EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

National Health (IVF Program) Special Arrangement Amendment Instrument 2017 (No. 1)

PB 59 of 2017

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 have effect subject to a special arrangement made under subsection 100(1).

Purpose

The purpose of this Legislative Instrument, made under subsection 100(2) of the Act, is to amend the *National Health (IVF Program) Special Arrangement 2015* (PB 60 of 2015) (the Special Arrangement) to make changes relating to the IVF Program.

The purpose of the Special Arrangement is to ensure that an adequate supply of pharmaceutical benefits is available for patients who require in vitro fertilisation treatment. Restrictions on the provision of this treatment mean that these pharmaceutical benefits can more conveniently or efficiently be supplied under a special arrangement.

This Instrument reflects changes made to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012), which commence on the same day.

This Instrument adds a new pharmaceutical benefit which is the listed drug 'Chorionic Gonadotrophin' in a specified form, with a specified manner of administration and brand.

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

Consultation

This amendment to the Special Arrangement was made having regard to advice provided by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent expert body established by section 100A of the Act, which makes recommendations to the Minister for Health about which drugs and medicinal preparations should be available as pharmaceutical benefits. Part VII of the Act only applies to drugs or medicinal preparations recommended by the PBAC. When making recommendations, the PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia and its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

PBAC members are selected from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of these interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and

experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC.

Pharmaceutical companies are consulted throughout the process for additions and changes to listings on the Pharmaceutical Benefits Scheme (PBS), including consultation through the PBAC process and agreement to final listing details.

This Instrument commences on 1 August 2017.

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

ATTACHMENT

PROVISION BY PROVISION DESCRIPTION OF THE NATIONAL HEALTH (IVF PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2017 (No. 1)

Section 1 Name of Instrument

This section provides that this Instrument is the *National Health (IVF Program) Special Arrangement Amendment Instrument 2017 (No. 1)*, and that it may also be cited as PB 59 of 2017.

Section 2 Commencement

This section provides that this Instrument commences on 1 August 2017.

Section 3 Amendment of PB 60 of 2015

This section provides that Schedule 1 amends the *National Health (IVF Program) Special Arrangement 2015* (PB 60 of 2015) (the Special Arrangement).

Schedule 1 Amendments

Item 1 amends Schedule 1 of the Special Arrangement by adding a pharmaceutical benefit which is the listed drug 'Chorionic Gonadotrophin' in the form 'Injection set containing powder for injection 1,500 units, 3 and solvent 1 mL, 3', with the manner of administration 'Injection' and brand 'Pregnyl'.

Statement of Compatibility with Human Rights

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

National Health (IVF Program) Special Arrangement Amendment Instrument 2017 (No. 1)

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 subsection 100(2) of the *National Health Act 1953*, is to amend the *National Health (IVF Program) Special Arrangement 2015* (PB 60 of 2015) (the Special Arrangement) to make changes relating to the IVF Program.

The purpose of the Special Arrangement is to ensure that an adequate supply of pharmaceutical benefits is available for patients who require in vitro fertilisation treatment. Restrictions on the provision of this treatment mean that these pharmaceutical benefits can more conveniently or efficiently be supplied under a special arrangement.

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Human Rights Implications

This Legislative Instrument engages Article 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 PBS is a benefit scheme which assists with the advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

Conclusion

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

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