EXPLANATORY STATEMENT

Issued by the authority of the Minister for Health and Aged Care

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

Private Health Insurance (Medical Devices and Human Tissue Products Levy) Rules 2025

Purpose

The purpose of the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Rules 2025* (Rules) is to prescribe the levy imposition day for the medical devices and human tissue products (MDHTP) levy. The MDHTP levy is charged for each listed item on the Prescribed List of Medical Devices and Human Tissue Products (Prescribed List). This levy charge is to recover the cost of the ongoing management and general administration of the Prescribed List in a financial year beginning on 1 July 2024.

The Rules specify that the MDHTP levy imposition day for the financial year beginning on 1 July 2024 will be 15 March 2025, and the levy imposition day for the financial year beginning on 1 July 2025 and for each subsequent financial year will be 15 September.

Background

The Prescribed List supports privately insured patients to access safe, clinically effective and cost-effective medical devices. 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* (the MDHTP Rules) made for the purposes of the table in subsection 72-1(2) of Part 3-3 of the *Private Health Insurance Act 2007*.

The Department of Health and Aged Care (Department) provides a range of listing and management services for the Prescribed List that have been cost recovered since 2007. In the 2021-22 Budget, the Australian Government announced the Modernising and Improving the Private Health Insurance Prostheses List measure, which included changes to the cost recovery arrangements for the Prescribed List (formerly known as the Prostheses List). The Rules support the implementation of this Budget measure.

The MDHTP levy supports list management, general administration and information technology system costs. These services are provided by the Department to a group of individuals or organisations and the cost of these services are not attributable to a specific individual or organisation. Under the Australian Government Charging Framework, these types of costs can be recovered as an annual levy charge.

Authority

The Rules are made under section 6 of the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007* (Act).

Section 6 of the Act provides that the Minister may, by legislative instrument, make Private Health Insurance (Medical Devices and Human Tissue Products Levy) Rules providing for matters required or permitted by the Act to be provided, or necessary or convenient to be provided to carry out or give effect to the Act.

Commencement

The Rules commence on the day after they are registered.

Consultation

Between September 2022 and May 2023, the Department consulted widely with medical device and human tissue product industry stakeholders on reforms to the Prescribed List cost recovery arrangements, including through public consultation papers, webinars and targeted consultations with the Medical Technology Association of Australia, Australian Private Hospitals Association, Private Health Care Australia and private health insurers. Based on stakeholder feedback, the costs for list management activities will be recovered through a levy rather than list management application fees. Feedback analysis reports for the various public consultation papers are published on the Department's website.

The Department also conducted public consultation in May 2024 on a draft 2024-25 Cost Recovery Implementation Statement (CRIS) for the administration of the Prescribed List of Medical Devices and Human Tissue Products that included an indicative levy amount, indicative levy imposition plan and legislative changes. A summary of consultation feedback and departmental responses are included in the final 2024-25 Prescribed List CRIS that is published on the Department's website.

General

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

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

The 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**.

ATTACHMENT A

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

Section 1 – Name

Section 1 provides that the name of the instrument is the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Rules 2025* (Rules).

Section 2 – Commencement

Section 2 provides that the Rules commence on the day after the instrument is registered on the Federal Register of Legislation.

Section 3 – Authority

Section 3 provides that the Rules are made under section 6 of the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007* (Act).

Section 4 – Definitions

Section 4 defines ***Act*** to mean the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007*.

Section 5 – Levy imposition days

Section 5 sets out the days that are a levy imposition day for the medical devices and human tissue product (MDHTP) levy for the purposes of subsection 4(2) of the Act.

Paragraph 5(1)(a) provides that, for the financial year beginning on 1 July 2024, the levy imposition day will be 15 March 2025.

Paragraph 5(1)(b) provides that for the financial year beginning on 1 July 2025 and for each subsequent financial year, the levy imposition day will be 15 September in that financial year.

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) Rules 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) Rules 2025* (Rules) set out the levy imposition day for the medical devices and human tissue products (MDHTP) levy.

The levy imposition day is the day on which the MDHTP levy amount is charged. The Rules provide that the following days are a levy imposition day:

- for the financial year beginning on 1 July 2024 – 15 March 2025;
- for the financial year beginning on 1 July 2025 and for each subsequent financial year - 15 September in that financial year.

The MDHTP levy will be charged for the management and general administration of Schedule 1 to the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (MDHTP Rules). Schedule 1 to the MDHTP Rules is also known as the Prescribed List.

Human rights implications

The Rules engage Article 12(1) 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.

The MDHTP 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 and human tissue products.

The MDHTP levy is payable by organisations mentioned for medical devices and human tissue products on Schedule 1 of the MDHTP Rules.

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.

Conclusion

The Rules are compatible with human rights because it 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