



# **Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Act 2023**

**No. 8, 2023**

**An Act to amend the law relating to private health  
insurance, and for related purposes**

Note: An electronic version of this Act is available on the Federal Register of Legislation  
(<https://www.legislation.gov.au/>)



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**An Act to amend the law relating to private health  
insurance, and for related purposes**

*[Assented to 16 March 2023]*

The Parliament of Australia enacts:

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*No. 8, 2023      Private Health Insurance Legislation Amendment (Medical Device and  
Human Tissue Product List and Cost Recovery) Act 2023      1*

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## 1 Short title

This Act is the *Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Act 2023*.

## 2 Commencement

- (1) Each provision of this Act 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.

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<b>Commencement information</b>		
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Provisions</b>	<b>Commencement</b>	<b>Date/Details</b>
1. The whole of this Act	1 July 2023.	1 July 2023

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Note: This table relates only to the provisions of this Act as originally enacted.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

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

## 3 Schedules

Legislation that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.

## **Schedule 1—Medical devices and human tissue products**

### **Part 1—Amendments**

#### *Private Health Insurance Act 2007*

##### **1 Section 50-5**

Omit “Private Health Insurance (Prostheses) Rules”, substitute “Private Health Insurance (Medical Devices and Human Tissue Products) Rules”.

##### **2 Subsection 72-1(2) (table item 4, column headed “There must be a benefit for ...”)**

Omit “a prosthesis, of a kind listed in the Private Health Insurance (Prostheses) Rules”, substitute “a \*medical device or \*human tissue product, of a kind listed in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules”.

##### **3 Subsection 72-1(2) (table item 4, column headed “There must be a benefit for ...”, paragraphs (c) and (d))**

Omit “prosthesis” (wherever occurring), substitute “medical device or human tissue product”.

##### **4 Subsection 72-1(2) (table item 4, column headed “The amount of the benefit must be ...”, paragraph (a))**

Omit “Private Health Insurance (Prostheses) Rules”, substitute “Private Health Insurance (Medical Devices and Human Tissue Products) Rules”.

##### **5 Subsection 72-1(2) (table item 4, column headed “The amount of the benefit must be ...”, paragraph (a))**

Omit “the prosthesis”, substitute “the medical device or human tissue product”.

**6 Subsection 72-1(2) (table item 4, column headed “The amount of the benefit must be ...”, paragraph (b))**

Omit “Private Health Insurance (Prostheses) Rules”, substitute “Private Health Insurance (Medical Devices and Human Tissue Products) Rules”.

**7 Subsection 72-1(2) (table item 4, column headed “The amount of the benefit must be ...”, paragraph (b))**

Omit “the prosthesis”, substitute “the medical device or human tissue product”.

**8 Section 72-10 (heading)**

Omit “prostheses”, substitute “medical devices and human tissue products”.

**9 Subsection 72-10(1)**

Omit “Private Health Insurance (Prostheses) Rules”, substitute “Private Health Insurance (Medical Devices and Human Tissue Products) Rules”.

**10 Subsection 72-10(1)**

Omit “a kind of prosthesis”, substitute “a kind of \*medical device or \*human tissue product”.

**11 Paragraph 72-10(1)(a)**

Omit “prosthesis”, substitute “medical device or human tissue product”.

**12 Subsection 72-10(2)**

Omit “Private Health Insurance (Prostheses) Rules list a prosthesis”, substitute “Private Health Insurance (Medical Devices and Human Tissue Products) Rules list a \*medical device or \*human tissue product”.

**13 Subsection 72-10(5)**

Omit “Private Health Insurance (Prostheses) Rules”, substitute “Private Health Insurance (Medical Devices and Human Tissue Products) Rules”.

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**14 Paragraph 72-10(5)(c)**

Omit “prosthesis”, substitute “\*medical device or \*human tissue product”.

**15 Paragraphs 72-10(5)(d) and (e)**

Omit “prosthesis”, substitute “medical device or human tissue product”.

**16 Subsection 72-10(6)**

Omit “Private Health Insurance (Prostheses) Rules”, substitute “Private Health Insurance (Medical Devices and Human Tissue Products) Rules”.

