EXPLANATORY STATEMENT

Issued by the authority of the Minister for Disability and the National Disability Insurance Scheme, Minister for Health and Ageing

Private Health Insurance Act 2007

Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2025

Purpose

The purpose of the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2025* (the MDHTP Rules) is to remake the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules 2025* (the Previous Rules) to update the list of medical devices and human tissue products for which a benefit must be paid, where the listed item is provided in the conditions and circumstances specified in the *Private Health Insurance Act 2007* (the Act). The MDHTP Rules set out the minimum benefit payable for each listed item.

Listed items and their minimum benefits are set out in Schedule 1 to the MDHTP Rules. Schedule 1 to the MDHTP Rules is known as the Prescribed List.

The Prescribed List has four parts:

- Part 1 - Part A – Medical Devices
- Part 2 - Part B – Human Tissue Products
- Part 3 - Part C – Other Medical Devices
- Part 4 - Part D – General Use Items (medical devices)

The MDHTP Rules also define circumstances in which fees for assessments in relation to listing and variation applications are required, and the associated fee for that assessment. The MDHTP Rules also prescribe cost-recovery arrangements, including the timing for when cost-recovery fees become due and payable, and when cost-recovery fees can be refunded, and waivers can be granted.

In line with the Australian Government Cost Recovery Policy, the MDHTP Rules include fees that reflect the efficient costs of providing services. Fees are calculated using an activity-based cost model. This ensures that the contemporary costs incurred by the Department of Health, Disability and Ageing (the department) when providing services relating to the assessment of applications to list or vary the Prescribed List are accurately reflected in fees. Standard application fees for listing and variation applications fees are due and payable within 28 days from the day demand for payment of the relevant fee is made.

The MDHTP Rules differ from the Previous Rules by:

- Addition of 203 new billing codes to Part A following accepted and granted new applications, and 130 new billing codes due to transfer of billing codes from one sponsor to a different sponsor.
- Changes to 99 billing codes in Part A following the accepted amendment applications, correction of the incorrectly listed billing codes, changes to the conditions, and changes to the Prescribed List benefits (due to the Prescribed List reforms or minor corrections).
- Deletion of 130 billing codes in Part A following acceptance of applications for transfer of billing codes to the new sponsors, and deletion of 235 billing codes following acceptance of deletion applications and other requests.
- Deletion of 4 billing codes in Part B following acceptance of the deletion applications and other requests.
- Addition of 4 new billing codes to Part C following accepted and granted new applications.
- Changes to 11 billing codes in Part C following the accepted amendment applications.

- Deletion of 3 billing codes in Part C following acceptance of deletion applications.
- Addition of 7 new billing codes to Part D following accepted and granted new applications, and 1 new billing code due to transfer of billing codes from one sponsor to a different sponsor.
- Changes to 6 billing codes in Part D following the accepted amendment applications.
- Deletion of 21 billing codes in Part D following acceptance of deletion applications and acceptance of 1 application for transfer of the billing code to the new sponsor.

The numbers of Prescribed List billing codes above were taken from reports produced by the Health Products Portal (HPP) when the Prescribed List was prepared.

When Prescribed List billing codes are transferred from one sponsor to a different sponsor, or billing codes are compressed or expanded following the respective application, the Prescribed List billing codes that are transferred, expanded, or compressed are deleted.

The MDHTP Rules changes to Part A stated above include correction of the incorrectly listed billing codes. This means correcting the listing details of the billing codes identified as being listed in incorrect groupings (meaning category-subcategory-group-subgroup-suffix); that is, the devices do not have the attributes to fit in the groupings they are currently listed in.

Changes to Section 17 Clinical assessment fee:

- 17 (1) (a) was revised to refer to the specific subsections of the listing criteria for which a clinical assessment must be conducted if expert clinical advice is needed to determine whether the medical device meets the listing criteria specified in such subsections: (12(2), 12(3), 12(4), 12(5), 14(2), 14(3), 15(2), 15(3), and 15(4)).
- Note 1 was reworded to specify that a device must not be listed on Schedule 1 unless it meets all criteria for listing.
- Note 2 was edited to be also applicable to Part D. For Part A and Part C, there was a minor edit to specify which subsection of the listing criteria the Note refers to.
- Note 4 had a minor amendment to specify that a formal notice of the decision to undertake a clinical assessment must be given if the Minister decision is for reasons other than those outlined paragraph 17 (1) (a).

Changes to Section 18 Economic assessment fee

- Note 1 was reworded to specify that a device must not be listed on Schedule 1 unless it meets all criteria for listing.
- Note 4 had a minor amendment to specify that a formal notice of the decision to undertake an economic assessment must be given if the Minister decision is for reasons other than those outlined paragraph 18 (1) (a).

Changes to Section 19 Full health technology assessment pathway fee

- Note 19 (2) the listing application is to identify that a full health technology assessment is required for the purposes of subsection (2) was removed

The Table in subsection 72-1(2) of Part 3-3 of the Act (Table) provides for benefit requirements a complying health insurance policy that covers hospital treatment must meet. Under item 4 of the Table, there must be a benefit for the provision of a medical device or human tissue product, of a kind listed in the MDHTP Rules, in specified circumstances and under any specified conditions. The specified circumstances are that the listed item is provided in circumstances in which a medicare benefit is payable or in other circumstances which may be set out in the MDHTP Rules. The specified conditions are any that may be set out in the MDHTP Rules.

If the complying health insurance policy also covers hospital-substitute treatment then under item 4 of the Table, the same requirements apply.

Subsection 72-10(2) of the Act provides that a person may apply to the Minister to have the MDHTP Rules list a medical device or human tissue product of the kind to which the application relates to (listed item). The applicant for these applications is known as the 'sponsor'. If the listing application is accepted, and the device or human tissue product is listed in Schedule 1 of the MDHTP Rules, the sponsor will be responsible for any obligations related to the billing code (listed item). The sponsor also has obligations to ensure the information in Schedule 1 relating to the billing code is accurate and up to date.

Personal information may be collected as part of the application for listing process. This is generally limited to the names and contact information for contact persons for sponsors. To the extent that any information collected in relation to an application is personal information within the meaning of the *Privacy Act 1988*, the department collects, stores, uses and discloses that information in accordance with the Privacy Act, including the Australian Privacy Principles. The department's Privacy Policy also applies to personal information collected as part of the application process, which is available on the department's website.

Legislative authority

Item 4 of the Table in section 333-20 of the Act provides that the Minister may make the MDHTP Rules, providing for matters required or permitted by Part 3-3 of the Act, or necessary or convenient in order to carry out or give effect to Part 3-3 of the Act.

Subsection 72-10(5) of the Act applies if the Minister grants the application and the applicant pays any cost-recovery fee that the applicant is liable to pay in relation to the initial listing of the kind of medical device or human tissue product to which the application relates. If the Minister grants the application and the applicant pays the cost-recovery fee, then the Minister must list the kind of medical device or human tissue product the next time the Minister makes or varies the MDHTP Rules.

Subsection 72-10(6) of the Act provides that the MDHTP Rules may set out criteria that must be satisfied in order for an application to be granted.

Section 72-15 of the Act provides for the MDHTP Rules to specify cost-recovery fees for 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 the Act in relation to the listing of kinds of medical devices and human tissue products in the MDHTP Rules.

Commencement

The MDHTP Rules commence on 1 November 2025.

Consultation

In making the MDHTP Rules and the billing codes in Schedule 1, the rule-maker had regard to recommendations made by the Medical Device and Human Tissue Advisory Committee (MDHTAC). MDHTAC is a ministerially appointed expert committee with the role to make recommendations and provide advice supporting the Minister in exercising their powers under the *Private Health Insurance Act 2007* and the department in administering the Prescribed List. The MDHTAC took into consideration advice provided by members of the Expert Clinical Advisory Groups with appropriate knowledge and expertise in medical devices, and advice provided by the Medical Services Advisory Committee, where required.

