



Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2024

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

Dated 21 June 2024

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

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Part 1—Preliminary

1 Name

This instrument is the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2024*.

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 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 July 2024.	1 July 2024

Note: This table relates only to the provisions of this instrument as originally made.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 Repeal

The *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023* is repealed.

5 Definitions

Note: A number of expressions used in this instrument are defined in the Act, including the following:

- (a) complying health insurance policy;
- (b) cost-recovery fee;
- (c) hospital-substitute treatment;
- (d) hospital treatment;
- (e) human tissue product;
- (f) medical device;
- (g) medicare benefit.

In this instrument:

Act means the *Private Health Insurance Act 2007*.

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active implantable medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

certified overnight Type C procedure has the same meaning as in the *Private Health Insurance (Benefit Requirements) Rules 2011*.

certified Type C procedure has the same meaning as in the *Private Health Insurance (Benefit Requirements) Rules 2011*.

clinical assessment fee: see subsection 19(2).

consultant physician has the same meaning as in the *Health Insurance Act 1973*.

default minimum benefit has the meaning given by subsection 10(7).

economic assessment fee: see subsection 20(2).

former Prescribed List means the Schedule to the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023* (as in force immediately before that instrument was repealed).

full health technology assessment pathway fee: see subsection 21(3).

implantable cardiac event recorder includes a component of an implantable cardiac event recorder.

implantable medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

insulin infusion pump includes a component of an insulin infusion pump.

listed item means a kind of medical device, or a kind of human tissue product, that is listed in Schedule 1.

listing application has the meaning given by subsection 72-10(6) of the Act.

listing criteria has the meaning given by subsection 72-10(6) of the Act.

MSAC means the body known as the Medical Services Advisory Committee.

National Law means:

- (a) for a Territory or a State other than Western Australia—the Health Practitioner Regulation National Law set out in the Schedule to the *Health Practitioner Regulation National Law Act 2009* (Qld) as it applies (with or without modification) as law of the State or Territory, as in force at the commencement of this instrument; or
- (b) for Western Australia—the *Health Practitioner Regulation National Law (WA) Act 2010* (WA), so far as that the Act corresponds to the Health Practitioner Regulation National Law set out in the Schedule to the *Health Practitioner Regulation National Law Act 2009* (Qld).

private hospital means a hospital in respect of which there is in force a statement under subsection 121-5(8) of the Act that the hospital is a private hospital.

professional attendance has the same meaning as in clause 1.2.5 of Schedule 1 to the *Health Insurance (General Medical Services Table) Regulations 2021*.

professional service has the same meaning as in the *Health Insurance Act 1973*.

public hospital means a hospital in respect of which there is in force a statement under subsection 121-5(8) of the Act that the hospital is a public hospital.

registered podiatric surgeon means a podiatric surgeon who holds specialist registration in the specialty of podiatric surgery under the National Law.

Note: The registration requirements for a registered podiatrist for the purposes of this instrument are the same registration requirements for podiatric surgeons as set out in rule 8 of the *Private Health Insurance (Accreditation) Rules 2011* as in force from time to time.

Regulations means the *Health Insurance (General Medical Services Table) Regulations 2021* made under section 4 of the *Health Insurance Act 1973*.

related: medical devices are **related** if:

- (a) the medical devices are designed to be used together for an expected clinical outcome; and
- (b) the medical devices are manufactured by the same manufacturer; and
- (c) the expected clinical outcome is outlined in the same technical or clinical documentation; and
- (d) that documentation is used to demonstrate the cost-effectiveness or clinical-effectiveness of the medical devices.

reviewable decision has the meaning given by section 26.

specified listed item means a listed item that is:

- (a) an irrigated cardiac ablation catheter; or
- (b) a mapping catheter for catheter cardiac ablation; or
- (c) a patch for cardiac ablation; or
- (d) a monopolar device for surgical cardiac ablation; or
- (e) a bipolar device for surgical cardiac ablation; or
- (f) a system for surgical cardiac ablation; or
- (g) a probe for surgical cardiac ablation; or
- (h) a non-irrigated ablation catheter; or
- (i) an intracardiac electrophysiology catheter.

standard application fee: see paragraph 18(2)(a).

sum of default minimum benefits has the meaning given by subsection 10(7).

variation application means a request to the Minister to vary this instrument by amending, in accordance with the request, an item in the table in Schedule 1 relating to a listed item, other than a request to make an amendment only to:

- (a) omit the table item; or
- (b) reflect a change in the sponsor (within the meaning of the *Therapeutic Goods Act 1989*) of the kind of medical device or human tissue product.

