



Private Health Insurance (Prostheses Application and Listing Fees) Bill 2006

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Private Health Insurance (Prostheses Application and Listing Fees) Bill 2006

Date introduced: 7 December 2006

House: House of Representatives

Portfolio: Health and Ageing

Commencement: The Act commences at the same time as the *Private Health Insurance Act 2006* which is 1 April 2007.

Purpose

The Bill proposes to impose, as a tax, fees for listing prostheses; including for the application to list, for the initial listing and for the ongoing listing of prostheses. The Bill proposes that the Private Health Insurance (Prostheses Application and Listing Fee) Rules specify these fees.

This Bill was introduced with six other Bills that amend or create a range of Acts to reflect the new regulatory regime detailed in the accompanying Private Health Insurance Bill 2006. On 7 December 2006 the Senate, on the recommendation of the Selection of Bills Committee, referred the suite of Bills to the Community Affairs Committee, for inquiry and report by 26 February 2007. The Committee intends to hold a public hearing in Canberra on 2 February 2007.

Background

What are prostheses?

Prostheses are artificial devices that are attached to the body as an aid, or substitute for body parts that are missing or non-functional. Prostheses can include cardiac pacemakers and defibrillators, cardiac stents, hip and knee replacements and intraocular lenses, as well as human tissues such as human heart valves, corneas, bones (part and whole) and muscle tissue.

Under current health insurance arrangements, private health insurance funds are required to pay benefits for prostheses that are provided as part of an episode of hospital treatment where a patient has cover and for which a Medicare benefit is payable for the associated professional service. Following changes to legislation in 2005 two categories of prostheses are available for which benefits are payable:

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- No-gap prostheses. No-gap prostheses are listed with a single benefit amount, and patients will have no out-of-pocket expenses for these prostheses. For each type of prosthesis there is at least one no-gap prosthesis available.
- Gap-permitted prostheses. Gap-permitted prostheses have both a minimum and maximum benefit amount listed. For these prostheses health funds are required to pay at least the minimum benefit amount. Patients may incur an out-of-pocket expense for these prostheses, which will be the difference between the minimum and the maximum benefit amount.¹

The Prostheses List

The Prostheses List (Schedule 1 of the *National Health Act 1953*) specifies the prostheses and human tissue products that attract health funds benefits and the amount of benefit to be paid, and is released twice a year.² There are currently more than 9,000 products on the Prostheses List.

A ministerially appointed committee called the [Prostheses and Devices Committee \(PDC\)](#) recommends to the Minister for Health and Ageing the prostheses that should be listed and the benefits payable for them. On average, for each Prostheses List released:

- 500 products are added;
- amendments are made to the details of some 700 listed prostheses; and
- 300 prostheses are deleted from it.³

The time taken to list a prosthesis averages around 24 weeks and involves clinical assessment and benefit negotiations.⁴

Items on the Prostheses List must first be registered on the Australian Register of Therapeutic Goods (for which fees are levied on a cost recovery basis).⁵

Since 1999 fees have been payable for applications to list products on the Prostheses List and to maintain a listing. However, payment of the fees has been voluntary.⁶

Listing fees

The suite of legislation comprising the Private Health Insurance Bill 2006 (PHI Bill 2006) and the six accompanying Bills, proposes changes to the current health insurance regime. This includes broadening the range of services covered by private health insurance to include benefits for out of hospital treatment and hospital substitute treatment. These benefits will also apply to prostheses, provided they are listed on the Prostheses List, and fees for listing are paid.

Specifically, the Private Health Insurance (Prostheses Application and Listing Fees) Bill 2006 (the current Bill) requires fees be paid in three stages: when an applicant (or sponsor,

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usually the manufacturer of the prostheses) first applies to have a prostheses listed, then when the initial listing occurs and finally for the ongoing listing of the prosthesis. It is anticipated these fees will apply from July 2007.

