



Australian Government

**Department of Health
and Aged Care**

COST RECOVERY IMPLEMENTATION STATEMENT

Administration of the Prescribed List of Benefits
for Medical Devices and Human Tissue Products

1 July 2023 to 30 June 2024

Version 1.2

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 Australian Government Charging Framework and the CRGs are available on the Department of Finance Website

1. INTRODUCTION

1.1 Purpose of the Cost Recovery Implementation Statement

This Cost Recovery Implementation Statement (CRIS):

- provides information on how the Department of Health and Aged Care (the department) implements cost recovery for the administration of the **Prescribed List of Benefits for Medical Devices and Human Tissue Products** (the Prescribed List) previously known as the Prostheses List;
- outlines the fees that will apply for the 2023-24 financial year;
- describes the legislative changes to support the administration of cost recovery arrangements relating to the Prescribed List; and
- provides financial forecasts for the 2023-24 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 Prostheses List Reforms

Cost recovery activities associated with the assessment and administration of applications for the listing of medical devices on the Prostheses List commenced in 2007 and the fees were last updated in 2009.

In the 2021-22 Budget, the Government committed \$22 million over four years to improve the Prostheses List and its arrangements. Under these new arrangements the Prostheses List has been renamed the **Prescribed List of Benefits for Medical Devices and Human Tissue Products**. The Prescribed List is the Schedule to the Private Health Insurance (Medical Devices and Human Tissue Products) Rules that provides privately insured patients access to safe, clinically effective and cost-effective medical devices.

As part of the Prostheses List reforms, the Prostheses List Advisory Committee (PLAC) has been replaced by the Medical Devices and Human Tissue Advisory Committee (MDHTAC). The MDHTAC will provide recommendations and advice on the comparative clinical effectiveness and cost-effectiveness of medical devices and human tissue products, and the benefits payable by private health insurers. The new MDHTAC will be supported by six Expert Clinical Advisory Groups (ECAGs).

A key aspect of the Prostheses List reforms is the introduction of modern listing pathways. Applicants (sponsors) will benefit from a contemporary, fit-for-purpose process which allows for applications of differing complexity to be dealt with via different pathways. In practice, this will be implemented through the introduction of 'Tiers', providing streamlined pathways for the application and assessment of medical devices and human tissue products. The three Tiers of assessment relate directly to the level of health technology assessment (HTA) required for these applications, which can be summarised as:

- Tier 1: Departmental Assessment Pathway
- Tier 2: Clinical / Focused HTA Assessment Pathway
 - Tier 2a: Clinical Assessment
 - Tier 2b: Clinical Assessment and Economic Assessment (simple, complex, other)
- Tier 3: Full HTA Pathway (Medical Services Advisory Committee [MSAC]).

The new cost recovery arrangements are aligned with these Tiers and the requisite level of HTA required. This CRIS will provide details of fees payable for each assessment pathway. This informs the presentation of the information, cost model and financial estimates below.

The Prescribed List will continue to be the way in which hospitals, insurers and medical device companies are aware of the benefit payable for listed medical devices and human tissue products.

More information pertaining to the Prostheses List reforms are available at the Department of Health and Aged Care's website: 'The Prostheses List reforms'.²

Revised Cost Recovery Arrangements

In the 2023-24 Budget the Government announced revised cost recovery arrangements for the Prostheses List to reflect the reforms in accordance with the Australian Government Charging Framework (AGCF). The costs of undertaking regulatory activities associated with the new Prescribed List will be recovered using a combination of cost recovery fees and levy.

1.3 Description of the regulatory charging activity

The assessment of new items, listing and management of items, the maintenance of the relevant supporting infrastructure of the Prescribed List, and, compliance actions, are the regulatory activities that will incur the relevant cost recovery fees and levy. These activities are undertaken by the department in order to ensure privately insured patients in Australia have access to safe and clinically effective medical devices. The statutory basis of this regulatory charging activity is outlined in the *Private Health Insurance Act 2007* and the relevant legislative framework (outlined in section 2.5).

