



**Australian Government**  
**Department of Health**

**COST RECOVERY IMPLEMENTATION STATEMENT**

Administration of the Protheses List

**1 July 2020 to 30 June 2021**

**Version 1.1**

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 Charging Framework, which incorporates the Cost Recovery Guidelines (the CRGs)<sup>1</sup>, sets out the framework under which government entities design, implement and review regulatory charging activities, consistent with the *Public Governance, Performance and Accountability Act 2013*.

---

<sup>1</sup> The CRGs are available on the Department of Finance website Cost Recovery Guidelines

# 1 INTRODUCTION

## 1.1 Purpose of the CRIS

This Cost Recovery Implementation Statement (CRIS) provides information on how the Department of Health (the Department) implements cost recovery for the administration of the Prostheses List.

It also reports financial and non-financial performance information for the administration of the Prostheses List and contains financial forecasts for 2020-21 and three forward years. The Department will maintain the CRIS until the activity or cost recovery for the activity has been discontinued.

This CRIS update reflects the continuation of previous years' cost recovery arrangements and reports the outcomes for the 2019-20 financial year, with no significant changes to forecast revenue or expenditure. The CRIS for the 2021-22 financial year will be released prior to 1 July 2021 for consultation on any changes to cost recovery to support the reform activities currently under consideration by Government (see Section 3.3.1).

## 1.2 Description of the activity

The Prostheses List (the List) is the schedule to the *Private Health Insurance (Prostheses) Rules* (the Prostheses Rules) that provides privately insured patients access to safe and clinically effective medical devices.

The Prostheses List (the List) is divided into 3 parts:

- Part A – Prostheses;
- Part B – Human Tissue items; and
- Part C – items from groups of products specified by the Minister for Health, including:
  - insulin infusion pumps;
  - implantable cardiac event recorders;
  - cardiac home/remote monitoring systems/cardiac ablation catheters; and
  - surgical ablation devices.

The activities involved in assessing applications and maintaining items on the List include:

- management of applications by Department staff, including:
  - initial assessment to ensure the application is valid; and
  - liaising with applicants on the requirements and 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 List 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 currently 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; and
- a fee to maintain the ongoing listing of each prosthesis on the List.

## **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 some costs associated with clinical assessment and benefit setting processes related to the List would be met by sponsors. Legislation to give effect to the decision commenced 31 October 2005.

In the early 2000s, private health insurance benefit setting was deregulated and a consequence was that the benefits paid through private health insurance arrangements increased significantly. The effect of increased benefit payments was an increase to annual private health insurance premium increases. A benefit setting mechanism was introduced to determine the amount private health insurers are legally bound to pay for prostheses benefits. The List is the policy instrument that assists in managing the costs of private health insurance by setting the appropriate benefit for each prostheses.

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

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

From 1 July 2007, full compulsory cost recovery arrangements were established through 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)*.

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 prostheses 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 prostheses.

## **3 COST RECOVERY MODEL**

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

The key output activity is the List, which is published three times per year in March, July and November.

The key business processes associated with applications to list new prostheses or amend current listings are:

- application input by sponsor into the Prostheses List Management System, which is facilitated by mandatory data fields to guide integrity of the application process;
- application fee;
- applications are assessed by the Department and relevant expert clinicians for compliance with the listing criteria and comparative clinical assessment of the device;
- if the device is new or novel, benefit validation through a health technology assessment;
- the PLAC consideration of clinical and/or cost-effectiveness recommendations;
- the PLAC advice provided to the Minister or Minister's Delegate;
- granting of application by the Minister or Minister's Delegate;
- initial listing fee;
- Prostheses Rules updated; and
- ongoing listing fee.

## 3.2 Costs of the regulatory charging activity

The main cost drivers for the cost recovered activity are:

- staffing and associated costs to manage applications, coordinate Health Technology Assessment and reviews, and provide secretariat and support services to the PLAC, Clinical Advisory Groups and Panel of Clinical Experts;
- maintenance and improvements to the IT systems that manage and store applications and related information;
- payment to clinicians and health technology assessors for application assessment and reviews; and
- Committee costs (including sitting fees for members).