The actual fee amounts will be specified in the yet to be released Private Health Insurance (Prostheses Application and Listing Fee) Rules following consultation with industry. However, in a recent circular to the industry the government indicated that the fees for the April 2007 Prostheses List would be:

- \$1,050 for each new prostheses application,
- \$180 for continued listing on the List.⁷

The Bill allows for the fees to not bear any relationship to the cost of the services (that is, the cost of the listing process itself); but, in a circular to industry, the Department indicated that the Bill is aimed at full cost recovery.⁸ This cost recovery would be for costs incurred by the following:

- the Prostheses and Devices Committee and associated committees
- the Clinical Advisory Groups and Panel of Clinical Experts
- cost of Benefit Negotiators (the Australian Health Insurance Association has agreed to meet this annual cost, estimated at \$952,000 p.a.); and
- secretariat services.⁹

The yet to be released Rules will specify the fees for each part of the listing process, that is, at application, at initial listing and for ongoing listing. However, section 5 (3) specifies that the maximum amount that can be levied in relation to each fee shall not exceed \$2,000 in the financial year in which the Act commences. Fees for subsequent years will be imposed according to the amount worked out under the indexation factor (based on the Consumer Price Index) specified in section 6 of the Bill. Fees for ongoing listing will be payable when the new Prostheses List is released twice a year.

The Bill also allows for the amount of a fee to be nil.

Basis of policy commitment

According to the Private Health Insurance Bill 2006 Guide the changes relating to Listing Fees for prostheses provide a 'framework' for sponsors of prostheses to have them listed, and allow for a cost recovery process. As noted above, the government had indicated to industry that it was proposing full cost recovery arrangements for the listing of prostheses in a circular to industry in July 2006.¹⁰

In addition, there has been ongoing concern over the growing cost of prostheses and medical devices to the health funds over the past decade. The benefits paid for prostheses

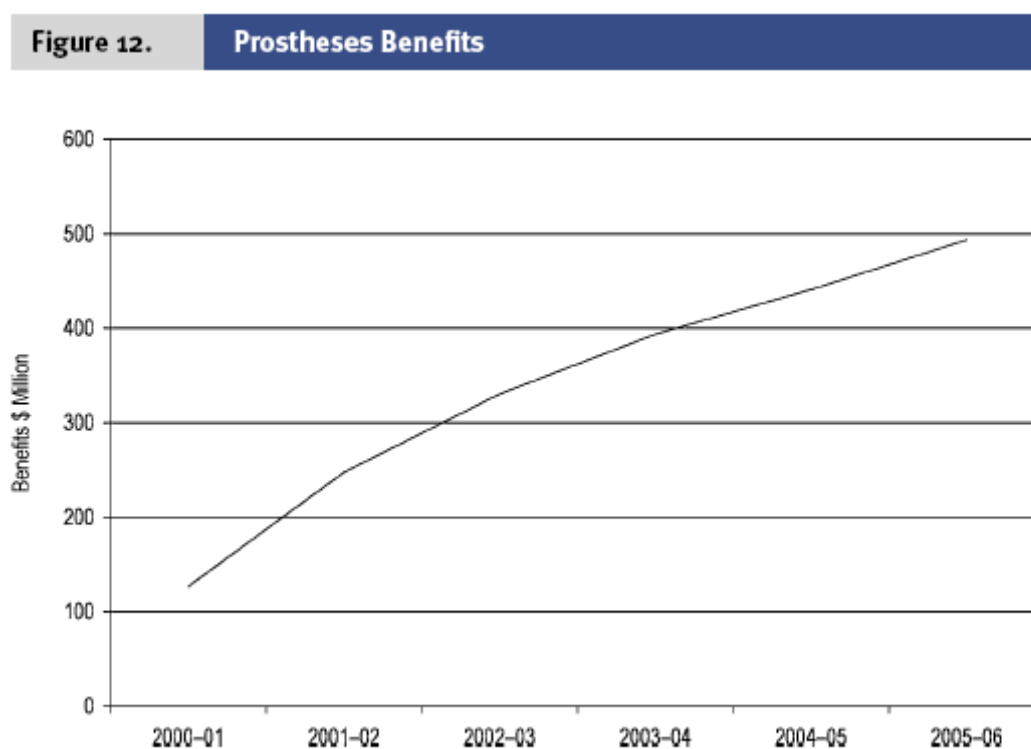
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benefits has been described as an area of ‘substantial growth’ by the industry regulator the Private Health Insurance Administration Council (PHIAC). The table below shows the growth in benefits paid for prostheses in recent years:

Figure 1: Prostheses Benefits 2000-01 to 2005-06¹¹



However, the regulator has also noted that anecdotal evidence suggests a slowing in the rate of growth of benefits for prostheses, although there is insufficient data to confirm this yet.¹²

Position of significant interest groups/press commentary

The Bill, along with Private Health Insurance Bill 2006 and the other five accompanying Bills, has been referred to the Senate Community Affairs Committee, but no significant views have yet been reported. Industry (in the form of the Medical Industry Association of Australia (MIAA) and medical device suppliers) has previously endorsed the principle of full cost recovery for the listing process.¹³ However, the MIAA has previously raised concerns regarding the cost recovery arrangements applied by the Therapeutic Goods Administration for listing products on the Australian Register of Therapeutic Goods. In a submission to the Productivity Commission inquiry into cost recovery arrangements, the MIAA pointed to high registration fees imposed by the TGA discouraging the introduction of new products to the Australian market.¹⁴

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Pros and cons

The current process for listing prostheses involves considerable application of resources and time by the Department. It is estimated by the Department that the cost of operating the Prostheses List will increase from the current cost of \$0.85 million to \$4.3 million per annum as more prostheses are listed.¹⁵ This Bill will effectively transfer the full cost of managing the Prostheses List to industry, generating savings for government.

On the other hand industry will have some certainty as to the annual cost of maintaining prostheses on the Prostheses List through the application of annual indexation for listing fees, effectively allowing industry to estimate with some certainty the future cost of applying for and maintaining a listing. Further, by passing listing costs back to industry the Bill may provide an incentive for sponsors of prostheses to ensure that prostheses are clinically proven before they apply for listing, and perhaps consider removing some less used prostheses from the list (rather than bear the cost of ongoing listing).

However, the Bill also allows the government to set fees that bear no relationship to the actual cost of the Prostheses Listing service, possibly jeopardising the transparency of the process. Sponsors may also seek to have less profitable prostheses removed from the list (or not sponsor these at all) in order to reduce the costs of listing; but this may reduce choice. As noted by the Productivity Commission, even small product registration charges 'can reduce the number of products that a firm may choose to market in Australia'¹⁶. Further, if industry found the cost recovery arrangements arduous they might seek to recoup some of their costs by passing these on to the health funds, in the form of higher cost prostheses. However, the peak health fund organisation, the AHIA, has indicated that it will continue to meet the annual cost for Benefit Negotiators (estimated at \$952,000) thereby reducing the financial cost to industry, and, arguably, reducing the likelihood of these costs being passed on.¹⁷

Financial implications

Currently the cost of running the Prostheses List is \$0.85 million, but the Department estimates that this will increase to around \$4.3 million annually; under full cost recovery the Government would recoup this amount from industry.

Main provisions

Imposition of fees

Clauses 3 and 4 specify that the Private Health Insurance (Prostheses Application and Listing Fee) Rules, specify the fees for application, initial listing and ongoing listing for a

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prosthesis listed for health benefits under the proposed *Private Health Insurance Act 2006*. It also specifies that these fees are imposed as a tax.

Clause 4 provides for the Rules to specify the days for which an ongoing listing fee is to be payable, but there must not be more than two fee imposition days in any twelve month period.

Matters relating to fees

Clause 5 allows the Rules to specify different application, initial listing or ongoing listing fees for different circumstances. It further allows that the maximum amount of an application or initial listing or ongoing fee is \$2,000 in the financial year the Act commences; and in later years as determined under indexation provisions of section 6. This section also allows for fees to be set that bear no relation to the cost of the service.

