EXPLANATORY STATEMENT

Private Health Insurance Act 2007

Private Health Insurance (Medical Devices and Human Tissue Products) Amendment Rules (No. 1) 2023

Purpose

The purpose of the *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment Rules (No. 1) 2023* (MDHTP Amendment Rules) is to amend the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2023* (MDHTP Rules), made under section 333-20 of the *Private Health Insurance Act 2007* (Act). The MDHTP Amendment Rules amend the associated fees for assessments required for listing and variation applications to list or vary an item on the Prescribed List of Medical Devices and Human Tissue Products and the time for when associated cost-recovery fees become due and payable, to correct inadvertent errors and decrease certain fees to align with those advised to industry in the relevant Cost Recovery Implementation Statement (CRIS).

Background

From 1 July 2023, the *Private Health Insurance (Prostheses) Rules (No. 1) 2023* (Prostheses Rules) were replaced by the MDHTP Rules.

The MDHTP Rules list the kinds of medical devices and human tissue products for which a private health insurance benefit must be paid, where the listed item is provided in the conditions and circumstances specified in the Act. The MDHTP Rules set out the minimum benefit payable for each listed item.

The MDHTP Rules also outline circumstances in which various assessments in relation to listing and variation applications are required and the associated fee for that assessment. Cost-recovery fees include a standard application fee and additional fees where clinical assessment, economic assessment or full health technology assessment is required. The MDHTP Rules also include cost-recovery provisions, which include the timing for when cost-recovery fees become due and payable, and when cost-recovery fees can be refunded and waivers can be granted.

The MDHTP Amendment Rules are required to correct an error and make an update to the prescribed fees associated with clinical assessment, economic assessment and full heath technology assessment. This will result in a decrease in fee amounts and will align the prescribed fees with the relevant CRIS. Additionally, the MDHTP Amendment Rules will amend the payment terms associated with these fees to state that fees must be charged within 28 calendar days. This will ensure the MDHTP Rules align with advice provided to industry.

Authority

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 Act, or necessary or convenient in order to carry out or give effect to Part 3-3 of the Act.

Section 72-15 of the Act provides for the MDHTP Rules to specify cost-recovery fees for activities carried out by, or on behalf of, the Commonwealth in connection with the performance of functions, or the exercise of powers, conferred by or under the Act in relation to the listing of kinds of medical devices and human tissue products in the MDHTP Rules.

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

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.

Commencement

The MDHTP Amendment Rules commence on 1 September 2023.

Consultation

The MDHTP Rules were made following consultation with the sponsors of the medical devices and human tissue products affected by the replacement of the Prostheses Rules with the MDHTP Rules. The Department engaged in significant stakeholder consultation with representatives of the medical device industry between July 2021 and May 2023 in relation to cost-recovery fees through the use of consultation papers and webinars. The outcomes of this engagement were utilised to develop the cost-recovery provisions in the CRIS, which advises industry of the changes to the cost-recovery arrangements for the 2023-24 financial year.

Consultation on the MDHTP Rules Exposure Draft identified the need for a correction to decrease the cost recovery fee amount per clinical assessment, simple economic assessment, complex economic assessment, other economic assessment, or a full health technology assessment. The amended fee amount is consistent with the fee amount industry representatives have been advised through consultation on the MDHTP Rules and the relevant CRIS. The MDHTP Amendment Rules also amend the payment term for clinical assessment, economic assessment, and full health technology assessment fees from 28 business days to 28 calendar days, which aligns with advice provided to industry.

As the MDHTP Amendment Rules align with the intended policy outcomes communicated to industry representatives throughout consultation of the MDHTP Rules, no further consultation was made in relation to the MDHTP Amendment Rules.

Impact Analysis

A Regulation Impact Statement was undertaken for the MDHTP Rules which covers measures including the listing criteria (OBPR ID 43619).

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.**

The MDHTP Amendment Rules are 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**.

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ATTACHMENT A

Details of the *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment Rules (No. 1) 2023*

Section 1 Name

Section 1 provides that the name of the instrument is the *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment Rules (No. 1) 2023* (MDHTP Amendment Rules).

Section 2 Commencement

Section 2 provides that the MDHTP Amendment Rules commence on 1 September 2023.