Sponsors who applied under subsection 72-10(2) of the Act for the listing of medical devices or human tissue products on the Prescribed List provide information in the approved form. The assessment process includes opportunities to provide further information and clarification regarding devices and products during assessment of applications.

Applicants are therefore aware of the decisions in respect to the devices or human tissue products in their applications.

General

The MDHTP Rules are a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the MDHTP Rules are set out in **Attachment A.**

The MDHTP Rules are 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**.

ATTACHMENT A

Details of the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2025

Part 1 Preliminary

Section 1 Name

Section 1 provides that the name of the instrument is the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2025.

Section 2 Commencement

Section 2 provides that the instrument commences on 1 November 2025.

The note below the table provides that the table relates only to the provisions of the instrument as originally made. It will not be amended to deal with any later amendment of the instrument (if any). The purpose of the note is to clarify that the commencement of any subsequent amendments is not reflected in the table.

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

Section 3 Authority

Section 3 provides that the instrument is made under item 4 of the Table in section 333-20 of the *Private Health Insurance Act 2007*.

Section 4 Definitions

Section 4 defines certain terms used in the MDHTP Rules. The note at the beginning of the section clarifies that some terms used in the MDHTP Rules have the same meaning as in the Act.

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

The Table in subsection 72-1(2) of the Act (the Table) sets out the requirements a policy that covers hospital treatment must meet for it to be a complying health insurance policy under section 63-10 of the Act. Item 4 of the Table provides that there must be a benefit for hospital treatment covered under the policy and hospital-substitute treatment, where the policy also covers hospital-substitute treatment. The benefit applies for hospital treatment or hospital-substitute treatment that involves the provision of a listed item:

- in the circumstances in which a medicare benefit is payable or those other circumstances set out in the MDHTP Rules; and
- when the conditions set out in the MDHTP Rules, if any, are also satisfied.

Section 5 Listing of medical devices and human tissue products

Section 5 of the MDHTP Rules specifies the list of medical devices and human tissue products for the purposes of item 4 of the Table in subsection 72-1(2) of the Act (column headed ‘There must be a benefit for…’). Section 5 provides that the Prescribed List sets out these listed items.

The first note under Section 5 provides that if the Minister or delegate grants a listing application and the listing fee is paid within the required timeframe, the instrument must list the medical device or human tissue product to which the application relates and must set out the minimum benefit for the device or product, and if considered appropriate, set out the maximum benefit for the device or product.

The second note under Section 5 provides that if an applicable cost-recovery fee is not paid for the application to list a medical device or human tissue product, then that medical device or human tissue product may be removed from the Prescribed List.

Section 6 Circumstances in which listed items are provided—other than circumstances in which a medicare benefit is payable

Section 6 of the MDHTP Rules specifies circumstances 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. Section 6 provides that a benefit must be payable under a complying health insurance policy for covered hospital treatment and hospital-substitute treatment (if the policy covers hospital-substitute treatment) for provision of a listed item that is associated with podiatric treatment by a registered podiatric surgeon. This applies even if a medicare benefit is not payable for the provision of that listed item.

The note in section 6 clarifies that the provision of a listed item in circumstances in which a medicare benefit is payable is dealt with in 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.

Section 7 Conditions to be satisfied in relation to the provision of listed items

Section 7 specifies conditions that must be satisfied in relation to the provision of a listed item. Subsection 7(1) of the MDHTP Rules provides that subsection 7(2) is made for the purposes of paragraphs (c) and (d) of the column headed "There must be a benefit for…" in item 4 in the Table in subsection 72-1(2) of the Act, the MDHTP Rules may set out conditions that must be satisfied in relation to the provision of a listed item in circumstances in which a medicare benefit is payable, or in the circumstances. If these conditions are not satisfied, no benefit is payable under a complying health insurance policy that covers hospital treatment or hospital-substitute treatment.

Paragraph 7(2)(a) provides that the conditions that must be satisfied in the case of a listed item are those conditions specified (if any) under the heading 'Condition' for that listed item in the Prescribed List. There are 123 billing codes listed in the Prescribed List with conditions.

If the listed item is for an insulin infusion pump, in addition to any conditions set out in Schedule 1, paragraph 7(2)(b) provides that the following conditions apply:

(i) the professional service associated with providing the insulin infusion pump to the patient 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.

The note under section 7 provides that 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.

The listed items (billing codes) in the Schedule 1 with the conditions are:

<u>Part A</u>
<u>BA310 (TissuePatchDural)</u>

BA313 (TissuePatchDural 100*100)
BB015 (Neuro-Patch)
BB113 (Neuropatch Dura Substitute)
BB118 (Neuropatch Dura Substitute)
BB356 (Lyoplant Onlay)
BB357 (Lyoplant Onlay)
BB358 (Lyoplant Onlay)
BB359 (Lyoplant Onlay)
BB363 (Neuropatch Dura Substitute)
DE669 (icotec Pedicle System Polyaxial Screw)
DE670 (icotec Pedicle System Rod)
DE671 (icotec Pedicle System Set Screw)
DE678 (icotec Anterior Cervical Plate System - Screw)
DE679 (icotec Anterior Cervical Plate)
DE680 (icotec Anterior Cervical Plate)
DE818 (BlackArmor Carbon Fibre/PEEK Curved / Multicurved Rods)
DE822 (Ligament Advanced Reinforcement System (LARS) Artificial Ligament)
DE824 (Ligament Advanced Reinforcement System (LARS) Artificial Ligament - AC30RA)
DE825 (Ligament Advanced Reinforcement System (LARS) Artificial Ligament – LAC 20)
DE826 (Ligament Advanced Reinforcement System (LARS) Artificial Ligament - LAC 30)
DE827 (Ligament Advanced Reinforcement System (LARS) Artificial Ligament - MCL 32)
DE828 (Ligament Advanced Reinforcement System (LARS) Artificial Ligament - Rotator Cuff CR 25)
DE829 (Ligament Advanced Reinforcement System (LARS) Artificial Ligament - Rotator Cuff CR 30)
DE830 (Ligament Advanced Reinforcement System (LARS) Artificial Ligament)
EL069 (PASCAL Precision System (PASCAL Implant and PASCAL ACE Implant))
FV015 (Simplant Surgical Guides)
HI001 (DDN Guide)
HI002 (DDN Biomodel)
HI005 (DDN Biomodel)
HI006 (DDN Guide)
HU402 (FiberTape Sternal Closure System Median Sternotomy Closure)
HU267 (Cerclage System)
HU397 (Arthrex Universal Glenoid Baseplate)
HW544 (Stryker Anatomical Biomodel for Mandible)
HW546 (Stryker Anatomical Biomodel for PEEK)
HW650 (VSP Orthognathics Bundle (Surgical Guide and Implants))
HW651 (VSP Orthognathics Bundle (Custom Biomodel and Implants))
HW652 (VSP Reconstruction Maxillofacial Case Bundle)
HW653 (VSP Reconstruction Mandibular/Maxillary Case Bundle)
HW776 (Cayman United Plate)
HW785 (AutoPlex Mixer and Delivery System with VertaPlex HV)
HW856 (Augment Bone Graft - rhPDGF-BB component)
IG038 (DuraGen)
IG040 (DuraGen)
IG041 (DuraGen Plus)
IG042 (DuraGen Suturable)
IG043 (DuraGen)
IG044 (DuraGen Plus)
IG045 (DuraGen Suturable)
IG046 (DuraGen)
IG047 (DuraGen Plus)
IG048 (DuraGen Suturable)
IG049 (DuraGen)
IG051 (DuraGen Suturable)
IG059 (DURAGEN PLUS)

