



# Australian Government

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## Department of Health

### **COST RECOVERY IMPLEMENTATION STATEMENT**

Administration of the Protheses List

**1 July 2017 to 30 June 2018**

Cost recovery involves government entities charging individuals or non-government organisations some or all of the efficient costs of a specific government activity. This may include goods, services or regulation, or a combination of them. The Australian Government Cost Recovery Guidelines (the CRGs)<sup>1</sup> set out the overarching framework under which government entities design, implement and review cost recovered activities.

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<sup>1</sup> The CRGs are available on the Department of Finance website ([Link to Department of Finance website](#)).

# 1 INTRODUCTION

## 1.1 Purpose of the CRIS

This CRIS provides information on how the Department of Health (Health) implements cost recovery for the administration of the Prostheses List. It also reports financial and non-financial performance information for administration of the Prostheses List and contains financial forecasts for 2017-18 and three forward years. Health will maintain the CRIS until the activity or cost recovery for the activity has been discontinued.

## 1.2 Description of the activity

The Prostheses List (the List) is the schedule to the *Private Health Insurance (Prostheses) Rules 2017 No. 2* (the Prostheses Rules) that helps ensure privately insured patients have access to safe and clinically effective medical devices.

The Prostheses List is divided into 3 parts: Part A (Prostheses), Part B (Human Tissue items) and Part C (items specified by the Minister for Health – currently insulin infusion pumps, implantable cardiac event recorders and cardiac home/remote monitoring systems).

Under Section 72-1 of the *Private Health Insurance Act 2007* (the PHI Act), private health insurers must pay at least the minimum benefit accorded to each prosthesis listed on the List:

- for which an insured person has appropriate cover
- that are provided as part of an episode of hospital treatment or hospital-substitute treatment; and
- for which a Medicare benefit is payable for the professional service associated with the provision of the prosthesis.

A benefit setting mechanism is required as Private Health Insurers are legally bound to pay prostheses benefits. In the early 2000s, benefit setting was deregulated and a consequence was that the benefits paid through private health insurance arrangements increased significantly. A natural effect of increased benefit payments is private health insurance premium increases. The Prostheses List, therefore, is a policy instrument that assists in managing the costs of private health insurance.

Medical device sponsors and suppliers (collectively referred to as ‘Sponsors’) apply to list prostheses on the Prostheses List so the listed item may be reimbursed by private health insurers. Through this process, Sponsors gain access to the private health market.

The activities involved in processing applications and maintaining listings on the Prostheses List include:

- management of applications by staff in the Department of Health, including
  - initial assessment to ensure the application is valid
  - liaising with applicant on the progress of the application
- provision of secretariat support by the Department to the Prostheses List Advisory Committee (PLAC) and its sub-committees, including organising meetings and preparing papers

- assessment of applications against the criteria for listing by the PLAC and its subcommittees and making recommendations to the Minister or the Minister's delegate
- making the Prostheses Rules
- developing and maintaining IT systems to support the prostheses listing arrangements; and
- providing and maintaining information for stakeholders about the Prostheses List processes and policy on the department's website.

The costs of administering the List, including assessing applications and producing the List, are recovered from prostheses sponsors via payment of:

- an application fee in respect of each application to list a new prosthesis
- a fee to initially list each new prosthesis on the List
- a fee to maintain the ongoing listing of each prosthesis on the List.

Amendments to listings do not currently have a separate fee.

## **2 POLICY AND STATUTORY AUTHORITY TO COST RECOVER**

### **2.1 Government policy approval to cost recover the activity**

In February 2003, a decision was made by Government that the costs associated with clinical assessment and benefit setting processes related to the Prostheses List would be met by Sponsors. Legislation to give effect to the decision commenced 31 October 2005.

### **2.2 Statutory authority to charge**

From 1 July 2007, full compulsory cost recovery arrangements were established through the *Private Health Insurance Act 2007*, the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007* and the *Private Health Insurance (Prostheses Application and Listing Fees) Rules 2008 (No.1)*.