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6 Meaning of *medical device*

- (1) This section is made for the purposes of paragraph 72-11(1)(b) of the Act.
- (2) A medical device includes any implant, material, or other article that:
 - (a) was listed in Part D of the former Prescribed List; and
 - (b) is not covered by paragraph 72-11(1)(a) or (c) of the Act.
- (3) A medical device includes any implant, material or other article that is comparable to any implant, material or other article that is specified in subsection (2).

Part 2—Benefit requirements for private health insurance policies that cover hospital treatment and hospital-substitute treatment

7 Listing of medical devices and human tissue products

For the purposes of item 4 (column headed “There must be a benefit for ...”) of the table in subsection 72-1(2) of the Act, Schedule 1 to this instrument:

- (a) lists the kinds of medical devices or human tissue products in relation to which the Minister has granted an application for listing under section 72-10 of the Act; and
- (b) lists kinds of medical devices or human tissue products in accordance with section 12 of the *Private Health Insurance (Transitional Provisions and Consequential Amendments) Act 2007* without an application being made.

Note 1: If the Minister grants a listing application and the applicant pays a listing fee within the required timeframe, the Minister must, on the next occasion when the Minister makes or varies this instrument:

- (a) list the kind of medical device or human tissue product to which the application relates in this instrument; and
- (b) set out in this instrument the minimum benefit for the device or product; and
- (c) if the Minister considers it appropriate, set out in this instrument the maximum benefit for the device or product.

Note 2: The Minister may remove a kind of medical device or human tissue product from Schedule 1 if a person is liable to pay a cost-recovery fee in connection with the kind of medical device or human tissue product and the person fails to pay that fee in accordance with this instrument (see section 72-20 of the Act).

8 Circumstances in which listed items are provided—other than circumstances in which a medicare benefit is payable

For the purposes of paragraph (d) of the column headed “There must be a benefit for ...” in item 4 of the table in subsection 72-1(2) of the Act, the circumstance is that a listed item is provided for podiatric treatment by a registered podiatric surgeon.

Note: Paragraph (c) of the column headed “There must be a benefit for ...” in item 4 of the table in subsection 72-1(2) of the Act deals with the provision of a listed item in circumstances in which a medicare benefit is payable.

9 Conditions to be satisfied in relation to the provision of listed items

- (1) For the purposes of paragraphs (c) and (d) of the column headed “There must be a benefit for ...” in item 4 of the table in subsection 72-1(2) of the Act, subsection (2) of this section sets out the conditions that must be satisfied in relation to the provision of a listed item in the circumstances mentioned in those paragraphs.
- (2) The conditions are:

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- (a) if a condition is specified in the column headed “Condition” of the table in Schedule 1 for that listed item—that condition; and
- (b) if the listed item is for an insulin infusion pump—the following additional conditions:
 - (i) the professional service associated with the provision of the insulin infusion pump must be a professional attendance by a consultant physician in the practice of the consultant physician’s specialty.
 - (ii) the professional service must be provided as a certified Type C procedure or a certified overnight Type C procedure;
 - (iii) the insulin infusion pump must be provided for the purpose of administering insulin.

Note: Item 4 of the table in subsection 72-1(2) of the Act sets out other requirements in relation to benefits for the provision of listed items that a policy that covers hospital treatment must meet. These requirements relate to benefits for hospital treatment and, if the policy covers hospital-substitute treatment, to the benefits of that coverage as well.

10 Benefits for listed items provided as part of hospital treatment

- (1) This section is made for the purposes of paragraph (a) of the column headed “The amount of the benefit must be ...” in item 4 of the table in subsection 72-1(2) of the Act and sets out the amount (or method for working out the amount) that is the minimum benefit for a listed item provided as part of hospital treatment.