IG060 (DURAGEN PLUS)
IJ022 (Regenerative Dural Repair Patch (ReDuraTM))
IJ023 (Regenerative Dural Repair Patch (ReDuraTM))
IJ024 (Regenerative Dural Repair Patch (ReDuraTM))
IJ025 (Regenerative Dural Repair Patch (ReDuraTM))
JN004 (ARDS Anatomic Biomodel)
KN004 (Invictus Spinal Cement System)
KT004 (UNIQOS Patient Specific Anatomical Biomodel)
KT005 (UNIQOS Patient Specific Surgical guides)
LB088 (CREO Stabilization System Locking Cap)
LB089 (CREO Stabilization System Preassembled Monoaxial Screw)
LB181 (REFLECT Staple)
LH765 (Neodura Dural Repair Patch ≤10cm²)
MA545 (Ligamys DIS Suture with button)
MI402 (Cobalt™ XT DR ICD MRI SureScan™ with BlueSync mobile remote monitoring)
MI403 (Cobalt™ DR ICD MRI SureScan™ with BlueSync mobile remote monitoring)
MI404 (Crome™ DR ICD MRI SureScan™ with BlueSync mobile remote monitoring)
MI405 (Cobalt™ XT DR ICD MRI SureScan™ with BlueSync mobile remote monitoring)
MI406 (Cobalt™ DR ICD MRI SureScan™ with BlueSync mobile remote monitoring)
MI407 (Cobalt™ XT VR ICD MRI SureScan™ with BlueSync mobile remote monitoring)
MI408 (Cobalt™ VR ICD MRI SureScan™ with BlueSync mobile remote monitoring)
MI409 (Crome™ VR ICD MRI SureScan™ with BlueSync mobile remote monitoring)
MI410 (Cobalt™ XT VR ICD MRI SureScan™ with BlueSync mobile remote monitoring)
MI411 (Cobalt™ VR ICD MRI SureScan™ with BlueSync mobile remote monitoring)
MI412 (Crome™ VR ICD MRI SureScan™ with BlueSync mobile remote monitoring)
MI413 (Crome™ DR ICD MRI SureScan™ with BlueSync mobile remote monitoring)
MI416 (Cobalt™ HF Quad CRT-D MRI SureScan™ with BlueSync mobile remote monitoring)
MI417 (Cobalt™ HF CRT-D MRI SureScan™ with BlueSync mobile remote monitoring)
MI418 (Crome™ HF Quad CRT-D MRI SureScan™ with BlueSync mobile remote monitoring)
MI419 (Crome™ HF CRT-D MRI SureScan™ with BlueSync mobile remote monitoring)
MI420 (Cobalt™ XT HF Quad CRT-D MRI SureScan™ with BlueSync mobile remote monitoring)
MI421 (Cobalt™ XT HF CRT-D MRI SureScan™ with BlueSync mobile remote monitoring)
MI422 (Crome™ HF Quad CRT-D MRI SureScan™ with BlueSync mobile remote monitoring)
MI423 (Crome™ HF CRT-D MRI SureScan™ with BlueSync mobile remote monitoring)
MI424 (Cobalt™ XT HF Quad CRT-D MRI SureScan™ with BlueSync mobile remote monitoring)
MI425 (Cobalt™ XT HF CRT-D MRI SureScan™ with BlueSync mobile remote monitoring)
MI426 (Cobalt™ HF Quad CRT-D MRI SureScan™ with BlueSync mobile remote monitoring)
MI427 (Cobalt™ HF CRT-D MRI SureScan™ with BlueSync mobile remote monitoring)
MI439 (Percepta Quad MRI SureScan CRT-P with BlueSync mobile remote monitoring)
MI440 (Percepta MRI SureScan CRT-P with BlueSync mobile remote monitoring)
MI441 (Serena Quad MRI SureScan CRT-P with BlueSync mobile remote monitoring)
MI442 (Serena MRI SureScan CRT-P with BlueSync mobile remote monitoring)
MI446 (Azure XT SR MRI SureScan with BlueSync mobile remote monitoring)
MI447 (Azure S SR MRI SureScanTM with BlueSync mobile remote monitoring)
MI448 (Azure XT DR MRI SureScan with BlueSync mobile remote monitoring)
MI449 (Azure S DR MRI SureScan with BlueSync mobile remote monitoring)
MV007 (MGuide)
MV025 (MGuide)
OG001 (OMX Solutions patient Optimized Guide system)
OG004 (The OMX Solutions Biomodel)
OG006 (MAXONIQ Surgical Guide Dental (Southern Implants))
OG007 (MAXONIQ Surgical Guide Dental (STMN))
QQ001 (Anatomics Biomodel)
QQ008 (Anatomics Patient Specifc Surgical Guide)
QQ013 (Anatomics Patient Specific Surgical Guide)

QQ014 (Anatomics Surgical Guide)
QQ164 (Neutrino NxT HF CRT-D Model CDHFA600Q)
QQ166 (Neodura Dural Repair Patch)
QQ167 (Neodura Dural Repair Patch)
QQ168 (Neodura Dural Repair Patch)
QQ199 (NEUTRINO NxT VR ICD Model CDVRA600Q)
QQ200 (Neutrino NxT DR ICD Model CDDRA600Q)
QQ311 (Stryker Patient-Matched TMJ – Anatomic Biomodel)
QQ312 (AI Guide)
RF055 (Alizea SR)
RF056 (Talentia 4LV SonR CRT-D 3844 with Bluetooth SmartView Connect remote monitoring)
RF057 (Alizea DR Bluetooth with Bluetooth SmartView Connect remote monitoring)
RF058 (Talentia DR 3540 with Bluetooth SmartView Connect remote monitoring)
RV021 (ReconPILOT Biomodelled Patient Specific Surgical Guide for Craniofacial Surgery)
RV022 (ReconPILOT Biomodelled Patient Specific Surgical guide for Maxillofacial surgery)
SJ499 (Neutrino NxT HF CRT-D Model CDHFA600B)
SJ500 (Neutrino NxT HF CRT-D Model CDHFA600D DF4/IS1)
SJ417 (Gallant VR ICD Model CDVRA500Q)
SJ418 (Gallant DR ICD Model CDDRA500Q)
SJ424 (Gallant HF CRT-D Model CDHFA500Q)
SJ482 (Navitor™ Transcatheter Aortic Valve)
SJ486 (Neutrino NxT VR ICD Model CDVRA600T)
SJ487 (Neutrino NxT DR ICD Model CDDRA600T)
SJ492 (Neutrino NxT HF CRT-D Model CDHFA600T)
SK492 (DuraMatrix)
SK494 (DuraMatrix)
SK495 (Dura Matrix)
SK496 (DuraMatrix)
SY777 (ProPlan)
SY778 (ProPlan)
SY779 (ProPlan)
SY829 (Custom made plates (including Megaplates) – Surgical Guides)
SY830 (Surgical Guide for OBL PorousiTi® PSI System – Orbital Floor)
UI001 (OsGuide)
UI002 (BIOMODEL)
UI003 (DGUIDE)
UI004 (OMF Model)
XU019 (OrthoTin Anatomic Biomodel)
XU020 (OrthoTin Surgical Guide)
XU022 (Lyka Smith Patient Specific Guides)
XU023 (Lyka-Smith Anatomical Biomodel)
ZZ108 (Materialise Titanium 3D Printed Guides)

Part C
BS432 (LUX-Dx II, LUX-Dx II+)
II001 (Omnipod DASH® Insulin Management System - Personal Diabetes Manager (PDM) & Software only)
QQ717 (Omnipod 5 Automated Insulin Delivery System)

Section 8 Benefits for listed items provided as part of hospital treatment

Section 8 of the MDHTP Rules provides for the minimum benefits paid for listed items provided as part of hospital treatment. Subsection 8(1) provides that 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, which provides that the minimum benefit is the amount that is set out, or worked out, in the MDHTP Rules.

