by reference to the lowest *pack quantity* of any brand of the pharmaceutical item. The Act provides for *proportional ex-manufacturer prices* for other pack quantities. Commonwealth payments to suppliers of pharmaceutical benefits are calculated from the *approved ex-manufacturer price* or the *proportional ex-manufacturer price*. Where applicable, a wholesale mark-up is included in the formula, thus ensuring that the overall level of remuneration is not affected by the change in the base price; and
* the provision for medicines to be included on the PBS for supply only under the prescriber bag provisions of the Act.

The prescriber bag provisions are sections 93, 93AA and 93AB of the Act. These sections provide for the supply of certain pharmaceutical benefits by medical practitioners, authorised midwives and authorised nurse practitioners, respectively, directly to patients (ie, as prescriber bag supplies). The pharmaceutical benefits available for supply under the prescriber bag provisions may be:

* + available for supply under the prescriber bag provisions and available for general supply on the PBS; or
  + available for supply only under the prescriber bag provisions and not available for general supply on the PBS (ie, prescriber bag only medicines). New subsections 85(2AA) and 85(7A) and section 85AAA of the Act provide for prescriber bag only medicines.

Prescriber bag only medicines are excluded from the scope of the Special Arrangement.

Details of each amendment made by this Instrument are set out in the Attachment.

**Consultation**

The changes made by this instrument are consequential to amendments to the Act and other legislative instruments. They are technical and machinery in nature. No consultation was undertaken.

This legislative instrument commences on 1 October 2012.

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

**ATTACHMENT**

**Details of the *National Health (Remote Aboriginal Health Services Program) Special Arrangements Amendment Instrument 2012 (No.2)***

**Section 1 Name of Instrument**

This section provides that the title of the instrument is the *National Health (Remote Aboriginal Health Services Program) Special Arrangements Amendment Instrument 2012 (No.2)* and that it may also be cited as PB 87 of 2012.

**Section 2 Commencement**

This section provides for the Instrument to commence on 1 October 2012.

**Section 3 Amendment of the *National Health (Remote Aboriginal Health Services Program) Special Arrangements Instrument 2010* (PB 65 of 2010)**

This section provides that Schedule 1 amends the *National Health (Remote Aboriginal Health Services Program) Special Arrangements Instrument 2010* (PB 65 of 2010).

**SCHEDULE 1 – AMENDMENTS**

**Item [1] – Section 3**This item inserts definitions for three new terms in the Special Arrangement.

**Item [2] – Section 5**This item substitutes a new section 5 into the Special Arrangement. The section sets out the pharmaceutical benefits that are available under the Special Arrangement. All ready-prepared pharmaceutical benefits are available, other than those which are listed on the PBS as available for supply only under the prescriber bag provisions of the Act or under a special arrangement under section 100 of the Act. The intention is that all ready-prepared pharmaceutical benefits which are generally available on the Pharmaceutical Benefits Scheme (PBS) are available under the Special Arrangement, other than Schedule 8 drugs which are controlled substances.

**Item [3] – Section 9**This item substitutes a new section 9 into the Special Arrangement. The section provides for payments to approved pharmacists and approved hospital authorities who supply pharmaceutical benefits to Aboriginal Health Services under the Special Arrangement. The new section provides for the same level of remuneration as the section which it replaces. Redrafting of the section was necessary to reflect amendments to the Act and other legislative instruments commencing on 1 October 2012.

**Statement of Compatibility with Human Rights**

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

***National Health (Remote Aboriginal Health Services Program) Special Arrangements Amendment Instrument 2012 (No.2)***

**PB 87 of 2012**

This Legislative 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 Legislative Instrument**

The purpose of this Legislative Instrument, made under subsections 100(1) and 100(2) of the Act, is to amend the *National Health (Remote Aboriginal Health Services Program) Special Arrangements Instrument 2010* (PB 65 of 2010) (the Special Arrangement), to reflect amendments to the Act made by the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2012* which commence on 1 October 2012.

This Instrument amends the Special Arrangement to reflect the amended concepts in the Act and to exclude pharmaceutical benefits that may only be supplied under the prescriber bag provisions of the Act from its scope.

**Human rights implications**

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) 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 Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. This Special Arrangement ensures more ready and equitable access to PBS medicines for Indigenous Australians and is part of the Australian Government’s Closing the Gap reform agenda. Closing the Gap is a commitment by all Australian governments to improve the lives of Indigenous Australians, and in particular provide a better future for Indigenous children.

**Conclusion**

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

**Kim Bessell**

**First Assistant Secretary (Acting)**

**Pharmaceutical Benefits Division**

**Department of Health and Ageing**