

## EXPLANATORY STATEMENT

### *Private Health Insurance Act 2007*

#### *Private Health Insurance (Prostheses) Amendment Rules (No. 4) 2019*

Section 333-20 of the *Private Health Insurance Act 2007* (the Act) provides that the Minister may make Private Health Insurance (Prostheses) 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.

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.

The table in subsection 72-1(2) of Part 3-3 of the Act provides for benefit requirements that a complying health insurance policy that covers hospital treatment must meet. Under item 4 of that table there must be a benefit for the provision of a prosthesis, of a kind listed in Private Health Insurance (Prostheses) Rules (i.e. a listed prosthesis), in specified circumstances and under any specified conditions. The specified circumstances are that the listed prosthesis is provided in circumstances in which a medicare benefit is payable or in other circumstances which may be set out in Private Health Insurance (Prostheses) Rules. The specified conditions are any that may be set out in Private Health Insurance (Prostheses) Rules.

If the complying health insurance policy also covers hospital-substitute treatment, under item 4 of the table in subsection 72-1(2) of Part 3-3 of the Act the same requirements apply.

The *Private Health Insurance (Prostheses) Rules 2019 (No. 1)* (Prostheses Rules) were made for the purposes of section 333-20 of the Act. Listed prostheses and their minimum benefits are set out in the Schedule to the Rules. The list of prostheses in the Schedule is commonly referred to as the Prostheses List.

### **Purpose**

The purpose of the *Private Health Insurance (Prostheses) Amendment Rules (No. 4) 2019* (the Amending Rules) is

- to update references to podiatric surgeons consistent with amendments that were made to the Private Health (Prostheses) Rules 2018 by the *Private Health Insurance (Reforms) Amendment Rules 2018*, but inadvertently omitted from the Prostheses Rules; and
- to update the listing criteria that must be met for a listing application to be granted for the listing of a kind of prostheses in Part C of Schedule 1 to the Prostheses Rules.

The Schedule to the Prostheses Rules has three parts:

- Part A – Prostheses List;
- Part B – Human Tissue List; and

- Part C – Other Prostheses.

Rule 13 sets out the listing criterion that must be met for a listing application to be granted by the Minister for listing a kind of prosthesis in Part C of Schedule 1. The criterion currently includes that the kind of prosthesis is either an insulin infusion pumps, an implantable cardiac event recorder, a cardiac home/remote monitoring system, a cardiac ablation catheter, a mapping catheter for cardiac ablation, or a patch for cardiac ablation.

The Amending Rules add to the listing criterion so that the kind of prosthesis may also be: a monopolar device for surgical cardiac ablation, a bipolar device for surgical cardiac ablation, a system for surgical cardiac ablation, or a probe for surgical cardiac ablation.

### **Consultation**

The Government made an agreement with the Medical Technology Association of Australia (MTAA) in October 2017 to promote the sustainability of privately insured healthcare and to support a viable, innovative and diverse medical technology sector in Australia. The agreement includes a commitment to review, through the Prostheses List Advisory Committee (PLAC), ways of listing new targeted medical devices on the Prostheses List that do not meet the current criteria for listing but are safe, clinically effective and cost effective, including, but not limited to, cardiac ablation catheters for atrial fibrillation.

Following advice from the Medical Services Advisory Committee and the PLAC that cardiac ablation is a clinically effective and cost effective treatment for atrial fibrillation, catheter cardiac ablation devices were listed on the Prostheses List in March 2019.

The PLAC then considered listing cardiac ablation devices used in surgical procedures to treat atrial fibrillation. Following advice from its sub-committee - the Cardiothoracic Prostheses Clinical Advisory Group – and consultation with the sponsors of these devices, the PLAC agreed in-principle on 16 May 2019 to recommend that the Minister list monopolar devices for surgical cardiac ablation, bipolar devices for surgical cardiac ablation, systems for surgical cardiac ablation, mapping catheters for surgical cardiac ablation, and probes for surgical cardiac ablation on Part C of the Prostheses List.

The PLAC is the ministerially appointed committee made up of experts in the health sector and advisory members nominated by the major stakeholder organisations, representing the interests of private health insurers, private hospitals and day hospitals, medical device sponsors, clinicians and the Department of Veterans' Affairs.

Details of the Amending Instrument are set out in the [Attachment](#).

