EXPLANATORY STATEMENT

Issued by the authority of the Minister for Health and Ageing

Private Health Insurance Act 2007

Private Health Insurance (Medical Devices and Human Tissue Products) Amendment Rules (No. 1) 2025

Purpose

The purpose of the *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment Rules (No. 1) 2025* (Amendment Rules) is to amend the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules 2025* (MDHTP Rules) made under section 333-20 of the *Private Health Insurance Act 2007* (the Act).

The Amendment Rules amend 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. Listed items and their minimum benefits are set out in Schedule 1 to the MDHTP Rules, which is known as the Prescribed List of Medical Devices and Human Tissue Products (the Prescribed List).

The Amendment Rules also update the cost recovery fees for applications to list a medical device or human tissue product or to make changes to a current listing. The cost recovery fees are consistent with the Australian Government Cost Recovery Policy and accurately reflect the efficient costs of providing services. Fees are calculated using an activity-based cost model.

The Amendment Rules also clarify the application process for new listings or variations to listings for Part D of the Prescribed List, and, that a payment of a full health technology assessment pathway fee is exempt where a clinical assessment fee and an economic assessment fee have already been paid by the applicant.

Background

The Table in subsection 72-1(2) of Part 3-3 of the Act (the Table) provides for the benefit requirements a complying health insurance policy, that covers hospital treatment, must meet. Item 4 of the Table requires a benefit to be paid for the provision of a Prescribed List medical device or human tissue product in specified circumstances and under any specified conditions. A listed item meets the specified circumstances when a medicare benefit is payable, or, in other circumstances set out in the MDHTP Rules. The specified conditions are any that are set out in the MDHTP Rules.

If the complying health insurance policy also covers hospital-substitute treatment, then the same Item 4 requirements apply.

A person may apply to the Minister, under subsection 72-10(2) of the Act, to have the MDHTP Rules list a medical device or human tissue product. If the listing application is granted, the device or human tissue product becomes a ‘listed item’ and is added to the Prescribed List. The applicant is responsible for any obligations related to the listed item and must ensure accurate and up-to-date information is provided to the Department of Health, Disability and Ageing (the department) if circumstances relating to the listed item change.

The Amendment Rules are required to reflect new listing applications that have been granted. The Amendment Rules also include changes to listings in approved variation applications as well as updates to the cost recovery fees to reflect the cost of providing Prescribed List application assessment services.

To the extent that any information collected as part of the application process 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. Personal information collected during this process is generally limited to applicant names and contact details. The department's Privacy Policy, which is available on the department's website, also applies.

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.

Section 72-15 of the Act enables 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.

Reliance on subsection 33(3) of the *Acts Interpretation Act 1901*

In addition to the power to make this instrument under section 333-20 of the Act, subsection 33(3) of the *Acts Interpretation Act 1901* provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Commencement

The Amendment Rules commence on 1 July 2025.

Consultation

In making the Amendment Rules and updating the Prescribed List, 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 that makes recommendations and provides advice to enable the Minister to exercise their powers under the *Private Health Insurance Act 2007* and the department to administer 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.

People who apply under subsection 72-10(2) of the Act to list a medical device or human tissue product on the Prescribed List apply in an approved form. The assessment process includes opportunities to provide further information and clarification where necessary. Under the Act, an applicant is informed of the decision whether or not to grant a listing application. If a listing application is not granted, the Minister must provide reasons for the decision. Applications to vary a listing are made through standard forms and the assessment process includes opportunities to provide further information and clarification where necessary. Applicants are notified of the outcome of these applications.

The Prescribed List has been subject to reforms announced in the 2021-22 Budget, which built on previous reform activities. The aim of these reforms includes improving sustainability of private health insurance and measures, including better aligning the Prescribed List benefits with the prices paid in the public hospital system. As part of this reform program, a reduction in benefits for Cardiac Implantable Electronic Devices (CIEDs) listed on the Prescribed List is being given effect. Consultation was undertaken in relation to this reform activity as part of the reform program.

The amended fee amounts are consistent with the fee amounts industry representatives have been advised through consultation on the MDHTP Rules and the draft 2025-26 Cost Recovery Implementation Statement (CRIS). Consultation on this CRIS occurred for a 3-week period from 16 May – 6 June 2025.

