Australian Government

Department of Health and Aged Care

Proposed Cost Recovery Arrangements

Frequently Asked Questions

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Note on Terminology

Prostheses List: Note that for ease of reference, this document refers to the Prostheses List, which is proposed to be renamed the Prescribed List of Medical Devices and Human Tissue Products (PL).

Applicant / sponsor: Note that sponsors (a person in relation to whom a medical device or human issue product is included in the Prostheses List) are referred to as applicants in the cost recovery legislation, as they are the person or organisation who lodges an application to be considered for listing on the Prostheses List. As such, in referring to the relevant cost recovery legislation, the term “applicant” may be used. Elsewhere, and in this document, the term sponsor is also used, especially when referring to where a medical device or human tissue product is already listed on the Prostheses List.

Cost Recovery Principles

What is Cost Recovery?

Cost recovery involves the Australian Government charging the non-government sector for some or all of the **efficient costs** of a specific government activity. That activity may include the provision of goods, services or regulation, or a combination of these.

The Australian Government’s overarching cost recovery policy is that, where appropriate, non-government recipients of specific government activities should be charged some or all of the costs of those activities. The cost recovery policy promotes consistent, transparent and accountable charging for government activities and supports the proper use of public resources.

The Cost Recovery Guidelines (CRGs) must be applied by all non-corporate Commonwealth entities and by selected corporate Commonwealth entities, such as the Department of Health and Aged Care (the Department).

The Australian Government Charging Framework (the Charging Framework) builds on the 2014 CRGs and encourages a common approach to planning, implementing, and reviewing government charging, which should lead to improved and consistent charging. The Framework supports the Australian Government’s role in delivering quality public programmes to Australian citizens, communities, and the economy more broadly, by assisting to improve programme funding decisions.

More information is available at the Department of Finance website.

How are the proposed cost recovery fees determined?

Consistent with the Charging Framework, non-government entities using the Prostheses List services provided by the Government should pay the minimum **efficient costs** of the work effort required to administer the regulation of such services. Relevant fees are established through an activity-based costing method that identifies the discrete activities involved for each application category and the cost of all products and services required to complete these activities, including:

- Direct costs: staff salaries for those directly involved in activities to process Prostheses List applications, committee costs and supplier costs.
- Indirect costs: overhead costs for staff directly involved in the activities using the Department of Finance’s approved costing methodology. These overhead costs include staff training and development, workers compensation premium, human resources support, organisational services, desktop ICT services and property operating expenses.

The proposed activity-based fees reflect the levels of effort, cost, and complexity of Departmental services provided to each applicant in relation to each application submitted.

How are the proposed cost recovery fees different to the current situation?

The key change from existing provisions under the *Private Health Insurance Act 2007* and the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007* is this alignment with the minimum efficient costs of the Government's provision of services to applicants, which replaces the fixed fee amounts under previous arrangements that have not changed since 2009. The same activity-based approach is used to calculate amounts of both cost recovery fees and cost recovery levies.

Will there be any circumstances for fee waivers or fee exemptions?

The Department has proposed that in the following situations, fees will not apply under the proposed cost recovery arrangements:

- No fee is payable if the application is for listing of a human tissue (Part B) product in the Prostheses List. This can be either for an application for a new listing, amendments to an existing listing or removing a listing.
- The Full HTA (MSAC) Pathway Assessment Fee may be waived in whole or in part if a clinical assessment and economic evaluation has been completed for the application.

Why is an Economic Evaluation Fee waived on human tissue applications?

Due to the altruistic nature of organ and tissue donation and the prohibition on trade in human tissues and organs, Australian tissue banks have historically operated as not-for-profit entities, although commercial suppliers have more recently begun supplying tissue. As such, the premise for the PL benefit setting for human tissue is currently that there is no additional margin or profit to tissue product providers. As such, the Department has proposed that applications for listing on Part B are not subject to cost recovery fees. This is consistent with the current situation, where applications for listing on Part B are not subject to application or listing fees.

Would any financial assistance be provided for cost recovery fees for small and medium-sized enterprises? The increase in cost is significant and potentially prohibitive for smaller Australian-owned companies.

