



Private Health Insurance (Medical Devices and Human Tissue Products) Amendment Rules (No. 2) 2023

I, Andrew Rintoul, as delegate of the Minister for Health and Aged Care, make the following rules.

Dated 10 November 2023

Andrew Rintoul
Acting Assistant Secretary
Prostheses List Reform Taskforce
Technology Assessment and Access Division
Health Resourcing Group
Department of Health and Aged Care

Contents

1 Name.....	1
2 Commencement	1
3 Authority.....	1
4 Schedules	1
Schedule 1—Amendments	2

1 Name

This instrument is the *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment Rules (No. 2) 2023*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 2
Provisions	Commencement	Date/Details
The whole of this instrument	The day after this instrument is registered	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under item 4 of the table in section 333-20 of the *Private Health Insurance Act 2007*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023

1 Section 5 (definition of clinical assessment fee)

Omit “17(2)”, substitute “18(2)”.

2 Section 5 (definition of economic assessment fee)

Omit “18(2)”, substitute “19(2)”.

3 Section 5 (definition of full health technology assessment pathway fee)

Omit “19(3)”, substitute “20(3)”.

4 Section 5 (definition of reviewable decision)

Omit “24”, substitute “25”.

5 Section 5 (definition of sum of default minimum benefits)

Omit “9(7)”, substitute “10(7)”.

6 Subsection 17(2)

Repeal subsection, substitute:

(2) The fees are:

- (a) a standard application fee of \$1,370; and
- (b) if a clinical assessment is required (see section 18)—the clinical assessment fee; and
- (c) if an economic assessment is required (see section 19)—the economic assessment fee; and
- (d) if a full health technology assessment is required (see section 20)—the full health technology assessment pathway fee.

7 Subsection 18(1) (note 2)

Repeal note, substitute:

Note 2: Notice must be given of a decision that the Minister is satisfied as mentioned in paragraph (1)(b) of this section (see subsection 26(1)). Such a decision made by a delegate of the Minister is reviewable (see section 27).

8 Subsection 19(1) (note 2)

Repeal note, substitute:

Note 2: Notice must be given of a decision that the Minister is satisfied as mentioned in paragraph (1)(b) of this section (see subsection 26(1)). Such a decision made by a delegate of the Minister is reviewable (see section 27).

9 Subsection 19(4) (note)

Omit “4”, substitute “5”.

10 Subsection 20(1) (note)

Repeal note, substitute:

Note: Notice must be given of a decision that the Minister is satisfied as mentioned in paragraph (1)(b) of this section (see subsection 26(1)). Such a decision made by a delegate of the Minister is reviewable (see section 27).

11 Subsection 23(3) (example)

Omit “27”, substitute “28”.

12 Subsection 23(5) (note 1)

Repeal note, substitute:

Note 1: Notice must be given of a decision to refuse to agree to an application under this subsection for a refund (see subsection 26(1)). Such a decision made by a delegate of the Minister is reviewable (see section 27).

13 Subsection 23(5) (note 2)

Omit “4”, substitute “5”.

14 Subsection 23(5) (note 3)

Repeal note, substitute:

Note 3: Notice must be given of a decision to refuse to agree to a request under this subsection for a waiver (see subsection 26(1)). Such a decision made by a delegate of the Minister is reviewable (see section 27).

15 Section 28 (note)

Omit “22”, substitute “23”.

16 Schedule 1

Repeal the Schedule (including both headings), substitute: the updated Schedule 1 – Listed medical devices and human tissue products.