Listed items (other than specified listed items)—private hospitals

- (2) For a listed item (other than a specified listed item) provided as part of an episode of hospital treatment in a private hospital, the minimum benefit for the listed item is the amount specified in the column headed “Minimum benefit” of the table in Schedule 1 for the listed item.

Specified listed items—private hospitals

- (3) For a specified listed item provided as part of an episode of hospital treatment in a private hospital, the minimum benefit for the specified listed item is the amount for the specified listed item worked out in accordance with subsection (6).

Listed items (other than specified listed items)—public hospitals

- (4) For a listed item (other than a specified listed item) provided as part of an episode of hospital treatment in a public hospital, the minimum benefit for the listed item is the lesser of the following amounts:
 - (a) the amount for the listed item specified in the column headed “Minimum benefit” of the table in Schedule 1;
 - (b) the amount of the insured person’s liability to the public hospital for the listed item.

Specified listed items—public hospitals

- (5) For a specified listed item provided as part of an episode of hospital treatment in a public hospital, the minimum benefit for the specified listed item is the lesser of the following amounts:
- (a) the amount for the specified listed item worked out in accordance with subsection (6);
 - (b) the amount of the insured person’s liability to the public hospital for the specified listed item.

Minimum benefits for specified listed items—private and public hospitals

- (6) The amount for a specified listed item worked out in accordance with this subsection is:
- (a) if the sum of default minimum benefits for the treatment in which the specified listed item was used is \$6,399 or less—the default minimum benefit for the specified listed item; or
 - (b) if the sum of default minimum benefits for the treatment in which the specified listed item was used is more than \$6,399—the amount worked out by dividing the default minimum benefit for the specified listed item by the sum of the default minimum benefits for the treatment in which the specified listed item was used and multiplying the result by \$6,399.

Example: If an irrigated cardiac ablation catheter, a mapping catheter for cardiac ablation and a patch for cardiac ablation are each listed in Schedule 1 and are used in a relevant treatment in accordance with any conditions, and if:

- (a) the default minimum benefit of the irrigated cardiac ablation catheter is X; and
- (b) the default minimum benefit of the mapping catheter for cardiac ablation is Y; and
- (c) the default minimum benefit of the patch for cardiac ablation is Z;

then the sum of the default minimum benefits for the treatment is $(X+Y+Z)$. If the sum of the default minimum benefits for the treatment $(X+Y+Z)$ is more than \$6,399, then the minimum benefit for the irrigated cardiac ablation catheter is worked out by taking X, dividing it by $(X+Y+Z)$, then multiplying the result by \$6,399.

- (7) For the purposes of this section:

default minimum benefit for a listed item is the amount specified in the column headed “Minimum benefit” of the table in Schedule 1 for the listed item.

sum of default minimum benefits for a treatment is the sum of the default minimum benefits for each specified listed item used in the treatment.

11 Benefits for listed items provided as part of hospital-substitute treatment

- (1) This section is made for the purposes of paragraph (a) of the column headed “The amount of the benefit must be ...” in item 4 of the table in subsection 72-1(2) of the Act and sets out the amount that is the minimum benefit for a listed item provided as part of hospital-substitute treatment.
- (2) For a listed item provided as part of an episode of hospital-substitute treatment, the minimum benefit for the listed item is the amount specified in the column headed “Minimum benefit” of the table in Schedule 1 for the listed item.

Part 2 Benefit requirements for private health insurance policies that cover hospital treatment and hospital-substitute treatment

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Note: Private health insurers cannot cover, as part of hospital-substitute treatment, a service for which medicare benefit is payable unless the service is specified in Private Health Insurance (Health Insurance Business) Rules (see paragraph 121-10(3)(a) of the Act).

Part 3—Listing criteria

12 Purpose

This Part is made for the purposes of subsection 72-10(6) of the Act and sets out the listing criteria to be satisfied in order for a listing application to be granted.

Note 1: Listing criteria are authorised under subsection 72-10(6) of the Act.

