Australian Government

Department of Health

COST RECOVERY IMPLEMENTATION STATEMENT

Administration of the Prostheses List

1 July 2018 to 30 June 2019

and

1 July 2019 to 30 June 2020

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)[1] set out the overarching framework under which government entities design, implement and review cost recovered activities.

[1] 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 Cost Recovery Implementation Statement (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 2018-19, 2019-20 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 2019 (as updated from time-to-time)* (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 – including: 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 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 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 List include:

- management of applications by staff in Health, including:
    - initial assessment to ensure the application is valid; and
    - liaising with applicant on the progress of the application.
- provision of secretariat support by Health 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; and
- 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 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 (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 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 MTAA Agreement), the Government has committed to publishing three Lists per year; in March, July and November, commencing in 2019.

The key business processes associated with applications to list new prostheses or amend current listings 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 through a health technology assessment;
- the PLAC consideration of clinical and/or cost-effectiveness recommendations;
- the PLAC advice provided to the Minister;
- granting of application by the Minister or Minister's Delegate;
- initial listing fee; and
- Prostheses 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; and
- committee costs (including travel, accommodation, venue and sitting fees for members).

A summary of cost components for 2018-19 and 2019-20 is at Table 1.

Table 1. Summary of cost components for 2018-19 and 2019-20

Output: Prostheses List	**2018-19**	**2019-20**
Employee expenses	$ 1,894,100	$ 2,279,300
Supplier expenses (including Secretariat services and Committee meeting and member payments)	$ 1,033,983	$ 1,146,000
IT depreciation and maintenance	$ 526,400	$ 530,900
Indirect costs	$ 444,500	$ 458,100
TOTAL	**$ 3,898,983**	**$ 4,414,300**

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), 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

The application fee is $600 per application and covers the cost of processing and assessing an application to list on the List.

The initial listing fee is $200 per prosthesis and covers the cost of granting applications and listing new prostheses on the List.

The ongoing listing fee is $200 and is paid every six months. The ongoing listing fee is required to be paid 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 2009. There are no changes to these fees in 2018-19 and 2019-20.

Under the MTAA Agreement, the Quality of Information and Guidance Industry Working Group (IWG) was established in March 2018 to improve the quality of information provided to support successful applications to list devices on the List. In the Agreement, the Government stated its intent to revise cost recovery arrangements, with changes to be implemented by 1 July 2020.

Cost recovery arrangements are currently being reviewed to take account of amended processes and timelines, and any associated efficiency gains, to ensure that prostheses listing and list management activities comply with the government's policy for recovery of the costs of all regulatory activities from the entity seeking the activity. The Government, in conjunction with the Quality of Information and Guidance IWG, will consult with industry before any changes to cost recovery arrangements are implemented.

4 RISK ASSESSMENT

A cost recovery risk assessment for this activity was undertaken in June 2019, 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. Cost recovery arrangements are currently being reviewed and any proposed changes to the existing arrangements will be provided to stakeholders for consultation in a draft CRIS prior to implementation. There are no changes to fees in the 2018-19 and 2019-20 financial years.

6 FINANCIAL ESTIMATES

Table 2. Financial estimates – 2018-19, 2019-20 and forward estimates

	2018-19 $	2019-20 $	2020-21 $	2021-22 $	2022-23 $
Expenses = X	3,899,000	4,414,300	4,481,100	4,544,900	4,618,000
Revenue = Y	4,400,000	4,400,000	4,400,000	4,400,000	4,400,000
Balance = Y-X	501,000	(14,300)	(81,100)	(144,900)	(218,000)
Cumulative balance	**1,825,596**	**1,811,296**	**1,730,196**	**1,585,296**	**1,367,296**
Explain balance management strategy	The forecast revenue estimates are based on past actual revenue. 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.				

7 FINANCIAL PERFORMANCE

Table 3. Financial performance for the past five financial years

	2013-14 $	2014-15 $	2015-16 $	2016-17 $	2017-18 $
Expenses = X	4,316,839	3,580,458	3,902,074	4,604,989	4,310,442
Revenue = Y	4,446,519	4,490,133	4,362,770	4,385,160	4,887,526
Balance = Y – X (negative deficit)	129,680	909,675	460,696	(219,829)	577,084
Cumulative balance (negative deficit)	**(403,030)^**	**506,645**	**967,341**	**747,512**	**1,324,596**

^ Includes carried forward deficit balance of $532,710 from 2012-13.

The forecast revenue for 2017-18 was $4.4 million, compared to the actual revenue of $4.8 million. The reason for the increase in revenue was that the Department undertook an audit and reconciliation of all outstanding listing fees. All fees have now been collected from sponsors.

8 NON-FINANCIAL PERFORMANCE

In line with the Department's Performance Measurement and Reporting Framework, the key performance indicators for the 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.

9 KEY FORWARD DATES AND EVENTS

- 1 July 2019 – updated Prostheses Rules effective
- 15 September 2019 – ongoing listing fee applied
- 1 November 2019 – updated Prostheses Rules effective
- November 2019 – CRIS update with financial results for 2018-19
- 1 March 2020- updated Prostheses Rules effective
- 15 March 2020 – ongoing listing fee applied

10 CRIS APPROVAL AND CHANGE REGISTER

Date of CRIS Change	CRIS Change	Approver	Basis for Change
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
24/10/2016	Agreement	Minister for Health	Review of Cost Recovery
16/08/2016	Certification	Secretary, Department of Health	Review of Cost Recovery