**EXPLANATORY STATEMENT**

***Private Health Insurance Act 2007***

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

**Purpose**

The purpose of the *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment Rules (No. 2) 2023*(MDHTP Amendment Rules) is to amend the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023* (MDHTP Rules). The MDHTP Amendment Rules amend the conditions applied to 37 billing codes listed in Part A of Schedule 1, commonly known as the Prescribed List of Medical Devices and Human Tissue Products (Prescribed List), correct the minimum benefit for one billing code in Part B of Schedule 1, correct benefits for 5 billing codes in Part D of Schedule 1, and to make editorial changes.

**Background**

The MDHTP Rules apply a condition on 37 billing codes for surgical guides and biomodels in the Plastic and Reconstructive category in Part A of the Prescribed List, that must be satisfied in relation to the provision of the listed items. This follows a post-listing review of these devices to test whether they satisfy the criteria for listing and the circumstances in which they are required to be reimbursed. The review found there is evidence to demonstrate that surgical guides and biomodels are clinically effective when used in craniomaxillofacial surgery procedures involving insertion of a medical device, but there is insufficient evidence to support listing of these billing codes for any other types of surgeries and that the Prescribed List reimbursement of the devices should be restricted in respect to number of devices reimbursed per procedure. Accordingly, the condition, placed on the billing codes for surgical guides and biomodels in the MDHTP Rules, specifies that: *Prescribed List reimbursement of the device is restricted to the use in craniomaxillofacial surgery procedures involving insertion of a medical device listed in Schedule 1, and for no more than 3 devices per procedure*.

Following registration of the MDHTP Rules, the Department of Health and Aged Care received queries from several stakeholders seeking clarification on the interpretation, intent, and scope of the condition. Stakeholders also raised concerns that insufficient notice had been given to stakeholders about the commencement of the condition on 1 November 2023.

The MDHTP Amendment Rules revise the condition to clarify the circumstances in which benefits are payable for the billing codes for surgical guides and biomodels. The MDHTP Amendment Rules also provide that the condition will become effective on 1 February 2024. The delayed commencement will allow the booked procedures to go ahead and for stakeholders to plan accordingly future procedures using the devices.

The revised condition specifies that: *Prescribed List reimbursement is restricted to the use of the device in craniomaxillofacial surgery procedures involving insertion of an implantable medical device, where that implantable device is listed in either sub-category 07.01 - Craniomaxillofacial Reconstruction & Fixation, or 07.02 – Craniomaxillofacial Implants, or 07.04 – Distractor Systems of Schedule 1, or sub-category 07.03 - Dental Implants, but only if the [dental] implantable medical device is explicitly identified in the product name or description of the billing code for the surgical guide or biomodel and is used in hospital. Not limiting the above, for a claim for any implantation procedure (defined by the respective MBS items stated in the claim) for a patient, the Prescribed List reimbursement is limited to 3 or less PL benefits for any billing codes for surgical guides or biomodels, or no more than 6 benefits if both surgical guides and biomodels (maximum 3 for each) have been used in an implantation procedure for a patient.* *This restriction is not impacted by a number of devices implanted during a procedure. The condition is taking effect on 1 February 2024.*

**Authority**

Section 333-20 of the Act provides that the Minister may make Private Health Insurance (Medical Devices and Human Tissue Products) 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.

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.

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

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 MDHTP Amendment Rules commence on the day after the instrument is registered on the Federal Register of Legislation.

**Consultation**

In making the MDHTP Amendment Rules, the rule-maker had regard to feedback from stakeholders, including hospitals, private health insurers and medical devices sponsors on the condition to be applied to surgical guides and biomodels, and advice from the sponsors of the billing codes regarding the incorrect benefits.

**General**

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

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

This instrument is 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. 2) 2023***

**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. 2) 2023.*

**Section 2 Commencement**

Section 2 provides that the instrument commences on the day after the instrument is registered.

**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 Schedules**

Section 4 provides that the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023* is amended as set out in Schedule 1.

**Schedule 1 – Amendments**

**Items 1 to 15**

Items 1 to 15 amend specific provisions of the MDHTP Rules which currently contain incorrect references to provisions in the MDHTP Rules. The following provisions affected are amended by the MDHTP Amendment Rules to correct these references: certain definitions within section 5; paragraphs (b) to (d) of subsection 17(2); note 2 to subsection 18(1); note 2 to subsection 19(1); the note to subsection 19(4); the note to subsection 20(1); the example to subsection 23(3); note 1 to subsection 23(5); notes 2 and 3 to subsection 23(5); and the note to subsection 28.