## **3 COST RECOVERY MODEL**

### **3.1 Outputs and business processes of the activity**

The key output activity is the Prostheses List, which has been published twice a year, in February and August. Under the *Improving access to breakthrough medical technology and affordability of medical devices for privately insured Australians: Agreement between the Government and the Medical Technology Association of Australia* (the Agreement), the Government has committed to publishing three Prostheses Lists per year; in March, July and November commencing in 2019.

Since December 2015, most applications to list new prostheses or amend current listings were submitted via the Prostheses List Management System (PLMS), a web-based tool enabling sponsors to submit their applications and supporting information online rather than through a paper-based system. All submissions related to the Prostheses List are now expected to be submitted via PLMS. Department of Health staff are available to assist with PLMS access. The key business processes associated with applications are:

- application input by sponsor into PLMS, which is facilitated by mandatory data fields to guide integrity of the application process
- application fee
- applications are forwarded to relevant expert clinicians for clinical assessment of the device against the criteria for listing
- if the device is new or novel, benefit validation is conducted by the Health Economics Sub-Committee
- PLAC consideration of clinical and/or cost-effectiveness recommendations
- PLAC advice provided to the Minister
- granting of application by the Minister or Minister’s Delegate
- initial listing fee
- Protheses Rules updated.

## 3.2 Costs of the regulatory charging activity

### 3.2.1 Overview of Costs

The main cost drivers for the activity are:

- staffing and associated costs to administer applications and provide secretariat and support services to the PLAC and its clinician sub-committees and Panel of Clinical Experts
- maintenance and improvements to the IT solutions that manage and store applications and related information
- payment to clinicians for application assessment
- committee costs (including travel, accommodation, venue and sitting fees for members).

A summary cost components for 2017-18 is at Table 1.

**Table 1. Summary of cost components 2017-18**

Output : Protheses List	Total
Employee expenses	\$2,119, 428
Management and assessment of applications, secretariat services and committee meeting and member payments	\$1,932,576
IT (Capital)	\$900,000
Indirect costs	\$281,196
<b>TOTAL</b>	<b>\$5,233,200</b>

### 3.2.1 Explanation of terms

**Indirect costs** are those costs that cannot be easily linked to a cost object or for which the costs of tracking this outweigh the benefits. Indirect costs are apportioned to a cost object using the Department of Health's documented internal costing methodology. Common indirect costs include overhead costs such as salaries of staff in corporate (e.g. finance, human resources) and technical support (e.g. legal) areas, or accommodation costs (e.g. rent, maintenance and utilities).

### 3.3 Design of regulatory charges

The application fee is \$600 per application and covers the cost of processing and assessing an application to list on the Prostheses List. The initial listing fee, \$200 per prosthesis, covers the cost of granting applications and listing new prostheses on the Prostheses List.

No change is proposed for the application and initial listing fees for this financial year.

Since 2009, the ongoing listing fee has been \$200 paid every six months. The ongoing listing fee is required to be paid as long as a prosthesis remains on the Prostheses List. The ongoing listing fee contributes to the cost of maintaining the Prostheses List, including making amendments to listing as required from time to time.

The fees outlined above have not been adjusted since 2009, in which time staffing costs and clinician time and assessments required have risen. Over this time the Department has absorbed costs in excess of \$2.2 million including IT related capital expenditure, amortisation and depreciation.

The Department has identified that improvements to the website and guidance documents are required, including clarification of assessment processes and ongoing investment in the IT system to promote more timely application processing and assessment and a more efficient service for Sponsors.

On 15 October 2017, the Australian Government entered into an Agreement with the Medical Technology Association of Australia (MTAA). In the Agreement, the Government stated its intent to revise cost recovery arrangements, with changes to be implemented by 1 July 2019. The points highlighted above will be considered as part of the cost recovery revision process.

## 4 RISK ASSESSMENT

A cost recovery risk assessment for this activity was undertaken in January 2018, resulting in a low risk rating.

