

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

Private Health Insurance (Prostheses Application and Listing Fees) Act 2007

Private Health Insurance (Prostheses Application and Listing Fee) Rules 2018

The *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007* (the Act) imposes, as a tax, fees in relation to applications for listing, and listing, of prostheses, and related purposes.

The table in subsection 72-1(2) of Part 3-3 of the *Private Health Insurance Act 2007* (the PHI 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.

Section 8 of the Act provides that the Minister may, by legislative instrument, make Private Health Insurance (Prostheses Application and Listing Fee) Rules providing for matters required or permitted by the Act to be provided, or necessary or convenient to be provided in order to carry out or give effect to the Act. The Act does not specify any conditions that need to be met before the power to make the Rules under section 8 of the Act may be exercised.

Sections 3 and 4 of the Act provide that the Rules may specify:

- an application fee for applications made under section 72-10 of the PHI Act (subsection 3(1) of the Act);
- an initial listing fee for the purposes of subsection 72-10(5) of the PHI Act (subsection 4(4) of the Act);
- an ongoing listing fee for the purposes of section 72-15 of the PHI Act (subsection 4(3) of the Act); and
- the ongoing listing fee imposition days (subsections 4(4) and (5) of the Act).

These specified fees are imposed as taxes (see subsections 3(2), 4(2) and 4(4) of the Act).

Purpose of the Rules

The purpose of the *Private Health Insurance (Prostheses Application and Listing Fee) Rules 2018* (the Rules) is to set the application fee, initial listing fee and ongoing listing fee to be paid by sponsors who wish to have a prosthesis listed on the Private Health Insurance (Prostheses) Rules.

The Rules are a substantive replication of the *Private Health Insurance (Prostheses Application and Listing Fee) Rules 2008 (No.1)* (the Previous Rules)—which were due to be automatically repealed (sunset) on 1 October 2018 under section 50 of the *Legislation Act 2003*—with a number of minor machinery changes. As part of the sunset process, a fit-for-purpose review of the Previous Rules was undertaken. The review determined that the instrument was still required. The Rules also repeal the Previous Rules.

Importantly, there has been no change in any of the fees from the Previous Rules. Section 5 and 6 of the Act specify the maximum amount of an application fee, initial listing fee and ongoing listing fee to be \$2000 (indexed each financial year). The fees set out in the Rules range from nil to \$600 and have not been increased since 2009. The purpose of these taxes is to recover the cost from industry for the administration of the prostheses list arrangements and for the clinical assessment of products using expert advisory groups established to advise on products placed on the list.

Consultation

The Rules have been made following consultation with Australia's two leading industry associations, the Medical Technology Association of Australia and Ausbiotech.

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA represents manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability.

AusBiotech is Australia's life sciences organisation, with a network of over 3,000 members in the life sciences, including therapeutics, medical technology (devices and diagnostics), digital health, food technology and agricultural, environmental and industrial sectors.

Consultation with these relevant industry associations was undertaken via email in August 2018. Both MTAA and AusBiotech did not make any objections to the Rules on the basis that the Rules are a substantive replication of the Previous Rules and have not increased the amount of any fees.

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

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

The Rules commence on the day after registration.

DETAILS OF THE *PRIVATE HEALTH INSURANCE (PROSTHESES APPLICATION AND LISTING FEE) RULES 2018*

Section 1 – Name

Section 1 provides that the name of the Rules is the *Private Health Insurance (Prostheses Application and Listing Fee) Rules 2018* (the Rules).

Section 2 – Commencement

Section 2 of the Rules provides that the Rules commence on the day after registration.

Section 3 – Authority

Section 3 of the Rules provides that the Rules are made under section 8 of the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*.

Section 4 – Definitions

Section 4 of the Rules provides the definitions of certain terms used in the Rules.

Section 5 – Schedules

Section 5 of the Rules 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.

Section 6 – Application Fees

Section 6 of the Rules provides application fees for applications made to the Minister under subsection 72-10(2) of the *Private Health Insurance Act 2007* (PHI Act).

Paragraph 6(1)(a) of the Rules provides that the application fee for an application made in relation to a human tissue prosthesis is nil.