Subsection 8(2) provides that the minimum benefit for a listed item (other than a specified listed item) that is provided to a private patient in a private hospital is the amount specified in the column headed "Minimum benefit" of the Table in the Prescribed List for that listed item. A specified listed item is defined in section 4 of the MDHTP Rules as 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.

Subsection 8(3) provides that the method for calculating the minimum benefit for a specified listed item for a private patient in a private hospital is outlined in subsection 8(6) of the MDHTP Rules.

In relation to treatment provided in a public hospital, subsection 8(4) specifies the method for calculating the minimum benefit amount for a listed item (other than a specified listed item). Subsection 8(5) specifies the method for calculating the minimum benefit amount for a specified listed item.

The provision of listed items and specified listed items in public hospitals are subject to different arrangements that reflect the public hospital procurement activities and therefore the cost for a specified listed item in a public hospital may be lower than in a private hospital. To reflect this, subsections 8(4) and 8(5) provide for a lower payable benefit for a listed item or a specified listed item that is consistent with the insured person's liability to the public hospital for the provision of that listed item or specified listed item. This only applies if the listed item or specified listed item is provided in a public hospital for an amount that is lower than the amount specified for that listed item or specified listed item in the Prescribed List.

Subsection 8(6) of the MDHTP Rules provides the method for the minimum benefit amount for a specified listed item. The method is defined as:

(a) if the sum of the default minimum benefits for the treatment in which the specified listed item was used is $6,399 or less, the minimum benefit is the default minimum benefit for the listed item; or
(b) if the sum of the default minimum benefits for the procedure treatment in which the specified listed item was used is more than $6,399, the benefit is 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.

The note under subsection 8(6) provides an example of calculating the minimum benefit for the purpose of paragraph 8(6)(b). The example states that if an irrigated cardiac ablation catheter, a mapping catheter for catheter cardiac ablation and a patch for cardiac ablation are each listed in the Prescribed List and are used in a relevant procedure 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 procedure is (X+Y+Z). If the sum of the default minimum benefits for the procedure (X+Y+Z) is more than $6,399, the minimum benefit for the

irrigated cardiac ablation catheter is calculated by taking X, dividing it by (X+Y+Z), then multiplying the result by $6,399.

Subsection 8(7) defines the meaning of 'default minimum benefit' and 'sum of default minimum benefits' for the purposes of section 8. *Default minimum benefit* for a listed item is the amount specified in the column headed "Minimum benefit" in the Prescribed List for the listed item. The *sum of default minimum benefits* for a treatment is defined as the sum of the default minimum benefits for each specified listed item used in the treatment.

Section 9 Benefits for listed items provided as part of hospital-substitute treatment

Section 9 of the MDHTP Rules provides for the minimum benefits paid for listed items provided as part of hospital-substitute treatment. Subsection 9(1) provides that 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 treatment.

Subsection 9(2) provides that, for a listed item provided as part of an episode of hospital-substitute treatment, the minimum benefit is the amount specified in the column headed "Minimum benefit" in the Prescribed List for that listed item.

The note under section 9 states that as part of hospital-substitute treatment, private health insurers cannot cover a service for which a medicare benefit is payable unless the service is specified in the Private Health Insurance (Health Insurance Business) Rules.

Part 3 Listing criteria

Section 10 Purpose

Section 10 of the MDHTP Rules explains that Part 3 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. The listing criteria operates with all the provisions in the Act, including the definitions of 'medical device' and 'human tissue product'.

The first note under section 10 clarifies that the listing criteria are authorised under subsection 72-10(7) of the Act.

The second note under section 10 provides that the Minister or delegate must not grant a listing application if any applicable listing criteria are not satisfied in relation to the application.

The third note under section 10 clarifies that the Minister may refuse to grant a listing application even if the listing criteria are satisfied.

Section 333-1 of the Act provides the authority for the Minister to delegate their powers or functions subject to the limitations provided within section 333-1. The Minister has made an instrument of delegation for the purposes of the *Private Health Insurance Act 2007* and the and the MDHTP Rules. References to 'delegate' in the MDHTP Rules are references to those who have been delegated powers or functions of the Minister under the instrument of delegation. Delegates are considered to have the appropriate skills, knowledge and expertise to perform the functions or powers on behalf of the Minister.

Section 11 General listing criteria

Section 11 of the MDHTP Rules provides that a medical device or human tissue product must not be listed in the Prescribed List unless it is included as a medical device or biological in the Australian Register of Therapeutic Goods maintained under section 9A of the *Therapeutic Goods Act 1989*.

This is to ensure that the department can independently verify that the medical device or human tissue products may be legally supplied in Australia.

Section 12 Listing criteria for medical devices to be listed in Part A of Schedule 1

Section 12 of the MDHTP Rules provides listing criteria for medical devices which are to be listed in Part A of the Prescribed List. To avoid doubt, these criteria are in addition to meeting section 11 of the MDHTP Rules.

Subsection 12(1) provides that a medical device must not be listed in Part A of the Prescribed List unless the criteria in subsections 12(2) to 12(5) are satisfied.

Subsection 12(2) specifies conditions that must be met for a medical device to be listed in Part A of the Prescribed List. Paragraph 12(2)(a) provides that the medical device must be an implantable medical device, or an active implantable medical device designed to either replace an anatomical body part, or combat a pathological process, or modulate a physiological process. 'Implantable medical device' and 'active implantable medical device' are defined in section 4 of the MDHTP Rules. Reference in relation to a 'modulating a physiological process' is intended to include blocking or facilitating a process.

Subsection 12(2) is also for associated products that are essential and specifically designed to enable the implantation (outlined in paragraph 12(2)(b)) or maintaining the implant (outlined in paragraph 12(2)(c)) of this subsection.

To meet these criteria, the device must be specifically designed as an integral single-use aid and be essential for implanting a device mentioned in paragraph 12(2)(a), or be critical to the continuing function of an implanted device mentioned in paragraph 12(2)(a), and only be suitable for use post-implantation by the patient in whom the device in subsection 12(2)(a) is implanted.

Single-use aid means a device that is intended to be used on one individual during a single procedure, and once it is used, the device cannot be used again and may only be discarded, and the expression 'integral' is intended to apply its common meaning.

The note following subsection 12(2) clarifies that these criteria effectively mean that there is a device in paragraph 12(2)(a) (with which the device in (b) or (c) is designed to be used with) that is a listed item or will be a listed item following a successful listing application or variation application. The non-implantable devices do not meet the criteria for listing if such connection in the design does not exist.

Subsection 12(3) provides that the medical device for listing in Part A of the Prescribed List must not be designed to be solely used for diagnosis, prediction or prognosis.

Subsection 12(4) provides that the medical device for listing in Part A of the Prescribed List must be for a specific treatment and indication. This means that the medical device is specifically designed to deliver the main treatment or be part of the main treatment rather than be designed to be supplementary to the main treatment or provide general support during a variety of different procedures.

The purpose of this criterion is to exclude medical devices that are listed in Part D from inclusion in Part A of the Prescribed List.

Subsection 12(5) provides that for listing a medical device in Part A of the Prescribed List it must be satisfied that the medical device has been compared to devices listed in the Prescribed List or alternative treatments and the comparison must demonstrate that the medical device is no less clinically effective than the devices listed in the Prescribed List or the alternative treatments; and the benefit amount for the medical device is proportionate to the clinical effectiveness of the device.

The term ‘alternative treatments’ is included to allow for new products or technology to be compared with current treatments for the same clinical condition, as not all products to be considered have an existing comparator on the Prescribed List. The alternative treatment is generally expected to be the current standard of care for the condition or indication.

The wording ‘no less clinically effective’ is used because products are rarely identical, and a range of factors may need to be balanced against each other when comparing clinical effectiveness.

