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Australian Government
Department of Health, Disability and Ageing

COST RECOVERY IMPLEMENTATION STATEMENT

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

1 July 2025 to 30 June 2026

Version 1.1

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 Australian Government Cost Recovery Policy (CRP) 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.

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1. INTRODUCTION

1.1. Purpose

This CRIS provides information on how the Department of Health, Disability and Ageing (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 2025-2026 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 charging 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 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.

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In 2024-25, the cost recovery arrangements were amended to include a combination of application fees and a levy to recover the cost of activities not directly attributed to an individual sponsor. Costs are not recovered for waivers and exemptions that are available under legislation in certain circumstances.

From 2024-25 onwards, 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. From 2024-25 onwards, these costs will be recovered as an annual levy payable by sponsors in accordance with the number of medical devices listed on the Prescribed List. The cost recovery levy will be payable annually, in September, for each listed billing code on the Prescribed List. The cost recovery levy will not be applicable to items listed under Part B of the Prescribed List.

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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 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 CRP, 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 Levy Act).

The *Private Health Insurance (Medical Devices and Human Tissue Products) Rules 2025* 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.

The *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Regulations 2025* (the Regulations) prescribe the amount of cost recovery levy that may be charged for the purposes of section 4(3) of the Levy Act. The levy is charged annually to recover the cost of the ongoing management and general administration of the Prescribed List in a financial year. The Regulations also outline the Prescribed List items that may be exempted from the levy charge.

The *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Rules 2025* outline the levy imposition day for each financial year starting 2024-25. For financial years 2025-26 and future financial years, the levy day is 15 September.

The *Private Health Insurance (Levy Administration) Rules 2015 outline* matters relating to the medical devices and human tissue products levy. The matters include who is responsible to pay the levy and the levy payment terms.

2.2.1. Legislative Instruments

Rules and Regulations apply to the fees and levy charges. Upcoming updates to legislative instruments are listed in Table 1 below with a summary of their purpose.

Table 1. Legislative instruments specifying details of the cost recovery fees and levy

Title of legislative instrument	Purpose
Private Health Insurance (Medical Devices and Human Tissue Products) Rules 2025	Specify the amount to be charged for cost recovery fees.
Private Health Insurance (Medical Devices and Human Tissue Products Levy) Regulations 2025	Specify the amount to be charged for the cost recovery levy.

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:

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Charge Category	Description
	• 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 • 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:

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Charge Category	Description
	• 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. * 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.

For 2025-26, the result of the review is an increase in fees in line with indexation. Indexation rates range between different regulatory activities. For example, staffing costs have increased by 3%. Further fee increases have been incurred for Tier 2a and Tier 2b application pathways. Clinical assessment fees under both pathways have increased by 6% due to the increase in committee costs. The tier 2b pathway fees have increased between 20% - 33% due to increased costs for externally contracted health technology assessments for economic evaluations. The increase in cost is reflective of current market prices.

From 1 July 2025, the levy will increase from $150 to $355 per device as a result of including compliance and post listing review costs and increased IT costs.

The Department will progress an independent review of the Prescribed List cost recovery arrangements during 2025. Industry will continue to be informed on the progress of the review and consulted on the outcomes.

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

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

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Direct costs: Direct costs include staff salaries (including on-costs for superannuation and leave) for those directly involved in the activity, committee costs, IT support costs for the Health Products Portal (HPP), and other 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.

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 application submissions per year were calculated based on the average number of past application 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 2025-26

Assessment Pathway (tier)	Direct costs	Indirect costs	Total unit cost
Tier 1	$1,175	$288	$1,463
Tier 2	$5,101	$573	$5,674
Tier 2 Economic - simple	$17,105	$724	$17,829
Tier 2 Economic - complex	$28,414	$724	$29,138
Tier 2 Economic - other	$39,723	$724	$40,447
Tier 3	$3,905	$662	$4,567
Prescribed List Levy	$322	$35	$357

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 and the Department's website.

