Australian Government
Department of Health and Aged Care

COST RECOVERY IMPLEMENTATION STATEMENT

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

1 July 2024 to 30 June 2025

Version 1.2

Charging for regulatory activity involves Government entities charging individuals or organisations in the non-government sector some or all of the minimum efficient costs of a specific Government activity. The Cost Recovery Policy along with the Australian Government Charging Framework (the Charging Framework) sets out the policy under which Government entities design, implement and review charging for regulatory activities. The Cost Recovery Implementation Statement (CRIS) is the public document to ensure the transparency and accountability for the level of the charging and to demonstrate that the purpose for charging, as decided by Government, is being achieved.

Contents

1. INTRODUCTION

1.1. Purpose

This CRIS provides information on how the Department of Health and Aged Care (the Department) implements cost recovery charging for:

- applications to the Medical Devices and Human Tissue Advisory Committee (MDHTAC) for medical devices seeking to be listed on the Prescribed List of Medical Devices and Human Tissue Products (the Prescribed List)
- applicant-driven listing and list management activities for the Prescribed List.

It reports actual financial and non-financial performance information, outlines legislative changes and contains financial and demand forecasts for 2024-2025 and three forward years. The Department will maintain the CRIS while the regulatory activity, or cost recovery for the activity, continues.

1.2. Description of the regulatory charging activity

1.2.1. What is the regulatory activity being cost recovered?

The Prescribed List details medical devices and human tissue products for which private health insurers must pay benefits, if they have been used for or implanted into patients with an appropriate private health insurance policy. The Prescribed List is a Schedule to the Private Health Insurance (Medical Devices and Human Tissue Products) Rules that supports privately insured patients to access safe, clinically effective and cost-effective medical devices.

The Department provides a range of evaluation, listing and management services for the Prescribed List that have been cost recovered since 2007. In 2015, the Charging Framework and the Cost Recovery Guidelines (now referred to as the Cost Recovery Policy) were introduced.

In 2023-24 new cost recovery arrangements, aligned with the Charging Framework, were introduced for the Prescribed List. This included a new cost model and streamlined activities to reflect the efficient costs of providing evaluation, listing and management services to industry for the Prescribed List.

The MDHTAC provides 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 MDHTAC is supported by six Expert Clinical Advisory Groups (ECAGs).

Three ‘tiers’ of assessment provide streamlined pathways for the application and assessment of medical devices and human tissue products related directly to the level of health technology assessment (HTA) required for the Prescribed List applications:

- 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][1]).

In 2023-24, only the costs of services directly attributable to individual sponsors were recovered, through application fees for the tiered pathways.

[1] MSAC fees are not subject to cost recovery.

From 2024-25, the costs of undertaking regulatory activities associated with the Prescribed List are to be recovered using a combination of application fees and a levy for activities not directly attributed to an individual sponsor. Costs are not recovered for waivers and exemptions that are available under legislation in certain circumstances.

The 2024-25 cost recovered services for evaluation, listing and management services for the Prescribed List include:

- assessment and administration of applications (for new items and amended items)
- management of items already listed on the Prescribed List and relevant supporting infrastructure.

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

The regulatory charging activity for the assessment and administration of applications includes:

- 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 sub-committees, including organising meetings and preparing papers
- assessment of applications as per MDHTAC and its sub-committees' listing criteria and making recommendations to the Minister or the Minister's delegate(s)
- reviewing the MDHTAC's recommendations

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

These activities will be cost recovered by charging fees.

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

The regulatory charging activity for the ongoing management of items already listed on the Prescribed List 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
- provision to support the effective administration of the Prescribed List compliance capability
- commissioning, coordinating and/or undertaking post-listing reviews where required
- updating 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 and
- providing and maintaining information for stakeholders about the Prescribed List processes and policy on the Department's website.

These activities are not attributable to a specific sponsor. Under the Charging Framework, these types of costs will be recovered as an annual levy from 2024-25 payable by sponsors in accordance with the medical devices listed on the Prescribed List. The cost recovery levy will be payable annually for each listed item on the Prescribed List. The cost recovery levy will not be applicable to items listed under Part B of the Prescribed List.