A product’s cost should be compared to alternative treatments and considered in relation to its clinical benefits.

Section 13 Listing criteria for human tissue products to be listed in Part B of Schedule 1

Section 13 provides that only human tissue products may be listed in Part B of the Prescribed List. To avoid doubt, these criteria are in addition to meeting the criteria in section 11 of the MDHTP Rules.

The note under this section refers the reader to section 72-12 of the Act, which defines ‘a human tissue product’.

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

Section 14 provides listing criteria for medical devices which are to be listed in Part C of the Prescribed List. To avoid doubt, these criteria are in addition to meeting the criteria in section 11 of the MDHTP Rules.

Subsection 14(1) provides that a medical device must not be listed in Part C of the Prescribed List unless subsections 14(2) and 14(3) are satisfied.

Subsection 14(2) specifies the list of existing groups of medical devices that are currently eligible to be listed in Part C of the Prescribed List. Unless a medical device is one of these items, it is not eligible to be listed.

The note under this subsection provides that the MDHTP Rules may be varied from time to time to add additional devices to, or remove devices from, this subsection.

Subsection 14(3) provides that for listing a medical device in Part C of the Prescribed List the Minister or delegate must be satisfied that the medical device has been compared to devices listed in the Prescribed List or alternative treatments and the comparison must demonstrate that the medial device is no less clinically effective than the devices listed in the Prescribed List or the alternative treatments; and the benefit amount for the medical device is proportionate to the clinical effectiveness of the device. This criterion is included with the intention that comparative clinical effectiveness and relative cost be considered for including items in Part C of the Prescribed List.

The term ‘alternative treatments’ is included to allow for new products or technology to be compared with current treatments for the same clinical condition, as not all products to be considered have an existing comparator on the Prescribed List. The alternative treatment is generally expected to be the current standard of care for the condition or indication.

Section 15 Listing criteria for medical devices to be listed in Part D of Schedule 1

Section 15 provides listing criteria for medical devices which are to be listed in Part D of the Prescribed List. To avoid doubt, these criteria are in addition to meeting the criteria in section 11 of the MDHTP Rules.

Subsection 15(1) provides that a medical device must not be listed in Part D of the Prescribed List unless subsections 15(2), 15(3) and 15(4) are satisfied.

Subsection 15(2) specifies that for a new Part D listing, the listing or variation application relating to the medical device must request listing in one of the categories, subcategories, groups, subgroups or suffixes that is already specified in Part D of the former Prescribed List. This is regardless of whether the billing code for the medical device has changed.

The note under subsection 15(2) clarifies that the Prescribed List groups medical devices according to their similarity in characteristics, functionality and clinical effectiveness. These groupings in the Prescribed List include categories, subcategories, groups, subgroups and suffixes. Any new or variation listings for Part D can only be listed in a category, subcategory, group, subgroup or suffix that already exists in the former Prescribed List. This means that new listing or variation applications cannot seek to establish a new category, subcategory, group, subgroup or suffix for Part D of the Prescribed List.

The former Prescribed List, which is the *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment Rules (No. 2) 2025,* is publicly available on the Federal Register of Legislation at www.legislation.gov.au.

Subsection 15(3) provides that the medical device must be comparable to a listed item in Part D of the Prescribed List.

Subsection 15(4) provides that for listing a medical device in Part D of the Prescribed List the Minister must be satisfied that the medical device has been compared to devices listed in the Prescribed List or alternative treatments and the comparison must demonstrate that the medial device is no less clinically effective than the devices listed in the Prescribed List or the alternative treatments; and the benefit amount for the medical device is proportionate to the clinical effectiveness of the device.

This criterion is included with the intention that comparative clinical effectiveness and relative cost be considered for including items in Part D of the Prescribed List.

Subsection 15(5) provides that 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 2025, or the item in Part D relating to the medical device would be varied on or after 1 July 2025 as the result of a variation application.

Part 4 Cost-recovery fees

Division 1 – Cost-recovery fees relating to medical devices

Section 16 Cost-recovery fees that may be charged

Section 16 specifies the cost-recovery fees that may be charged for the purposes of section 72-15 of the Act. Subsection 16(1) provides that cost-recovery fees will be charged for the activities undertaken by, or on behalf of the Commonwealth, in connection with the Ministers (or delegates) consideration of a listing application or a variation application relating to a medical device on the Prescribed List.

An application to list medical devices on the Prescribed List through the Health Products Portal can cover more than one medical device. The cost recovery fee is charged for each medical device as its own listing or variation application. For example, if an application requires a clinical assessment of 3 medical devices within the application, the cost recovery fee for a clinical assessment would be charged three times. The applicant may seek a waiver in relation to cost recovery fees in accordance with the MDHTP Rules (see section 23).

The note under this subsection clarifies that cost-recovery fees will not apply to listing or variation applications relating to human tissue products in Part B of the Prescribed List.

Cost recovery fees are charged by the department to recover the cost of providing services in response to applications to list a medical device on the Prescribed List or a variation application. Fees have been determined via an activity-based charging model following a review of all costs associated with the administration of the Prescribed List.

Subsection 16(2) specifies a standard application fee of $1,460 that applies to all listing applications and variation applications.

The standard application fee recovers the costs associated with the departmental assessment of the application, including consideration of the information provided, eligibility of the medical devices for listing, correctness of the grouping, etc.

Subsection 16(2) also specifies additional fees that will be applied according to the level and type of assessment (assessment pathway) required as defined in sections 17, 18 and 19 of the MDHTP Rules.

Section 17 Clinical assessment fee

Section 17 outlines circumstances in which a clinical assessment fee is applicable for a clinical assessment. Paragraph 72-15(2)(c) of the Act enables the MDHTP Rules to specify the circumstances in which a cost-recovery fee is charged.

Subsection 17(1) provides that a clinical assessment is required for a listing application or variation application relating to medical devices where expert clinical advice from a clinical expert with relevant expertise is necessary to determine whether or not the medical device satisfies all listing criteria.

Assessment of the listing criteria includes consideration on whether the devices in the applications are no less clinically effective than other devices listed on the Prescribed List or the alternative treatments, and whether the benefits stated in the application (or for the billing codes in case of variation applications) are proportionate in context of the clinical effectiveness of the devices.

An example of “any other grounds” that may satisfy the Minister or delegate that an application requires a clinical assessment is if the sponsor submits a variation application and the Minister or delegate is satisfied a clinical assessment is required to assess if the medical device satisfies the listing criteria.

The first note under subsection 17(1) specifies that a device must not be listed on Schedule 1 unless it meets all criteria for listing.

The second note clarifies that the listing criteria referred to in paragraph 17(1)(a) for Parts A, C or D of the Prescribed List relate to whether the medical device was compared to medical devices listed in the Prescribed List or alternative treatments, and the medical device is no less clinical effective than alternative devices or treatments and the benefit amount is proportionate to the clinical effectiveness of the device.

The third note under subsection 17(1) clarifies that the listing criteria referred to in paragraph 17(1)(a) for Part D of the Prescribed List relate to whether the medical device was compared to medical devices listed in the Prescribed List, and the medical device is no less clinical effective than alternative devices and the benefit amount is proportionate to the clinical effectiveness of the device.

The fourth note under subsection 17(1) draws to readers' attention that where the Minister or delegate is satisfied that the application requires a clinical assessment for reasons other than those outlined in paragraph 17 (1) (a), formal notice of the decision must be given to the applicant and, if the decision was made by a delegate, the decision is a reviewable decision for section 26.

Subsection 17(2) prescribes the applicable clinical assessment fee of $4,210. This fee has been determined through an activity-based costing model, which has been developed to align with the principles outlined in the Australian Government Charging Framework.