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 $1,460	N/A	N/A	$1,460
Tier 2a	Standard Application Fee $1,460	Clinical Assessment Fee: $4,210	N/A	$5,670

Assessment Pathway (Tier)	Initial fee	Additional fee	Additional fee	Total fee per application
Tier 2b	Standard Application Fee $1,460	Clinical Assessment Fee: $4,210	Economic Evaluation fee: $12,150 (Simple) $23,460 (Complex) $34,770 (Other)	$17,820 (Simple) $29,130 (Complex) $40,440 (Other)
Tier 3	Standard Application Fee $1,460	Full HTA (MSAC) Pathway Assessment fee: $3,100	N/A	$4,560

3.3. Design of the regulatory charge

Table 5 provides the estimated volumes, costs and revenue from the regulatory charging activities for 2025-26. Table 5 includes the estimated cost recovery charges from 1 July 2025 to 30 June 26, subject to legislative instrument updates. Volume estimates relate to the number of devices assessed by tier (as an application submitted via the HPP portal 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. Further information can be sought from the Draft Prescribed List Guide. Fee waiver requests are considered as part of the departmental assessment process for Prescribed List applications.

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

Table 5. Estimated volumes and revenue for 2025-26

Assessment Pathway (Tier)	Type	Unit cost	Unit price	Estimated Invoiced volume	Estimated total cost	Estimated total revenue
Tier 1	Fee	$1,463	$1,460	901	$ 1,317,883	$1,315,460
Tier 2	Fee	$5,674	$5,670	565	$3,206,059	$3,203,550
Tier 2 Economic - Simple	Fee	$17,829	$17,820	10	$178,292	$178,200
Tier 2 Economic - Complex	Fee	$29,138	$29,130	8	$233,104	$233,040
Tier 2 Economic - Other	Fee	$40,447	$40,440	2	$80,894	$80,880
Tier 3	Fee	$4,567	$4,560	15	$68,502	$68,400
Prescribed List Levy	Levy	$357	$355	10,360	$3,694,694	$3,677,800
Total					**$8,779,428**	**$8,757,330**

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4. RISK ASSESSMENT

Consistent with the requirements of the Charging Framework, a Charging Risk Assessment (CRA) was conducted following consultation on the draft 2025-26 CRIS. The overall risk rating is 'medium' due to the increase in the estimated revenue and levy amount.

5. STAKEHOLDER ENGAGEMENT

Annual consultation occurs through the publishing of a draft CRIS. Public consultation was conducted from 16 May to 6 June 2025 to seek stakeholder feedback on the 2025-26 CRIS. A summary of the feedback received from three submissions along with 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 2025-26 financial year and three forward years are in Table 6.

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.

A new financial estimates table will be provided if there is any change to the underlying charging model.

Table 6. Financial estimates for Prescribed List cost recovery activities

Financial estimates	2025-26 $'000	2026-27 $'000	2027-28 $'000	2028-29 $'000
Total revenue	$8,757	$9,055	$9,155	$9,387
Total expenses	$9,108	$9,354	$9,531	$9,751
Balance (revenue - expense)	-$350	-$299	-$377	-$364
Cumulative balance	-$7,072	-$7,371	-$7,747	-$8,111
Balance management strategy explanation	New cost recovery arrangements commenced on 1 July 2023, consistent with the 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

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.

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Table 7. Financial performance for cost recovered activities

Financial Outcomes	2021-22 $'000	2022-23 $'000	2023-24 $'000	2024-25 $'000
Estimates				
Revenue (X)	$4,735	$4,750	$4,780	$6,228
Expenses (Y)	$5,844	$4,751	$7,527	$7,802
Balance (X-Y)	-$1,109	-$1	-$2,747	-$1,574
Actuals				
Revenue (X)	$4,600	$4,583	$1,315	
Expenses (Y)	$4,639	$4,613	$6,462	
Balance (X-Y)	-$39	-$30	-$5,147	
Cumulative balance	$2,146	$2,116	-$5,147*	
Material variance explanation	In 2023-24 there was an under-recovery of $5,147 million. This resulted from: • lower-than-expected number of applications received; • delays in raising invoices for 281 clinical assessment fees from the January 2024 intake. These invoices were 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 the Charging Framework. The Department's balance management strategy is to aim for alignment between revenue and expenses following the full implementation of levy arrangements. **** Note: as the new cost recovery arrangements** were **implemented on 1 July 2023, the cumulative balance was reset in the 2023-24 financial year.***			

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
- amending and publishing of the Private Health Insurance (Medical Devices and Human Tissue Products Levy) Regulations each year
- supporting the MDHTAC to implement the Prescribed List arrangements; and
- updating the Prescribed List to enable 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
30/11/2025	Update of CRIS with 2024-25 financial performance data