Paragraph 6(1)(b) of the Rules provides that the application fee for an application made in relation to any other prosthesis, except where subsection 6(2) applies, is \$600.

Subsection 6(2) of the Rules provides that the fee for applications that involve a ‘revocation and relisting’ or a ‘duplicate listing’ is, and is taken always to have been, nil. The specific circumstances in which an application will result in a revocation and relisting are described in subsection 6(4) of the Rules. The definition of ‘duplicate listing’ is provided in subsection 6(5) of the Rules.

Subsection 6(3) of the Rules provides that if the approved form for an application permits more than one application for listing of a kind of prosthesis to be made on the same form, the application for each kind of prosthesis is a separate application and each listing, if granted, is a separate listing.

Section 7 – Initial Listing fee

Section 7 of the Rules provides the initial listing fees imposed for the purposes of subsection 72-10(5) of the PHI Act.

Paragraph 7(1)(a) of the Rules provides that the initial listing fee for a human tissue prosthesis is nil.

Paragraph 7(1)(b) of the Rules provides that the initial listing fee for any other prosthesis, except where subsection 7(2) applies or rule 9 applies, is \$200.

Subsection 7(2) of the Rules concerns applications that involve a ‘revocation and relisting’ or a duplicate listing.

Section 8 – Ongoing Listing fee

Section 8 of the Rules provides the ongoing listing fee for the purposes of section 72-15 of the PHI Act.

Paragraph 8(a) of the Rules provides that the ongoing listing fee for a human tissue prosthesis is nil.

Paragraph 8(b) of the Principal Rules provides that the ongoing listing fee for any other prosthesis, except where section 9 applies, is \$200.

Section 9 – First ongoing listing fee following grant of application

Section 9 of the Rules provides that the first ongoing listing fee immediately following the granting of an application (other than an application for a ‘revocation and relisting’ or a ‘duplicate listing’) is nil.

Section 10 – Ongoing listing fee imposition day

Section 10 of the Rules provides the ongoing listing fee imposition days of each year as 15 March and 15 September.

Schedule 1 – Repeals

Schedule 1 of the Rules specifies and repeals the *Private Health Insurance (Prostheses Application and Listing Fee) Rules 2008 (No.1)*.

Statement of Compatibility with Human Rights

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

Private Health Insurance (Prostheses Application and Listing Fee) Rules 2018

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 *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007* (the Act) imposes, as a tax, fees in relation to applications for listing, and listing, of prostheses, and related purposes. The purpose of the *Private Health Insurance (Prostheses Application and Listing Fee) Rules 2018* (the Rules) is to set these fees.

The table in subsection 72-1(2) of Part 3-3 of the *Private Health Insurance Act 2007* (the PHI 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 Rules are a substantive replication of the *Private Health Insurance (Prostheses Application and Listing Fee) Rules 2008 (No.1)* (the Previous Rules)—which were due to be automatically repealed (sunset) on 1 October 2018—with a number of minor machinery changes. Importantly, there has been no change in any of the fees from the Previous Rules. The Act specifies the maximum amount of an application fee, initial listing fee and ongoing listing fee to be \$2000 (indexed each financial year). The fees set out in the Rules range from nil to \$600 and have not been increased since 2009.

The purpose of these taxes is to recover the cost from industry for the administration of the prostheses list arrangements and for the clinical assessment of products using expert advisory groups established to advise on products placed on the list. The assessment process ensures that privately insured Australians have access to a range of medical devices that are clinically effective and value for money.

Human rights implications

Strictly speaking, the Rules do not raise any human rights issues. However, the Rules indirectly engage article 12(1) of the International Covenant on Economic Social and Cultural Rights by assisting with the progressive realisation of the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The collection of fees is associated with the listing of kinds of prostheses in the Private Health Insurance (Prostheses) Rules, which ensures that persons with appropriate private health insurance will receive a minimum benefit for the provision of the prosthesis as hospital treatment (or hospital-substitute treatment); and that the prosthesis is provided in circumstances where a Medicare benefit is payable.

Conclusion

The Rules are compatible with human rights because it supports the protection of human rights.

Greg Hunt
Minister for Health