The new MDHTAC (as with the previous PLAC that it replaces) provides recommendations and advice about the comparative clinical effectiveness and cost-effectiveness of medical devices and human tissue products using the best available evidence, and the benefits payable by private health insurers.

Assessment and administration of applications (for new items and amended items)

The regulatory charging activity involved in assessing and administering applications encompasses the following:

- management of applications by department staff, including:
 - undertaking departmental assessments and providing advice to applicants (sponsors) (Tier 1);
 - liaising with applicants on the requirements and progress of the application;
 - commissioning HTA for Tier 2 and Tier 3 applications where required.
- provision of secretariat support by the department to the MDHTAC and its subcommittees, including organising meetings and preparing papers;
- assessment of applications against the criteria for listing by the MDHTAC and its subcommittees and making recommendations to the Minister or the Minister's delegate(s);
- making the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules*;
- developing and maintaining IT systems to support the Prescribed List (enabling access for applicants, external assessors and departmental staff);
- updating guidance material and relevant legislation;
- reviewing the MDHTAC's recommendations; and
- providing and maintaining information for stakeholders about the Prescribed List processes and policy on the department's website.

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

²<https://www.health.gov.au/topics/private-health-insurance/the-prostheses-list/the-prostheses-list-reforms>

Management of items already listed on the Prescribed List and relevant supporting infrastructure

The regulatory charging activity involved the ongoing management of items already listed on the Prescribed List, as undertaken by the department, includes:

- administration of the Prescribed List;
- provision of advice to and facilitating discussions with sponsors and other stakeholders about the Prescribed List arrangements;
- maintenance and provision of advice on the compliance, assurance and enforcement principles and provisions to support the effective administration of the Prescribed List compliance capability;
- commission, coordination and/or undertaking of post-listing reviews where required; and
- depreciation of IT systems used in the administration of the Prescribed List.

These activities performed are not attributable to a specific sponsor. Under the AGCF, these types of costs can be recovered as an annual levy and will be payable by sponsors in accordance with the medical devices included on the Prescribed List. As outlined in section 2.4, charging for the cost recovery levy is expected to commence in the 2024-25 financial year. Once implemented, this fee will be payable once annually for each item (billing code) that a sponsor has listed on the Prescribed List.

2 POLICY AND STATUTORY AUTHORITY TO COST RECOVER

2.1 What policy outcomes will the activity achieve?

The activities are appropriate for cost recovery for the following reasons:

- They provide an important means of improving the efficiency and equity with which Government services are provided;
- The charging of fees and the levy sends price signals to individuals or groups about the cost or value of a government activity;
- The services are requested by an identifiable group of parties who cause regulatory effort for the listing of their products on the Prescribed List;
- The charging of fees and the levy supports the ongoing sustainability of the Prescribed List as a regulatory activity.

This CRIS describes the cost recoverable activities that have contributed to the achievement of Outcome 2 (Program 2.4) as outlined in the 2022-23 Health Portfolio Budget Statement³.

Outcome 2: Individual Health Benefits

- Ensuring improved access for all Australians to cost-effective and affordable medicines, medical, dental and hearing services; improved choice in healthcare services, through guaranteeing Medicare and the Pharmaceutical Benefits Scheme; supporting targeted assistance strategies and private health insurance.

Program 2.4: Private Health Insurance

- Promote affordable, quality private health insurance and greater choice for consumers.
 - Modernising and improving the Prostheses List to reduce the cost of medical devices for privately insured consumers, and to streamline access to new medical devices.

³ <https://www.health.gov.au/resources/publications/budget-2022-23-portfolio-budget-statements?language=en>

2.2 Who will pay the regulatory charges?

The applicants, medical device companies and suppliers (collectively referred to as applicants or sponsors), who apply to list medical devices and human tissue products on the Prescribed List so that the listed item may be reimbursed by private health insurers, will be liable to pay any relevant cost recovery fees and levies. Through this process, sponsors effectively gain access to the private health market.

All sponsors who apply to list or vary an item on the Prescribed List are charged fees for services provided. Sponsors will also be required to pay for the general administration and management of the Prescribed List through an annual cost recovery levy for each item listed on the Prescribed List.

