EXPLANATORY STATEMENT

Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007

Private Health Insurance (Medical Devices and Human Tissue Products Levy) Amendment (2025 Measures No. 1) Regulations 2025

Purpose and operation

The *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Amendment (2025 Measures No. 1) Regulations 2025* (Amendment Regulations) amend the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Regulations 2025* (Regulations) to specify the amount of the levy payable for each listed item on the Prescribed List of Medical Devices and Human Tissue Products (Prescribed List) (formerly the Prostheses List) for the financial year commencing 1 July 2025.

Background

The Prescribed List specifies medical devices and human tissue products for which private health insurers must pay a benefit, where the listed item is provided in the conditions and circumstances specified in the *Private Health Insurance Act 2007*. The Prescribed List, set out in Schedule 1 of the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules* (MDHTP Rules), helps ensure privately insured patients have access to safe and clinically effective medical devices.

In the 2021-22 Budget, the Government announced the *Modernising and Improving the Private Health Insurance Prostheses List* measure, which included changes to the cost recovery arrangements. The Amendment Regulations support the implementation of this Budget measure.

The Department of Health, Disability and Ageing provides a range of listing and management services for the Prescribed List that have been cost recovered since 2007. The levy supports the work for these services, which includes list management, general administration and information technology system costs. These activities are not attributable to a specific sponsor.

Under the Australian Government Charging Framework, these types of costs will be recovered as an annual levy charge in accordance with the medical devices and human tissue products listed on the Prescribed List.

Authority

Section 7 of the Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed by the regulations, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Section 4 of the Act provides for a levy to be charged for the ongoing listing of each listed item on the Prescribed List.

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 Instrument commences on the day after it is registered on the Federal Register of Legislation.

Consultation

Public consultation on the Prescribed List Cost Recovery Implementation Statement, which included advice that the Regulations would be amended, occurred between 16 May and 6 June 2025. Stakeholders were generally accepting of the legislative changes.

General

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

Details of the Instrument are set out in **Attachment A**.

The 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 Levy) Amendment (2025 Measures No. 1) Regulations 2025*

Section 1 - Name

This section provides that the title of the Amendment Regulations is the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Amendment (2025 Measures No. 1) Regulations 2025.*

Section 2 - Commencement

This section provides for the Amendment Regulations to commence the day after this instrument is registered on the Federal Register of Legislation.

Section 3 - Authority

This section provides that the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Amendment (2025 Measures No. 1) Regulations 2025* is made under the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007*.

Section 4 – Schedules

This section provides that each instrument specified in the Schedule is amended or repealed as set out in the applicable items in the Schedule and that any other item in the Schedule has effect according to its terms.

Schedule 1 – Amendments

Item [1] – Section 5

This section substitutes "1 July 2024 is $150" with "1 July 2025 is $355."

This provides that the levy amount for the financial year starting 1 July 2025 is $355.

The levy recovers costs for activities including list management services, general administration, compliance functions, post listing reviews and IT system costs.

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 Levy) Amendment (2025 Measures No. 1) Regulations 2025

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 *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Amendment (2025 Measures No. 1) Regulations 2025* (Amendment Regulations) amend the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Regulations 2025* (Regulations) to specify the amount of the levy payable for each listed item on the Prescribed List of Medical Devices and Human Tissue Products (Prescribed List) (formerly the Prostheses List) for the financial year commencing 1 July 2025.

Human rights implications

This Instrument engages Article 12(1) of the *International Covenant on Economic Social and Cultural Rights* (ICESCR) by assisting with the progressive realisation by all appropriate means of the right to the enjoyment of the highest attainable standard of physical and mental health.

Medical Devices and Human Tissue Products levy

The Medical Devices and Human Tissue Products levy facilitates the ongoing management and general administration of the Prescribed List. The purpose of the Prescribed List is to support privately insured patients to access safe, clinically effective and cost-effective medical devices.

Right to Health

This supports the right to the enjoyment of the highest attainable standard of physical and mental health 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.

Conclusion

The Instrument is compatible with human rights as it further promotes the realisation of relevant rights under Article 12 of the ICESCR, in particular the right to health.

The Hon Mark Butler MP

The Minister for Health and Ageing