The amendments to section 15 in relation to applications for new listings or variation to a listing for Part D of the Prescribed List, and the amendments to section 19 in relation to the full health technology assessment pathway fee are minor clarifications and no consultation was undertaken as a result.

Impact Analysis

A Regulation Impact Statement was undertaken for the reforms to the Prescribed List (formerly known as the Prostheses List) which covers legislative implementation through the MDHTP Rules, including cost recovery (OBPR ID 43619).

General

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

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

The Amendment 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) Amendment Rules (No. 1) 2025*

Section 1 Name

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

Section 2 Commencement

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

Section 3 Authority

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

Section 4 Schedules

Section 4 provides that the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules 2025* (MDHTP Rules) are amended as set out in Schedule 1.

Schedule 1 – Amendments

Item 1 – Section 4

Section 4 of the MDHTP Rules provides defined terms and concepts that apply to the Rules. Item 1 is a consequential amendment to section 4 that repeals the redundant definition of 'former Prescribed List'.

Item 2, 3 and 4 – Section 15

Section 15 of the MDHTP Rules provides listing criteria for medical devices that are to be listed in Part D of the Prescribed List (Schedule 1 of the MDHTP Rules).

Subsection 15(1) sets out that a medical device must not be listed on Part D of the Prescribed list unless it has met subsections (2), (3) and (4). Item 2 is a consequential amendment that omits the word 'former' from the heading above this provision, as the term' former Prescribed List' has been removed from Section 4 (definitions) of the MDHTP Rules under Item 1 of the Amendment Rules.

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.

Item 3 amends subsection 15(2) of the MDHTP Rules to repeal the reference to the 'former Prescribed List' and substitute it with a reference to Schedule 1 of the MDHTP Rules. As such the applicant must make their application consistent with the Prescribed List in force at the time of the application.

The note under subsection 15(2) clarifies the structure of the Prescribed List and that an application for Part D must be consistent with the current structure of the Part. Item 4 updates the note under subsection 15(2) consistent with the update to subsection 15(2) under Item 3 of the Amendment Rules.

Item 5 – Paragraph 16(2)(a)

Section 16 of the MDHTP Rules specifies the cost-recovery fees that may be charged for the purposes of section 72-15 of the Act. Item 5 amends subsection 16(2) of the MDHTP Rules to increase the cost recovery fee for a standard application for listing and variation applications from "$1,420" to "$1,460".

Item 6 – Subsection 17(2)

Section 17 of the MDHTP Rules sets out when a clinical assessment is required for a listing or variation application relating to a medical device, and the related cost recovery fee amount.

Item 6 amends subsection 17(2) of the MDHTP Rules to increase the cost recovery fee for a clinical assessment from "$3,970" to "$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.

Items 7, 8 and 9 – Subsection 18(2)

Section 18 of the MDHTP Rules sets out when an economic assessment is required for a listing or variation application relating to a medical device, and the related cost-recovery fee amounts depending on whether the fee is considered a 'simple fee', 'complex fee' or 'other fee'.

Item 7 amends subsection 18(2)(a) of the MDHTP Rules to increase the 'simple' economic assessment fee – increased from "$9,250" to "$12,150".

Item 8 amends subsection 18(2)(b) of the MDHTP Rules to increase the 'complex' economic assessment fee – increased from "$17,680" to "$23,460"

Item 9 amends subsection 18(2)(c) of the MDHTP Rules to increase the 'other' economic assessment fee – increased from "$28,920" to "$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.

Items 10, 11 and 12 – Section 19

Section 19 of the MDHTP Rules sets out when a full health technology assessment pathway is required for a listing or variation application relating to a medical device, and the related cost recovery fee amount.

Item 10 amends repeals and substitutes subsection 19(2) of the MDHTP Rules. The substituted subsection omits current paragraph (2)(b) and renumbers the subsection to reflect the removal of paragraph (2)(b). The removal of paragraph (2)(b) is consequential to the amendment in item 12.

Item 11 amends subsection 19(3) of the MDHTP Rules to increase the cost recovery fee for a full health technology assessment pathway from "$2,990" to "$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.

