EXPLANATORY STATEMENT

Private Health Insurance Act 2007

Private Health Insurance (Medical Devices and Human Tissue Products) Amendment (No. 3) Rules 2024

Purpose

The purpose of the *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment (No. 3) Rules 2024* (MDHTP Amendment No. 3 Rules) is to repeal and substitute the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2024* (MDHTP Rules No. 2) by:

- adding 13 new listed items (billing codes) to Part A and Part D of the Prescribed List as a result of listing medical devices following successful new applications;
- correcting the listing details of 1 billing code in Part A and 2 billing codes in Part C of the Prescribed List.

Listed items and their minimum benefits are set out in Schedule 1 to the MDHTP Rules. Schedule 1 to the MDHTP Rules is known as the Prescribed List of medical devices and human tissue products (Prescribed List).

The Prescribed List has four parts:

- Part 1 - Part A – Medical Devices
- Part 2 - Part B – Human Tissue Products
- Part 3 - Part C – Other Medical Devices
- Part 4 - Part D – General Use Items (medical devices)

Background

The table in subsection 72-1(2) of Part 3-3 of the Act (Table) provides for benefit requirements a complying health insurance policy that covers hospital treatment must meet. Under item 4 of the Table, there must be a benefit for the provision of a medical device or human tissue product, of a kind listed in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules, in specified circumstances and under any specified conditions. The specified circumstances are that the listed item 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 (Medical Devices and Human Tissue Products) Rules. The specified conditions are any that may be set out in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules.

If the complying health insurance policy also covers hospital-substitute treatment then under item 4 of the Table, the same requirements apply.

Subsection 72-10(2) of the Act provides that a person may apply to the Minister to have the Private Health Insurance (Medical Devices and Human Tissue Products) Rules list a medical device or human tissue product of the kind to which the application relates to (listed item). The applicant for these applications is known as the 'applicant' and for a listed item, the 'sponsor' is the person who made the listing application as a result of which the device or product was listed.

The MDHTP Amendment No. 3 Rules will repeal and substitute Schedule 1 of the MDHTP Rules.

Authority

Item 4 of the table in section 333-20 of the Act provides that the Minister may make MDHTP Rules providing for matters required or permitted by Part 3-3 of the *Private Health Insurance Act 2007* (the Act), or necessary or convenient in order to carry out or give effect to Part 3-3 of the Act.

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

If the complying health insurance policy also covers hospital-substitute treatment then under item 4 of the Table, the same requirements apply.

Subsection 72-10(5) of the Act also provides that the Minister may vary the MDHTP Rules to list medical devices and human tissue products and set out the minimum benefit and if appropriate, the maximum benefit, for the listed product if the Minister grants the application and the applicant pays the cost-recovery fee in connection to the application.

Reliance on subsection 33(3) of the *Acts Interpretation Act 1901*

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.

Commencement

The MDHTP Amendment No. 3 Rules commence on 1 November 2024.

Consultation

In making the MDHTP Amendment No. 3 Rules, the rule-maker had regard to feedback from stakeholders, including medical devices sponsors.

General

The MDHTP Amendment No. 3 Rules are a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the MDHTP Amendment No. 3 Rules are set out in **Attachment A.**

This instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

ATTACHMENT A

Details of the *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment (No. 3) Rules 2024*

Section 1 Name

Section 1 provides that the name of the instrument is the *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment (No. 3) Rules 2024.*

Section 2 Commencement

Section 2 provides that the instrument commences on 1 November 2024.

Section 3 Authority

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

Section 4 Schedules

Section 4 provides that the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2024* is amended as set out in Schedule 1.

Schedule 1 – Amendments

Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2024

Item 1 Schedule 1

Item 1 repeals and substitutes Schedule 1 of the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2024* with an updated Schedule 1.

ATTACHMENT B

Statement of Compatibility with Human Rights

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

Private Health Insurance (Medical Devices and Human Tissue Products) Amendment (No. 3) Rules 2024

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 Disallowable Legislative Instrument

The table in subsection 72-1(2) of Part 3-3 of the *Private Health Insurance Act 2007* (Table) provides for benefit requirements a complying health insurance policy that covers hospital treatment must meet. Under item 4 of the Table, there must be a benefit for the provision of a medical device or human tissue product, of a kind listed in the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules* (MDHTP Rules), in specified circumstances and under any specified conditions. The specified circumstances are that the listed item is provided in circumstances in which a medicare benefit is payable or in other circumstances which may be set out in the MDHTP Rules. The specified conditions are any that may be set out in the MDHTP Rules.

Subsection 72-10(5) of the *Private Health Insurance Act 2007* also provides that the Minister may vary the Private Health Insurance (Medical Devices and Human Tissue Products) Rules to list medical devices and human tissue products and set out the minimum benefit and if appropriate, the maximum benefit, for the listed product if the Minister grants the application and the applicant pays the cost-recovery fee in connection to the application.

The purpose of the *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment (No. 3) Rules 2024* (MDHTP Amendment No. 3 Rules) is to repeal and substitute the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2024* by:

- adding 13 new listed items (billing codes) to Part A and Part D of the Prescribed List as a result of listing medical devices following successful new applications;
- correcting the listing details of 1 billing code in Part A and 2 billing codes in Part C of the Prescribed List.

Listed items and their minimum benefits are set out in Schedule 1 to the MDHTP Rules. Schedule 1 to the MDHTP Rules is known as the Prescribed List of medical devices and human tissue products (Prescribed List).

The numbers of Prescribed List billing codes were taken from reports produced by the Health Products Portal (**HPP**) when the list was run.

When billing codes are transferred from one sponsor to a different sponsor, or billing codes are compressed or expanded following the respective application, the codes that they are transferred, or expanded, or compressed from are deleted.

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 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 repeal and substitution of Schedule 1 to the Private Health Insurance (Medical Devices and Human Tissue Products) Rules ensures that all benefits are accurately listed on the Prescribed List, which ensures that privately insured patients are reimbursed appropriately for the medical devices they receive.

Conclusion

The Disallowable Legislative Instrument is compatible with human rights because it promotes the protection of human rights, in particular the right to health.

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