There will be some circumstances where no cost recovery fee is payable. Policies and processes relating to circumstances where no cost recovery fee is payable have been approved by Government and are stipulated in the supporting regulations.

2.3 Government policy approval to cost recover the activity

Deregulation of private health insurance benefit setting in the early 2000s resulted in a significant increase in benefit payments through private health insurance arrangements. This led to an increase to annual private health insurance premiums. To counteract this, a benefit setting mechanism was introduced to determine the amount private health insurers are legally bound to pay for prostheses benefits. The Prostheses List was established as the policy instrument to manage the costs of private health insurance by setting the appropriate benefit for each prosthesis. In February 2003, a decision was made by the Government that some costs associated with clinical assessment and benefit setting processes related to the Prostheses List would be met by sponsors. Legislation to give effect to this decision commenced on 31 October 2005.

In the 2021-22 Budget, the Government committed \$22 million over four years for the Modernising and Improving the Private Health Insurance Prostheses List Budget⁴ measure. This was announced following broad consultation on reform options. The Government considered these improvements necessary to benefit consumers, because a number of reviews of the system have consistently found a high variance in the prices on the Prostheses List compared to prices paid in the public hospital system, with a limited ability for market forces to exert a downward pressure that would benefit consumers.

Changes to cost recovery arrangements were included in this initial announcement. Revised cost recovery arrangements have since been provided for through the passage of amendments to the *Private Health Insurance Act 2007* and the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*.

2.4 Statutory authority to charge

Legislative amendments

In March 2023, the Australian Parliament passed the:

- *Private Health Insurance Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Act 2023*;
- *Private Health Insurance (Prostheses Application and Listing Fees) Amendment (Cost Recovery) Act 2023*; and
- *Private Health Insurance (National Joint Replacement Register Levy) Amendment (Consequential Amendments) Act 2023*.

⁴ <https://www.health.gov.au/resources/publications/private-health-insurance-modernising-and-improving-the-private-health-insurance-prostheses-list>

The purpose of these legislative changes was to provide authority for the revised cost recovery arrangements aligned with the AGCF and the CRGs under the following Acts:

- *Private Health Insurance Act 2007*; and
- *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*.

The existing application and listing fees under the *Private Health Insurance Act 2007* have been repealed.

Under the amended subsection 72-10 of the *Private Health Insurance Act 2007*, a person may apply to the Minister to have the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules* list the kind of medical device or human tissue product to which the application relates. The application must be accompanied by any fee that the applicant is liable to pay at the time the application is made. Under subsection 72-15, these fee amounts will be specified in the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules*.

The *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007* has been amended to be named the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007*. This Act provides statutory authority for the imposition of a cost recovery levy on each kind of medical device or human tissue product on the Prescribed List Regulations and Rules made under this Act will specify details relating to the levy, including the annual levy amount. These Regulations and Rules will be made prior to the commencement of the levy in the 2024-25 financial year.

As a result of these changes to the cost recovery arrangements, the *Private Health Insurance (Prostheses Application and Listing Fee) Rules 2018* have been repealed.

All Regulations and Rules which relate to cost recovery are outlined below, with a brief summary of their intended purpose.

Table 1. Subordinate legislation specifying details of cost recovery including charges payable

Title of subordinate legislation	Intended start date	Purpose in plain English
<i>Private Health Insurance (Medical Devices and Human Tissue Products) Rules</i>	1 July 2023	To set out the details for the charging of cost recovery fees
<i>Private Health Insurance (Medical Devices and Human Tissue Products Levy) Rules</i>	1 July 2024	To set out the details for the charging of cost recovery levies
<i>Private Health Insurance (Medical Devices and Human Tissue Products Levy) Regulations</i>	1 July 2024	To specify the amount to be charged for cost recovery levies
<i>Private Health Insurance (Levy Administration) Rules</i>	1 July 2024	To amend overarching levy rules which apply to all Private Health Insurance levies to incorporate the new proposed cost recovery levy

3 COST RECOVERY MODEL

The changes to the cost recovery arrangements will result in the imposition of both fees and a levy. The characteristics of a government activity determine the type of cost recovery charge used. There are two types of cost recovery charges.