A summary of the forecast cost components for 2020-21 is at Table 1.

**Table 1 – Summary of forecast cost components for 2020-21**

<b>Output: Prostheses List</b>	<b>2020-21</b>
Employee expenses	\$ 2,038,692
Supplier expenses (including Secretariat services and Committee meeting and member payments)	\$ 1,928,000
IT depreciation and maintenance	\$ 681,331
Indirect costs*	\$ 377,566
<b>TOTAL</b>	<b>\$ 5,025,589</b>

\* 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), technical support areas, accommodation costs (e.g. rent, maintenance and utilities), as well as staff training and workers compensation.

## 3.3 Design of regulatory charges

There are three fees associated with the List:

1. An application fee of \$600 per application that covers the cost of processing and assessing an application to include an item on the List.
2. An initial listing fee of \$200 per prostheses that covers the cost of granting applications and adding new prostheses on the List.
3. An ongoing listing fee of \$200 that is paid every six months. The ongoing listing fee is required to be paid for as long as a prostheses remains on the List. The ongoing listing fee contributes to the cost of maintaining the List, including making amendments to listing as required from time to time.

The fees outlined above have not been adjusted since 2009.

### 3.3.1 PLAC Reforms and Review Arrangements

Under the MTAA Strategic Agreement, Industry Working Groups (IWG) were established aiming to improve the quality of information provided to support applications seeking to add devices to the List, review framework and benefit setting arrangements, and consider remuneration for cardiac devices. In the Agreement, the Government stated its intent to revise cost recovery arrangements, with changes to be implemented by 1 July 2019. However, consultation and implementation of revised cost recovery arrangements was delayed while reform activities were being undertaken. The reform was further delayed due to the impact of COVID-19 and agreement between the Government and MTAA to a hibernation of activities listed in the MTAA Agreement<sup>2</sup>.

---

<sup>2</sup> <https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-phicircular2020-37>

In December 2020, the Department released a consultation paper on options for reforms and improvements to the Prostheses List to inform Government considerations around the direction and implementation of options for Prostheses List reform. Both reform options that have been put forward would have implications for existing cost recovery arrangements. Enhanced administration of the Prostheses List would require an increase in resourcing to the Department of Health which would be funded through cost recovery fees. Any future changes to cost recovery arrangements will need to ensure compliance with the Australian Government Cost Recovery Guidelines introduced in 2014 and will be consistent with requirements under the *Public Governance, Performance and Accountability Act 2013*.

## 4 RISK ASSESSMENT

A cost recovery risk assessment for this activity was undertaken in June 2020, resulting in a low risk rating.

## 5 STAKEHOLDER ENGAGEMENT

The CRIS will be reviewed and updated at least annually, and published on the Department's website for stakeholders. The reform options under consideration will be subject to a future decision of Government and could be introduced in a staged manner from February 2022. Consultation on any changes to the cost recovery arrangements in the 2021-22 financial year will be undertaken through the release of a draft CRIS prior to 1 July 2021.

## 6 FINANCIAL ESTIMATES

Table 2 reflects the forecast expenses along with the estimated revenue for 2020-21 and three forward years. Should there be any change to the cost recovery fees and charges as set out in this CRIS, a new financial estimates table will be provided.

**Table 2 – Financial estimates for PLAC cost recovery activities for 2019-20, 2020-21 and three forward years**

	2019-20	2020-21	2021-22	2022-23	2023-24
	\$	\$	\$	\$	\$
Expenses = X	4,414,300	5,025,589	5,101,991	5,114,627	4,984,818
Revenue = Y	4,400,000	4,665,000	4,665,000	4,665,000	4,665,000
Balance = Y – X (negative deficit)	(14,300)	(360,589)	(436,991)	(449,627)	(319,818)
<b>Cumulative balance</b>	<b>1,978,326</b>	<b>1,617,737</b>	<b>1,180,746</b>	<b>731,119</b>	<b>411,301</b>
Balance management strategy explanation	<p>The forecast revenue estimates are based on past actual revenue. Expenses are expected to drop in 2023-24 due to certain assets being fully depreciated by 2022-23.</p> <p>In recent years there has been a mis-alignment between revenue and expenses in the administration of the Prostheses List. In accordance with Australian Government policy, the costs associated with this program are currently being reviewed and the fees charged to sponsors will be aligned with these costs.</p> <p>The 2021-22 CRIS will be released for consultation prior to 1 July 2021 and will provide further details on Prostheses List reforms and possible future changes to PLAC cost recovery.</p>				