The fee associated with this assessment type is charged to recover the costs of obtaining a clinical assessment from clinical experts with relevant expertise from the Expert Clinical Advisory Groups (ECAGs) and the Medical Device and Human Tissue Advisory Committee (MDHTAC). The clinical assessment fee is charged per application for the billing code.

Section 18 Economic assessment fee

Section 18 outlines circumstances in which an economic assessment fee is required for an economic assessment. Paragraph 72-15(2)(c) of the Act enables the MDHTP Rules to specify the circumstances in which a cost-recovery fee is charged.

Subsection 18(1) prescribes that an economic assessment is required for a listing or variation application relating to a medical device where an economic assessment from an expert with health economics expertise is necessary to determine whether or not the medical device satisfies the listing criteria for Parts A, C or D of the Prescribed List, or, under the Minister is satisfied on "any other grounds" that the application for a listing or variation requires an economic assessment.

An example of "any other grounds" that may satisfy the Minister or delegate that an application requires a clinical assessment is if the sponsor submits a variation application and the Minister or delegate is satisfied that an economic assessment is required to assess if the medical device satisfies the listing criteria.

The first note under subsection 18(1) specifies that a device must not be listed on Schedule 1 unless it meets all criteria for listing.

The second note clarifies that the listing criteria referred to in paragraph 18(1)(a) for Parts A and C of the Prescribed List relate to whether the medical device was compared to medical devices listed in the Prescribed List or alternative treatments, and 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.

The third note under subsection 18(1) clarifies that the listing criteria referred to in paragraph 18(1)(a) for Part D of the Prescribed List relate to whether the medical device was compared to medical devices listed in the Prescribed List, and the medical device is no less clinical effective than alternative devices and the benefit amount is proportionate to the clinical effectiveness of the device.

The fourth note under subsection 18(1)(a) draws to readers' attention that where the Minister or delegate is satisfied that the application requires an economic assessment for reasons other than those outlined in paragraph 17 (1) (a), formal, notice of the decision must be given to the applicant and, if the decision was made by a delegate, the decision is a reviewable decision for section 26.

The economic assessment fee is charged per medical device as its own listing or variation application, even if a single application is made to the Health Products Portal.

Subsection 18(2) prescribes the following three applicable economic assessment fee types:

(a) simple fee of $12,150
(b) complex fee of $23,460
(c) other fee of $34,770

These fees have been determined through an activity-based costing model, which has been developed to align with the principles outlined in the Australian Government Charging Framework.

Subsection 18(3) specifies that the simple economic assessment fee applies to a listing application or variation application where the Minister or delegate is satisfied the economic assessment will provide cost-effective advice for a single medical device with a single clinical purpose and will be a critique of information supplied by the person who made the application relating to the medical device.

This fee includes the development of a commentary (or appraisal) of the economic claims and providing a critique on information supplied by the applicant, and for the evaluation performed by the ECAGs and MDHTAC.

Subsection 18(4) specifies that the complex economic assessment fee under paragraph 18(2)(b) applies to a listing application or variation application where the Minister or delegate is satisfied the economic assessment will provide cost-effective advice for a single medical device for more than one clinical purpose, or for more than one 'related' devices and will be a critique of information supplied by the person who made the application relating to the medical device.

This fee includes the development of a commentary (or appraisal) of the economic claims and providing a critique on information supplied by the applicant.

The note under subsection 18(4) provides that 'related' in relation to medical devices is defined in section 4 of the MDHTP Rules.

Subsection 18(5) specifies that the other economic assessment fee under paragraph 18(2)(c) applies where the Minister or delegate is satisfied that a listing application or variation application requires the preparation of 'fit-for-purpose' cost-effectiveness advice that extends beyond a critique of the information supplied by the applicant relating to the medical device. And therefore, beyond the evaluation performed by the ECAGs.

Section 19 Full health technology assessment pathway fee

Section 19 of the MDHTP Rules outlines circumstances in which a full health technology assessment fee is required for a full health technology pathway assessment. Paragraph 72-15(2)(c) of the Act enables the MDHTP Rules to specify the circumstances in which a cost-recovery fee is charged.

Subsection 19(1) provides that a listing or variation application relating to a medical device requires a full health technology assessment if subsection 19(2) applies, or, under subsection 19(1)(b), if the Minister is satisfied on 'any other grounds' that a health technology assessment is required. An example of "any other grounds" that may satisfy the Minister or delegate that an application requires a full health assessment is if the sponsor submits a variation application and the Minister or delegate is satisfied that a full health assessment is required to assess if the medical device satisfies the listing criteria.

The note to subsection 19(1) clarifies for readers that where the Minister (including a delegate) is satisfied that the application requires a full health technology assessment, notice of the decision must be given to the applicant and, if the decision was made by a delegated, the decision is a reviewable decision for section 26.

Subsection 19(2) applies if the application is, or will be, subject to a request to the Medical Services Advisory Committee (MSAC) for the assessment of the application.

Services provided under this pathway are required when a full health technology assessment is necessary to establish comparative clinical effectiveness and cost-effectiveness of the medical device and related medical service.

As the full health technology assessment is performed by MSAC, the fee recovers only the activities performed in establishing eligibility for listing; correctness of the grouping; appropriateness of the information provided in the application; and final advice considered by the ECAGs and MDHTAC directly in relation to listing the medical device on the Prescribed List.

Subsection 19(3) prescribes the full health technology assessment pathway fee of $3,100.

This fee has been determined through an activity-based costing model, which has been developed to align with the principles outlined in the Australian Government Charging Framework. The full health technology assessment pathway fee is charged per medical device as its own listing or variation application.

Division 2—Payment of cost-recovery fees

Section 20 When cost-recovery fee must be paid

Subsection 20(1) of the MDHTP Rules provides that section 20 specifies the timing for when cost-recovery fees become due and payable for the purposes of paragraph 72-30 of the Act.

Notes below subsection clarify that the Minister or delegate:

- may not list a medical device product in the Schedule until all relevant cost-recovery fees are paid; and
- may remove the medical device from the Schedule should the applicant fail to pay the relevant cost-recovery fees.

Notes below this subsection also clarify that the Commonwealth:

- may not carry out activities on assessment of the medical device application until relevant cost-recovery fees are paid at the time they are due and payable; and
- may commence debt-recovery activities in relation to any unpaid cost-recovery fees.

Subsection 20(2) provides that the standard application fee for a listing application is due and payable within 28 days from the day demand for payment of the relevant fee is made.

Subsection 20(3) provides that the standard application fee for a variation application is due and payable within 28 days from the day demand for payment of the relevant fee is made.

Subsection 20(4) provides that a clinical assessment fee, economic assessment fee, or full health technology pathway fee is due and payable within 28 days from the day a demand for payment of the relevant fee is made.

Section 21 Person liable to pay cost-recovery fee

Section 21 of the MDHTP Rules provides that the person liable to pay the related cost-recovery fee is the person who made the relevant listing application or variation application.

Division 3—Refunds and waiver of cost-recovery fees

Section 22 Refunds

Subsection 22(1) of the MDHTP Rules provides that section 22 is made for the purposes of paragraph 72-45(d) of the Act. This section specifies the circumstances in which the Minister or delegate may or may not refund relevant cost-recovery fees.

Subsection 22(2) provides that subject to subsections 22(3) and 22(4), a cost-recovery fee is not refundable in any circumstance, including where:

- the applicant chooses to withdraw the listing or variation application;
- the Minister or delegate decides not to grant the listing application; or
- the Minister or delegate decides not to grant a variation application.

In relation to the withdrawal of applications, both listing and variation applications are to be submitted through the Health Products Portal (HPP). Processing of an application occurs as soon as possible following receipt of payment. In circumstances where a submission is made through the HPP and no payment is received, no processing of the application will commence.

In relation to listing applications that are not successful in obtaining the relevant listing, this provision outlines that the applicant is still liable to pay fees incurred for the services that have been provided for the assessment of their application.

