EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

National Health (IVF Program) Special Arrangement Amendment Instrument 2016 (No. 1)

PB 58 of 2016

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 subsections 100(1) and (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 to the special arrangement relating to the IVF Program.

Under the Special Arrangement a PBS prescriber, who prescribes an IVF pharmaceutical benefit to a patient and is satisfied that the particular patient meets the conditions for the administration of that medicine under the PBS, must write a prescription for that supply. Supply of that pharmaceutical benefit occurs 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 may then claim for reimbursement from the Commonwealth.

The purpose of this amendment is to require approved suppliers to provide the Commonwealth with information at the time of claiming such reimbursements. Specifically, from 1 July 2016, approved suppliers must include a Reproductive Technology Accreditation Committee (RTAC) Accredited Unit Number when claiming payment under the PBS.

An RTAC Accredited Unit Number is the number by which RTAC identifies a person or body as being an accredited Assisted Reproductive Technology (ART) centre. The RTAC is a Committee of the Fertility Society of Australia. The Committee operates an accreditation scheme under which accredited ART centres comply with the RTAC Code of Practice when providing ART services to patients. This compliance is a requirement under section 11 of the *Research Involving Human Embryos Act 2002* and compliance is regularly reviewed.

The new claiming requirement will enable the Commonwealth to ascertain that the funding made available under the PBS is being used for legal purposes in accountable, best practice circumstances. The Commonwealth will not pay a claim that has been made for the supply of pharmaceutical benefits under the Special Arrangement unless the approved supplier has also specified the relevant RTAC Accredited Unit Number.

This Instrument also repeals transitional arrangements that were established for the program changes introduced on 1 July 2015. These arrangements ceased on 1 January 2016.

A further description of this instrument is contained in the Attachment.

Consultation

The amendments made by this Instrument finalise the implementation of recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC) and agreement by Government to align the process for prescribing and dispensing of IVF pharmaceutical benefits closer 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 about the RTAC Accredited Unit Number, introduced on 1 July 2015 occurred with the IVF Directors' Group, within the Fertility Society of Australia, who represent IVF clinics and affiliated prescribers and other key industry stakeholders including the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia. This Instrument commences on 1 July 2016.

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

ATTACHMENT

DETAILS OF THE NATIONAL HEALTH (IVF PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2016 (No. 1)

Section 1 Name of Instrument

This section provides the name of this instrument as the *National Health (IVF Program) Special Arrangement Amendment Instrument 2016 (No. 1)* and that it may also be cited as PB 58 of 2016.

Section 2 Commencement

This section provides that this instrument commences on 1 July 2016.

Section 3 Amendments to 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

Item 1

This item inserts a new definition of accredited ART centre and indicates that it has the same meaning as contained within the *Research Involving Human Embryos Act 2002.*

Item 2

This item inserts a new definition of RTAC Accredited Unit number and indicates that this means the number by which the Reproductive Technology Accreditation Committee of the Fertility Society of Australia identifies a person or body as being an accredited ART centre.

Item 3

This item repeals previous transitional arrangements contained in PB 60 of 2015 which ceased on 1 January 2016.

This item inserts a new part, "Part 7 – Claiming". This part contains new section 19.

New subsection 19(1) requires approved suppliers, who wish to receive payment from the Commonwealth for the supply of pharmaceutical benefits listed in this Special Arrangement, to make a claim for payment to the Chief Executive Medicare on behalf of the Secretary of the Department of Health.

New subsection 19(2) requires approved suppliers to make those claims in accordance with the rules made under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953*; these are currently the *National Health (Claims and under co-payment data) Rules 2012* (No. PB 19 of 2012). New subsection 19(2) modifies the effect of PB 19 of 2012 so that approved suppliers must provide an RTAC Accredited Unit number in any claim for payment relating to the supply of a pharmaceutical benefit that is listed in Schedule 1 of the Special Arrangement.

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 2016 (No. 1) **PB 58 of 2016**

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 the Special Arrangement is to ensure that an adequate supply of the relevant 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 builds on program changes introduced on 1 July 2015 by introducing new requirements for the claiming of pharmaceutical benefits listed in Schedule 1 of the Special Arrangement. Specifically, the changes add the requirement that from 1 July 2016, approved suppliers must include a Reproductive Technology Accreditation Committee (RTAC) Accredited Unit Number when claiming for PBS payments. Without this number, claims for the supply of pharmaceutical benefits listed in this Special Arrangement will not be paid. The purpose is to ensure that Commonwealth funding is used appropriately for legal and best practice treatment.

This Instrument also repeals transitional arrangements that were established for the program changes introduced on 1 July 2015. These arrangements ceased on 1 January 2016.

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 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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