The Department has currently not proposed waivers for financial non-viability or on the basis that a sponsor is a small and medium-sized enterprise. Sponsors are invited to provide specific feedback about how increased cost recovery fees might affect small and medium-sized enterprises through the open consultation if this is a significant concern.

The significant increase in application fees potentially create barriers for niche products with very small patient populations. Will a waiver be possible?

The Department has currently not proposed waivers for niche products with very small patient populations. Sponsors are invited to provide specific feedback about how increased cost recovery fees might affect niche products with very small patient populations through the open consultation if this is a significant concern. Sponsors are invited to provide as much detail as possible regarding potential financial implications, and relevant examples of such medical devices.

Are amendment application fees the same as new applications?

Amendment applications will be treated in the same way as new applications and subject to the same application fees as the new applications. This means sponsors will need to select the appropriate Tier that the application should be considered under. This is because amendments to a listed device will require the same level of Health Technology Assessment (HTA) as applications to list a new device and therefore are subject to the same efficient costs.

If the amendment required is only for transfer of sponsor, the Department has proposed that only the relevant List Management for Transfer Applications must be paid. In the case of the transfer of sponsor only, the proposed fee amount reflects that this is purely administrative action as no level of HTA is required.

Implementation of Proposed Cost Recovery

When will these fees come into effect?

The legislation is planned to commence from 1 July 2023. However, the first opportunity that cost recovery fees will be charged to applications will be from September 2023.

If the application pathway chosen by the applicant is incorrect, will a fee associated with a new application pathway need to be paid?

In line with the Charging Framework, the costs paid by the applicant are for the minimum efficient effort and resources required by the Department to complete the requested service. If an additional assessment is required, the relevant fees for this assessment will need to be paid.

Applicants will be able to withdraw applications and make a new application in the same or amended form. The new application can be made for the same or a different category (Tier). No refunds of fees already paid will be offered in cases where the application is withdrawn.

Will the Department advise sponsors if they have chosen the wrong Tier?

In the first place, the onus is on the applicant to select the correct tier for their application in consultation with the PL Guide (which will be released for consultation). The Department will inform sponsors if the choice of the Tier is incorrect.

Are the application fee and clinical assessment fee intended to be charged by billing code or system application? For example, if an application related to multiple billing codes (components), would a single Clinical Assessment Fee be payable?

The Department has proposed that each related Billing Code will pay the relevant Non-Refundable Application Fee, Clinical Assessment Fee or Economic Evaluation Fee. Sponsors may wish to provide additional information regarding this through the open consultation process.

What does the Economic Evaluation involve? How is the complexity of an economic evaluation and resultant fees determined?

An Economic Evaluation involves the Department seeking external health technology advice for a medical device application in the case that some aspect of cost-effectiveness must be established in the course of assessment. The three levels of complexity for an Economic Evaluation may be defined as follows:

- A ‘Simple Economic’ Evaluation is a commentary focusing on critique of information supplied by the applicant, for one device and one main clinical purpose.
- A ‘Complex’ Economic Evaluation is a commentary focusing on critique of information supplied by the applicant, for one device for multiple clinical purposes or multiple related devices for a similar clinical purpose.
- An ‘Other’ Economic Evaluation is an assessment report for the applicant.

What fees are application for an application that has just undergone Medical Services Advisory Committee (MSAC) Evaluation be in?

If an application that has just gone through MSAC with a positive recommendation, then the relevant application should be submitted in Tier 3 and with the payment of the Full HTA (MSAC) Pathway Assessment Fee. Note that currently no part of this fee includes the cost of services provided as part of the MSAC application process. The cost recovery fee associated with the Tier 3 pathway only reflects the PL associated activities.

The fee amount reflects the efficient costs of the activities involved. The activities involved include:

- 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.
- Department decision.
- Departmental preparation of relevant regulation and legislation.
- Departmental invoicing for application cost recovery.
- Application assessment and recommendation by HTA committees:
    - Expert Clinical Advisory Groups.
    - Prostheses List Advisory Committee.