In relation to variation applications that are not successful in obtaining the relevant variation, this provision outlines that the applicant is still liable to pay fees incurred for the services that have been provided for the assessment of their application.

Subsection 22(3) provides that in the circumstance where the person making the application pays more than what is required, the department, on behalf of the Commonwealth, must refund an amount equal to the amount that was overpaid.

This will ensure that where a waiver or an exceptional circumstance exists and the applicant has paid fees that are not required to be paid, the applicant is assured of a refund equal to that which was overpaid. For example, this provision will apply where an applicant is eligible to receive a waiver for all services but has paid all cost-recovery fees prior to the waiver being granted. In such a case, the department will refund the full amount that was waived.

Subsection 22(4) provides that if the Minister or delegate is satisfied that exceptional circumstances exist, the whole, or part of the cost-recovery fee that has been paid may be refunded.

This provision is intended to provide applicants with refunds in specific circumstances which the Minister or delegate may determine are appropriate to provide a refund. Without limitation, the Minister or delegate may be satisfied for subsection 24(4) that “exceptional circumstances” exist where an error in the administration of the application has a material impact on the listing or requires the applicant to remake the application, such as:

- overpayment because of a fee waiver deemed eligible post payment of cost recovery fees;
- overpayment because of a request to review certain decisions related to cost recovery fees; or
- an administrative or system error, which resulted in the generation of an invoice and payment of that invoice by the applicant, where the relevant service was not provided.

Refunds under subsection 22(4) may be at the Minister’s or delegate’s own initiative, or on written application by the applicant, meaning applicants can put forward other grounds for consideration by the Minister or delegate.

Subsection 22(5) provides the Minister or delegate with the discretionary power to issue a refund for a reviewable decision on their own initiative or following receipt of a written application from the relevant applicant. This provision is intended to allow the applicant to receive a refund where a

reviewable decision, for example such as whether the application in question is eligible for a cost-recovery fee waiver, has been made, and the applicant has successfully obtained a favourable review in which the Minister or delegate determines that the relevant fees should be waived.

The first note under subsection 22(5) provides that where the Minister or delegate refuses a request for a refund of the whole or part of a cost-recovery fee, notice must be given to the applicant (see subsection 25(1)) and, where the decision was made by a delegate, the decision is a reviewable decision under section 26 of the MDHTP Rules.

The second note under subsection 22(5) refers the reader to section 77 of the *Public Governance, Performance and Accountability Act 2013* which provides the appropriation for refunds under section 22.

Section 23 Waiver of cost-recovery fees

Subsection 23(1) provides that section 23 is made for the purposes of paragraph 72-15(2)(e) of the Act and specifies the circumstances in which the Minister or delegate may waive relevant cost-recovery fees.

Waivers have been incorporated to provide for circumstances where it is inappropriate to charge cost-recovery fees and to ensure that applications that are likely to be financially unviable but will still provide benefit to the Australian public, will continue to be submitted to the department for consideration.

Subsection 23(2) provides that a waiver of some of the clinical assessment fees or the economic assessment fees may be applicable for listing applications or variation applications (the relevant application) that relates to a medical device if:

- one or more than one listing application or variation application (the 'other applications') are made in addition to the relevant application; and
- the relevant application and the other applications are made specifically in relation for the assessment of related devices; and
- in relation to the clinical assessment fee, the Minister or delegate is satisfied that:
    - a single clinical assessment or one or more abridged clinical assessments can be conducted for the related medical devices, and
    - the fee for at least one clinical assessment has not otherwise been waived; and
- in relation to the economic assessment fee, the Minister or delegate is satisfied that:
    - a single economic assessment or one or more abridged economic assessments can be conducted for the related medical devices, and
    - the fee for one economic assessment has not otherwise been waived; and
- the applicant requested the waiver at the time of making an application; and
- the applicant provided reasons why the clinical assessment fee or the economic assessment fee should not apply to their application.

As defined in section 4 of the MDHTP Rules, medical devices are ***related*** if the main equipment and the accessory and ancillary medical devices are designed to be utilised together for an expected clinical outcome. Related medical devices are covered under the same product material (product brochure, surgical technique, instructions for use, etc) and the clinical data for these devices is provided under the same report from the same source (clinical trial, registry, etc) and this information allows the assessment of all devices together. The device requires the submission of more than one application (an application for each component of the system) resulting in the incurrence of multiple cost-recovery fees.

As these related medical devices may be assessed together, some applications may be subjected to the same or abridged clinical and/or economic assessment(s). As such, the Minister or delegate may determine that one or more of the payable clinical and/or economic assessment fee(s) could be

waived. This subsection provides applicants who are required to submit multiple applications to list all the respective components of the related devices on the Prescribed List, an option to request a waiver of each of the duplicative cost-recovery fees.

The first note under subsection 23(2) clarifies that applications referred to in this subsection may not be the only listing application or variation application made by the person.

The second note under subsection 23(2) refers the reader to the section 4, which defines the circumstances for when medical devices are ***related***.

The third note under subsection 23(2) provides that where the Minister or delegate decides to refuse to a request for the waiver of a cost-recovery fee, notice must be given to the applicant for the refund (see subsection 25(1)) and where the decision was made by a delegate, the decision is a reviewable decision under section 26 of the MDHTP Rules.

Division 4—Review

Section 24 Reviewable decisions

Section 24 prescribes the following decisions made by the Minister or delegate as reviewable decision and therefore subject to internal review:

- that an application requires clinical assessment on any grounds other than those specified in the listing criteria.
- that an application requires economic assessment on any grounds other than those specified in the listing criteria.
- that an application requires a full health technology assessment on any grounds other than requests for MSAC advice to include or amend an MBS item, or where advice on cost-effectiveness or clinical-effectiveness is sought.
- that exceptional circumstances do not exist to justify the refund of either the whole or part of a cost-recovery fee.
- that cost-recovery fee(s) should not be waived for applications made for related devices on the grounds that fewer or abridged clinical and/or economic assessment may be conducted on some of the relevant applications.

The note to this section clarifies that the decision of the Minister could be made by a delegate of the Minister.

Section 25 Notice of review rights

Subsection 25(1) of the MDHTP Rules provides that if a reviewable decision is made, the Minister or delegate must notify the applicant of the decision in writing within 10 business days of making the decision. A written notice of the decision must be accompanied by a statement of the applicant's rights to review.

Subsection 25(2) provides that the written notice must provide instructions on how the applicant may respond to the notice for the purpose of requesting a review of the decision.

Subsection 25(3) clarifies that reviewable decisions remain valid in circumstances where the Minister or delegate does not provide written notice of the decision along with the applicants review rights within 10 days business days of making the decision.

Section 26 Internal review of decisions made by delegates

Subsection 26(1) of the MDHTP Rules provides for the person affected by a reviewable decision under Part 4 (the applicant) to apply in writing, for the Minister or delegate to undertake an internal review of the reviewable decision.

This provision provides applicants who are dissatisfied with a decision with the means to dispute and request review of discretionary decisions made during the application assessment process. As reviewable decisions have a direct impact on determining the total amount payable in relation to cost-recovery fees, the review process may alter the total amount payable by the applicant.

The internal review will be undertaken by a different person with appropriate delegation (not the same person who made the original decision). Should a further review be requested (second internal review), a different third delegate would review the original decision.

The internal review provisions rely on the necessary and convenient power in paragraph 333-20(1)(b) of the Act.

The purpose of the internal review is to provide applicants with the means to request reconsideration of the circumstances informing the outcome of a reviewable decision. It provides applicants with the opportunity to submit additional relevant information (justification) to inform either the level of assessment necessary on their application, or the circumstances that enhance their eligibility to qualify for a waiver. Each stage of the internal review will be conducted fairly by appropriate delegates of the Minister that have not been involved in making the reviewable decision, or if required, have not been involved in making the subsequent internal review decision.

