



Australian Government
Department of Health

COST RECOVERY IMPLEMENTATION STATEMENT

Administration of the Protheses List

1 July 2021 to 30 June 2022

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)¹, 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*.

¹ 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 Prosthesis List (the List).

It also reports financial and non-financial results for the 2020-21 financial year for the administration of the Prosthesis List and contains financial forecasts for the 2021-22 financial year and three forward years. The Department will maintain the CRIS until the activity or cost recovery for the activity has been discontinued.

1.2 Description of the activity

The Prosthesis 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 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 the product meets the criteria for listing; and
 - liaising with applicants on the requirements and progress of the application.
- provision of secretariat support by the Department to the Prosthesis List Advisory Committee (PLAC) and its sub-committees, including organising meetings and preparing papers;
- assessment of applications 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 Prosthesis List arrangements; and
- providing and maintaining information for stakeholders about the Prosthesis 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 companies 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 effectively gain access to the private health market.

Following broad consultation on Prostheses List reform options, in the 2021-22 Budget, the Australian Government announced its intention to implement reforms to improve and modernise the Prostheses List arrangements, which will include changes to cost recovery arrangements (see Section 3.3.1 for more details).

2.2 Statutory authority to charge

Under Section 72-10 of the *Private Health Insurance Act 2007* (the PHI Act), an application for listing in the *Private Health Insurance (Prostheses) Rules* must be accompanied by a fee set out in the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*.

From 1 July 2007, 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)*.

3 COST RECOVERY MODEL

3.1 Outputs and business processes of the activity

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

The key business processes associated with applications to list prostheses on the List first time, or amend current codes on the List 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 effectiveness 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 2021-22 is at Table 1.

Table 1 – Summary of forecast cost components for 2021-22

Output: Prostheses List	2021-22 \$
Employee expenses	2,429,554
Supplier expenses (including Secretariat services and Committee meeting and member payments)	2,341,000
IT depreciation and maintenance	616,331
Indirect costs*	456,663
TOTAL	5,843,547

* 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 prosthesis 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 2008.

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 Agreement².

In December 2020, the Department released a consultation paper on options for reforms and improvements to the List to inform Government considerations around the direction and implementation of options for Prostheses List reform. Both reform options put forward will have implications for existing cost recovery arrangements. Enhanced administration of the List will require an increase in resourcing to the Department of Health which would be funded through revised cost recovery arrangements.

In the 2021-22 Budget, the Government has committed \$22 million over four years to improve the List and its arrangements. Building on the previous reform activities, the Government has agreed to maintain the List, with some improvements.

The List will continue to be the way in which hospitals, insurers and device companies know what benefits are payable for listed prostheses. Over time, the List benefits will better align with the price paid in the public

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

hospital system, supported by the Independent Hospital Pricing Authority (IHPA). Other key features of the reforms include:

- Clarifying the scope of the List by defining which prostheses are eligible for inclusion on the List and removing ineligible products.
- Regrouping the items on the List to better align devices with similar intended use or health outcomes.
- Streamlining the listing of new devices and reviewing the functions of the PLAC.
- Improving the post-listing activities, including reviews and compliance activities.
- Updating the existing cost recovery arrangements to align with the Australian Government Charging Framework.

These reforms will be implemented over a number of years, commencing 1 February 2022. The reforms are expected to be implemented by 2025. A review of these reforms will be conducted in 2024.

All future changes to cost recovery arrangements will ensure compliance with the Australian Government Charging Framework 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 November 2021, 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. Consultation will be undertaken in 2022 on proposed changes to cost recovery arrangements to support the modernised listing processes prior to implementation. An updated CRIS will be published outlining the changes to cost recovery arrangements, prior to commencement of the new charges.

6 FINANCIAL ESTIMATES

Table 2 reflects the forecast expenses along with the estimated revenue for 2020-21, 2021-22 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 2021-22 and three forward years

	2021-22	2022-23	2023-24	2024-25
	\$	\$	\$	\$
Expenses = X	5,843,547	5,832,345	5,698,626	5,774,867
Revenue = Y	4,735,000	4,735,000	4,735,000	4,735,000
Balance = Y – X (negative deficit)	(1,108,547)	(1,097,345)	(963,626)	(1,039,867)
Cumulative balance	509,190	(588,156)	(1,551,781)	(2,591,649)
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>The existing fees and levies charged do not reflect the assessment effort and activities undertaken, resulting in non-alignment of revenue and expenses incurred to perform the administration of PL and cross-subsidisation of charging. In the 2021-22 Budget, the Government agreed to update the cost recovery arrangements to align with the Australian Government Charging Framework and to support a modern listing process for PL applications.</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

Actual Financial Results	2016-17 \$	2017-18 \$	2018-19 \$	2019-20 \$	2020-21 \$
Expenses = X	4,604,989	4,310,442	3,840,471	5,018,799	4,529,491
Revenue = Y	4,385,160	4,887,526	4,721,600	4,791,400	4,736,200
Balance = Y – X (negative deficit)	(219,829)	577,084	881,129	(227,399)	206,709
Cumulative balance (negative deficit)	747,512	1,324,596	2,205,725	1,978,326	2,185,035
Variance explanation	Net over-recovery of \$206,709 (or 4.4%) in 2020-21 is due to lower than anticipated contracts for service expenses reported.				
Balance management strategy explanation	The existing fees and levy charged do not reflect the efforts and activities performed, resulting in non-alignment of revenue and expenses incurred to perform the administration of PL and cross-subsidisation of charging. In the 2021-22 Budget, the Government agreed to update the cost recovery arrangements to align with the Australian Government Charging Framework. A modern listing process and revised cost recovery arrangements are currently developed as part of the PL reforms.				

~ Includes carried forward cumulative deficit balance of \$967,341 from 2015-16.

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
Consultation on revised cost recovery arrangements to reflect PL reforms	During 2022
Commence Portfolio Charging Review for 2023-24 Budget	During 2022
Update CRIS to reflect 2023-24 financial forecasts	By 1 July 2022

9 CRIS APPROVAL AND CHANGE REGISTER

Date of CRIS Change	CRIS Change	Approver	Basis for Change
November 2021	Update of CRIS with 2020-21 financial performance data (Version 1.1)	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2020-21 financial results
June 2021	Update of CRIS for 2021-22 (Version 1.0)	First Assistant Secretary, Technology Assessment and Access Division	Annual CRIS update
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