**17 After section 72-10**

Insert:

**72-11 Meaning of *medical device***

(1) A *medical device* is:

- (a) any instrument, apparatus, appliance, software, implant, reagent, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
  - (i) prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
  - (ii) monitoring, treatment, alleviation of or compensation for an injury or disability;
  - (iii) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;
  - (iv) control or support of conception;
  - (v) in vitro examination of a specimen derived from the human body for a specific medical purpose;and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

- (b) any instrument, apparatus, appliance, software, implant, reagent, material or other article specified in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules; or
  - (c) an \*accessory to an instrument, apparatus, appliance, software, implant, reagent, material or other article covered by paragraph (a) or (b).
- (2) For the purposes of paragraph (1)(a), the purpose for which an instrument, apparatus, appliance, software, implant, reagent, material or other article (the **main equipment**) is to be used is to be ascertained from the information supplied, by the person under whose name the main equipment is or is to be supplied, on or in any one or more of the following:
- (a) the labelling on the main equipment;
  - (b) the instructions for using the main equipment;
  - (c) any advertising material relating to the main equipment;
  - (d) any technical documentation describing the mechanism of action of the main equipment.
- (3) In relation to a \*medical device covered by paragraph (1)(a) or (b), an **accessory** is a thing that the manufacturer of the thing specifically intended to be used together with the device to enable or assist the device to be used as the manufacturer of the device intended.

## 72-12 Meaning of *human tissue product*

A **human tissue product** is a thing that:

- (a) either:
    - (i) comprises, contains or is derived from human cells or human tissues; or
    - (ii) is specified in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules for the purposes of this subparagraph; and
  - (b) is represented in any way to be, or is, whether because of the way in which it is presented or for any other reason, likely to be taken to be:
    - (i) for use in the treatment or prevention of a disease, ailment, defect or injury affecting persons; or
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- (ii) for use in influencing, inhibiting or modifying a physiological process in persons; or
- (iii) for use in the replacement or modification of parts of the anatomy in persons; and
- (c) is not specified in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules as a thing that is not a human tissue product for the purposes of this Act.

**18 Subsection 333-20(1) (table item 4, column headed “Private Health Insurance Rules”)**

Omit “Private Health Insurance (Prostheses) Rules”, substitute “Private Health Insurance (Medical Devices and Human Tissue Products) Rules”.

**19 Clause 1 of Schedule 1**

Insert:

*accessory* has the meaning given by subsection 72-11(3).

*human tissue product* has the meaning given by section 72-12.

*medical device* has the meaning given by section 72-11.

**20 Clause 1 of Schedule 1 (paragraph (f) of the definition of *private health insurance arrangement*)**

Omit “Private Health Insurance (Prostheses) Rules”, substitute “Private Health Insurance (Medical Devices and Human Tissue Products) Rules”.

***Private Health Insurance (Transitional Provisions and Consequential Amendments) Act 2007***

**21 Subsection 12(1)**

Omit “(1)”.

**22 Subsection 12(1)**

Omit “Private Health Insurance (Prostheses) Rules”, substitute “Private Health Insurance (Medical Devices and Human Tissue Products) Rules”.

**23 Subsection 12(2)**

Repeal the subsection.

## **Part 2—Application and transitional provisions**

### **24 Applications made before commencement**

- (1) This item applies in relation to an application made before the commencement of this item under subsection 72-10(2) of the *Private Health Insurance Act 2007* in relation to a kind of prosthesis.
- (2) The *Private Health Insurance Act 2007* and any instruments made under that Act have effect, after the commencement of this item, as if the application had been made under subsection 72-10(2) of that Act as amended by Part 1 in relation to a kind of medical device or human tissue product.

### **25 Private health insurance arrangement**

Paragraph (f) of the definition of *private health insurance arrangement* in clause 1 of Schedule 1 to the *Private Health Insurance Act 2007* has effect after the commencement of this item as if a reference to Private Health Insurance (Medical Devices and Human Tissue Products) Rules made for the purposes of item 4 of the table in subsection 72-1(2) of that Act included a reference to Private Health Insurance (Prostheses) Rules made for the purposes of that item before that commencement.