Indexation of fees

Clause 6 allows for the calculation of the maximum amount of a fee by multiplying the indexation factor of the financial year by the maximum amount of the fee in the previous financial year. The formula to be used to calculate the indexation factor for the financial year is described as the sum of the index numbers for the quarters leading up to March 31, divided by the sum of index numbers for the quarters leading up to the previous March 31. The index number for a quarter is the All Groups Consumer Price Index number, as published by the Australian statistician. If the indexation factor is less than 1 the ongoing listing fee remains the previous year's maximum.

Person liable for fee

Clause 7 specifies that the person who makes an application to list a prosthesis is responsible for paying the application fee at the time of application; further it specifies that if an application to list is granted the person who made the application is liable for the initial listing fee which is payable at the time of notification of the successful application; and they are liable for the ongoing listing fee payable on the ongoing listing fee imposition day.

Rules and Regulations

Clauses 8 and 9 allow for the Minister (by legislative instruments) and the Governor General to make rules and regulation for the purposes of the proposed Act.

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Concluding comments

The Bill proposes full cost recovery arrangements, whereby industry will meet the costs associated with listing prostheses for health benefits from July 2007. This will generate savings for Government, provide the industry with a more formal framework for prostheses listing and encourage greater accountability from sponsors of prostheses. The measure may result in fewer prostheses on the Prostheses List over time.

Endnotes

1. Department of Health and Ageing ‘[Prostheses List](http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-privatehealth-prostheseslist.htm)’ webpage, <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-privatehealth-prostheseslist.htm>, accessed 22 Jan 2007.
2. The Prostheses Schedule exists by virtue of a determination issued by the Minister under Schedule 1 of the National Health Act.
3. Department of Health and Ageing ‘[Prostheses List: guide to listing and setting benefits for prostheses and devices](#)’ The Department, August 2006, p 14. URL: [http://www.health.gov.au/internet/wcms/publishing.nsf/Content/05CFBCDCE7A7A0C1CA2571C600227D49/\\$File/PL%20Guide%20April07.pdf](http://www.health.gov.au/internet/wcms/publishing.nsf/Content/05CFBCDCE7A7A0C1CA2571C600227D49/$File/PL%20Guide%20April07.pdf) , accessed 7 February 2007.
4. *ibid.*, pp. 15–16.
5. For details of fees levied by the Therapeutic Goods Administration for listing items on the ARTG see website <http://www.tga.gov.au/docs/html/feesach.htm#fees> , accessed 24 January 2007.
6. ‘[Prostheses List: guide to listing and setting benefits for prostheses and devices](#)’ *op. cit.*, p. 18.
7. Department of Health and Ageing ‘[Funding of the prostheses arrangements through full cost recovery](#)’ *Private Health Insurance Circular—PHI 45/06* 19 July 2006, URL: [http://www.health.gov.au/internet/wcms/publishing.nsf/Content/0E3999D7D3AECFFCCA2571B00009657D/\\$File/45_06.pdf](http://www.health.gov.au/internet/wcms/publishing.nsf/Content/0E3999D7D3AECFFCCA2571B00009657D/$File/45_06.pdf), accessed 7 February 2007. This was expected to be an interim *voluntary* arrangement, pending the final passage of legislation.
8. *ibid.*
9. *ibid.*
10. *ibid.*
11. Private Health Insurance Administration Council, *Operations of the Registered Health Benefits Organisations—Annual Report 2005–06*, PHIAC, Canberra, 2006, p. 63.
12. *ibid.*, p. 2.
13. *Private Health Insurance Circular—PHI 45/06*, *op. cit.*

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14. Productivity Commission *Cost recovery by government agencies: inquiry report* Productivity Commission, Report no. 15, 2001, p. 105.
15. *Private Health Insurance Circular–PHI 45/06*, op. cit.
16. Productivity Commission, op. cit, p. 106.
17. Benefit Negotiators negotiate benefits for prostheses and devices with manufacturers, suppliers and distributors and advise the Prostheses and Devices Committee on the appropriate level of benefit to be recommended to the Minister. Members of the BNG are drawn from health funds and are appointed by the PDC.

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