

## EXPLANATORY STATEMENT

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

#### *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Regulations 2025*

#### **Purpose and operation**

The *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Regulations 2025* (Regulations) prescribe the levy amount that is charged for each listed item on the Prescribed List of Medical Devices and Human Tissue Products (Prescribed List) to recover the cost of the ongoing management and general administration of the Prescribed List in a financial year.

The Regulations also specify that human tissue products listed on the Prescribed List will be exempt from the levy charge. Human tissue products are defined in section 72-12 of the *Private Health Insurance Act 2007* (PHI Act). A human tissue product is a thing that comprises, contains or is derived from human cells or human tissues. Part B of the Prescribed List include listings of human tissue products.

#### **Background**

The Prescribed List details medical devices and human tissue products for which private health insurers must pay benefits, if they have been used for, or implanted into, patients with an appropriate private health insurance policy. The Prescribed List is a Schedule to the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules* that supports privately insured patients to access safe, clinically effective and cost-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 Regulations support the implementation of this Budget measure.

The Department of Health and Aged Care 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 listed on the Prescribed List.

## Authority

Section 7 of the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007* (the Act) provides that the Governor General may make regulations prescribing matters required or permitted by the Act to be prescribed by the Regulations.

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

Between September 2022 and May 2023, medical device and human tissue product industry stakeholders including the Medical Technology Association of Australia, Australian Private Hospitals Association, Private Health Care Australia and private health insurers were consulted through public consultation processes on Prescribed List cost recovery arrangements. Based on stakeholder feedback, the costs for list management will be recovered through a levy, instead of application fees.

Public consultation also occurred throughout May 2024 on an indicative levy amount and legislative changes via a draft Cost Recovery Implementation Statement.

A summary of consultation feedback and departmental responses is included in the final 2024-25 CRIS published on the Department's website.

## 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**.

**Details of the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Regulations 2025***

Section 1 - Name of Regulations

This section provides that the title of the Regulations is the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Regulations 2025* (the Regulations).

Section 2 - Commencement

This section provides that the Regulations commence the day after this instrument is registered.

Section 3 - Authority

This section provides that the Regulations are made under the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007* (the Act).

Section 4 – Definitions

This section provides the definition of the Act for the purposes of the Regulations.

This section notes that human tissue product is defined in the Act.

Section 5 – Levy amount charged for ongoing listing of listed items

This section provides that the amount of the levy for the financial year starting on 1 July 2024 is \$150.

Section 6 – Exemptions from levy

This section provides that for the purposes of subsection 5(5) of the Act, human tissue products will be exempt from the levy.

## 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) 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) Regulations 2025* (the Regulations) give effect to matters in the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007*. This includes matters relating to the amount of the levy payable for each listed item on the Prescribed List of Medical Devices and Human Tissue Products (Prescribed List) and the circumstances for which listed items are exempt from the levy.

The purpose of the Regulations is to specify the amount of the levy charged for each listed item on the Prescribed List for a financial year, and to outline the circumstances for which listed items would be exempt from the levy.

### **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 Aged Care**