9. CRIS APPROVAL AND CHANGE REGISTER

Table 9. CRIS approval and change register

Date of change	CRIS change	Approver	Basis for change
01/07/2025	Approval of 2025-26 CRIS	First Assistant Secretary, Technology Assessment and Access Division	Annual CRIS update and response to stakeholder consultation feedback
16/05/2025	Approval of draft 2025-26 CRIS for stakeholder consultation	First Assistant Secretary, Technology Assessment and Access Division	Annual CRIS consultation including revised estimates
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

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Date of change	CRIS change	Approver	Basis for change
30/11/2021	Update of CRIS with 2020-21 financial performance data	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2020-21 financial results
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

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ATTACHMENT A – SUMMARY OF STAKEHOLDER CONSULTATION FEEDBACK ON THE DRAFT 2025-26 CRIS AND DEPARTMENT RESPONSES

Public consultation for the 2025-26 Draft CRIS occurred from 16 May to 6 June 2025. Three responses were received and stakeholder feedback is summarised below with the responses from the Department.

Stakeholder feedback	Department response
Charging increases for 2025-26	
Further information was sought on the significant increase in total estimated revenue and charges since the 2022-23 financial year in comparison to the 2025-26 financial year.	The Department notes the 2022-23 financial year was prior to the Prescribed List reforms, where the cost recovery arrangements were not aligned with the Australian Government Charging Framework (the Charging Framework). The total estimate revenue, fees and charges for 2025-26 are aligned with the Charging Framework and reflect the minimum efficient cost of administering the Prescribed List as agreed with the Department of Finance in 2023-24 Budget as part of the reforms.
Further information was sought on the fees for amendment application assessments because of "upclassification" of products by the TGA.	Where necessary the TGA may reclassify a medical device to enhance the safety, performance and quality of the product. Where reclassification of a medical device by the TGA results in an amendment application for the Prescribed List, the relevant application fees apply. This may include the standard application fee, clinical and/or economic assessment fees depending on the nature of the specific device.
Stakeholders sought relief from cost pressures on sponsors due to the combined effect of the increase in 2025-26 Prescribed List charges and increases for TGA fees and the National Joint Replacement Registry (NJRR) levy.	The Department acknowledges that sponsors of products listed on the Prescribed List are subject to TGA and other regulatory charges such as the NJRR levy. The Department will continue to review fees and charges for administering the Prescribed List as required under the Charging Framework and provide policy advice to Government. This includes advice on stakeholder and other impacts from the charging arrangements.
Clarification was sought on the number of billing codes used to determine the 2025-26 levy amount.	The levy amount presented in the draft 2025-26 CRIS ($380 per listed item) did not reflect the latest updates to the Prescribed List on 1 March 2025 as these were not available at the time of initial drafting.

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Stakeholder feedback	Department response
	The levy amount in the final 2025-26 CRIS ($355 per listed item) reflects the 1 March 2025 updates to the Prescribed List and a total of 11,021 billing codes, with 10,360 devices being charged the levy and 661 Part B products being exemption from the levy.
Costs associated with compliance activities and post-listing reviews should not be charged solely to the medical device industry. These post-listing activities are initiated by the private health insurance industry, which may directly benefit from the outcome of these reviews and compliance measures through potential reductions in device expenditures.	Compliance activities and post-listing reviews safeguard the integrity and sustainability of the Prescribed List. Under the 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. Sponsors are also 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.
Levy and specific costs	
Further information was sought on the increase in costs of economic evaluations, driven by external HTA contractor costs, across the three tier 2b assessment pathway evaluation types (simple, complex and other).	In 2025-26 the tier 2b pathway fees have increased between 20% - 33% due to increased market costs for externally contracted HTA for economic evaluations. In engaging external HTA contractors, the Department adheres to the Commonwealth Procurement Rules including its core rule to achieve value for money. This includes consideration of relevant financial and non-financial costs and benefits.
Increased transparency and granularity around the cost analysis of the Prescribed List was sought including for example: • delineation of groups by pathways. • planned resource allocation including FTE • cost breakdown for parts A, B, C & D.	The Department is committed to providing transparent and appropriate granular information about the Prescribed List through the CRIS and other communication activities. While *Table 2* in the CRIS (p7) outlines the different charge/activity categories and presents a breakdown of business processes, the Department plans to work with stakeholders through established industry engagement mechanisms to better understand the additional information sought and what can be provided.

