

# EXPOSURE DRAFT

2022

The Parliament of the  
Commonwealth of Australia

HOUSE OF REPRESENTATIVES

EXPOSURE DRAFT (03/11/2022)
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## **Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill 2022**

**No.     , 2022**

*(Health and Aged Care)*

**A Bill for an Act to amend the law relating to  
private health insurance, and for related purposes**

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1 column 2 of the table. Any other statement in column 2 has effect  
2 according to its terms.

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## Commencement information

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Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table	The day this Act receives the Royal Assent.	
2. Schedules 1 and 2	A single day to be fixed by Proclamation. However, if the provisions do not commence within the period of 6 months beginning on the day this Act receives the Royal Assent, they commence on the day after the end of that period.	

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

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

## 3 Schedules

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12 repealed as set out in the applicable items in the Schedule  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

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Medical devices and human tissue products **Schedule 1**  
Amendments **Part 1**

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

3 **Part 1—Amendments**

4 *Private Health Insurance Act 2007*

5 **1 Section 50-5**

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

9 **2 Subsection 72-1(2) (table item 4, column headed “There**  
10 **must be a benefit for ...”)**

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

15 **3 Subsection 72-1(2) (table item 4, column headed “There**  
16 **must be a benefit for ...”, paragraphs (c) and (d))**

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

19 **4 Subsection 72-1(2) (table item 4, column headed “The**  
20 **amount of the benefit must be ...”, paragraph (a))**

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

24 **5 Subsection 72-1(2) (table item 4, column headed “The**  
25 **amount of the benefit must be ...”, paragraph (a))**

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

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## Schedule 1 Medical devices and human tissue products

### Part 1 Amendments

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- 1     **6 Subsection 72-1(2) (table item 4, column headed “The**  
2         **amount of the benefit must be ...”, paragraph (b))**  
3         Omit “Private Health Insurance (Prostheses) Rules”, substitute “Private  
4         Health Insurance (Medical Devices and Human Tissue Products)  
5         Rules”.
- 6     **7 Subsection 72-1(2) (table item 4, column headed “The**  
7         **amount of the benefit must be ...”, paragraph (b))**  
8         Omit “the prosthesis”, substitute “the medical device or human tissue  
9         product”.
- 10    **8 Section 72-10 (heading)**  
11         Omit “**prostheses**”, substitute “**medical devices and human tissue**  
12         **products**”.
- 13    **9 Subsection 72-10(1)**  
14         Omit “Private Health Insurance (Prostheses) Rules”, substitute “Private  
15         Health Insurance (Medical Devices and Human Tissue Products)  
16         Rules”.
- 17    **10 Subsection 72-10(1)**  
18         Omit “a kind of prosthesis”, substitute “a kind of \*medical device or  
19         \*human tissue product”.
- 20    **11 Paragraph 72-10(1)(a)**  
21         Omit “prosthesis”, substitute “medical device or human tissue product”.
- 22    **12 Subsection 72-10(2)**  
23         Omit “Private Health Insurance (Prostheses) Rules list a prosthesis”,  
24         substitute “Private Health Insurance (Medical Devices and Human  
25         Tissue Products) Rules list a \*medical device or \*human tissue product”.
- 26    **13 Subsection 72-10(5)**  
27         Omit “Private Health Insurance (Prostheses) Rules”, substitute “Private  
28         Health Insurance (Medical Devices and Human Tissue Products)  
29         Rules”.



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Medical devices and human tissue products **Schedule 1**  
Amendments **Part 1**

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1 **14 Paragraph 72-10(5)(c)**

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

4 **15 Paragraphs 72-10(5)(d) and (e)**

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

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

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

10 **17 After section 72-10**

11 Insert:

12 **72-11 Meaning of *medical device***

13 (1) A *medical device* is:

- 14 (a) any instrument, apparatus, appliance, software, implant,  
15 reagent, material or other article (whether used alone or in  
16 combination, and including the software necessary for its  
17 proper application) intended, by the person under whose  
18 name it is or is to be supplied, to be used for human beings  
19 for the purpose of one or more of the following:  
20 (i) prevention, monitoring, prediction, prognosis, treatment  
21 or alleviation of disease;  
22 (ii) monitoring, treatment, alleviation of or compensation  
23 for an injury or disability;  
24 (iii) investigation, replacement or modification of the  
25 anatomy or of a physiological or pathological process or  
26 state;  
27 (iv) control or support of conception;  
28 (v) in vitro examination of a specimen derived from the  
29 human body for a specific medical purpose;  
30 and that does not achieve its principal intended action in or  
31 on the human body by pharmacological, immunological or

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## Schedule 1 Medical devices and human tissue products

### Part 1 Amendments

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- 1 metabolic means, but that may be assisted in its function by  
2 such means; or
- 3 (b) any instrument, apparatus, appliance, software, implant,  
4 reagent, material or other article specified in the Private  
5 Health Insurance (Medical Devices and Human Tissue  
6 Products) Rules; or
- 7 (c) an \*accessory to an instrument, apparatus, appliance,  
8 software, implant, reagent, material or other article covered  
9 by paragraph (a) or (b).
- 10 (2) For the purposes of paragraph (1)(a), the purpose for which an  
11 instrument, apparatus, appliance, software, implant, reagent,  
12 material or other article (the *main equipment*) is to be used is to be  
13 ascertained from the information supplied, by the person under  
14 whose name the main equipment is or is to be supplied, on or in  
15 any one or more of the following:
- 16 (a) the labelling on the main equipment;  
17 (b) the instructions for using the main equipment;  
18 (c) any advertising material relating to the main equipment;  
19 (d) any technical documentation describing the mechanism of  
20 action of the main equipment.
- 21 (3) In relation to a \*medical device covered by paragraph (1)(a) or (b),  
22 an *accessory* is a thing that the manufacturer of the thing  
23 specifically intended to be used together with the device to enable  
24 or assist the device to be used as the manufacturer of the device  
25 intended.