**Item 16**

Item 16 repeals Schedule 1 – Listed medical devices and human tissue products and substitutes a new Schedule 1 – Listed medical devices and human tissue products, with the revised condition applied to 37 billing codes listed in Part A of Schedule 1, and the minimum benefits corrected for one billing code in Part B and 5 billing codes in Part D.

**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.  2) 2023***This 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 Disallowable Legislative Instrument**

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 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.

The purpose of the *Private Health Insurance (Medical Devices and Human Tissue Products) Amendment Rules (No. 2) 2023*(MDHTP Amendment Rules) is to amend the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023* (MDHTP Rules), made under section 333-20 of the *Private Health Insurance Act 2007* (Act). The MDHTP Amendment Rules amend the condition applied to 37 billing codes listed in Part A of the Schedule, commonly known as the Prescribed List of Medical Devices and Human Tissue Products (Prescribed List), correct the minimum benefit for one billing code in Part B of the Schedule 1, correct benefits for 5 billing codes in Part D of the Schedule 1, and to make editorial changes.

The MDHTP Rules apply a condition on 37 billing codes for surgical guides and biomodels in Part A of the Prescribed List, that must be satisfied in relation to the provision of the listed items. This follows a post-listing review of these devices to test whether they satisfy the criteria for listing and the circumstances in which they are required to be reimbursed. The review found that there is evidence to demonstrate that surgical guides and biomodels are clinically effective when used in craniomaxillofacial surgery procedures involving insertion of a medical device, but there is insufficient evidence to support listing of these billing codes for any other types of surgeries and that the Prescribed List reimbursement of the devices should be restricted in respect to number of devices reimbursed per procedure. Accordingly, the condition, placed on the billing codes for surgical guides and biomodels in the MDHTP Rules, specifies that: *Prescribed List reimbursement of the device is restricted to the use in craniomaxillofacial surgery procedures involving insertion of a medical device listed in Schedule 1, and for no more than 3 devices per procedure*.

Following registration of the MDHTP Rules, the Department of Health and Aged Care received queries from several stakeholders seeking clarification on the interpretation, intent, and scope of the condition. Stakeholders also raised concerns that insufficient notice had been given to stakeholders about the commencement of the condition on 1 November 2023.

The MDHTP Amendment Rules revise the condition to clarify the circumstances in which benefits are payable for the billing codes for surgical guides and biomodels. The MDHTP Amendment Rules also provide that the condition will become effective on 1 February 2024. The delayed commencement will allow the booked procedures to go ahead and for stakeholders to plan accordingly future procedures using the devices.

The revised condition specifies that: *Prescribed List reimbursement is restricted to the use of the device in craniomaxillofacial surgery procedures involving insertion of an implantable medical device, where that implantable device is listed in either sub-category 07.01 - Craniomaxillofacial Reconstruction & Fixation, or 07.02 – Craniomaxillofacial Implants, or 07.04 – Distractor Systems of Schedule 1, or sub-category 07.03 - Dental Implants, but only if the [dental] implantable medical device is explicitly identified in the product name or description of the billing code for the surgical guide or biomodel and is used in hospital. Not limiting the above, for a claim for any implantation procedure (defined by the respective MBS items stated in the claim) for a patient, the Prescribed List reimbursement is limited to 3 or less PL benefits for any billing codes for surgical guides or biomodels, or no more than 6 benefits if both surgical guides and biomodels (maximum 3 for each) have been used in an implantation procedure for a patient. This restriction is not impacted by a number of devices implanted during a procedure. The condition is taking effect on 1 February 2024.*

**Human rights implications**

This instrument engages 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 clarification of the condition applied to the 37 billing codes ensures that insured patients will have access to medical devices that have been demonstrated to be comparatively clinically effective and cost effective. Correcting the benefits for the 6 billing codes will ensure that privately insured patients will be reimbursed appropriately for the human tissue product and medical devices. This will impact positively on the right to health of insured persons.

**Conclusion**

The Disallowable Legislative Instrument is compatible with human rights because it promotes the protection of human rights, in particular the right to health.

 **Andrew Rintoul**

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**Prostheses List Reform Taskforce**

**Technology Assessment and Access Division**

**Health Resourcing Group**

**Department of Health****and Aged Care**