

EXPLANATORY STATEMENT

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

Private Health Insurance Act 2007

Private Health Insurance (National Joint Replacement Register Levy) Act 2009

Private Health Insurance Legislation Amendment (Prostheses—Repeal and Consequential Amendments) Rules 2023

Purpose

From 1 July 2023, the *Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Act 2023* will make amendments to the *Private Health Insurance Act 2007* (PHI Act). This includes renaming the Private Health Insurance (Prostheses) Rules to the Private Health Insurance (Medical Devices and Human Tissue Products) Rules and changing the current terms ‘prostheses’ and ‘prosthesis’ to definitions of ‘medical device’ and ‘human tissue product’ that are aligned (where relevant) to the *Therapeutic Goods Act 1989*.

The purpose of the Private Health Insurance Legislation Amendment (Prostheses—Repeal and Consequential Amendments) Rules 2023 (the Amendment Rules) is to repeal the *Private Health Insurance (Prostheses) Rules (No. 1) 2023* as this instrument will be replaced by the renamed *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2023*. The Amendment Rules also make consequential amendments to the following Rules to incorporate changes that will be made to the PHI Act:

- *Private Health Insurance (Benefit Requirements) Rules 2011*;
- *Private Health Insurance (Complying Product) Rules 2015*; and
- *Private Health Insurance (National Joint Replacement Register Levy) Rule 2015*.

Authority

Subsection 333-20(1) of the PHI Act authorises the Minister to, by legislative instrument, make Private Health Insurance Rules providing for matters required or permitted by the corresponding Chapter, Part, section or Schedule to be provided or necessary or convenient to be provided in order to carry out or give effect to that Chapter, Part, section or Schedule.

Section 8 of the *Private Health Insurance (National Joint Replacement Register Levy) Act 2009* (the NJRR Levy Act) provides that the Minister may make Private Health Insurance (National Joint Replacement Register Levy) Rules providing for matters required or permitted by the NJRR Levy Act to be provided, or necessary or convenient to be provided, in order to carry out or give effect to the NJRR Levy Act.

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

In addition, 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 at the same time as the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2023* commence.

Consultation

Consultation was not necessary to undertake in relation to the Amendment Rules as the amendments are consequential in nature to incorporate changes that will be made to the PHI Act from 1 July 2023.

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 the **Attachment A**.

This 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 Legislation Amendment (Prostheses—Repeal and Consequential Amendments) Rules 2023*

Section 1 – Name

Section 1 provides that the name of the Amendment Rules is the *Private Health Insurance Legislation Amendment (Prostheses—Repeal and Consequential Amendments) Rules 2023*.

Section 2 – Commencement

Section 2 provides that the Amendment Rules commence at the same time as the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2023* commence.

Section 3 – Authority

Section 3 provides that the Amendment Rules are made under the *Private Health Insurance Act 2007* and the *Private Health Insurance (National Joint Replacement Register Levy) Act 2009*.

Section 4 – Schedules

Section 4 provides that each instrument that is specified in a Schedule to the Amendment Rules is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the instrument has effect according to its terms.

Schedule 1 – Repeals

Private Health Insurance (Prostheses) Rules (No. 1) 2023

Item 1 – The whole of the instrument

Item 1 repeals the *Private Health Insurance (Prostheses) Rules (No. 1) 2023*. This is a consequential change as this instrument will be replaced with the renamed *Private Health Insurance (Medical Devices and Human Tissue Products) Rules 2023* from 1 July 2023.

Schedule 2 – Consequential Amendments

Private Health Insurance (Benefit Requirements) Rules 2011

Item 1 – Subparagraph 3(7)(b)(i) and (ii) of Schedule 5

Item 1 amends subparagraphs 3(7)(b)(i) and (ii) of Schedule 5 of the *Private Health Insurance (Benefit Requirements) Rules 2011* to substitute ‘prostheses’ with ‘medical devices and human tissue products’.

