

EXPLANATORY STATEMENT

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

Private Health Insurance Act 2007

Private Health Insurance (Levy Administration) Amendment Rules 2025

Purpose

The purpose of the *Private Health Insurance (Levy Administration) Amendment Rules 2025* (Amendment Rules) is to amend the *Private Health Insurance (Levy Administration) Rules 2015* (Rules) to provide for matters relating to the medical devices and human tissue products (MDHTP) levy. The matters include who is responsible to pay the MDHTP levy and the time for payment of the levy.

The MDHTP levy will be charged for the management and general administration of the Prescribed List of Medical Devices and Human Tissue Products (Prescribed List). The Amendment Rules additionally amend the Rules to update information about the imposition day for the national joint replacement register levy.

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 made for the purposes of the table in subsection 72-1(2) of Part 3-3 of the *Private Health Insurance Act 2007* (Act).

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 Amendment 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 is 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 Amendment Rules are made under item 14 of the table in subsection 333-20(1) of the Act.

Subsection 333-20(1) of the Act enables the Minister to make, by legislative instrument, Private Health Insurance (Levy Administration) Rules providing for matters required or permitted by Part 6-6 of the Act to be provided, or necessary or convenient to be provided in order to carry out or give effect to Part 6-6 of the Act.

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 Amendment Rules commence on the day after they are registered on the Federal Register of Legislation.

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, an 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 Amendment Rules are a legislative instrument for the purposes of the *Legislation Act 2003*.

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

The 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**.

Details of the *Private Health Insurance (Levy Administration) Amendment Rules 2025*

Section 1 – Name

Section 1 provides that the name of the instrument is the *Private Health Insurance (Levy Administration) Amendment Rules 2025* (Amendment Rules).

Section 2 – Commencement

Section 2 provides that the Amendment Rules commence on the day after they are registered on the Federal Register of Legislation.

Section 3 – Authority

Section 3 provides that the Amendment Rules are made under item 14 of the table in subsection 333-20(1) of the *Private Health Insurance Act 2007* (Act).

Section 4 – Schedules

Section 4 provides that the Amendment Rules are an amendment to the *Private Health Insurance (Levy Administration) Rules 2015* (Rules).

Schedule 1 – Amendments

Item 1 – Section 5

Item 2 – Section 5 (note)

Items 1 and 2 amend section 5 of the Rules. Item 1 inserts new definitions into section 5:

- ***listed item***, defined to have the same meaning as in the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007* (MDHTP Levy Act). Section 3 of that Act defines ***listed item*** to mean a kind of medical device or human tissue product that is listed in Private Health Insurance (Medical Devices and Human Tissue Products) Rules;
- ***medical devices and human tissue products levy imposition day***, defined to mean a levy imposition day specified for the purposes of subsection 6(2) of the MDHTP Levy Act in the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Rules 2025*;
- ***Private Health Insurance (Medical Devices and Human Tissue Products) Rules***, defined to mean the rules referred to in item 4 of the table in subsection 333-20(1) of the Act.

Item 2 repeals and substitutes the note to section 5. The new note provides that where an expression that is used in the Rules is defined for the purposes of the Act, it has the same meaning in the Rules as it has in the Act. The note informs readers that

expressions used in the Rules that are defined in the Act include complaints levy, late payment penalty, and medical devices and human tissue products levy.

Item 3 - Section 9 (note)

Item 3 repeals and substitutes the note to section 9 of the Rules.

Section 9 of the Rules defines the payment day for national joint replacement register (NJRR) levy. The note informs readers about the NJRR levy imposition day.

The previous note provided that the imposition day was 31 October in each financial year. This is no longer the NJRR levy imposition day. The new note informs readers that the *Private Health Insurance (National Joint Replacement Register Levy) Rule 2015* specifies the NJRR levy imposition day. This is currently specified to be 30 November in each financial year.

Item 4 – After section 9

Item 4 inserts new section 10 into the Rules.

New section 10 sets out who is liable to pay the MDHTP levy and the payment day for the MDHTP levy.

Subsection 10(1) provides that, for the purposes of subsection 307-30(2) of the Act, the MDHTP levy imposed for a financial year in relation to a listed item is payable by the person mentioned for the listed item in Schedule 1 to the Private Health Insurance (Medical Devices and Human Tissue Products) Rules in force on the MDHTP levy imposition day in respect of that financial year.

The person that is mentioned above the billing code, product name and description of a listed item in Schedule 1 to the Private Health Insurance (Medical Devices and Human Tissue Products) Rules in force on the MDHTP levy imposition day will be liable to pay the MDHTP levy for that financial year in relation to the listed item.

Subsection 10(2) provides that, for the purposes of paragraph 307-1(1)(b) of the Act, the payment day for the MDHTP levy imposed on a MDHTP levy imposition day is 28 days from the imposition day.

A note at the end of subsection 10(2) informs readers that the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Rules 2025* specify the MDHTP levy imposition day.

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 (Levy Administration) Amendment 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 purpose of the *Private Health Insurance (Levy Administration) Amendment Rules 2025* (Amendment Rules) is to amend the *Private Health Insurance (Levy Administration) Rules 2015* (Rules) to set out the persons who are liable to pay the medical devices and human tissue products (MDHTP) levy, and the payment day for the MDHTP levy.

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 is also known as the Prescribed List. The MDHTP levy is intended to cover the costs of the ongoing management and general administration of the Prescribed List in a financial year.

The Amendment Rules provide that the MDHTP levy imposed for a financial year in relation to a listed item (i.e. a kind of medical device or human tissue product) will be payable by the person mentioned for the listed item in the Prescribed List in force on the relevant MDHTP levy imposition day. The payment day will be 28 days from the MDHTP levy imposition day.

The Amendment Rules additionally amend the Rules to provide updated information about the imposition day for the national joint replacement register levy.

Human rights implications

The Amendment Rules engage 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 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.

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

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 Amendment Rules are 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