## 5 STAKEHOLDER ENGAGEMENT

The CRIS is to be reviewed and updated at least annually, with an update of financial performance to occur after publication of the Department's Annual Report. This 2017-18 CRIS is an update to the 2016-17 CRIS, there has been no change to the charging structure or policy. If the CRIS is required to be amended to incorporate changes to the charging structure or policy, a draft will be provided to stakeholders for consultation.

## 6 FINANCIAL ESTIMATES

Table 2. Charge rates and revenue estimates – 2017-18 and forward estimates

	2017-18 \$	2018-19 \$	2019-20 \$	2020-21 \$
Expenses = X	4,500,000	4,466,000	4,537,000	4,614,000
Revenue = Y	4,400,000	4,400,000	4,400,000	4,400,000
Balance = Y-X	(100,000)	(66,000)	(137,000)	(214,000)
Cumulative balance	647,513	581,513	444,513	230,513
Explain balance management strategy	<p>The forecast estimates are based on past actual revenue. Revenue from fees no longer covers the costs of providing this service as fees have not increased since 2009. In accordance with Australian Government policy, the costs associated with this program will be reviewed and the fees charged to Sponsors will be aligned with these costs. These fees will be indexed annually. The cost recovery structure will be considered as part of the work being delivered under the Government's Agreement with the MTA. It is expected revised fees will be in place commencing 1 July 2019.</p> <p>The Department has also identified that not all Sponsors have paid their required fees, which is contributing to a projected deficit over the forward estimates. The Department is implementing structures to ensure that all fees owing are collected from Sponsors. This will lead to an increase in revenue and a decrease in the forecast deficit.</p>			

## 7 FINANCIAL PERFORMANCE

	2012-13 \$	2013-14 \$	2014-15 \$	2015-16 \$	2016-17 \$
Expenses = X	5,206,706	4,316,839	3,580,458	3,902,074	4,604,989
Revenue = Y	4,390,400	4,446,519	4,490,133	4,362,770	4,385,160
Balance = Y – X (negative deficit)	(816,306)	129,680	909,675	460,696	(219,829)
<b>Cumulative balance (negative deficit)</b>	<b>(532,710)<sup>a</sup></b>	<b>(403,029)</b>	<b>506,646</b>	<b>967,342</b>	<b>747,513</b>
Balance management strategy	<p>The expenses above do not include capital expenditure, nor do they include depreciation or amortisation. The total capital expenditure up to 30 June 2016 (net of capital appropriation) has been in excess of \$2.2 million.</p>				

<sup>a</sup> Includes carried forward balance of \$283,597 from 2011-12.

## 8 NON-FINANCIAL PERFORMANCE

The key performance indicator for Prostheses List activity is the percentage of applications completed within 22 weeks of the date of application. In this context, “completed” means that the application has been assessed against the criteria for listing and the PLAC has made a recommendation to the Minister regarding listing. It does not include applications where the PLAC has made a recommendation to grant but the device has not yet been registered on the ARTG or there is currently no appropriate Medicare Benefit Schedule item for the professional service associated with the use of the prosthesis.

The performance target was 87 per cent of applications in 2016/17 and is 87 per cent of applications in 2017/18. In 2016/17 the actual performance was 97 per cent.

## 9 KEY FORWARD DATES AND EVENTS

- 15 March 2018 – ongoing listing fee imposition day
- 1 July 2018 – implementation of the next cost recovery implementation statement
- 15 September 2018 – ongoing listing fee imposition day
- October 2018 – CRIS update with actual financial results for 2017-18
- 15 March 2019 – ongoing listing fee imposition day

## 10 CRIS APPROVAL AND CHANGE REGISTER

Date of CRIS Change	CRIS Change	Approver	Basis for Change
February 2018	Update of 2016-17 performance data	Secretary, Department of Health	Updated actual financial results following publication of the Department’s 2016-17 annual report
24/10/2016	Agreement	Minister for Health	Review of Cost Recovery
16/08/2016	Certification	Secretary, Department of Health	Review of Cost Recovery