1.2.2. What policy outcomes will the activity achieve?

The regulatory activities contribute to achieving Outcome 2 (Program 2.4) outlined in the Health Portfolio Budget Statements.

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.

1.2.3. Why is charging appropriate for the regulatory activity?

Charging for evaluation, listing and management services for products on the Prescribed List is appropriate because:

- Charging is 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.
- It supports the ongoing sustainability of the Prescribed List as a regulatory activity.

Cost recovery involves Government entities charging individuals or non-government organisations some or all the efficient costs of a specific Government activity. This may include goods, services, regulation, or a combination of these. The Australian Government Cost Recovery Policy (CRP) sets out the framework under which Government entities design, implement and review cost-recovered activities.

The Charging Framework applies to non-corporate and corporate Commonwealth entities as defined in the *Public Governance, Performance and Accountability Act 2013* (PGPA Act). The Department is a non-corporate Commonwealth entity.

The policy statement for government charging, as stated in the Australian Government Charging Policy, is:

'Where specific demand for a government activity is created by identifiable individuals or groups they should be charged for it unless the Government has decided to fund that activity. Where it is appropriate for the Australian Government to participate in an activity, it should fully utilise and maintain public resources, through appropriate charging. The application of charging should not, however, adversely impact disadvantaged Australians'.

There are two types of cost recovery charges. The characteristics of a Government activity determine the type of cost recovery charge used.

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 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 medical devices industry.

1.2.4. Who will pay the regulatory charges?

Medical device companies and suppliers (collectively referred to as applicants or sponsors) who apply to list or vary medical device products on the Prescribed List will be charged fees for services provided.

Sponsors will also be required to pay for compliance, post-listing review activities, general administration and management of the Prescribed List through an annual cost recovery levy for each item listed on the Prescribed List.

The cost recovery fees and levy will not be applicable to human tissue products listed under Part B of the Prescribed List.

In certain circumstances, applicants may request that fees are waived if the application is seeking to list 'related medical devices' where abridged clinical or economic assessment can be conducted.

2. POLICY AND STATUTORY AUTHORITY TO CHARGE (COST RECOVER)

2.1. Government policy approval to charge for this regulatory activity

2.1.1. When and what did the Government announce?

In February 2003, the Government decided some costs associated with clinical assessment and benefit setting processes related to the Prostheses List (now the Prescribed List) would be met by sponsors. Legislation to give effect to this decision commenced on 31 October 2005.

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

In the 2021-22 Budget, the Government announced $22 million over four years for the *Modernising and Improving the Private Health Insurance Prostheses List* measure, which included changes to the cost recovery arrangements. The announcement followed extensive policy development work, including a number of reviews that consistently found a high variance in prices on the Prostheses List compared to prices paid in the public hospital system, with limited ability for market forces to exert downward pressure on prices to benefit consumers.

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

In May 2024, the Minister for Health and Aged Care announced that General Use Items (GUIs) will continue to be funded through the Prescribed List. GUIs were scheduled to be removed from the Prescribed List on 1 July 2024.

2.2.Statutory authority to charge

The statutory basis of this regulatory charging activity is outlined in the *Private Health Insurance Act 2007* (the Act) and the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007*.

The Private Health Insurance (Medical Devices and Human Tissue Products) Rules outline the cost recovery fees that may be charged for the purposes of section 72-15 of the Act. This includes fee amounts for activities undertaken to consider listing or variation applications relating to a medical device on the Prescribed List.

2.2.1. Legislative Amendments

Regulations and Rules will apply to the levy. These are listed in Table 1 below with a summary of their purpose. The levy will commence in 2024-25.

Table 1. Subordinate legislation specifying details of the cost recovery levy

Title of subordinate legislation	Purpose
Private Health Insurance (Medical Devices and Human Tissue Products Levy) Rules	Set out the details for the charging of cost recovery levies.
Private Health Insurance (Medical Devices and Human Tissue Products Levy) Regulations	Specify the amount to be charged for the cost recovery levy.
Private Health Insurance (Levy Administration) Rules	Specify other matters related to the levy, including payment date.