The Amending Instrument commences the day after registration.

The Amending Instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

**Details of the Private Health Insurance (Prostheses) Amendment Rules (No. 4) 2019**

Rule 1 – Name

Rule 1 provides for the Amending Rules to be referred to as the *Private Health Insurance (Prostheses) Amendment Rules (No. 4) 2019*.

Rule 2 – Commencement

Rule 2 provides that the Amending Rules commence the day after registration.

Rule 3 – Authority

Rule 3 provides that the Amending Rules is made under item 4 of the table in section 333-20 of the *Private Health Insurance Act 2007*.

Rule 4 – Schedules

Rule 4 provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – Amendments

***Private Health Insurance (Prostheses) Rules 2019 (No. 1)***

**Item 1 - Rule 4 (definition of accredited podiatrist)**

Item 1 repeals the current definition of “accredited podiatric surgeon” (and the associated note about this definition).

**Item 2 – Rule 4**

Item 2 inserts a new definition into Rule 4. The new definition of “registered podiatric surgeon” as “a podiatric surgeon who holds specialist registration in the specialty of podiatric surgery under the National Law” will be consistent with the definition for this type of health professional under the *Private Health Insurance (Accreditation) Rules 2011* and the *Private Health Insurance (Complying Product) Rules 2015*.

The note to this new definition makes it clear that the registration requirements for a registered podiatric surgeon for the purposes of these Rules are the same as those for the Private Health Insurance (Accreditation) Rules as made from time to time.

**Item 3 – Paragraph 7(a)**

Item 3 makes a consequential amendment to paragraph 7(a).

#### **Item 4 - Rule 13**

Item 1 repeals and substitutes the current rule 13. The listing criterion in current rule 13 remain except that “a mapping catheter for cardiac ablation” has been replaced with “a mapping catheter for catheter cardiac ablation” and additional paragraphs have been added specifying the following kinds of prosthesis: a monopolar device for surgical ablation, a bipolar device for surgical cardiac ablation, a system for surgical cardiac ablation, and a probe for surgical cardiac ablation.

The Note remains.

## Statement of Compatibility with Human Rights

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

### ***Private Health Insurance (Prostheses) Amendment Rules 2019 (No. 4)***

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 instrument**

The *Private Health Insurance (Prostheses) Amendment Rules 2019 (No. 4)* amends the *Private Health Insurance (Prostheses) Rules 2019 (No. 1)* to make technical changes to references to podiatric surgeons and to amend the listing criterion that must be met for a listing application to be granted for listing a kind of prosthesis in Part C of Schedule 1 to the *Private Health Insurance (Prostheses) Rules 2019 (No. 1)*.

The listing criterion currently includes that the kind of prosthesis is either an insulin infusion pumps, an implantable cardiac event recorder, a cardiac home/remote monitoring system, a cardiac ablation catheter, a mapping catheter for cardiac ablation or a patch for cardiac ablation. The instrument adds to the listing criterion so that the kind of prosthesis may also be: a monopolar device for surgical cardiac ablation, a bipolar device for surgical cardiac ablation, a system for surgical cardiac ablation, or a probe for surgical cardiac ablation.

This will enable the Minister to include these kinds of prostheses in Part C of Schedule 1 if the Minister decides to grant an application for the listing of that kind of prosthesis, so an insured person with appropriate cover will receive a minimum benefit for the provision of the prosthesis (within the requirements of the legislation).

#### **Human rights implications**

This instrument engages article 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health.

##### *Right to Health*

The 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.

##### *Analysis*

This instrument ensures that privately insured patients can receive a minimum benefit for the provision of a prosthesis they receive from a registered podiatric surgeon (if other requirements are met).

By amending the listing criteria for prosthesis to be listed in Part C of Schedule 1, the instrument also enables the Minister to include additional kinds of items in Part C of the Schedule if the Minister decides to do so. The addition of new items, as a consequence of the amended listing criteria, will ensure that an insured person with appropriate cover will receive a minimum benefit for the provision of the listed prosthesis (if other requirements are met). This will impact positively on the right to health of insured persons.

## **Conclusion**

The instrument is compatible with human rights because it enables advances in the protection of human rights.

**Karen Binnekamp**  
**Acting Assistant Secretary**  
**Office of Health Technology Assessment**  
**Technology Assessment and Access Division**  
**Department of Health**