Cost Recovery Levy

What is the difference between cost recovery fees and cost recovery levies?

Under the CRGs, there are various government charges which may be applied:

- A **cost recovery fee** is charged when a good, service or regulation (in certain circumstances) is provided directly to a specific individual or organisation.
- A **cost recovery levy** is imposed when a good, service or regulation is provided to a group of individuals or organisations (e.g., an industry sector) rather than to a specific individual or organisation. A cost recovery levy is a tax and is imposed with separate taxation legislation. It differs from general taxation as it is 'earmarked' to fund activities provided to the group that pays the levy.

The proposed cost recovery arrangements for the Prostheses List include activity-based 'fee for service' application fees. As the fees are attached to each application, and each application is initiated by the applicant, these cost recovery charges are characterised as cost recovery fees.

Additionally, it is proposed that the existing levy-based 'fee' system be amended to reflect the costs of ongoing management of the Prostheses List (including ongoing listing of medical devices and human tissue products).

The proposed levy arrangements reflect the efforts involved in maintaining the Prostheses List for the whole industry. As the costs associated with this ongoing management cannot be individually assigned to an applicant and the service is provided to a group of individuals or organisations with items on the Prostheses List, this is appropriately charged as a cost recovery levy payable by all sponsors for a listed medical device or human tissue product.

It is proposed that the cost recovery levy be payable for each billing code on the Prostheses List on a given imposition day. These proposed cost recovery arrangements are consistent with the Charging Framework.

Why aren't the fees associated with the proposed deletions and transfer applications captured under the levy?

Cost recovery fees for Deletion applications and Transfer applications are directly linked to a sponsor submitting an application and receiving a specific service from the Department. By contrast, a cost recovery levy is imposed when a good, service or regulation is provided to a group of individuals or organisations (e.g. an industry sector) rather than to a specific individual or organisation. As the specific individual or organisation receiving the service can be identified in the case of Deletion applications and Transfer applications, it is more appropriate to charge a cost recovery fee.

If sponsors have concerns regarding this aspect of the cost recovery proposal, sponsors are invited to provide feedback through the open consultation.

Will there be a cost recovery levy and when will it commence? When will applicants (sponsors) find out about the levy arrangements?

Yes, the proposed cost recovery arrangements include a cost recovery levy.

The cost recovery levy funds the ongoing administration of the Prostheses List. The legislation relating to the amounts of the proposed cost recovery levy will be developed before the planned commencement of the levy in the 2024-25 financial year. Legislation changes to the *Private Health Insurance Prostheses Application and Listing Fees Act 2007* to enact the proposed levy are outlined in the *Private Health Insurance (Prostheses Application and Listing Fees) Amendment (Cost Recovery) Act 2023*. Details are available on the Federal Register of Legislation or the Australian Parliament House website.

It is expected that delegated legislation will be made to specify the details of this cost recovery levy, including the levy amount and the day in each year when applicants must pay the levy. Stakeholders will be provided with an opportunity to comment on the delegated legislation prior to 1 July 2024. This is because the levy will not commence until the 2024-25 financial year to support transition to the proposed cost recovery arrangements. Note that while the levy will commence in the 2024-25 financial year, the date that the levy must be paid in each year may or may not be 1 July.

Why is the device industry being charged for the post-listing reviews and/or other compliance activities?

The *Private Health Insurance (Prostheses Application and Listing Fees) Amendment (Cost Recovery) Act 2023* amends the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*, such that a levy may be imposed for a financial year in respect of the ongoing listing of each listed item. This ongoing listing includes post-listing review and compliance activities in relation to the Prostheses List. These activities ensure products are regularly reviewed to address any post-listing issues and to safeguard the integrity of the Prostheses List.

These compliance and review activities are primarily services delivered in respect of listed items where the sponsors of theses listed items benefit from having their product listed on the Prostheses List.

Services involved in review and compliance activities are likely provided to a significant number of sponsors, and therefore charged as a levy rather than attributed to a single sponsor as a cost recovery fee.