Item 12 adds subsection (4), so that the full health technology assessment fee applies to an application except where the applicant has paid, or will be liable to pay, both a clinical assessment fee and an economic assessment fee in relation to the application. This amendment clarifies that it is only the fee

for the assessment that is exempt where the clinical assessment and economic assessment have already been paid, or are liable to be paid, consistent with the policy intent.

Item 13 – Schedules 1 and 2

Schedule 1 contains a list of medical devices and human tissue products, as well as the 'minimum benefit' and conditions for provision of those medical devices and human tissue products when used in private and public hospital treatment, and hospital-substitute treatment. Schedule 1 is known as the Prescribed List of Medical Devices and Human Tissue Products (Prescribed List).

Item 4 repeals Schedule 1 and substitutes it with an updated list of medical devices and human tissue products. Schedule 2 is repealed. There is no intention for a Schedule 2 to be included in the instrument after commencement.

Schedule 1 of the Amendment Rules (the Prescribed List) differs from the previous Prescribed List (which commenced on 1 March 2025) by:

- Addition of 198 new billing codes to Part A following accepted and granted new applications, 2 billing codes as the result of expansion applications and 348 new billing codes due to transfer of billing codes from one sponsor to another.
- Changes to 345 billing codes in Part A following accepted amendment applications, correction of 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 348 billing codes from Part A following acceptance of applications for transfer of billing codes to the new sponsors, removing 1 billing code following completion of expansion application, and deletion of 395 billing codes following acceptance of deletion applications and other requests.
- Addition of 9 new billing codes to Part B following accepted and granted new applications, and 8 new billing codes due to transfer of billing codes from one facility to another.
- Changes to 52 billing codes in Part B following accepted amendment applications and minor corrections.
- Deletion of 8 billing codes in Part B following acceptance of applications for transfer of the billing codes to the new sponsors, and deletion of 68 billing codes following acceptance of the deletion applications and other requests.
- Addition of 1 new billing code to Part C following accepted and granted new application.
- Changes to 4 billing codes in Part C following accepted amendment applications.
- Deletion of 2 billing codes in Part C following acceptance of deletion applications.
- Addition of 6 new billing codes to Part D following accepted and granted new applications, 2 billing codes as the result of expansion applications, and 5 new billing codes due to transfer of billing codes from one sponsor to another.
- Changes to 10 billing codes in Part D following accepted amendment applications.
- Deletion of 5 billing codes in Part D following acceptance of applications for transfer of billing codes to new sponsors, removing 1 billing code following completion of expansion application, and deletion of 19 billing codes following acceptance of deletion applications and other requests.

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

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.

Further, the Prescribed List differs from the previous (March 2025) Prescribed List by correcting the listing details of some of the billing codes that were 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.

The changes also include benefit reductions for Cardiac Implantable Electronic Devices (CIEDs). One of the measures under the Prescribed List reforms was reducing the gap between the prices payable for medical devices in public hospitals and the Prescribed List benefits payable for the same devices for privately insured patients. The last scheduled reduction of the PL benefits under this measure occurred in 2024, however commencement of the benefit reductions for the Cardiac Implantable Electronic Devices (CIEDs) was delayed until July 2023 (with 3 reductions every 12 months).

The current Prescribed List benefits for CIEDs consist of two components, which are the benefits for devices and the reimbursement for the costs of technical support services for maintaining the CIED for the life of the device. In 2024 the Medical Services Advisory Committee (MSAC) advised on the rate between these two components, and it was agreed that the benefits reductions for CIED will only apply on the device component of the benefits. The Amendment Rules will give effect to the last reduction to the Prescribed List benefits payable for 248 billing codes for CIEDs.

The Prescribed List also differs to the previous (March 2025) Prescribed List by applying a change to the condition applying to 41 relevant billing codes, plus one new billing code, for surgical guides and biomodels devices. Following review of the existing condition, including the seeking of expert advice, it was decided to amend the condition and the restriction for the reimbursement. The current condition limits the reimbursement to 3 or less benefits for any billing codes for surgical guides or biomodels, and no more than 6 in total. The new condition will allow for reimbursement of 6 Prescribed List benefits for any combination of billing codes for surgical guides or biomodels used in a procedure.