Note 2: The Minister must not grant a listing application if any applicable listing criteria are not satisfied in relation to the application (see subsection 72-10(7) of the Act).

Note 3: The Minister may refuse to grant a listing application even if the listing criteria are satisfied (see the note to subsection 72-10(7) of the Act).

13 General listing criteria

A medical device or human tissue product must not be listed in Schedule 1 unless it is included in the Australian Register of Therapeutic Goods maintained under section 9A of the *Therapeutic Goods Act 1989*.

14 Listing criteria for medical devices to be listed in Part A of Schedule 1

- (1) A medical device must not be listed in Part A of Schedule 1 unless subsections (2), (3), (4) and (5) are satisfied.
 - (2) The medical device:
 - (a) must be an implantable medical device, or an active implantable medical device, that is designed to:
 - (i) replace an anatomical body part; or
 - (ii) combat a pathological process; or
 - (iii) modulate a physiological process; or
 - (b) must:
 - (i) be specifically designed as an integral single-use aid and be essential for implanting a device mentioned in paragraph (a); and
 - (ii) be designed for use for the patient in whom the device mentioned in paragraph (a) is intended to be implanted; or
 - (c) must be:
 - (i) critical to the continued functioning of an implanted device mentioned in paragraph (a); and
 - (ii) only suitable for use by the patient in whom the device mentioned in paragraph (a) is implanted.
 - Note: The alternatives in paragraphs 14(b) and (c) will not apply unless a device (the *listed device*) mentioned in paragraph 14(a) is listed in Schedule 1 (or will be listed in Schedule 1 following a successful listing application or variation application) and the device mentioned in paragraphs (b) and (c) is designed to be used with the listed device.
 - (3) The medical device must be a medical device that is not used solely for diagnosis, prediction, or prognosis.
 - (4) The medical device must be for a specific treatment and indication.
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- (5) Both of the following must be satisfied:
- (a) the medical device must have been compared to:
 - (i) devices that are listed in Schedule 1; or
 - (ii) alternative treatments;
 - (b) the comparison must demonstrate that:
 - (i) the medical device is no less clinically effective than the devices listed in Schedule 1 or the alternative treatments; and
 - (ii) the benefit amount for the medical device is proportionate to the clinical-effectiveness of the device.

15 Listing criteria for human tissue products to be listed in Part B of Schedule 1

Only a human tissue product may be listed in Part B of Schedule 1.

Note: A human tissue product is defined in section 72-12 of the Act.

16 Listing criteria for medical devices to be listed in Part C of Schedule 1

- (1) A medical device must not be listed in Part C of Schedule 1 unless subsections (2) and (3) are satisfied.
- (2) The medical device must be one of the following:
- (a) an insulin infusion pump;
 - (b) an electronic device and software designed to control an insulin infusion pump;
 - (c) an implantable cardiac event recorder;
 - (d) a cardiac home/remote monitoring system;
 - (e) an irrigated cardiac ablation catheter;
 - (f) a mapping catheter for catheter cardiac ablation;
 - (g) a patch for cardiac ablation;
 - (h) a monopolar device for surgical cardiac ablation;
 - (i) a bipolar device for surgical cardiac ablation;
 - (j) a system for surgical cardiac ablation;
 - (k) a probe for surgical cardiac ablation;
 - (l) a non-irrigated cardiac ablation catheter;
 - (m) an intracardiac electrophysiology catheter;
 - (n) a vascular drug eluting balloon catheter;
 - (o) a coronary drug eluting balloon catheter;
 - (p) a radiofrequency delivery device for transurethral water vapour ablation (TUWA).
- Note: This instrument may be varied from time to time to add additional devices to, or remove devices from, subsection 16(2).
- (3) Both of the following must be satisfied:
- (a) the medical device must have been compared to:
 - (i) alternative devices listed in Schedule 1; or
 - (ii) alternative treatments;
 - (b) the comparison must demonstrate that:
-

- (i) the medical device is no less clinically effective than the alternative devices or the alternative treatments; and
- (ii) the benefit amount for the medical device is proportionate to the clinical-effectiveness of the medical device.