Cost recovery fees will be charged where a direct relationship exists between the regulatory activity and the individual or organisation requesting that specific activity. All regulated entities are charged the same fee for the same activity. Under these circumstances, the activities performed, and their associated costs are driven by a specific need and demand created by the applicant. For example, applications for new listings on the Prescribed List will be charged a cost recovery fee.

Cost recovery levy will be charged when the cost of the activity can be reasonably attributed to a broader group of organisations (or individuals) rather than a single entity. In these instances, the level of demand for Government activity or intervention is collectively driven by the industry as a whole rather than a single entity within it. For example, ongoing management of already-listed items on the Prescribed List will be funded through a levy payable by the industry as a whole.

3.1 Regulatory activities included in the model

The following business processes are included for each cost recovery fee and the cost recovery levy. The table also outlines what assessment pathway (Tier) that a relevant fee would be liable to be paid.

Table 2. Charge categories and business processes

Fee Name	Which Assessment Pathway (Tier) Would Pay this Fee?	Business Processes (Description of service)
Standard Application Fee	<ul style="list-style-type: none">• Tier 1;• Tier 2a;• Tier 2b (simple, complex and other); and• Tier 3	The following activities are included: <ul style="list-style-type: none">• department assessment of application;• administrative processing of the request following application submission through Health Products Portal (HPP);• departmental preparation of relevant legislation; and• departmental invoicing for application cost recovery.
Clinical Assessment Fee	<ul style="list-style-type: none">• Tier 2a; and• Tier 2b (simple, complex and other)	The following business processes are included: <ul style="list-style-type: none">• clinical and expert advice sought to assess the clinical aspects of the application;• administrative processing of the request following application submission through HPP;• departmental preparation of relevant legislation;• departmental invoicing for application cost recovery; and• application assessment and recommendation by HTA committees:<ul style="list-style-type: none">• ECAGs; and• MDHTAC

Fee Name	Which Assessment Pathway (Tier) Would Pay this Fee?	Business Processes (Description of service)
Economic Assessment Fee	Tier 2b (simple, complex and other)	<p>The following business processes are included:</p> <ul style="list-style-type: none"> • development of an economic assessment; • liaison between sponsor and the department to inform the development of the economic assessment of an application; • HTA and expert advice (supplier costs); • administrative processing of the request following application submission through HPP; • departmental preparation of relevant legislation; and • departmental invoicing for application cost recovery.
Full Health Technology Pathway Assessment Fee*	Tier 3	<p>The following business processes are included:</p> <ul style="list-style-type: none"> • administrative processing of the request following application submission through HPP; • clinical and expert advice sought to assess clinical aspects of the application; • liaison between internal areas of the department throughout the MSAC application process: <ul style="list-style-type: none"> • department decision; • departmental preparation of relevant regulation and legislation; • departmental invoicing for application cost recovery; and • application assessment and recommendation by ECAG and the MDHTAC <p>* Note that currently no part of this fee includes the costs of services provided as part of the MSAC application process. This indicative fee of \$4,670 relates only to the services provided in relation to the administration and assessment of the application relating to the Prescribed List.</p>
Prescribed List Cost Recovery Levy	All applicable listed items	<p>A cost recovery levy charges the industry for costs which cannot be assigned to a specific sponsor.</p> <p>The following are in-scope for the cost recovery levy:</p> <ul style="list-style-type: none"> • Prescribed List administration; • depreciation of IT systems; • compliance reviews; and • post listing reviews

3.2 Costs and assumptions of the regulatory charging activity

In line with the CRGs, the activity-based costing model includes the following costs⁵:

Direct costs: Direct costs included in this model are staff salaries (including on-costs for superannuation and leave) for those directly involved in the activity, committee costs and supplier costs (e.g. contractors, consultants and legal).

Indirect costs: Indirect costs included in this model are allocated as overheads for staff directly involved in performing the activities using the Department of Finance's approved costing methodology. Indirect costs include staff training and development, workers compensation

⁵ Definition of the direct and indirect costs are from the CRGs.

premium, human resources support, organisational services, desktop ICT services and property operating expenses.