This is a consequential amendment to reflect the new definitions of ‘medical device’ and ‘human tissue products’, which will apply from 1 July 2023.

Private Health Insurance (Complying Product) Rules 2015

Item 2 – Subrule 8(1) (table item 2, column headed “Kind of policy”, paragraph (a))

Item 2 repeals paragraph (a) in item 2 in the table with the column headed ‘Kind of policy’ under subrule 8(1) of the *Private Health Insurance (Complying Product) Rules 2015* (Complying Product Rules) and substitutes with a new paragraph.

The new paragraph references the new definitions of ‘medical device’ and ‘human tissue product’ instead of the term ‘prosthesis’, and replaces the reference to ‘Private Health Insurance (Prostheses) Rules’ with ‘Private Health Insurance (Medical Devices and Human Tissue Products) Rules’.

This is a consequential amendment to reflect the new definitions of ‘medical device’ and ‘human tissue product’ and to reflect the renamed Rules, which will apply from 1 July 2023.

Item 3 – Subrule 8(1) (table item 2, column headed “Kind of policy”, paragraph (b))

Item 3 amends paragraph (b) in item 2 in the table with the column headed ‘Kind of policy’ under subrule 8(1) of the Complying Product Rules to substitute the term ‘prosthesis’ wherever occurring with ‘medical device or human tissue product’.

This is a consequential amendment to reflect the new definitions of ‘medical device’ and ‘human tissue product’, which will apply from 1 July 2023.

Item 4 – Subrule 8(1) (table item 2, column headed “Treatments the policy must cover”)

Item 4 amends item 2 in the table with the column headed ‘Treatments the policy must cover’ under subrule 8(1) of the Complying Product Rules to substitute the term ‘prosthesis’ with ‘medical device or human tissue product’.

This is a consequential amendment to reflect the new definitions of ‘medical device’ and ‘human tissue product’, which will apply from 1 July 2023.

Item 5 – Subrule 8(1) (table item 3, column headed “Kind of policy”, paragraph (a))

Item 5 repeals paragraph (a) in item 3 in the table with the column headed ‘Kind of policy’ under subrule 8(1) of the Complying Product Rules and substitutes with a new paragraph that references the new definitions of ‘medical device’ and ‘human tissue product’ instead of the term ‘prosthesis’, and that references the ‘Private Health Insurance (Medical Devices and Human Tissue Products) Rules’ instead of the ‘Private Health Insurance (Prostheses) Rules’.

This is a consequential amendment to reflect the new definitions of ‘medical device’ and ‘human tissue product’ and to reflect the renamed Rules, which will apply from 1 July 2023.

Item 6 – Subrule 8(1) (table item 3, column headed “Kind of policy”, paragraph (b))

Item 6 amends paragraph (b) in item 3 in the table with the column headed ‘Kind of policy’ under subrule 8(1) of the Complying Product Rules to substitute the term ‘prosthesis’ with “‘medical device or human tissue product’”.

This is a consequential amendment to reflect the new definitions of ‘medical device’ and ‘human tissue product’, which will apply from 1 July 2023.

Item 7 – Subrule 8(1) (table item 3, column headed “Treatments the policy must cover”)

Item 7 amends item 3 in the table with the column headed ‘Treatments the policy must cover’ under subrule 8(1) of the Complying Product Rules to substitute the term ‘prosthesis’ with ‘medical device or human tissue product’.

This is a consequential amendment to reflect the new definitions of ‘medical device’ and ‘human tissue product’, which will apply from 1 July 2023.

Items 8 and 9 – Subrule 8(1) (note)

Items 8 and 9 amend the note under subrule 8(1) of the Complying Product Rules to reference the new definitions of ‘medical device’ and ‘human tissue product’ instead of the term ‘prostheses’, and to replace references to the ‘Private Health Insurance (Prostheses) Rules’ with the ‘Private Health Insurance (Medical Devices and Human Tissue Products) Rules’.

This is a consequential amendment to reflect the new definitions of ‘medical device’ and ‘human tissue product’ and to reflect the renamed Rules, which apply from 1 July 2023.