Section 3 Authority

Section 3 provides that the MDHTP Amendment Rules are 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) 2023* are amended as set out in Schedule 1.

Schedule 1 – Amendments

Item 1 – Subsection 17(2)

Section 17 of the MDHTP Rules provides the circumstances in which a clinical assessment is required in respect of a listing or variation application relating to a medical device, and the related cost-recovery fee amount. Item 1 amends subsection 17(2) of the MDHTP Rules to decrease the cost-recovery fee amount for clinical assessment fee from "$5,460" to "$4,090".

Item 2 – Subsection 18(2)

Section 18 of the MDHTP Rules provides the circumstances in which an economic assessment is required in respect of a listing or variation application relating to a medical device, and the related cost-recovery fee amounts depending on whether the fee is considered a 'simple fee', 'complex fee' or 'other fee'. Item 2 amends subsection 18(2) of the MDHTP Rules to decrease the following cost-recovery fees:

- 'simple' economic assessment fee – decreased from "$14, 400" to "$8,940";
- 'complex' economic assessment fee – decreased from "$22,540" to "$17,080";
- 'other' economic assessment fee – decreased from "$33,400" to "$27,940".

Item 3 – Subsection 19(3)

Section 19 of the MDHTP Rules provides the circumstances in which a full health technology assessment is required in respect of a listing or variation application relating to a medical device, and the related cost-recovery fee amount. Item 3 amends subsection 19(3) of the MDHTP Rules to decrease the cost-recovery fee amount for full health technology assessment fee from "$4,670" to "$3,300".

Item 4 – Subsection 20(4)

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Section 20 of the MDHTP Rules specifies when cost-recovery fees become due and payable. Item 4 amends subsection 20(4) to provide that a clinical assessment fee, economic assessment fee, or full health technology pathway fee are due and payable within 28 calendar days, rather than current 28 business days, from the day a demand for payment is made. This amendment ensures payment term aligns with advice to industry.

The commencement date for making applications under the MDHTP Rules is 11 September 2023. No demands for payment of a clinical assessment, economic assessment or full health technology assessment pathway fee will yet have been made when this amendment takes effect on 1 September 2023.

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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 Rules (No. 1) 2023

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 *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment Rules (No. 1) 2023* (MDHTP Amendment Rules) are made under section 333-20 of the *Private Health Insurance Act 2007* (Act). 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 Act, or necessary or convenient in order to carry out or give effect to Part 3-3 of the Act. The current version of these rules are the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2023* (MDHTP Rules). Part 3-3 of the Act deals with requirements for complying private health insurance policies and, relevantly, includes requirements for insurers to pay private health insurance benefits for the provision of a medical device or human tissue product listed in the MDHTP Rules, the item is provided in the circumstances specified in the Act. Section 72-15 of the Act enables the MDHTP Rules to specify cost-recovery fees for activities carried out by, or on behalf of, the Commonwealth in connection with the performance of functions, or the exercise of powers, conferred by or under the Act in relation to the listing of kinds of medical devices and human tissue products in the MDHTP Rules.

The MDHTP Amendment Rules amend the MDHTP Rules to decrease the associated fee for clinical, economic and full health technology assessments required for listing and variation applications. The MDHTP Amendment Rules also amend the MDHTP Rules to provide that the associated cost-recovery fees become due and payable 28 calendar days after a demand for payment is made, rather than 28 business days.

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 amendments to decrease associated fees for clinical, economic or full health technology assessments required for listing and variation applications and the time for when associated cost-recovery fees become due and payable corrects a drafting error in the MDHTP Rules. The

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amendments ensure the costs of assessing applications are recovered accurately, timely and aligns with advice provided to industry through consultation and the relevant CRIS.

The amendments also ensure the process to assess and list medical device or human tissue product is financially sustainable and contributes towards accessibility of devices and products by privately insured persons in Australia.

In relation to the amendments to the time for paying cost-recovery fees from 28 business days after a demand for payment is made to 28 calendar days, the commencement date for making applications under the MDHTP Rules is 11 September 2023. No demands for payment of a clinical assessment, economic assessment or full health technology assessment pathway fee will yet have been made when the amendments take effect on 1 September 2023.

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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