3. CHARGING (COST RECOVERY) MODEL

3.1. Outputs and business processes of the activity

The cost recovery charge categories are:

- standard application assessment fee
- clinical assessment fee
- economic assessment fee
- full HTA pathway fee
- Prescribed List levy.

Activity descriptions are detailed in Table 2, with cost breakdowns in Tables 3 and 4.

Table 2. Charge categories and business processes

Charge Category	Description
Standard application fee	Assessment pathway: • Tier 1 • Tier 2a • Tier 2b (simple, complex, and other) • Tier 3 Activities include: • departmental assessment for each medical device listed in an application • administrative processing of the request following application submission through the Health Products Portal (HPP) • departmental preparation of relevant legislative instruments and documentation

Charge Category	Description
	• departmental invoicing for each medical device listed in an application for cost recovery.

Clinical assessment fee	Assessment pathway:
	• Tier 2a
	• Tier 2b (simple, complex and other).
	Activities include:
	• clinical and expert advice sought to assess the clinical aspects for each medical device listed under the application
	• administrative processing of the request following application submission through HPP
	• departmental preparation of relevant legislative instruments and documentation
	• departmental invoicing for application cost recovery, and
	• application assessment and recommendation by HTA committees:
	  • MDHTAC
	  • ECAGs.

Economic assessment fee	Assessment pathway: • Tier 2b (simple, complex and other) Activities include: • development of an economic assessment • liaison between sponsor and the Department to inform the development of the economic assessment for each medical device listed under an application • HTA and expert advice (supplier costs) • administrative processing of the request following application submission through HPP • departmental preparation of relevant legislative instruments and documentation • departmental invoicing for application cost recovery

Full HTA pathway fee*	Assessment pathway:
	• Tier 3
	Activities include:
	• administrative processing of the request following application submission through HPP
	• clinical and expert advice sought to assess clinical aspects for each medical device listed under the application
	• liaison between internal areas of the Department throughout the MSAC application process:
	  • Department decision
	  • departmental preparation of relevant legislative instruments and documentation
	  • departmental invoicing for application cost recovery, and
	  • application assessment and recommendation by ECAG and the MDHTAC.

Charge Category	Description
	* Note that currently no part of this fee includes the costs of services provided as part of the MSAC application process. This fee relates only to the services provided in relation to the administration and assessment of the application relating to the Prescribed List.
Prescribed List Levy	Applies to all applicable listed items to recover costs which cannot be attributed to an individual sponsor. Activities in-scope for inclusion: • Prescribed List administration • IT system costs • compliance reviews • post listing reviews • list management services

3.2. Costs of the regulatory activity

Fees and charges are determined by the Department using an activity-based costing methodology agreed with the Department of Finance. Indexation is applied annually, to reflect the current minimum efficient costs of delivering the services and charges. This approach is consistent with the Charging Framework. Cost Recovery fees are payable for each device included within the application.

A review of fees and charges is undertaken on an annual basis, which consists of assessing the cost of the regulatory activities and applying indexation. In 2024-25 fees for Tier 1 and Tier 2b economic assessment applications increased ranging from 1.7% to 3.8%. Tier 2a and Tier 3 applications decreased by 1.2% and 5.6% respectively.

A number of drivers impacted these fee changes including:

- Increases in salary costs ranging between 3% - 4.4%
- Supplier costs increase of 3.5%
- Decrease in committee costs by 6.2%
- Corporate overhead costs increase of 6%.

The Department has committed to initiate an independent review of the Prescribed List cost recovery arrangements 18-24 months after implementation (by 1 July 2025). Industry will be kept informed as the review is progressed and consulted on the outcomes including through the annual CRIS process.

In line with the CRP, the following costs[2] are included in the activity based costing model:

Direct costs: Direct costs include 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 include overheads for staff directly involved in performing the activities using the Department of Finance's approved costing methodology. These costs include overhead costs such as staff training and development, human resources, organisational services, technical support (e.g., legal), desktop ICT services and property operating expenses.