Item 10 – Clause 2 of Schedule 5 (table item dealing with implantation of hearing devices, column 2)

Item 10 amends column 2 of the table item dealing with implantation of hearing devices under Clause 2 of Schedule 5 of the Complying Product Rules to remove the word “‘prosthetic” in relation to a hearing device.

This change will provide that the scope of cover in relation to the implantation of hearing devices is hospital treatment to correct hearing loss, including implantation of a hearing device (as opposed to a prosthetic hearing device).

This is a consequential amendment to remove the reference to a prosthetic hearing device, as the term ‘prosthetic’ will no longer apply from 1 July 2023.

Item 11 – Clause 2 of Schedule 5 (table item dealing with joint replacements, column 2)

Item 11 amends column 2 of the table item dealing with joint replacements under Clause 2 of Schedule 5 of the Complying Product Rules to substitute the term ‘prostheses’ with ‘medical devices’ in relation to the removal of the prostheses.

This change provides that the scope of cover in relation to joint replacements is hospital treatment for surgery for joint replacements, including revisions, resurfacing,

partial replacements, and removal of medical devices (as opposed to removal of prostheses).

This is a consequential amendment to reflect the new definition of ‘medical device’ which will apply from 1 July 2023.

Item 12 – Clause 2 of Schedule 5 (table item dealing with podiatric surgery, column 2)

Item 12 amends column 2 of the table dealing with podiatric surgery under Clause 2 of Schedule 5 of the Complying Product Rules to reference the new definitions of ‘medical device’ and ‘human tissue product’ instead of the terms ‘prosthesis’ and ‘prostheses’, and to replace the references to the ‘Private Health Insurance (Prostheses) Rules’ with the ‘Private Health Insurance (Medical Devices and Human Tissue Products) Rules’.

This is a consequential amendment to reflect the new definitions of ‘medical device’ and ‘human tissue product’ and to reflect the renamed Rules, which will apply from 1 July 2023.

Private Health Insurance (National Joint Replacement Register Levy) Rule 2015

Item 13 – Section 4 (paragraph (a) of the note to heading)

Item 13 amends the note to the heading under section 4 of the *Private Health Insurance (National Joint Replacement Register Levy) Rule 2015* (the NJRR Levy Rule) to substitute ‘prosthesis’ with ‘device’.

This is a consequential amendment which will reference a ‘joint replacement device’ (as opposed to a ‘joint replacement prosthesis’), as the term ‘prosthesis’ will no longer apply from 1 July 2023.

Item 14 – Section 6 (heading)

Item 14 amends the heading under section 6 of the NJRR Levy Rule to substitute references of ‘prostheses’ with ‘medical devices’.

The new heading will be changed to ‘Rate of levy—hand articulation medical devices and foot articulation medical devices’. This is a consequential amendment which will reflect the new definition of ‘medical device’ which will apply from 1 July 2023.

Item 15 – Section 6

Item 15 amends section 6 of the NJRR Levy Rule to substitute ‘joint replacement prosthesis’ with ‘joint replacement device’.

This is a consequential amendment to reference the new term ‘device’ as opposed to the term ‘prosthesis’, which will apply from 1 July 2023.

Item 16 – Paragraphs 6(a) and (b)

Item 16 amends paragraphs 6(a) and (b) of the NJRR Levy Rule to substitute ‘prosthesis’ with ‘medical device’.

This is a consequential amendment to remove the term ‘prosthesis’, which will no longer apply from 1 July 2023, to reference a ‘hand articulation medical device’ and a ‘foot articulation medical device’ (as opposed to a ‘hand articulation prosthesis’ and a ‘foot articulation prosthesis’).

Item 17 – Section 7 (heading)

Item 17 amends the heading under section 7 of the NJRR Levy Rule to substitute ‘prostheses’ with ‘devices’. The new heading will be changed to ‘Rate of levy – other joint replacement devices’.