17 Listing criteria for medical devices to be listed in Part D of Schedule 1

Criteria 1 – comparable medical device to listings under Part D of the former Prescribed List

- (1) A medical device must not be listed in Part D of Schedule 1 unless subsections (2), (3) and (4) are satisfied.
- (2) For a medical device that would be a new Part D listing — the listing application or variation application relating to the medical device must request listing in one of the categories, subcategories, groups, subgroups, or suffixes specified in Part D of the former Prescribed List.

Note: The Prescribed List groups medical devices according to similarity in characteristics, functionality and clinical effectiveness. These grouping are, in descending order of generality: categories, subcategories, groups, subgroups and suffixes.

This criterion requires that listing and variation applications for Part D must seek listing of the medical device in a category, subcategory, group, subgroup or suffix (as applicable) that existed in Part D of Schedule 1 immediately before the former Prescribed List was repealed and cannot seek establishment of a new category, subcategory, group, subgroup or suffix in Part D.

The former Prescribed List can be located free of charge on the Federal Register of Legislation at www.legislation.gov.au.

- (3) The medical device must be comparable to a listed item in Part D of Schedule 1.

Criteria 2 – comparison of clinical effectiveness and proportionality of benefit amount

- (4) Both of the following must be satisfied:
 - (a) the medical device must have been compared to alternative devices listed in Schedule 1;
 - (b) the comparison must demonstrate that:
 - (i) the medical device is no less clinically effective than the alternative devices; and
 - (ii) the benefit amount for the medical device is proportionate to the clinical-effectiveness of the medical device.
- (5) In this section **new Part D listing** means a medical device that would be listed for the first time in Part D of Schedule 1 on or after 1 July 2024, or the item in Part D relating to the medical device would be varied on or after 1 July 2024 as the result of a variation application.

Part 4—Cost-recovery fees

Division 1—Cost-recovery fees relating to medical devices

18 Cost-recovery fees that may be charged

- (1) For the purposes of section 72-15 of the Act, this section specifies the fees that may be charged in relation to activities carried out by, or on behalf of, the Commonwealth in connection with the Minister's consideration of:

- (a) a listing application relating to a medical device; or
- (b) a variation application relating to a medical device.

Note: Fees are not charged for listing applications, or variation applications, relating to human tissue products.

- (2) The fees are:

- (a) a standard application fee of \$1,420; and
- (b) if a clinical assessment is required (see section 19)—the clinical assessment fee; and
- (c) if an economic assessment is required (see section 20)—the economic assessment fee; and
- (d) if a full health technology assessment is required (see section 21)—the full health technology assessment pathway fee.

19 Clinical assessment fee

When a clinical assessment is required

- (1) A listing application or variation application relating to a medical device requires a clinical assessment if:

- (a) expert clinical advice from a clinical expert with relevant expertise in the use of the medical device is necessary to determine whether or not the medical device satisfies the listing criteria set out in any of the following subsections:
 - (i) 14(5); or
 - (ii) 16(3); or
 - (iii) 17(4); or
- (b) the Minister is satisfied on any other grounds that the application requires a clinical assessment.

Note 1: The listing criteria for Part A and Part C of Schedule 1 mentioned in paragraph (a) relate to whether the medical device was compared to medical devices listed in Schedule 1 or alternative treatments, and whether the comparison demonstrated that the medical device is no less clinically effective than alternative devices or treatments, and the benefit amount is proportionate to the clinical-effectiveness of the device.

Note 2: The listing criteria for Part D of Schedule 1 mentioned in paragraph (a) relate to whether the medical device was compared to medical devices listed in Schedule 1, and whether the comparison demonstrated that the device is no less clinically effective than alternative devices, and the benefit amount is proportionate to the clinical-effectiveness of the device.

Note 3: Notice must be given of a decision that the Minister is satisfied as mentioned in paragraph (1)(b) of this section that an application requires a clinical assessment (see subsection 27(1)). Such a decision made by a delegate of the Minister is reviewable (see section 28).

Amount of clinical assessment fee

- (2) The clinical assessment fee is \$3,970.

