EXPLANATORY STATEMENT

Private Health Insurance Act 2007

Private Health Insurance (Medical Devices and Human Tissue Products) Amendment (No. 1) Rules 2024

Purpose

The purpose of the *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment (No. 1) Rules 2024* (MDHTP Amendment Rules) is to replace Schedule 1 to the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2024* (MDHTP Rules) with a new Schedule. The MDHTP Rules set out the minimum benefit payable for each listed item.

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)

The MDHTP Amendment Rules differ to the MDHTP Rules by:

- adding 12 new listed items (billing codes) to Part A of the Prescribed List as a result of listing medical devices following successful new applications, and two (2) new billing codes due to transfer of billing codes from one sponsor to another;
- changing the listing details of one (1) billing code in Part A of the Prescribed List following successful amendment application;
- changing the listing details of 127 billing codes in Part A of the Prescribed List rectifying the errors and omissions identified in the MDHTP Rules;
- deleting 12 billing codes from Part A of the Prescribed List as a result of accepting 10 deletion applications submitted by the sponsors (including those relating to spinal cord stimulator (SCS) system devices) and removing two (2) billing codes after transferring billing codes to the new sponsors;
- adding four (4) new billing codes to Part B of the Prescribed List as a result of listing human tissue products following successful new applications;
- changing the listing details of one (1) billing code in Part B of the Prescribed List rectifying the errors and omissions identified in the MDHTP Rules.
- changing the listing details of one (1) billing code in Part C of the Prescribed List following successful amendment application; and
- changing the listing details of one (1) billing code in Part D of the Prescribed List rectifying the errors and omissions identified in the MDHTP Rules.

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.

After the MDHTP Rules had been made, stakeholders advised, and the department became aware of, errors (including omitted applications and incorrectly listed billing codes) in the Schedule of the MDHTP Rules. The MDHTP Amendment Rules are made to rectify these errors.

Authority

Item 4 of the table in section 333-20 of the Act provides that the Minister may make Private Health Insurance (Medical Devices and Human Tissue Products) 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 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(5) of the Act 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.

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 Rules commence on 8 August 2024.

Consultation

In making the MDHTP Amendment Rules, the rule-maker had regard to feedback from stakeholders, including hospitals, private health insurers and medical devices sponsors. The department also met with the key industry representative bodies to discuss the accuracy of the 1 July 2024 Prescribed List and sought feedback to ensure all issues required to be rectified have been identified.

General

The MDHTP Amendment Rules are a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the MDHTP Amendment 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. 1) 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. 1) Rules 2024.*

Section 2 Commencement

Section 2 provides that the instrument commences on 8 August 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. 1) 2024* is amended as set out in Schedule 1.

Schedule 1 – Amendments

Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2024

Item 1 Schedule 1
Item 1 repeals Schedule 1 of the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2024* and substitutes that repealed Schedule 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. 1) 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, 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.

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. 1) Rules 2024* (MDHTP Amendment Rules) is to amend the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2024* (MDHTP Rules) to replace Schedule 1 with an updated Schedule 1.

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 MDHTP Amendment Rules differ to the MDHTP Rules by:

- adding 12 new listed items (billing codes) to Part A of the Prescribed List as a result of listing medical devices following successful new applications, and two (2) new billing codes due to transfer of billing codes from one sponsor to another;
- changing the listing details of one (1) billing code in Part A of the Prescribed List following successful amendment application;
- changing the listing details of 127 billing codes in Part A of the Prescribed List rectifying the errors and omissions identified in the MDHTP Rules;
- deleting 12 billing codes from Part A of the Prescribed List as a result of accepting 10 deletion applications submitted by the sponsors (including those relating to spinal cord stimulator (SCS) system devices) and removing two (2) billing codes after transferring billing codes to the new sponsors;
- adding four (4) new billing codes to Part B of Schedule 1 as a result of listing human tissue products following successful new applications;
- changing the listing details of one (1) billing code in Part B of the Prescribed List rectifying the errors and omissions identified in the MDHTP Rules;

- changing the listing details of one (1) billing code in Part C of the Prescribed List following successful amendment application; and
- changing the listing details of one (1) billing code in Part D of the Prescribed List rectifying the errors and omissions identified in the MDHTP Rules.

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 addition of new items in the Prescribed List will increase the amount of choice an insured person can have in relation to the kind of medical device or human tissue product for which they must receive a minimum private health insurance benefit. This will impact positively on the right to health of insured persons.

The correction to the 129 billing codes certifies that benefits are accurately listed on the Prescribed List, which ensures that privately insured patients are reimbursed appropriately for the medical devices they receive. The deletion of the nine (9) spinal cord stimulation system devices which have been removed by the Therapeutic Goods Administration from the Australian Register of Therapeutic Goods ensures that medical devices that are listed on the Prescribed List continue to be relevant and safe for privately insured patients. This will impact positively on the right to health of insured persons.

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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