This is a consequential amendment which will reference ‘joint replacement devices’ (as opposed to a ‘joint replacement prostheses’), as the term ‘prostheses’ will no longer apply from 1 July 2023.

Item 18 – Subsection 7(1)

Item 18 amends subsection 7(1) of the NJRR Levy Rule to substitute the terms ‘prosthesis’ with ‘device’ or ‘medical device’.

This is a consequential amendment to remove the term ‘prosthesis’, which will no longer apply from 1 July 2023, to reference a ‘joint replacement device’ (as opposed to a ‘joint replacement prosthesis’) and to reference a ‘hand articulation medical device’ or a ‘foot articulation medical device’ (as opposed to a ‘hand articulation prosthesis’ or a ‘foot articulation prosthesis’).

Item 19 – Subsection 7(2)

Item 19 amends subsection 7(2) of the NJRR Levy Rule to substitute the term ‘the prosthesis’ wherever occurring with ‘the joint replacement device’.

This is a consequential amendment to reflect the new definition of a ‘device’ and remove reference to the term ‘prosthesis’, which will apply from 1 July 2023.

Item 20 – Subsection 7(2) (formula)

Item 20 repeals the formula under subsection 7(2) of the NJRR Levy Rule to replace with a formula that substitutes the term ‘prosthesis benefit amount’ with ‘device benefit amount’.

This is a consequential amendment to reflect the new definition of a ‘device’ and remove reference to the term ‘prosthesis’, which will apply from 1 July 2023. The formula in subsection 7(2) will not change – the only change is the term ‘prosthesis benefit amount’ will become a ‘device benefit amount’.

Items 21 and 22 – Subsection 7(3)

Items 21 and 22 amend subsection 7(3) of the NJRR Levy Rule to substitute the term ‘prosthesis’ with ‘joint replacement device’.

This is a consequential amendment to reflect the new definition of a ‘device’ and to remove reference to the term ‘prosthesis’, which will apply from 1 July 2023.

Item 23 – Subsection 7(3)

Item 23 amends subsection 7(3) of the NJRR Levy Rule to substitute the term ‘relevant prosthesis’ with ‘relevant joint replacement device’.

This is a consequential amendment to reflect the new definition of a ‘device’ and remove reference to the term ‘prosthesis’, which will apply from 1 July 2023.

Item 24 – Subsection 7(3) (formula)

Item 24 repeals the formula under subsection 7(3) of the NJRR Levy Rule to replace with a formula that substitutes the term ‘prosthesis benefit amount’ with ‘device benefit amount’.

This is a consequential amendment to reflect the new definition of a ‘device’ and remove reference to the term ‘prosthesis’, which will apply from 1 July 2023. The formula in subsection 7(3) will not change – the only change is the term ‘prosthesis benefit amount’ will become a ‘device benefit amount’.

Items 25, 26 and 27 – Subsection 7(3) (paragraph (b) and subparagraph (b)(i) of the definition of *adjusted total benefit amount*)

Items 25, 26 and 27 amend the definition of an ‘adjusted total benefit amount’ under subsection 7(3) of the NJRR Levy Rule by substituting:

- ‘prosthesis benefit’ with ‘device benefit’ to refer to a ‘device benefit amount’;
- ‘prosthesis’ with ‘joint replacement device’; and
- ‘relevant prosthesis’ with ‘relevant joint replacement device’.

These are consequential amendments to reflect the new term ‘device’, and to remove reference to the term ‘prosthesis’, which will apply from 1 July 2023. The definition of ‘prosthesis benefit amount’ will also be replaced with a definition of ‘device benefit amount’ (refer to items 30 and 31).

Item 28 – Subsection 7(3) (definition of *n*)

Item 28 amends the definition of ‘n’ under subsection 7(3) of the NJRR Levy Rule to substitute the term ‘prostheses’ with ‘joint replacement devices’.

This is a consequential amendment to reflect the new definition of a ‘device’ and remove reference to the term ‘prostheses’, which will apply from 1 July 2023.