[2]Definitions of direct and indirect costs are from the CRP.

An 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 were calculated based on the average number of past submissions
- supplier costs were determined based on signed contracts, and
- staff costs/overheads include salaries and rates provided by the Department of Finance.

Table 3. Unit cost per activity by Tier for 2024-25

Assessment Pathway (tier)	Direct costs	Indirect costs	Total unit cost
Tier 1	$1,144	$278	$1422
Tier 2	$4,840	$553	$5,393
Tier 2 Economic - simple	$13,942	$699	$14,641
Tier 2 Economic - complex	$22,370	$699	$23,068
Tier 2 Economic - other	$33,607	$699	$34,305
Tier 3	$3,770	$639	$4,408
Prescribed List Levy	$140	$11	$151

In the previous version of the 2024-25 CRIS, it was advised that the levy amount was still to be determined and was anticipated to be in the range of $350 - $450 per listed item. This advice was provided on the basis that the levy would consist of costs associated with compliance, IT, post listing reviews, list management and administration. Subsequently, the Government made the decision that for 2024-25 only, compliance and post listing review costs are to be excluded from the levy. As a result, the charge for the levy in 2024-25 will be $150 per item listed on the Prescribed List.

The 2024-25 levy is dependent on the development of legislative instruments and the levy imposition date is expected to be in early 2025.

Table 4 outlines the cost recovery fees payable for an application in each tier.

Details of the invoicing processes are provided to sponsors via the draft Prescribed List of Medical Devices and Human Tissue Products Guide.

Table 4. Fees payable for each fee category by tier of application

Assessment Pathway (Tier)	Initial fee	Additional fee	Additional fee	Total fee per application
Tier 1	Standard Application Fee $1,420	N/A	N/A	$1,420

Assessment Pathway (Tier)	Initial fee	Additional fee	Additional fee	Total fee per application
Tier 2a	Standard Application Fee $1,420	Clinical Assessment Fee: $3,970	N/A	$5,390
Tier 2b	Standard Application Fee $1,420	Clinical Assessment Fee: $3,970	Economic Evaluation fee: $9,250 (Simple) $17,680 (Complex) $28,920 (Other)	$14,640 (Simple) $23,070 (Complex) $34,310 (Other)
Tier 3	Standard Application Fee $1,420	Full HTA (MSAC) Pathway Assessment fee: $2,990	N/A	$4,410

3.3. Design of the regulatory charge

Table 5 provides the estimated volumes, costs and revenue from the regulatory charging activities for 2024-25. Volume estimates relate to the number of devices assessed by tier (as an application may be for multiple devices).

The Private Health Insurance (Medical Devices and Human Tissue Products) Rules provide for waivers in certain circumstances. Applicants may request fees to be waived if the application is seeking to list 'related medical devices' where abridged clinical or economic assessment can be conducted. Fee waiver requests are considered as part of the Prescribed List application assessment process.

Listing applications, or variation applications, relating to human tissue products for listing under Part B of the Prescribed List will be exempt from cost recovery charges.

Table 5. Estimated volumes and revenue for 2024-25

Assessment Pathway (Tier)	Type	Unit cost	Unit price	Estimated volume	Estimated total cost	Estimated total revenue
Tier 1	Fee	$1,422	$1,420	901	$ 1,280,883	$1,279,420
Tier 2	Fee	$5,393	$5,390	565	$3,047,268	$3,045,350
Tier 2 Economic - Simple	Fee	$14,641	$14,640	10	$146,406	$146,400
Tier 2 Economic - Complex	Fee	$23,068	$23,070	8	$184,546	$184,560
Tier 2 Economic - Other	Fee	$34,305	$34,310	2	$68,611	$68,620
Tier 3	Fee	$4,408	$4,410	15	$66,124	$66,150
Prescribed List Levy	Levy	$151	$150	9,585	$1,449,392	$1,437,750
Total					**$6,243,229**	**$6,228,150**

4. RISK ASSESSMENT

A Charging Risk Assessment (CRA) was undertaken in December 2024. The overall risk rating is 'medium' due to the increase in total annual estimated revenue in 2024-25 as a result of charging the levy.