The proposed cost recovery arrangements will mean that the levy is transparent and will reflect the efficient overall costs of the cost recovered activities. Stakeholders will have a clear understanding of the ‘earmarked’ services which the amount of the levy will fund each year, including any factor that leads to potential increases as required.

According to the legislative provisions for the cost recovery levy, before the Governor-General makes regulations prescribing the amount of the levy for a financial year, the Minister must be satisfied that the amount is set at a level that is designed to recover no more than the Commonwealth’s likely costs in connection with the ongoing listing of all listed items for that financial year. This ensures that the levy is aligned with the Charging Framework.

Implications of the proposed cost recovery arrangements

How will the Department ensure the transparency of the cost recovery arrangements?

Review of the cost recovery charges, and amendments to cost recovery arrangements will be undertaken annually as a minimum. These reviews seek to ensure any changes to the minimum efficient costs of managing the Prostheses List are reflected in the charges.

All stakeholders will have the opportunity to comment on significant changes to the cost recovery charges through the Cost Recovery Implementation Statement (CRIS). This is generally published twice a year. The CRIS reports on how the Department’s cost recovery is in compliance with the CRGs. The CRIS provides transparency as to the cost recovered activities undertaken by the Department and reports on the financial outcomes of the cost recovered activities (e.g. reporting on expenditure, revenue and variance). An example of CRIS documentation under the existing cost recovery arrangements is published on the Department’s website.

The Department intends to conduct a full independent review of the cost recovery arrangements between 12 to 24 months following implementation, with outcomes of this review to be reflected in changes to cost recovery arrangements. Stakeholders will be provided with the opportunity to contribute as part of this process.

Additionally, a portfolio charging review is undertaken periodically in relation to all cost recovered activities per the schedule provided by the Department of Finance.

Will the cost recovery fees and cost recovery levy amounts remain the same over time?

Activity-based costing focuses on activity-based cost drivers, which convert indirect costs into direct costs and assign them to a cost object. The use of an activity-based costing method enables an informed analysis of the efficiency of outputs and business processes of the activity that is being charged. Based on this model, the cost recovery fees and cost recovery levy will not remain the same over time.

The activity-based cost model will be reviewed on a regular basis to ensure that the cost recovery fees and levy remain reflective of the minimum efficient costs of the work effort required to administer the regulation of such services. The model will be reviewed by including performance indicators to measure the effectiveness of stakeholder engagement and will be revised based on the feedback received to further improve the management of the Prostheses List charging activities.

There will be periodic reviews of all existing and potential charging activities within their portfolios at least every five years, in accordance with the published schedule of portfolio charging reviews.

The portfolio charging review will look at a broader range of charges including:

- assess the extent of charging activities across the portfolio
- compare and analyse different charging activities
- evaluate the performance of cost recovered activities
- identify charging potential for new and existing activities
- identify opportunities to amend or discontinue cost recovered and other charging activities
- assess the effectiveness of stakeholder engagement strategies and opportunities for improvement.

Will sponsors be consulted before any significant costs in an assessment is incurred?

All applicants will be informed and notified as an application proceeds through the PLAC process. Before cost recovery fees are paid, the relevant invoices will be generated for the application and sent to the applicant before the service is conducted.

Will this cost recovery proposal affect other cost recovered activities undertaken by the Department?

All activities in scope for this cost recovery proposal relate only to the Prostheses List.

Cost recovery principles apply to all relevant Australian Government activities as outlined in the Charging Framework. While the Charging Framework and the CRGs similarly apply to other activities undertaken by the Department (for example, in relation to submissions to the Pharmaceutical Benefits Advisory Committee for the public funding of medicines or assessments by the Therapeutic Goods Administration), these other cost recoverable activities are not in any way related to this cost recovery proposal.

How will the National Joint Replacement Register Levy be handled under new cost recovery arrangements?

The National Joint Replacement Register (NJRR) Levy is out of scope of these new cost recovery arrangements. It will continue to be charged to relevant sponsors as per current arrangements. Information about the NJRR Levy cost recovery arrangements is consulted on and published annually through the Cost Recovery Implementation Statement (CRIS) which is available on the Department of Health website.