## Schedule 2—Cost recovery

### Part 1—Amendments

#### *Private Health Insurance Act 2007*

##### **1 Paragraph 72-10(3)(b)**

Repeal the paragraph, substitute:

- (b) accompanied by any \*cost-recovery fee that the applicant is liable to pay at the time the application is made.

##### **2 Paragraph 72-10(5)(b)**

Repeal the paragraph, substitute:

- (b) the applicant pays to the Commonwealth any \*cost-recovery fee that the applicant is liable to pay in connection with the initial listing of the kind of \*medical device or \*human tissue product to which the application relates;

##### **3 At the end of subsection 72-10(5)**

Add:

- Note: Despite this subsection, the Minister may, under section 72-25, refuse to perform a function under this subsection if the applicant fails to pay a cost-recovery fee or medical devices and human tissue products levy that is due and payable.

##### **4 Sections 72-15 and 72-20**

Repeal the sections, substitute:

##### **72-15 Fees for certain activities**

- (1) The Private Health Insurance (Medical Devices and Human Tissue Products) Rules may specify fees (*cost-recovery fees*) that may be charged in relation to activities carried out by, or on behalf of, the Commonwealth in connection with the performance of functions, or the exercise of powers, conferred by or under this Act in relation to the list of kinds of \*medical devices and \*human tissue products in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules.

- (2) Without limiting subsection (1), the Private Health Insurance (Medical Devices and Human Tissue Products) Rules may do any of the following:
- (a) specify 2 or more \*cost-recovery fees for the same matter;
  - (b) specify a method for working out a cost-recovery fee;
  - (c) specify the circumstances in which a specified cost-recovery fee is payable, including by providing that the fee is payable if the Minister is satisfied of specified matters;
  - (d) specify the circumstances in which a person is exempt from paying a specified cost-recovery fee;
  - (e) specify the circumstances in which the Minister may waive a cost-recovery fee.
- (3) A \*cost-recovery fee specified under this section must not be such as to amount to taxation.

### **72-20 Delisting because of unpaid fees or levy**

- (1) The Minister may remove a kind of \*medical device or \*human tissue product from the list in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules if:
- (a) a person is liable to pay a \*cost-recovery fee in connection with the kind of medical device or human tissue product; and
  - (b) the person fails to pay that fee in accordance with those Rules.

Note: Matters relating to payment of cost-recovery fees, such as the time for payment, may be specified in Private Health Insurance (Medical Devices and Human Tissue Products) Rules (see sections 72-30 and 72-45).

- (2) The Minister may remove a kind of \*medical device or \*human tissue product from the list in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules if:
- (a) a person is liable to pay \*medical devices and human tissue products levy in respect of the ongoing listing of the kind of medical device or human tissue product; and
  - (b) the person fails to pay the levy in accordance with the Private Health Insurance (Levy Administration) Rules.

Note: Matters relating to payment of the levy, such as the time for payment, may be specified in Private Health Insurance (Levy Administration) Rules (see sections 307-1 and 307-30).

### **72-25 Minister may direct that activities not be carried out**

- (1) This section applies if:
  - (a) a person (the *debtor*) is liable to pay a \*cost-recovery fee or \*medical devices and human tissue products levy; and
  - (b) the fee or levy is due and payable.
- (2) Despite any other provision of this Act, the Minister may refuse to carry out, or direct a person not to carry out, specified activities or kinds of activities in relation to the debtor under this Division until the fee or levy has been paid.

### **72-27 Matters to have regard to before exercising certain powers**

In deciding whether to exercise a power under section 72-20 or 72-25, the Minister must have regard to the following:

- (a) whether the exercise of the power would be detrimental to the interests of insured persons;
- (b) whether the exercise of the power would significantly limit medical practitioners' professional freedom, within the scope of accepted clinical practice, to identify and provide appropriate treatments.

### **72-30 When cost-recovery fee must be paid**

A \*cost-recovery fee becomes due and payable at the time specified in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules.

### **72-35 Payment of cost-recovery fee**

A \*cost-recovery fee must be paid to the Commonwealth.

### **72-40 Recovery of fee**

A \*cost-recovery fee that is due and payable:

- (a) is a debt due to the Commonwealth; and

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- (b) may be recovered as a debt by action in a court of competent jurisdiction by the Commonwealth.