5. STAKEHOLDER ENGAGEMENT

Annual consultation occurs through the publishing of a draft CRIS. Public consultation was undertaken from 8 May 2024 to 29 May 2024 to seek stakeholder feedback on the 2024-25 CRIS. Three submissions were received, and a summary of stakeholder feedback and Departmental responses is at **Attachment A**.

6. FINANCIAL PERFORMANCE

6.1. Financial Estimates

The forecast expenses and estimated revenue of the Prescribed List cost recovery arrangements for the 2024-25 financial year and three forward years are in Table 6. The financial estimates do not include the levy and will be updated when the levy amount is determined.

There is an ongoing net deficit, which is supplemented by Government appropriation to the Department for the under recovery. Forward projections demonstrate the difference between expenses and revenue increases every year.

Should there be any change to the underlying cost recovery model, a new financial estimates table will be provided.

Table 6. Financial estimates for Prescribed List cost recovery activities

Financial estimates	2024-25 $'000	2025-26 $'000	2026-27 $'000	2027-28 $'000
Total revenue	$6,228	$7,799	$8,000	$8,169
Total expenses	$7,802	$8,013	$8,189	$8,377
Balance (revenue - expense)	-$1,574	-$213	-$189	-$208
Cumulative balance	-$6,721	-$6,934	-$7,123	-$7,331
Balance management strategy explanation	New cost recovery arrangements commenced on 1 July 2023, consistent with Australian Government Charging Framework. The Department's balance management strategy is to aim for alignment between revenue and expenses following the full implementation of levy arrangements.			

6.2. Financial Outcomes

Error! Reference source not found. is updated after each financial year to report on the actual financial performance. The forecast financial performance as published in the CRIS will be compared with the actual financial performance for each financial year. Any variance greater than 5 per cent will be identified and explained.

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

Table 7. Financial performance for cost recovered activities

Financial Outcomes	2020-21 $'000	2021-22 $'000	2022-23 $'000	2023-24 $'000
Estimates				
Revenue (X)	$4,665	$4,735	$4,750	$4,780
Expenses (Y)	$5,026	$5,844	$4,751	$7,527
Balance (X-Y)	-$361	-$1,109	-$1	-$2,747
Actuals				
Revenue (X)	$4,736	$4,600	$4,583	$1,315
Expenses (Y)	$4,529	$4,639	$4,613	$6,462
Balance (X-Y)	$207	-$39	-$30	-$5,147
Cumulative balance	$2,185	$2,146	$2,116	-$5,147
Material variance explanation	In 2023-24 there was an under-recovery of $5,147 million. This resulted from: • a lower-than-expected number of applications received; • delays in raising invoices for 281 clinical assessment fees from the January 2024 intake. It is expected these invoices will be raised in 2024-25; and • the decision of Government not to charge a levy in 2023-24.			
Balance management strategy explanation	New cost recovery arrangements commenced on 1 July 2023, consistent with Australian Government Charging Framework. The Department's balance management strategy is to aim for alignment between revenue and expenses following the full implementation of levy arrangements.			

7. NON-FINANCIAL PERFORMANCE

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

- remaking and publishing of the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules* three times per year
- the MDHTAC is supported to implement the reforms for the Prescribed List arrangements; and
- the updated Prescribed List enables access to devices, including cardiac ablation catheters for atrial fibrillation for privately insured patients.