## 7 PERFORMANCE

### 7.1 Financial Performance

The following table will be updated after each financial year to report on the actual financial performance and has been compared with the forecast financial performance for 2019-20 as published in the CRIS for the 2019-20 financial year. Any variance greater than 5% has been identified and explained.

The aim of comparing the actual financial results with forecast financial estimates over a 5-year period is to ensure that the degree of alignment of under or over recovery of costs is agreed by the Australian Government as part of the department's balance management strategy.

**Table 3 – Financial performance for cost recovered activities**

<b>Actual Financial Results</b>	<b>2015-16</b> \$	<b>2016-17</b> \$	<b>2017-18</b> \$	<b>2018-19</b> \$	<b>2019-20</b> \$
Expenses = X	3,902,074	4,604,989	4,310,442	3,840,471	5,018,799
Revenue = Y	4,362,770	4,385,160	4,887,526	4,721,600	4,791,400
Balance = Y – X (negative deficit)	460,696	(219,829)	577,084	881,129	(227,399)
<b>Cumulative balance (negative deficit)</b>	<b>967,341~</b>	<b>747,512</b>	<b>1,324,596</b>	<b>2,205,725</b>	<b>1,978,326</b>
Variance explanation	The revenue for 2019-20 was more than originally forecast due to more applications received than anticipated. Actual expenses were also higher than originally anticipated due to additional costs to evaluating applications and compliance review activities now being required and borne by the Department, resulting in a deficit for 2019-20.				
Balance management strategy explanation	In recent years there has been a mis-alignment between revenue and expenses in the administration of the Prostheses List. In accordance with Australian Government policy, the costs associated with this program are currently being reviewed and the fees charged to sponsors will be aligned with these costs. The cost recovery arrangements will be considered as part of the work being delivered under the Government's Agreement with the MTAA.				

~ Includes carried forward cumulative deficit balance of \$506,645 from 2014-15.

### 7.2 NON-FINANCIAL PERFORMANCE

In line with the Department's Performance Measurement and Reporting Framework, the key performance indicators for Prostheses List activity are:

- The Prostheses List Advisory Committee was supported to reform the prostheses listing arrangements; and
- The Updated Prostheses List enabled access to devices, including cardiac ablation catheters for atrial fibrillation for privately insured patients.

## 8 KEY FORWARD DATES AND EVENTS

Activity	Date
CRIS for 2021-22 published on Department's website	By 1 July 2021
Update 2021-22 CRIS to report 2020-21 actual financial result	By 30 November 2021
Commence Portfolio Charging Review for 2023-24 Budget	From January 2022

## 9 CRIS APPROVAL AND CHANGE REGISTER

Date of CRIS Change	CRIS Change	Approver	Basis for Change
April 2021	Update of CRIS for 2019-20 performance data	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2019-20 financial results
June 2020	Update of CRIS for 2020-21	First Assistant Secretary, Technology Assessment and Access Division	Annual CRIS update
November 2019	Update of CRIS for 2018-19 performance data	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2018-19 financial results
June 2019	Update of CRIS for 2018-19 and 2019-20	Secretary, Department of Health	Updated for 2017-18 financial results and financial estimates
July 2018	Update of CRIS for 2017-18	First Assistant Secretary, Technology Assessment and Access Division	Update of financial estimates
February 2018	Update of 2016-17 performance data	Secretary, Department of Health	Updated for 2016-17 financial results
24 October 2016	Agreement	Minister for Health	Review of Cost Recovery
16 August 2016	Certification	Secretary, Department of Health	Review of Cost Recovery