#### **72-45 Other matters**

The Private Health Insurance (Medical Devices and Human Tissue Products) Rules may, in relation to \*cost-recovery fees, specify, or provide for matters relating to, any or all of the following:

- (a) the person who is liable to pay;
- (b) methods for payment;
- (c) extending the time for payment;
- (d) refunding, in whole or in part, an amount paid;
- (e) applying overpayments;
- (f) rules relating to fees to be paid in relation to specified activities.

#### **5 After paragraph 304-10(d)**

Insert:

- (da) levy imposed under the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007* (*medical devices and human tissue products levy*);

#### **6 At the end of subsection 307-10(1)**

Add:

- ; (e) a \*medical devices and human tissue products levy;  
(f) a late payment penalty in respect of a medical devices and human tissue products levy.

#### **7 After paragraph 307-20(1)(b)**

Insert:

- or (c) \*medical devices and human tissue products levy;

#### **8 Section 307-30**

Before “The Private”, insert “(1)”.

#### **9 At the end of section 307-30**

Add:

**Schedule 2** Cost recovery

**Part 1** Amendments

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- (2) The Private Health Insurance (Levy Administration) Rules may specify persons who are liable to pay \*medical devices and human tissue products levy.

**10 Clause 1 of Schedule 1**

Insert:

*cost-recovery fee* has the meaning given by subsection 72-15(1).

*medical devices and human tissue products levy* is defined in paragraph 304-10(da).

## **Part 2—Application and transitional provisions**

### **11 Definitions**

In this Part:

*amended Act* means the *Private Health Insurance Act 2007* as amended by Part 1.

*commencement time* means the commencement of this Part.

*initial listing fee* means an initial listing fee mentioned in paragraph 72-10(5)(b) of the *Private Health Insurance Act 2007* as in force immediately before the commencement time.

*ongoing listing fee* means an ongoing listing fee mentioned in section 72-15 of the *Private Health Insurance Act 2007* as in force immediately before the commencement time.

### **12 Application provision—cost-recovery fees regarding listing applications**

Paragraphs 72-10(3)(b) and (5)(b) of the amended Act apply in relation to an application made under subsection 72-10(2) after the commencement time.

### **13 Transitional provisions—initial listing fees for applications granted before commencement time**

- (1) This item applies in relation to an application under subsection 72-10(2) of the *Private Health Insurance Act 2007* if:
  - (a) the application is granted before the commencement time; and
  - (b) the kind of prosthesis to which the application relates is not listed in the Private Health Insurance (Prostheses) Rules before the commencement time.
- (2) Paragraph 72-10(5)(b) of the amended Act applies in relation to the application as if the reference to cost-recovery fee in that paragraph were a reference to the initial listing fee that the applicant is liable to pay in respect of the application.

#### **14 Transitional provisions—ongoing listing fees imposed before commencement time**

- (1) This item applies if:
- (a) immediately before the commencement time, an ongoing listing fee is due and payable in respect of a kind of prosthesis; and
  - (b) after the commencement time, the kind of prosthesis is listed as a kind of medical device or human tissue product in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules.
- (2) Subsection 72-20(2) of the amended Act has effect, in relation to that kind of medical device or human tissue product, as if:
- (a) a reference in that subsection to medical devices and human tissue products levy in respect of the ongoing listing of the kind of medical device or human tissue product included a reference to the ongoing listing fee; and
  - (b) the reference in paragraph (b) of that subsection to the Private Health Insurance (Levy Administration) Rules were, in relation to the ongoing listing fee, a reference to subsection 72-15(2) of the *Private Health Insurance Act 2007* as in force immediately before the commencement time.

#### **15 Transitional provisions—power to direct that activities not be carried out**

Section 72-25 of the amended Act has effect as if:

- (a) a reference in that section to a cost-recovery fee included a reference to an initial listing fee; and
- (b) a reference in that section to medical devices and human tissue products levy included a reference to an ongoing listing fee.

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*[Minister's second reading speech made in—  
House of Representatives on 1 December 2022  
Senate on 8 February 2023]*

(141/22)

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*No. 8, 2023      Private Health Insurance Legislation Amendment (Medical Device and  
Human Tissue Product List and Cost Recovery) Act 2023      17*