20 Economic assessment fee

When an economic assessment is required

- (1) A listing application or variation application relating to a medical device requires an economic assessment if:
- (a) an economic assessment from an expert with health economics expertise in medical devices is necessary to determine whether or not the medical device satisfies the listing criteria set out in either of the following subsections:
 - (i) 14(5); or
 - (ii) 16(3); or
 - (iii) 17(4); or
 - (b) the Minister is satisfied on any other grounds that the application requires an economic assessment.

Note 1: The listing criteria for Part A and Part C of Schedule 1 mentioned in paragraph (a) relate to whether the medical device was compared to medical devices listed in Schedule 1 or alternative treatments, and whether the comparison demonstrated that the medical device is no less clinically effective than alternative devices or treatments, and the benefit amount is proportionate to the clinical-effectiveness of the device.

Note 2: The listing criteria for Part D of Schedule 1 mentioned in paragraph (a) relate to whether the medical device was compared to medical devices listed in Schedule 1, and whether the comparison demonstrated that the device is no less clinically effective than alternative devices, and the benefit amount is proportionate to the clinical-effectiveness of the device.

Note 3: Notice must be given of a decision that the Minister is satisfied as mentioned in paragraph (1)(b) of this section that an application requires an economic assessment (see subsection 27(1)). Such a decision made by a delegate of the Minister is reviewable (see section 28).

Amount of economic assessment fee

- (2) The economic assessment fee is:
- (a) if the simple fee applies (see subsection (3))— \$9,250; or
 - (b) if the complex fee applies (see subsection (4))— \$17,680; or
 - (c) if the other fee applies (see subsection (5))— \$28,920.

Simple fee

- (3) For the purposes of paragraph (2)(a), the simple fee applies if the Minister is satisfied that the economic assessment:
- (a) will provide cost-effectiveness advice for one medical device, and one main clinical purpose; and

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- (b) will be a critique of information supplied by the person who made the application relating to the medical device.

Complex fee

- (4) For the purposes of paragraph (2)(b), the complex fee applies if the Minister is satisfied that the economic assessment:
 - (a) will provide cost-effectiveness advice:
 - (i) for one medical device, for more than one clinical purpose; or
 - (ii) for more than one related medical device; and
 - (b) will be a critique of information supplied by the person who made the application for each medical device referred to in paragraph (a).

Note: For when medical devices are *related*, see section 5.

Other fee

- (5) For the purposes of paragraph (2)(c), the other fee applies if the Minister is satisfied that the economic assessment requires the preparation of a fit-for-purpose cost-effectiveness advice that is more complex than a critique of information provided by the person who made the application relating to the medical device.

21 Full health technology assessment pathway fee

When a full health technology assessment is required

- (1) A listing application or variation application relating to a medical device requires a full health technology assessment if:
 - (a) subsection (2) applies; or
 - (b) the Minister is satisfied on any other grounds that the application requires a full health technology assessment.

Note: Notice must be given of a decision that the Minister is satisfied as mentioned in paragraph (1)(b) of this section that an application requires a full health technology assessment (see subsection 27(1)). Such a decision made by a delegate of the Minister is reviewable (see section 28).

- (2) This subsection applies if:
 - (a) the application is, or will be, the subject of any of the following requests to MSAC:
 - (i) a request that an item be included in the table (within the meaning of the *Health Insurance Act 1973*) for a medical service involving the medical device;
 - (ii) a request that an item in the table (within the meaning of the *Health Insurance Act 1973*) be amended to cover a medical service involving the medical device;
 - (iii) a request for advice about the cost-effectiveness or clinical-effectiveness of the medical device; and
 - (b) the applicant has not paid both a clinical assessment fee and an economic assessment fee in relation to the application.

Amount of full health technology assessment pathway fee

- (3) The full health technology assessment pathway fee is \$2,990.

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Division 2—Payment of cost-recovery fees

22 When cost-recovery fee must be paid

- (1) For the purposes of section 72-30 of the Act, this section specifies the time when cost-recovery fees become due and payable.