8. KEY FORWARD DATES AND EVENTS

Table 8. Key forward dates and events

Date	Activity
30/06/2025	Indexation of fees and levy for 2025-26 CRIS

9. CRIS APPROVAL AND CHANGE REGISTER

Table 9. CRIS approval and change register

Date of change	CRIS change	Approver	Basis for change
15/01/2025	Update of 2024-25 CRIS to report 2023-24 financial performance data, advise of the 2024-25 levy amount and updates to Attachment A	Minister for Health and Aged Care	Updated for 2023-24 financial results and revised cost recovery levy arrangements.
28/06/2024	Approval of 2024-25 CRIS	First Assistant Secretary, Technology Assessment and Access Division	Respond to stakeholder consultation feedback
06/05/2024	Approval of draft 2024-25 CRIS for stakeholder consultation	First Assistant Secretary, Technology Assessment and Access Division	Annual CRIS consultation including revised estimates
30/11/2023	Update of CRIS with 2022-23 financial performance data	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2022-23 financial results
30/06/2023	Approval of CRIS for 2023-24	Minister for Health and Aged Care	Approval of revised cost recovery arrangements
07/05/2023	Approval of draft 2023-24 CRIS for stakeholder consultation	First Assistant Secretary, Technology Assessment and Access Division	Revised Cost Recovery arrangements to be implemented in line with the Charging Framework
30/11/2022	Update of CRIS with 2021-22 financial performance data	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2021-22 financial results
30/06/2022	Approval of CRIS for 2022-23	First Assistant Secretary, Technology Assessment and Access Division	Annual CRIS update
30/11/2021	Update of CRIS with 2020-21 financial performance data	First Assistant Secretary, Technology	Updated for 2020-21 financial results

Date of change	CRIS change	Approver	Basis for change
		Assessment and Access Division	
30/06/2021	Approval of CRIS for 2021-22	First Assistant Secretary, Technology Assessment and Access Division	Annual CRIS update
04/2021	Update of CRIS with 2019-20 performance data	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2019-20 financial results
30/06/2020	Approval of CRIS for 2020-21	First Assistant Secretary, Technology Assessment and Access Division	Annual CRIS update
20/11/2019	Update of CRIS with 2018-19 performance data	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2018-19 financial results
30/06/2019	Approval of CRIS for 2018-19 and 2019-20	Secretary, Department of Health	Updated for 2017-18 financial results and financial estimates
01/07/2018	Approval of CRIS for 2017-18	First Assistant Secretary, Technology Assessment and Access Division	Annual CRIS update
02/2018	Update of CRIS with 2016-17 performance data	Secretary, Department of Health	Updated for 2016-17 financial results
24/10/2016	Approval of 2016-17 CRIS	Minister for Health	Review of cost recovery arrangements
16/08/2016	Certification of 2016-17 CRIS	Secretary, Department of Health	Review of cost recovery arrangements

ATTACHMENT A – SUMMARY OF STAKEHOLDER CONSULTATION FEEDBACK ON THE DRAFT 2024-25 CRIS AND RELATED DEPARTMENT RESPONSE

Stakeholder Comments	Department Response
Fee changes for 2024-25	
Further information was sought on the source of the application fee increases in 2024-25.	There are a number of drivers impacting these fee changes including: • Consumer Price Index increase of 3.5% • Increases in salary costs ranging between 3.0% - 4.4% • Supplier costs increase of 3.5% • Decrease in committee costs by 6.2% • Corporate overhead costs increase of 6.0%. This information is now included at Section 3.2.
Further information was sought on Tier 1 and Tier 2 volume and revenue estimates.	Volume estimates relate to the number of devices assessed by tier (as an application may be for multiple devices). The 2024-25 estimated volumes in the activity-based costing model are consistent with the 2023-24 estimates, which was the first year of the revised Prescribed List application pathways. A review of the estimates for each application pathway will be commence in the 2024-25 financial year and the activity-based costing model updated as appropriate. The actual revenue recovered is reported after each financial year, through an updated CRIS usually around November. Any material variations to volume and revenue estimates (5 per cent or more) are approved by the Department of Finance.
Assurance was sought that other sponsors collectively are not being charged for work related to Part B and is being covered by the Government.	Costs related to Part B will not be charged to other sponsors, i.e. through the levy. While these expenses contribute to the underlying cost base, they are not recovered from sponsors of items listed on Part A, C and D. The Department is appropriated separately for the services it provides on behalf of Government, including for the administration of Part B.
Assurance was sought about alignment of the activity based costing model with the Australian Government Charging Framework.	The activity-based costing model is aligned with Australian Government Charging Framework and agreed with the Department of Finance. The Department has committed to initiate an independent review of the Prescribed List cost recovery arrangements 18-24 months after implementation (by 1 July 2025). Industry will be kept informed as the review is progressed and consulted on the outcomes of the independent review including through the annual CRIS process.
Non-financial performance	