The utilisation of an internal review process allows for the fair and efficient resolution of disputed reviewable decisions. The efficient resolution of all disputes in relation to the payable cost-recovery fees are of high importance to ensure that the application in dispute may still have sufficient time and resources allocated to the assessment to be able to obtain an outcome from the MDHTAC, and if recommended, timely inclusion on the Prescribed List. This ensures that applicants will not be delayed in accessing the public market, and the Australian public will continue to access new medical devices and human tissue products without delay. The internal review process aligns that process which is also in place for similar committees that also conduct a Health Technology Assessment review.

The significant volume of highly technical applications requires the department to efficiently manage all resources allocated and contracted to assess applications within each assessment cycle. It was considered that there was a significant risk to the efficient provision of services if an external process, (requiring dedicated departmental resources to facilitate) was implemented. An external process was judged likely to adversely impact other applicants (those who make applications within the same cycle) due to the disruption to services, and the likely need to continue to allocate resources to the application in dispute. Such external processes were considered likely to have extensive cost and timelines, and likely to significantly delay access to market for the applicant, and access to the product for consumers.

Subsection 26(2) provides that the application seeking a review of a reviewable decision must be made within 10 business days (or longer if approved by the Minister) of receipt of the written notice of the decision. The application must also include the reasons for requesting review of the decision.

Subsection 26(3) provides that within 10 business days of receipt of a written application, the Minister or delegate must review the reviewable decision, and determine whether to affirm or vary the decision, or revoke the decision and make any other decision that is appropriate. The applicant must be notified in writing of the outcome of the ‘initial review decision’ within that period.

Subsection 26(4) provides that an applicant may subsequently apply to review the initial review decision by making an application in writing to a delegate or the Minister within 10 days of receipt of the outcome to the initial review decision.

Subsection 26(5) provides that within 10 days of receipt of a written application to review the initial review decision, the Minister or delegate, who differs from the previous decision maker (further reviewer), must review the initial review decision. The Minister or delegate must determine whether to affirm or vary the initial review decision, or to revoke the initial review decision. The applicant must be notified of the outcome of the further review decision within that period.

Subsections 26(6) and (7) provide limitations to the operation of subsections 26(3) and (5) respectively as it relates to a delegate making an initial review decision and a further review decision. Subsection 26(6) provides that a delegate must not review a reviewable decision under subsection (3) if that delegate was involved in making the reviewable decision. Similarly, subsection 26(7) provides that a delegate must not review an initial review decision under subsection (5) if the delegate was involved in making either the initial review decision or the reviewable decision that relates to the initial review decision.

The reference to a 'delegate' under section 26 refers to a delegate of the Minister who is an SES officer, or acting SES officer in the Department of Health, Disability and Ageing.

Whilst decisions under Part 4 can be subject to internal review, they are not subject to independent merits review. Independent merits review is not available because the Administrative Review Tribunal's (ART) jurisdiction to review administrative decisions (section 12 of the *Administrative Review Tribunal Act 2024* (ART Act)) is only enlivened if an Act or a legislative instrument provides for an application to be made to the ART for review of the decision.

The MDHTP Rules are made under item 4 of the Table in section 333-20 of the Act, which permits the Minister to make Rules for the purposes of Part 3-3 of the Act (requirements for complying health insurance products). Section 328-5 of the PHI Act lists the decisions under the Act that are reviewable by the ART, which do not include any decisions under the MDHTP Rules.

Section 27 Notice of overpayment as a result of a review decision

Section 27 provides that if an applicant is found to have overpaid their cost-recovery fees as a result of either an initial review decision or a further review decision, the Minister or delegate must within 20 business days of the decision being made notify the applicant of the overpayment and refund the amount equal to the amount overpaid.

The note under section 27 refers the reader to section 24 of the MDHTP Rules in relation to refunds for overpayments.

Part 5 Miscellaneous

Section 28 Minister may have regard to recommendations and advice

Section 28 of the MDHTP Rules provides that, in making a decision under section 72-10 of the Act, the Minister or delegate may have regard to a recommendation or advice from the MDHTAC when deciding whether or not to grant an application to list a kind of medical device or human tissue product. Subsection 28(2) clarifies that subsection 28(1) does not limit the matters the Minister or delegate may have regard to in deciding whether or not to grant an application.

The MDHTAC provides recommendations and advice to the Minister for Disability and the National Disability Insurance Scheme, Minister for Health and Ageing and the department about the listing of products on the Prescribed List and the benefits payable by private health insurers. This section is

made for the purposes of paragraph 333-20(1)(b) of the Act, which provides for the MDHTP Rules to deal with matters that are necessary or convenient to be provided for to carry out or give effect to Part 3-3 of the Act.

Schedule 1 – Prescribed List

Schedule 1 lists the listed items (billing codes) for kinds of medical devices and human tissue products and contains the 'minimum benefit' and conditions for provision of the kinds of medical devices and human tissue products for private and public hospital treatment, and hospital-substitute treatment. Schedule 1 is to be known as the Prescribed List.

ATTACHMENT B

Statement of Compatibility with Human Rights

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

Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2025

This legislative 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

The Table in subsection 72-1(2) (the Table) of Part 3-3 of the *Private Health Insurance Act 2007* (the Act) provides for benefit requirements a complying health insurance policy that covers hospital treatment must meet. Under item 4 of the Table, there must be a benefit for the provision of a medical device or human tissue product, of a kind listed in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules, in specified circumstances and under any specified conditions. The specified circumstances are that the listed item is provided in circumstances in which a medicare benefit is payable or in other circumstances which may be set out in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules. The specified conditions are any that may be set out in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules.

Listed items and their minimum benefits are set out in Schedule 1 to *the Private Health Insurance (Medical Devices and Human Tissue Products) Rules*. Schedule 1 is known as the Prescribed List.

The MDHTP Rules also define circumstances in which fees for assessments in relation to listing and variation applications are required, and the associated fee for that assessment. The MDHTP Rules also prescribe cost-recovery arrangements, including the timing for when cost-recovery fees become due and payable, and when cost-recovery fees can be refunded, and waivers can be granted.

The purpose of the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2025* (the MDHTP Rules) is to remake the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules 2025* (the Previous Rules) to update the list of medical devices and human tissue products for which a benefit must be paid, where the listed item is provided in the conditions and circumstances specified in the Act and include some minor clarifications for the operation of the MDHTP Rules. The MDHTP Rules set out the minimum benefit payable for each listed item.

Human rights implications

The MDHTP Rules engage article 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the right to health.

Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in article 12(1) of the ICESCR. Whilst the UN Committee on Economic Social and Cultural Rights has stated that the right to health is not to be understood as a right to be healthy, it does entail a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health. In addition, the right to health must meet certain key requirements, including that health care must be scientifically and medically appropriate and of good quality.

Analysis

The addition of new items in the Prescribed List will increase the amount of choice an insured person can have in relation to the kind of medical device or human tissue product for which they must receive

a minimum private health insurance benefit. This will impact positively on the right to health of insured persons.

The removal of entries at the request of the sponsors of devices or products is usually because these devices or products are no longer being supplied for use to privately insured persons in Australia. Generally, the devices and products removed from the MDHTP Rules have been replaced by newer models due to upgraded technologies or advancements in surgical procedures, or are still available for privately insured patients, but are supplied by different sponsors.

The MDHTP Rules will continue listing medical devices in Part D and provide listing criteria for these devices. This will ensure that devices that have historically been included in Part D of Schedule 1 to the Previous Rules will continue to be listed, and patients will continue to access these devices.

Conclusion

The MDHTP Rules is compatible with human rights because it enables advances in the protection of human rights, in particular the right to health.

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