Note 1: The Minister may not list a medical device in Schedule 1 as a result of a listing application until any cost-recovery fee payable in connection with the initial listing of the kind of medical device has been paid (see subsection 72-10(5) of the Act).

Note 2: The Minister may remove a kind of medical device from Schedule 1 if a person is liable to pay a cost-recovery fee in connection with the kind of medical device and the person fails to pay that fee in accordance with this instrument (see section 72-20 of the Act).

Note 3: Activities may not be carried out under Division 72 of the Act in relation to a person who is liable to pay a cost-recovery fee that is due and payable until the fee has been paid (see section 72-25 of the Act).

Note 4: A cost-recovery fee that is due and payable may be recovered as a debt due to the Commonwealth by action in a court of competent jurisdiction (see section 72-40 of the Act).

Standard application fee

- (2) A standard application fee in relation to a listing application is due and payable before the end of 28 days starting on the day a demand for payment of the fee is made.
- (3) A standard application fee in relation to a variation application is due and payable before the end of 28 days starting on the day a demand for payment of the fee is made.

Other cost-recovery fees

- (4) A clinical assessment fee, economic assessment fee, or full health technology assessment pathway fee is due and payable before the end of 28 days starting on the day a demand for payment of the fee is made.

23 Person liable to pay cost-recovery fee

For the purposes of paragraph 72-45(a) of the Act:

- (a) a cost-recovery fee in relation to a listing application is payable by the person who made the application; and
- (b) a cost-recovery fee in relation to a variation application is payable by the person who made the relevant request.

Division 3—Refunds and waiver of cost-recovery fees

24 Refunds

- (1) This section is made for the purposes of paragraph 72-45(d) of the Act.
- (2) Subject to subsections (3) and (4), a cost-recovery fee is not refundable in any circumstances, including:
 - (a) if the applicant withdraws the listing application or variation application to which the fee relates; or
 - (b) for a fee relating to a listing application—if the Minister decides not to grant the application; or
 - (c) for a fee relating to a variation application—if the Minister decides not to agree to the relevant request.
- (3) If:
 - (a) a person pays an amount as a cost-recovery fee; and
 - (b) the amount paid is greater than the amount required to be paid under this instrument;the Department must, on behalf of the Commonwealth, refund an amount equal to the amount overpaid.
- (4) The Minister may refund an amount equal to the whole or part of a cost-recovery fee paid by a person if the Minister is satisfied that exceptional circumstances exist.
- (5) The Minister may refund an amount under subsection (4) on the Minister's own initiative or on written application by the person.

Note 1: Notice must be given of a decision to refuse to agree to an application under this subsection for a refund (see subsection 27(1)). Such a decision made by a delegate of the Minister is reviewable (see section 28).

Note 2: For the appropriation for a refund under this section, see section 77 of the *Public Governance, Performance and Accountability Act 2013*.

25 Waiver of cost-recovery fees

- (1) For the purposes of paragraph 72-15(2)(e) of the Act, this section specifies the circumstances in which the Minister may waive a cost-recovery fee.

Related medical devices

- (2) The Minister may waive a clinical assessment fee or economic assessment fee (the **relevant fee**) payable by a person in relation to a listing application or variation application (the **relevant application**) that relates to a medical device if:
 - (a) the person has also made one or more other listing applications or variation applications (the **other applications**) that relate to medical devices; and
 - (b) each of the medical devices to which the relevant application and the other applications relate are related medical devices; and
 - (c) in the case of a clinical assessment fee—the Minister is satisfied that:

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- (i) the related medical devices can be considered as part of a single clinical assessment or as part of one or more abridged clinical assessments; and
- (ii) a clinical assessment fee in relation to at least one of the other applications has not been waived under this subsection; and
- (d) in the case of an economic assessment fee—the Minister is satisfied that:
 - (i) the related medical devices can be considered as part of a single economic assessment or as part of one or more abridged economic assessments; and
 - (ii) an economic assessment fee in relation to at least one of the other applications has not been waived under this subsection; and
- (e) the person makes a request, at the same time the relevant application is made, for waiver of the relevant fee; and
- (f) the waiver request includes reasons why paragraph (c) or (d) (as the case may be) is expected to apply in relation to the relevant application.