#### 26 **72-12 Meaning of *human tissue product***

- 27 A *human tissue product* is a thing that:
- 28 (a) either:
- 29 (i) comprises, contains or is derived from human cells or  
30 human tissues; or
- 31 (ii) is specified in the Private Health Insurance (Medical  
32 Devices and Human Tissue Products) Rules for the  
33 purposes of this subparagraph; and

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Medical devices and human tissue products **Schedule 1**  
Amendments **Part 1**

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- 1 (b) is represented in any way to be, or is, whether because of the  
2 way in which it is presented or for any other reason, likely to  
3 be taken to be:  
4 (i) for use in the treatment or prevention of a disease,  
5 ailment, defect or injury affecting persons; or  
6 (ii) for use in influencing, inhibiting or modifying a  
7 physiological process in persons; or  
8 (iii) for use in the replacement or modification of parts of the  
9 anatomy in persons; and  
10 (c) is not specified in the Private Health Insurance (Medical  
11 Devices and Human Tissue Products) Rules as a thing that is  
12 not a human tissue product for the purposes of this Act.

13 **18 Subsection 333-20(1) (table item 4, column headed**  
14 **“Private Health Insurance Rules”)**

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

18 **19 Clause 1 of Schedule 1**

19 Insert:

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

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

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

23 **20 Clause 1 of Schedule 1 (paragraph (f) of the definition of**  
24 ***private health insurance arrangement*)**

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

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Schedule 1 Medical devices and human tissue products

Part 1 Amendments

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

3 **21 Subsection 12(1)**

4 Omit “(1)”.

5 **22 Subsection 12(1)**

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

9 **23 Subsection 12(2)**

10 Repeal the subsection.

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Medical devices and human tissue products **Schedule 1**  
Application and transitional provisions **Part 2**

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

2 **24 Applications made before commencement**

3 (1) This item applies in relation to an application made before the  
4 commencement of this item under subsection 72-10(2) of the *Private*  
5 *Health Insurance Act 2007* in relation to a kind of prosthesis.

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

11 **25 Private health insurance arrangement**

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

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## Schedule 2 Cost recovery

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1 **Schedule 2—Cost recovery**  
2

3 *Private Health Insurance Act 2007*

4 **1 Paragraph 72-10(3)(b)**

5 Repeal the paragraph, substitute:

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

8 **2 Paragraph 72-10(5)(b)**

9 Repeal the paragraph, substitute:

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

14 **3 At the end of subsection 72-10(5)**

15 Add:

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

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

21 Repeal the sections, substitute:

22 **72-15 Fees for certain activities**

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

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Cost recovery **Schedule 2**

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

## 15 **72-20 Delisting because of unpaid fees or levy**

- 16 (1) The Minister may remove a kind of \*medical device or \*human  
17 tissue product from the list in the Private Health Insurance  
18 (Medical Devices and Human Tissue Products) Rules if:  
19 (a) a person is liable to pay a \*cost-recovery fee in respect of the  
20 kind of medical device or human tissue product; and  
21 (b) the person fails to pay that fee in accordance with those  
22 Rules.
- 23 Note: Matters relating to payment of cost-recovery fees, such as the time for  
24 payment, may be specified in Private Health Insurance (Medical  
25 Devices and Human Tissue Products) Rules (see sections 72-30 and  
26 72-45).
- 27 (2) The Minister may remove a kind of \*medical device or \*human  
28 tissue product from the list in the Private Health Insurance  
29 (Medical Devices and Human Tissue Products) Rules if:  
30 (a) a person is liable to pay \*medical devices and human tissue  
31 products levy in respect of the ongoing listing of the kind of  
32 medical device or human tissue product; and  
33 (b) the person fails to pay the levy in accordance with the Private  
34 Health Insurance (Levy Administration) Rules.

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## Schedule 2 Cost recovery

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

### 4 **72-25 Minister may direct that activities not be carried out**

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

### 13 **72-30 When cost-recovery fee must be paid**

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

### 17 **72-35 Payment of cost-recovery fee**

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

### 19 **72-40 Recovery of fee**

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

21 (a) is a debt due to the Commonwealth; and  
22 (b) may be recovered as a debt by action in a court of competent  
23 jurisdiction by the Commonwealth.

### 24 **72-45 Other matters**

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

- 28 (a) the person who is liable to pay;  
29 (b) methods for payment;



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Cost recovery **Schedule 2**

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- 1 (c) extending the time for payment;  
2 (d) refunding, in whole or in part, an amount paid;  
3 (e) applying overpayments;  
4 (f) rules relating to [*fees / amounts*] to be paid in relation to  
5 specified activities.

## 6 **5 After paragraph 304-10(d)**

7 Insert:

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

## 11 **6 At the end of subsection 307-10(1)**

12 Add:

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

## 16 **7 After paragraph 307-20(1)(b)**

17 Insert:

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

## 19 **8 Section 307-30**

20 Before “The Private”, insert “(1)”.

## 21 **9 At the end of section 307-30**

22 Add:

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

## 26 **10 Clause 1 of Schedule 1**

27 Insert:

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

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