Capital costs: Capital costs included in this model comprise of depreciation costs associated with the Prescribed List IT system (the HPP).

Activity-based costing methodology has been applied to allocate costs to activities and outputs using volume-based cost drivers. This method enables more informed analysis of the efficiency of outputs and business processes. Costs were estimated on the following basis:

- the regulatory activities to be delivered were identified in consultation with relevant staff;
- MDHTAC and ECAG costs were estimated based on the number of members and meetings, and include wages/salary of members, travel allowances, accommodation, flights and catering as applicable;
- the number of submissions per year was calculated through use of the average number of submissions over a 3-year period;
- supplier costs were determined based on signed contracts; and
- staff costs/overheads include salaries as recommended by the Department of Finance.

Regulatory activities undertaken but not charged: These include largely direct costs, i.e. staff salaries, committee costs and supplier costs (e.g. contractors, consultants and legal), associated with the assessment and management of applications which could not be attributed to a single applicant (sponsor). This amounts to a total of \$82,000 for this regulatory charging activity.

Using the activity-based cost mode, the estimated unit cost for each payable fee category were determined as follows:

Table 3. Estimated unit cost per activity by Tier, effective from 1 July 2023 (2023-24 financial year)

Assessment Pathway (Tier) 2023-24	Direct Costs	Indirect Costs	Total Cost	Total Fee Amount from July 2023
Tier 1	\$ 1,108	\$ 265	\$ 1,373	\$ 1,370
Tier 2a	\$ 4,934	\$ 527	\$ 5,461	\$ 5,460
Tier 2b Simple	\$ 13,730	\$ 666	\$ 14,396	\$ 14,400
Tier 2b Complex	\$ 21,873	\$ 666	\$ 22,539	\$ 22,540
Tier 2b Other	\$ 32,730	\$ 666	\$ 33,396	\$ 33,400
Tier 3	\$ 4,062	\$ 609	\$ 4,671	\$ 4,670
Levy	n/a	n/a	n/a	n/a

Using the activity-based cost model and estimated volumes, the estimated total revenue of the regulatory charging activity was determined as follows:

Table 4. Estimated volumes and revenue for 2023-24, effective from 1 July 2023 (2023-24 financial year)

Assessment Pathway (Tier) 2023-24	Type	Total Fee Amount from July 2023	Estimated Volume	Estimated Revenue for 1 July 2023– 30 June 2024
Tier 1	Fee	\$ 1,370	901	\$ 1,234,370
Tier 2a	Fee	\$ 5,460	565	\$ 3,084,900
Tier 2b Simple	Fee	\$ 14,400	10	\$ 144,000
Tier 2b Complex	Fee	\$ 22,540	8	\$ 180,320
Tier 2b Other	Fee	\$ 33,400	2	\$ 66,800
Tier 3	Fee	\$ 4,670	15	\$ 70,050

Assessment Pathway (Tier) 2023-24	Type	Total Fee Amount from July 2023	Estimated Volume	Estimated Revenue for 1 July 2023– 30 June 2024
Levy	Levy	n/a	n/a	\$ -
Total Revenue				\$ 4,780,440

3.3 Cost recovery fees

The following table outlines the indicative cost recovery fees payable for an application in each Tier. This table shows how the regulatory charging will be implemented for the Prescribed List.

Details of the invoicing processes will be provided to applicants (sponsors) in supporting documentation. The standard application fee will be payable at the time of application. Subsequent requests for payment of the clinical and economic assessment fees will be made by the department when it is confirmed that the service is required during the assessment of the application.