Note 1: The relevant application, and the other applications, referred to in subsection (2) may not be the only listing applications and variation applications that have been made by the person.

Note 2: For when medical devices are *related*, see section 5.

Note 3: Notice must be given of a decision to refuse to agree to a request under this subsection for a waiver (see subsection 27(1)). Such a decision made by a delegate of the Minister is reviewable (see section 28).

Division 4—Review

26 Reviewable decisions

This Division applies to the following decisions (*reviewable decisions*) of the Minister:

- (a) a decision that the Minister is satisfied as mentioned in paragraph 19(1)(b) that an application requires a clinical assessment;
- (b) a decision that the Minister is satisfied as mentioned in paragraph 20(1)(b) that an application requires an economic assessment;
- (c) a decision that the Minister is satisfied as mentioned in paragraph 21(1)(b) that an application requires a full health technology assessment;
- (d) a decision to refuse to agree to an application under subsection 24(5) for a refund of the whole or part of a cost-recovery fee;
- (e) a decision to refuse to agree to a request under subsection 25(2) for the waiver of a cost-recovery fee.

Note: The decision could be made by a delegate of the Minister (see section 333-1 of the Act).

27 Notice of review rights

- (1) If the Minister makes a reviewable decision, the Minister must, within 10 business days after making the decision, give the person affected by the decision:
 - (a) written notice of the decision; and
 - (b) a statement setting out particulars of the person's review rights.
- (2) The notice must include particulars about how the person may respond to the notice.
- (3) Failure to comply with subsection (1) does not affect the validity of the decision.

28 Internal review of decisions made by delegates

Initial internal review

- (1) If a reviewable decision is made by a delegate of the Minister, the person affected by the decision may apply, in writing, to the Minister for review of the decision.
- (2) The application must:
 - (a) be made within:
 - (i) 10 business days after the applicant received notice under this instrument of the reviewable decision; or
 - (ii) such longer period (if any) allowed by the Minister; and
 - (b) set out the reasons for making the application.
- (3) Subject to subsection (6), the Minister or a delegate of the Minister must, within 10 business days after receiving the application:
 - (a) review the reviewable decision; and

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- (b) make a decision (the *initial review decision*):
 - (i) to affirm or vary the reviewable decision; or
 - (ii) to revoke the reviewable decision, and make any other decision that the person thinks appropriate; and
- (c) give the applicant written notice of the initial review decision.

Further internal review

- (4) The applicant may, within 10 business days after receiving notice of the initial review decision under paragraph (3)(c), request the Minister, in writing to review the initial review decision.
- (5) Subject to subsection (7), the Minister or a delegate of the Minister (the *further reviewer*) must, within 10 business days after receiving the request under subsection (4):
 - (a) review the initial review decision and decide (the *further review decision*):
 - (i) to affirm or vary the initial review decision; or
 - (ii) to revoke the initial review decision, and make any other decision that the further reviewer thinks appropriate; and
 - (b) give written notice to the applicant of the further review decision.

Limitations to subsections (3) and (5)

- (6) A delegate of the Minister must not review a reviewable decision under subsection (3) if the delegate was involved in making the reviewable decision.
- (7) A delegate of the Minister must not review an initial review decision under subsection (5) if the delegate was involved in making:
 - (a) the initial review decision; or
 - (b) the reviewable decision to which the initial review decision relates.

29 Notice of overpayment as a result of a review decision

If a person has overpaid an amount as a cost-recovery fee as a result of a decision made under either of the following provisions, the Minister must, within 20 business days after the decision was made, notify the person accordingly:

- (a) paragraph 28(3)(b) (an initial review decision);
- (b) paragraph 28(5)(a) (a further review decision).

Note: For refunds of overpayments, see section 24.

Part 5—Miscellaneous**30 Minister may have regard to recommendations and advice**

- (1) In making a decision under section 72-10 of the Act whether or not to grant a listing application, the Minister may have regard to a recommendation or advice from the body known as the Medical Devices and Human Tissue Advisory Committee.
- (2) Subsection (1) does not limit the matters to which the Minister may have regard.