Stakeholder Comments	Department Response
Stakeholders sought a service commitment and performance indicators on the new PL application arrangements, to be jointly developed and agreed with sponsors, before 2024-25 fee increases are implemented.	While a service commitment and performance indicators on the new Prescribed List application arrangements are out-of-scope of the financial performance information reported via the CRIS, the Department is monitoring and evaluating implementation of the new Prescribed List application pathways. The Department notes the 2024-25 fee changes commencing on 1 July 2024 include both fee increases and decreases.
Cost recovery levy	
Further information was sought on the underlying assumptions for the higher-than-expected levy range.	Stakeholder feedback has been considered in determining final levy amount. Compliance activities and post-listing reviews safeguard the integrity and sustainability of the Prescribed List. Compliance activities and post listing review costs are not included in the levy charge until 2025-26 financial year. However, the levy amount may increase in the future years from 2024-25 to incorporate compliance and post-listing review costs.
Further information was sought on the total revenue estimated for the levy for 2024-25 and forward financial years.	The levy amount has been finalised for 2024-25 financial year and the tables in the CRIS have been amended to reflect these updates.
Costs associated with compliance activities and post-listing reviews should not be charged solely to sponsors. These costs should be shared with insurers and other stakeholders that directly or indirectly derive some form of commercial benefit through the PL listed items.	Compliance activities and post-listing reviews safeguard the integrity and sustainability of the Prescribed List. Under the Australian Government Charging Framework, where an identifiable group creates extra or specific demand for a regulatory activity, they should be charged for the activity. Medical device companies and suppliers (sponsors) who apply to list or vary medical device products on the Prescribed List are charged fees for applications for medical devices to be listed on the Prescribed List, and applicant-driven listing and list management activities. Sponsors will also be required to pay for compliance, post-listing review activities, general administration and management of the Prescribed List through an annual cost recovery levy for each item listed on the Prescribed List. The transition to the new cost recovery arrangements included phased implementation of the levy, with no levy on industry in 2023-24, and compliance activities and post listing review costs not included until 2025-26.
Request for a phased approach to implementing the levy, to allow industry sufficient time for	Transition to the new cost recovery arrangements included phased implementation of the levy, with no levy on industry in 2023-24.

Stakeholder Comments	Department Response
business planning and to account for the current cost pressures on industry.	The Department has considered stakeholder feedback in finalising the 2024-25 levy amount.
Efficiency of the Health Products Portal (HPP)	
Concerns were raised about the effectiveness and efficiency of the HPP, including increased time pressures associated with introduction of the HPP.	The Department acknowledges the feedback on the introduction and transition to the HPP. This will be further considered at the Prescribed List program level, as part of broader HPP strategic planning, and any related advice to Government. Stakeholders are encouraged to provide feedback and suggestions via email to HPP.Support@health.gov.au. Enquiries related to system issues or functionality will be implemented based on their relative priority and user impact, as part of the Department's commitment to continually improving HPP.
Listing communications	
Concerns were raised about sponsors experiencing ongoing communications issues related to their listings including very short timeframes or no opportunity at all to respond to ECAG recommendations.	The Department acknowledges the feedback around listing communications experienced by sponsors during the first year of implementation of the Prescribed List reforms and will continue to work with sponsors to address the concerns raised.
Prescribed List Guide	
Updated guidance material was requested with additional information on the application process and pathway eligibility.	The *Prescribed List of Medical Devices and Human Tissue Products Guide – draft* (Prescribed List Guide) is published on the Department's website to help sponsors prepare applications. The Prescribed List Guide is designed to be read together with information about the HPP and other resources available on the Department's website (these are listed in the Guide). The Prescribed List Guide is currently being finalised and an updated version will be published as soon as possible.