Table 5: Fees payable for each fee category displayed by Tier of Application

Assessment Pathway (Tier) 2023-24	Payable Fee	Additional Payable Fee	Additional Payable Fee	Total indicative fee payable per application
Tier 1	Standard Application Fee Indicative amount: \$1,370	N/A	N/A	Indicative total amount: \$1,370
Tier 2a	Standard Application Fee Indicative amount: \$1,370	Clinical Assessment Fee Indicative amount: \$4,090	N/A	Indicative total amount: \$5,460
Tier 2b	Standard Application Fee Indicative amount: \$1,370	Clinical Assessment Fee Indicative amount: \$4,090	Economic Evaluation Fee Indicative amounts: <ul style="list-style-type: none"> • \$8,940 (simple) • \$17,080 (complex) • \$27,940 (other) 	Indicative total amount: <ul style="list-style-type: none"> • \$14,400 (simple) • \$22,540 (complex) • \$33,400 (other)
Tier 3	Standard Application Fee Indicative amount: \$1,370	Full HTA (MSAC) Pathway Assessment Fee Indicative amount: \$3,300	N/A	Indicative total amount: \$4,670 ⁶

⁶ Please note this fee only includes the Prescribed List component of work and does not include any future fees that may be payable for MSAC assessment

3.4 Cost recovery levy

The cost recovery levy has been deferred to the 2024-25 financial year. Details on the levy will be provided in the 2024-25 CRIS, prior to its implementation.

4 RISK ASSESSMENT

A charging risk assessment (CRA) is required for any regulatory charging policy proposal.

A CRA for this activity was undertaken in April 2023, resulting in a 'medium' risk rating. This rating is due to the implementation of revised cost recovery arrangements which has resulted in changes to legislation and the imposition of both new fees and a levy.

5 STAKEHOLDER ENGAGEMENT

The department has engaged in significant stakeholder consultation since the Prostheses List reform work commenced on 1 July 2021. The cost recovery provisions in this CRIS have been developed following extensive consultation. Consultation has included specific consultation papers, webinars, and responses to written questions from stakeholders. Key consultations pertaining to cost recovery of the Prescribed List include the following:

- between 16 September and 28 October 2022: Consultation Paper 3(b) – Pathways for applications to the Prostheses List included details of the new proposed cost recovery model, including a draft schedule of indicative fees;
- between 4 November and 11 November 2022: Consultation Paper 4(b) included three Exposure Drafts of the 'first tranche' legislative changes and an accompanying Explanatory Memorandum which outlined the intent of the most notable amending items; and
- between 20 March and 1 May 2023: Consultation paper 6(b) on the proposed legislation for cost recovery arrangements. As part of the consultation process, the department convened an information webinar on Monday 3 April, where information detailed in the consultation paper, was presented, and stakeholders had the opportunity to ask questions or raise concerns.

The CRIS will be reviewed and updated at least twice annually and published on the department's website for stakeholders.

Any future changes to the cost recovery charges will require the development of a new CRIS, which will be informed by stakeholder consultation.

6 FINANCIAL ESTIMATES

Table 6 reflects the forecast expenses along with the estimated revenue for 2023-24 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 6. Financial estimates for Prescribed List cost recovery activities for 2023-24 and three forward years (new cost recovery arrangements)

Forecast Financial Estimates	2023-24 \$'000	2024-25 \$'000	2025-26 \$'000	2026-27 \$'000
Combined Expenses = X	7,527	7,772	7,904	8,045
Combined Revenue = Y	4,780	7,692	7,827	7,977
Balance = X - Y	-2,747	-79	-76	-68
Cumulative Balance	-2,747	-2,826	-2,902	-2,971

Forecast Financial Estimates	2023-24 \$'000	2024-25 \$'000	2025-26 \$'000	2026-27 \$'000
Balance Management Strategy	The forecast deficit is largely due to the decision of the Government not to charge a levy in the 2023-24 financial year. This deficit, together with the small deficits forecast for the following three years, will be funded by a Government appropriation.			

7 PERFORMANCE

7.1 Financial Performance

Table 7 reports and compares the actual financial performance against financial forecast for each financial year, over a 5-year period.

Table 7. Financial performance for cost recovered activities

Actual Financial Results	2018–19 \$'000	2019–20 \$'000	2020–21 \$'000	2021–22 \$'000	2022–23 \$'000
Combined Expenses = X	3,840	5,019	4,529	4,639	4,613
Combined Revenue = Y	4,722	4,791	4,736	4,600	4,583
Balance = X - Y	881	-227	207	-39	-31
Cumulative balance	2,206 ⁷	1,978	2,185	2,146	2,115
Balance Management Strategy	The alignment between revenue and expenses have been reviewed as part of ongoing reforms to the administration of the PL. New cost recovery arrangements commenced on 1 July 2023, consistent with Australian Government Charging Framework.				

