

EXPLANATORY STATEMENT

Private Health Insurance Act 2007

Private Health Insurance (Prostheses) Amendment Rules (No. 1) 2021

Authority

Section 333-20 of the *Private Health Insurance Act 2007* (the Act) provides that the Minister may make Private Health Insurance (Prostheses) Rules, providing for matters required or permitted by Part 3-3 of the Act, or necessary or convenient in order to carry out or give effect to Part 3-3 of the Act.

In addition to the power to make this instrument under section 333-20 of the Act, subsection 33(3) of the *Acts Interpretation Act 1901* provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Subsection 72-10(6) of the Act provides that the Private Health Insurance (Prostheses) Rules may set out listing criteria that must be satisfied in order for an application for a prosthesis to be listed to be granted.

Background

The table in subsection 72-1(2) of Part 3-3 of the Act provides for benefit requirements that a complying health insurance policy that covers hospital treatment must meet. Under item 4 of that table there must be a benefit for the provision of a prosthesis, of a kind listed in the Private Health Insurance (Prostheses) Rules (i.e. a listed prosthesis), in specified circumstances and under any specified conditions. The specified circumstances are that the listed prosthesis is provided in circumstances in which a medicare benefit is payable or in other circumstances which may be set out in the Private Health Insurance (Prostheses) Rules. The specified conditions are any that may be set out in the Private Health Insurance (Prostheses) Rules.

If the complying health insurance policy also covers hospital-substitute treatment, under item 4 of the table in subsection 72-1(2) of Part 3-3 of the Act the same requirements apply.

The Private Health Insurance (Prostheses) Rules (No. 3) 2020 (Prostheses Rules) are made for the purposes of section 333-20(1) of the Act. Listed prostheses and their minimum benefits are set out in the Schedule to the Prostheses Rules. The list of prostheses in the Schedule is commonly referred to as the Prostheses List.

Purpose

The purpose of the Private Health Insurance (Prostheses) Amendment Rules (No. 1) 2021 (the Amending Rules) is to remove 12 urogynaecological mesh prostheses from 'Part 1 – Prostheses List – Part A' of the Schedule.

The 12 prostheses in Part A of the Prostheses List are being removed as a result of the cancellation of their entries from the Australian Register of Therapeutic Goods (ARTG). As these prostheses are no longer included in the ARTG they cannot be lawfully supplied in Australia.

Consultation

The Amending Rules have been made following consultation with the sponsors of the prostheses affected.

According to the Therapeutic Goods (Medical Devices) Regulations 2002, all surgical mesh devices have been reclassified from Class IIb to Class III (high-risk). In order to meet the transitional arrangements [and be able to continue to legally supply their products], sponsors of the surgical mesh devices on the ARTG as Class IIb had to submit applications to the Therapeutic Goods Administration (TGA) to include their meshes in the ARTG as Class III devices. For urogynaecological mesh devices, the deadline for submitting such an application was 1 December 2020.

Some sponsor did not reclassify their urogynaecological meshes prior to the specified date, and requested the TGA to cancel their Class IIb ARTG entries.

The Department of Health contacted sponsors whose entries were no longer on the ARTG, advising that given their devices were no longer on the ARTG, the Department would be recommending to the Minister's delegate to remove the respective billing codes for the urogynaecological mesh devices from the Prostheses List.

The sponsors' responses had been given due consideration prior to making the decision.

Details of the Amending Rules are set out in the Attachment.

The Amending Rules commence the day following registration.

The Amending Rules is a legislative instrument for the purposes of the Legislation Act 2003.

Details of the *Private Health Insurance (Prostheses) Amendment Rules (No. 1) 2021*

Rule 1 Name

Rule 1 provides that the title of the Amending Rules is the *Private Health Insurance (Prostheses) Amendment Rules (No. 1) 2021*.

Rule 2 Commencement

Rule 2 provides that the Amending Rules commence the day after the instrument is registered on the Federal Register of Legislation.

Rule 3 Authority

Rule 3 provides that the Amending Rules is made under item 4 of the table in section 333-20 of the *Private Health Insurance Act 2007*.

Rule 4 Schedules

Rule 4 provides that each instrument that is specified in Schedule 1 to the Amending Rules is amended or repealed as set out in the applicable items in the Schedule, and any other item in a Schedule to this instrument has effect according to its terms.

Schedules 1 – Amendments

Private Health Insurance (Prostheses) Rules (No. 3) 2020

Items 1 to 12 remove 12 billing codes for prostheses that are no longer included in the ARTG and cannot be lawfully supplied in Australia.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011
Private Health Insurance (Prostheses) Amendment Rules (No. 1) 2021

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 Legislative Instrument

The table in subsection 72-1(2) of Part 3-3 of the *Private Health Insurance Act 2007* (the Act) provides for benefit requirements that a complying health insurance policy that covers hospital treatment must meet. Under item 4 of that table there must be a benefit for the provision of a prosthesis, of a kind listed in Private Health Insurance (Prostheses) Rules (i.e. a listed prosthesis), in specified circumstances and under any specified conditions.

The *Private Health Insurance (Prostheses) Rules (No. 3) 2020* (Prostheses Rules) were made for the purposes of section 333-20 of the Act. Listed prostheses and their minimum benefits are set out in the Schedule to the Rules. The list of prostheses in the Schedule is commonly referred to as the Prostheses List.

The *Private Health Insurance (Prostheses) Amendment Rules (No. 1) 2021* amends the Prostheses Rules by removing 12 prostheses from ‘Part 1 – Prostheses List – Part A’ of the Schedule.

Human rights implications

This instrument engages article 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the right to health.

Right to Health

The right to health – the right to the enjoyment of the highest attainable standard of physical and mental health – is contained in article 12(1) of the ICESCR. Whilst the UN Committee on Economic Social and Cultural Rights has stated that the right to health is not to be understood as a right to be healthy, it does entail a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health. In addition, the right to health must meet certain key requirements, including that health care must be scientifically and medically appropriate and of good quality.

Analysis

The removal of 12 prostheses reflects that they are no longer included in the Australian Register of Therapeutic Goods (ARTG) and cannot be lawfully supplied in Australia. This impacts positively on the right to health of insured persons by preventing them from being exposed to prostheses that have not been adequately assessed for safety and performance.

Conclusion

The instrument is compatible with human rights because it enables advances in the protection of human rights, in particular the right to health.

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