Some of the conditions placed on the billing codes have been updated. The listed items and billing codes with conditions in the Prescribed List imposed under section 7 of the MDHTP Rules are:

<u>Part A</u>
BA313 (TissuePatchDural 100*100)
IJ022 (Regenerative Dural Repair Patch (ReDuraTM))
IJ023 (Regenerative Dural Repair Patch (ReDuraTM))
IJ024 (Regenerative Dural Repair Patch (ReDuraTM))
IJ025 (Regenerative Dural Repair Patch (ReDuraTM))
LH765 (Neodura Dural Repair Patch $\leq$10cm^2)
SK494 (DuraMatrix)
HU397 (Arthrex Universal Glenoid Baseplate)
BF031 (MixMax Bone Cement)
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)
HU267 (Cerclage System)
HW785 (AutoPlex Mixer and Delivery System with VertaPlex HV)
HW856 (Augment Bone Graft - rhPDGF-BB component))
KN004 (Invictus Spinal Cement System))
MA545 (Ligamys DIS Suture with button)
FV015 (Simplant Surgical Guides)
HI001 (DDN Guide)

HI002 (DDN Biomodel)
HI005 (DDN Biomodel)
HI006 (DDN Guide)
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)
JN004 (ARDS Anatomic Biomodel)
KT004 (UNIQOS Patient Specific Anatomical Biomodel)
KT005 (UNIQOS Patient Specific Surgical guides)
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)
QQ311 (Stryker Patient-Matched TMJ – Anatomic Biomodel)
QQ312 (AI Guide)
RV021 (ReconPILOT Biomodelled Patient Specific Surgical Guide for Craniofacial Surgery)
RV022 (ReconPILOT Biomodelled Patient Specific Surgical guide for Maxillofacial surgery)
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)
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)
QQ199 (NEUTRINO NxT VR ICD Model CDVRA600Q)
SJ417 (Gallant VR ICD Model CDVRA500Q)
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)
MI413 (Crome™ DR ICD MRI SureScan™ with BlueSync mobile remote monitoring)
QQ200 (Neutrino NxT DR ICD Model CDDRA600Q)

SJ418 (Gallant DR ICD Model CDDRA500Q)
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)
QQ164 (Neutrino NxT HF CRT-D Model CDHFA600Q)
SJ424 (Gallant HF CRT-D Model CDHFA500Q)
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)
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)
EL069 (PASCAL Precision System (PASCAL Implant and PASCAL ACE Implant)
SJ482 (Navitor™ Transcatheter Aortic Valve)
BF025 (Pedicle Screw)
BF026 (Pedicle Screw)
DE669 (icotec Pedicle System Polyaxial Screw)
DE678 (icotec Anterior Cervical Plate System - Screw)
LB089 (CREO Stabilization System Preassembled Monoaxial Screw)
BF027 (Locking Element)
DE671 (icotec Pedicle System Set Screw)
LB088 (CREO Stabilization System Locking Cap)
DE679 (icotec Anterior Cervical Plate)
DE680 (icotec Anterior Cervical Plate)
HW776 (Cayman United Plate)
BF028 (Rods, Curved)
BF029 (Rods)
DE670 (icotec Pedicle System Rod)
DE818 (BlackArmor Carbon Fibre/PEEK Curved / Multicurved Rods)
LB181 (REFLECT Staple)

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

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) Amendment Rules (No. 1) 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) Act2011*.

Overview of the Legislative Instrument

The purpose of the *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment Rules (No. 1) 2025* (Amendment Rules) is to amend the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules 2025* (MDHTP Rules) made under section 333-20 of the *Private Health Insurance Act 2007* (the Act).

The Amendment Rules amend 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. Listed items and their minimum benefits are set out in Schedule 1 to the MDHTP Rules known as the Prescribed List of Medical Devices and Human Tissue Products (Prescribed List).

The Amendment Rules also update the cost recovery fees that apply to applications to list a medical device or human tissue product or to make changes to a current listing. The amended fees are consistent with the Australian Government Cost Recovery Policy and ensure they accurately 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. The Amendment Rules also clarify a number of other minor matters.

Human rights implications

The Amendment 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 to list 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 will continue to be listed, and patients will continue to access these devices.

Conclusion

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

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