7.2 Non-financial Performance

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

- the remaking and publication of the relevant Rules (of which the Prescribed List is the Schedule) three times in a year;
- the MDHTAC is supported to implement the reforms for the Prescribed Listing arrangements; and
- the updated Prescribed List enables access to devices, including cardiac ablation catheters for atrial fibrillation for privately insured patients.

⁷ The cumulative balance includes carried forward cumulative balance of \$1,325,000 from 2017-18. The cumulative balance will reset from the 2023-24 financial year following introduction of revised cost recovery arrangements.

8 KEY FORWARD DATES AND EVENTS

Activity	Date
Update CRIS for 2024-25	June 2024

9 CRIS APPROVAL AND CHANGE REGISTER

Date of CRIS Change	CRIS Change	Approver	Basis for Change
November 2023	Approval of amended 2023-24 CRIS (V 1.2)	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2022-23 financial results
June 2023	Update of CRIS for 2023-24 (Version 1.1)	Minister for Health and Aged Care	Annual CRIS update
May 2023	Consultation draft for the 2023-24 CRIS approved for publication	First Assistant Secretary, Technology Assessment and Access Division	Revised Cost Recovery arrangements to be implemented in line with the Australian Government Charging Framework
November 2022	Update of CRIS with 2021-22 financial performance data (Version 1.2)	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2021-22 financial results
June 2022	Update of CRIS for 2022-23 (Version 1.1)	First Assistant Secretary, Technology Assessment and Access Division	Annual CRIS update
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

Date of CRIS Change	CRIS Change	Approver	Basis for Change
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 and Aged Care	Review of Cost Recovery
16 August 2016	Certification	Secretary, Department of Health	Review of Cost Recovery

9. ATTACHMENT A – SUMMARY OF MAIN STAKEHOLDER VIEWS ON REQUIRED CRIS CONSULTATION AND RELATED DEPARTMENT RESPONSES 2023-24

Stakeholder Comment	Response
Fees	
<p>Stakeholders indicated that the level of cost recovery is higher than expected.</p>	<p>The department has developed an activity-based cost model in alignment with the Australian Government Charging Framework. The fees represent the minimum efficient cost of administering the Prescribed List as determined by a comprehensive review of all relevant expenses incurred during administration and assessment of applications. The relative increase in the fees in comparison to the previous cost recovery arrangements is due to factors such as:</p> <ul style="list-style-type: none"> • the move from partial to full cost recovery; • existing cost recovery fees have not been amended since 2009; • the inclusion of new expenses hitherto not included in the cost recovery model (i.e. were not included in the model determining fees payable from 2009); and • increase in expenses relating to staffing, supplier costs and IT maintenance, etc.
<p>Stakeholders indicated that the fees charged for certain types of applications will not be consistent with the Australian Government Charging Framework. Notably, that the initial assessment fee for amendment applications should be less than that for listing applications. Stakeholders report the proposed fee does not account for the differing types of amendment applications, the different levels of action or assessment required, nor the potential for the Health Products Portal to provide automated services.</p> <p>Stakeholders proposed waiving fees on amendment applications in which only the ARTG details are being updated on the Prescribed List, and that the List Management application fee is more appropriate for applications seeking to compress multiple billing codes into one.</p>	<p>The department acknowledges this feedback and confirms that each fee category has been designed using an activity-based costing model in alignment with the Australian Government Charging Framework and represents an accurate account of the work required to assess and process each application received.</p> <p>The department remains committed to finding efficiencies in process and will conduct regular review of the cost model to ensure that all fees and charges are appropriate, commensurate with the level of work involved, fit for purpose and are reflective of the effort and technology involved in achieving required outcomes.</p> <p>The department notes that in some circumstances fee waivers may be available to sponsors submitting applications.</p>