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Stakeholder feedback	Department response
	The Department notes that costs related to Part B are not 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.
Application volume estimates	
Stakeholders sought further clarification on the lower number of applications in 2023-24 and no change to actual staffing, and advisory groups and committees still held.	Volume estimates relate to the number of devices assessed by Tier (as a HPP application may be for multiple devices). The 2025-26 estimated volumes in the Prescribed List charging model remain consistent with the 2023-24 and 2024-25 estimates during the reform period. The volume estimates for each assessment pathway are currently being reviewed and will also be examined as part of the independent review of the Prescribed List charging model expected to commence in July 2025 (and completed by November 2025). The volume estimates will be updated for 2026-27 as appropriate. The Department notes the actual revenue recovered is reported after each financial year, through an updated CRIS usually around November.
Pharmaceutical Benefits Scheme (PBS) charging arrangements	
Stakeholders sought clarity on why the Prescribed List charges a levy on the medical device industry, while the PBS does not charge a levy on the biopharmaceutical industry.	The Charging Framework provides that where an individual or organisation creates the demand for a government activity, they should generally be charged for it. The Government's overarching cost recovery policy is that, where appropriate, non-government recipients of specific government activities should be charged some or all the costs of those activities. The cost recovery arrangements, including fees and charges for the administration of the Prescribed List and the PBS, are Government policy decisions. The Department will continue to review the cost recovery arrangements for both the Prescribed List and the PBS as required by the Charging Framework, and provide

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Stakeholder feedback	Department response
	ongoing advice to Government to inform the respective policy deliberations.
Efficiency of the Health Products Portal (HPP)	
Stakeholders raised concerns 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 by the Department as part of broader strategic planning to continually improve the HPP, and any related advice to Government. Stakeholders continue to be encouraged to provide feedback and suggestions via email to HPP.Support@health.gov.au. System enhancements will be implemented based on their relative priority and user impact.
Communication and service level	
Stakeholders seek additional channels to discuss open applications or to have pre-meetings with the Department/ECAGs on significant submissions with the Department.	The Department acknowledges the feedback around listing communications experienced by sponsors during the two-year Prescribed List reform period and remains committed to continuing to work with individual sponsors and their representatives to address the concerns raised.
Non-financial performance	
Stakeholders sought performance metrics and a commitment to co-design a service charter with minimum standards for services provided to industry.	While a service commitment and performance metrics for the Prescribed List application arrangements are out-of-scope of the financial performance information reported via CRIS, the Department acknowledge this feedback and will consider this feedback as part of broader strategic planning.
Flow on impact to hospitals and patients	
Stakeholders noted that significant application fees and annual levies may alter the commercial viability of maintaining PL listings, potentially leading to product withdrawals or limiting clinical and patient choice for accessing new technologies. Clarity was sought on how sponsors can manage additional regulatory costs, such as through increased device benefits on the Prescribed List.	The Prescribed List regulates benefits for patients holding private health insurance policies that cover the relevant PL benefits. The Prescribed List supports claiming transactions between sponsors and hospitals and is a voluntary program. The Prescribed List does not regulate the national market for medical devices or commercial matters between sponsors, insurers and private hospitals. The Department notes: • Prescribed List fees and charges reflect the minimum efficient cost for providing the regulatory activities. • fee waivers may be requested for related devices when submitting an application

Stakeholder feedback	Department response
	(further guidance is available on the Department's website). • Sponsors can apply to amend the details of existing billing codes, including changing the grouping the billing code is listed in (e.g. with a different benefit). The Department continues to monitor the effectiveness, efficiency, and sustainability of the Prescribed List and provide advice to Government.
Lack of a transparent and well-structured clinical input process means there is a risk that decisions about which technologies are accessible to patients through the PL become overly technocratic or financially driven, at the expense of clinical judgement and patient-centred care. Stakeholder confidence that the PL reflects the latest clinical standards and accommodates patient diversity and complexity, is essential for preserving trust in the sustainability and integrity of the private health system.	The Department acknowledges this feedback. A key element of the Prescribed List reforms has been to improve the consistency of clinical assessments and advice. To support this, there are now six Expert Clinical Advisory Groups structured to cover all categories of medical devices on the Prescribed List. There are also mechanisms enabling the representatives of the key bodies for private hospitals, medical device industry, and private health insurers to provide inputs into the application assessments and other matters considered by the MDHTAC, with the procedures in place ensuring the appropriate management of commercial-in-confidence information. The Department will continue to monitor any issues concerning administration of the Prescribed List to ensure it continues to support the sustainability and integrity of the private hospital system.