Item 29 – Subsection 7(3) (paragraph (a) of the definition of *n*)

Item 29 amends the definition of ‘n’ under subsection 7(3) of the NJRR Levy Rule to substitute the term ‘relevant prosthesis’ with ‘relevant joint replacement device’.

This is a consequential amendment to reflect the new definition of a ‘device’ and remove reference to the term ‘prosthesis’, which will apply from 1 July 2023.

Item 30 – Subsection 7(4)

Item 30 inserts a new definition of a ‘device benefit amount’ under subsection 7(4) of the NJRR Levy Rule.

The meaning of the definition of a ‘device benefit amount’ is the same as the meaning of the definition of a ‘prosthesis benefit amount’, however the new definition of a ‘device benefit amount’ includes updated references to a ‘joint replacement device’ instead of a ‘prosthesis’ and refers to the updated ‘Private Health Insurance (Medical Devices and Human Tissue Products) Rules’ instead of the ‘Private Health Insurance (Prostheses) Rules’. These are consequential amendments, which will apply from 1 July 2023.

Item 31 – Subsection 7(4) (definition of *prosthesis benefit amount*)

Item 31 repeals the current definition of ‘prosthesis benefit amount’ under subsection 7(4) of the NJRR Levy Rule. This is a consequential amendment to replace the current definition with the definition of a ‘device benefit amount’ (refer to item 30).

Items 32, 33 and 34 – Subsection 7(4) (definition of *total benefit amount*)

Items 32, 33 and 34 amend the definition of a ‘total benefit amount’ under subsection 7(4) of the NJRR Levy Rule by substituting:

- ‘each prosthesis’ with ‘each device’ to refer to a ‘device benefit amount’;
- ‘prosthesis (other than a hand articulation prosthesis or a foot articulation prosthesis)’ with ‘device (other than a hand articulation medical device or a foot articulation medical device)’; and
- ‘the prosthesis’ with ‘the joint replacement device’.

These are consequential amendments to reflect the new term ‘device’ and to remove reference to the term ‘prosthesis’, which will apply from 1 July 2023. The definition of ‘prosthesis benefit amount’ will also be replaced with a definition of ‘device benefit amount’ (refer to items 30 and 31).

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Private Health Insurance Legislation Amendment (Prostheses—Repeal and Consequential Amendments) Rules 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 legislative instrument

From 1 July 2023, the *Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Act 2023* will make amendments to the *Private Health Insurance Act 2007* (PHI Act). The amendments include renaming the Private Health Insurance (Prostheses) Rules to the Private Health Insurance (Medical Devices and Human Tissue Products) Rules and changing the current terms ‘prostheses’ and ‘prosthesis’ to definitions of ‘medical device’ and ‘human tissue product’, that are aligned (where relevant) to the *Therapeutic Goods Act 1989*.

The purpose of the Private Health Insurance Legislation Amendment (Prostheses—Repeal and Consequential Amendments) Rules 2023 (the Amendment Rules) is to repeal the *Private Health Insurance (Prostheses) Rules (No. 1) 2023* as this instrument will be replaced by the renamed *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2023*. The Amendment Rules also make consequential amendments to the following Rules to incorporate changes that will be made to the PHI Act:

- *Private Health Insurance (Benefit Requirements) Rules 2011*;
- *Private Health Insurance (Complying Product) Rules 2015*; and
- *Private Health Insurance (National Joint Replacement Register Levy) Rule 2015*.

Human Rights implications

This instrument does not engage any of the applicable rights or freedoms as the instrument only makes the following consequential amendments which will apply from 1 July 2023:

- update references to reflect the renamed legislative instrument; and
- update the terms ‘prostheses’ and ‘prosthesis’ to reference the definitions of ‘medical device’ and ‘human tissue product’ where appropriate.

Conclusion

This instrument is compatible with human rights as it does not raise any human rights issues.

Hon Mark Butler MP
Minister for Health and Aged Care