Stakeholders indicated that List Management Application fees for deletion and transfer applications should not be charged for deletion and transfer applications citing 'no assessment is required'	The department recognises stakeholder concerns regarding these types of applications and confirms that cost recovery fees will not be payable for deletion and transfer applications.
Stakeholders requested a grace period from cost recovery fees of 12 months for applications to compress billing codes that will not be required following the restructure that has occurred for the Prescribed List.	The department notes that in some circumstances fee waivers may be available to sponsors submitting applications, however as cost recovery fees are already in place for these types of applications, no additional grace periods will be available.
Non-Financial Performance	
Stakeholders recommended that key performance indicators should be developed in consultation with stakeholders, indicating that performance indicators and metrics should be published on a regular basis.	The department notes stakeholder feedback in relation to key performance indicators and remains committed to the reporting of financial performance of the Prescribed List through regular updates of the CRIS. The Department also reiterates its commitment to continue to consult with stakeholders in relation to the reporting of the performance of the Prescribed List.
Terminology	
Stakeholders noted discrepancy in the terminology used in previous consultation papers in relation to the CRIS and specified the assumption that 'Non-Refundable Application Fee' (Consultation Paper 6(b)) and 'Initial Assessment Fee' mean the same thing.	<p>The department acknowledges the discrepancy in terminology and confirms that the following terms are synonymous:</p> <ul style="list-style-type: none"> • 'Non-Refundable Application Fee' (as previously described in Consultation Paper 6(b)); • 'Initial Assessment Fee' (as described in the Draft CRIS); and • 'Standard Application Fee' (which replaces the omitted term 'initial assessment fee' in the finalised CRIS).
Policy Details	
<p>Stakeholders indicated that in addition to the CRIS, further context was needed in order to provide further feedback on the cost recovery proposal.</p> <p>Stakeholders requested that the Guidance document be released to provide the additional details on the application flow and pathway eligibility.</p>	<p>The department acknowledges the need for further context and the need to provide stakeholders with more granular detail regarding the new application pathways.</p> <p>The Guidance Document will be published on the Department of Health and Aged Care's website prior to the commencement of cost recovery arrangements.</p>
Impact on Industry	
Stakeholders noted that increased cost recovery, and the introduction of new cost recovery arrangements directly impact the medical technology	The department reiterates its commitment to the principles of cost recovery, in which it is established that it is appropriate in cases where

<p>sector, and that compounding fees for services across the department of Health and Aged Care is likely to delay access to innovative technology to Australian patients.</p>	<p>commercial benefit is gained from Government activity, the minimum efficient costs may be recovered in order to ensure the recipients of that government activity, rather than the general public, bear its costs.</p> <p>Further the department remains committed to improving the efficiency, and productivity of the Prescribed List in order to ensure that the Australian public is not impacted by these changes.</p>
<p>Stakeholders requested clarification on the forecasted expenses of administering the Prescribed List noting an increase in expenses \$4.75m in FY23 (CRIS 2022-23) to \$7.69m in FY25 (CRIS 2023-24 Draft).</p>	<p>The previous cost recovery arrangements reflected a 'partial cost recovery' arrangement, which has been in place without change since 2009. To align with the Government's decision to implement 'whole of program' cost recovery, the department undertook a full review of all the associated direct and indirect costs that are essential to the administration of the Prescribed List to develop an activity-based costing model. This model reports all expenses, including those which were previously funded through Government appropriation (and as such excluded from the 2009 model), relating to the administration of the Prescribed List.</p> <p>The observable increase in the forecast expenses is directly attributable to the increase and/or inclusion of the following expenses:</p> <ul style="list-style-type: none"> • staffing costs; • IT maintenance and depreciation; • supplier costs; and • overhead costs.
<p>The relationship between Budget expenditure in 2021-22 and the cost recovery fees is unclear and clarification that reform activities should always be funded by the government not industry is requested.</p>	<p>The department confirms that reform work undertaken for the Prescribed List was funded through Government appropriation and does not form any component of the cost recovery fees.</p> <p>References to the 2021-22 Budget were provided to give context to the reform work that has been undertaken in relation to the Prescribed List, which occurred in tandem with the development of the cost recovery model.</p>