Australian Government
Department of Health and Aged Care

Prostheses List Reform Consultation Paper 6(b)

Proposed Cost Recovery Arrangements

Context for the consultation paper

In the 2021-22 Federal Budget, the Australian Government committed $22 million over four years for the *Modernising and Improving the Private Health Insurance Prostheses List* Budget measure. Following extensive consultation over recent years, this consultation paper will canvass views on proposed implementation of improvements to the Prostheses List as announced in the Budget. The Government considers these improvements are necessary to benefit consumers, because a number of reviews of the system have consistently found a high variance in the prices on the Prostheses List compared to prices paid in the public hospital system, with a limited ability for market forces to exert a downward pressure that would benefit consumers.

The Prostheses List is the primary mechanism governing the reimbursement for the medical devices and human tissue products as part of the private health system in Australia.

The Prostheses List specifies a set benefit amount for listed prostheses. The Prostheses List benefit is payable to appropriately covered privately insured patients that receive a prosthesis as part of treatment, where there is a Medicare benefit payable for the medical service associated with the provision of the prosthesis. The treatment can be delivered in a private or public hospital, or in a hospital substitute setting.

The *Private Health Insurance (Prostheses) Rules* (**the Prostheses Rules**) is a legislative instrument made under the Private Health Insurance Act 2007 (**PHI Act**), that sets up requirements in relation to provision of minimum price for prostheses. The Schedule to the Prostheses Rules is known as the Prostheses List.

This consultation paper builds upon the previous consultations and furthers the Government reforms to the Prostheses List, with some improvements to reduce the cost of medical devices used in the private health sector.

Purpose

The purpose of this consultation paper is to provide stakeholders with the opportunity to understand, in greater detail, the proposed cost recovery arrangements related to the renamed Prostheses List which are planned to commence on 1 July 2023. This includes details related to legislative changes required to enact the proposed cost recovery arrangements.

This consultation paper will:

- provide general information on the legislation changes which will enact the proposed cost recovery,
- provide specific details of the cost recovery provisions to be made as subordinate legislation in the Private Health Insurance (Medical Device and Human Tissue Product) Rules,
- provide general information relating to other subordinate legislation which will be made to fully implement the cost recovery levy from 1 July 2024, and
- provide examples and information about the implications of the cost recovery proposal for Sponsors (also referred to as applicants in the legislation) and other relevant stakeholders, so all stakeholders will be able to understand the practical application of legislative changes.

Outcomes and feedback from previous consultation

The Department of Health and Aged Care (the Department) acknowledges stakeholders' time and effort to help shape the first-tranche legislation and the cost recovery proposal. All feedback

received from stakeholders through the webinars and consultation papers has been reviewed and has been considered in the development of this consultation paper. This consultation paper aims to answer key questions from stakeholders in relation to the new cost recovery proposal.

A range of stakeholder communication and educational materials will also be provided to all stakeholders prior to the commencement of the new cost recovery proposal. In addition to this consultation paper, an opportunity to provide stakeholder feedback will be made available through the publication of the Cost Recovery Implementation Statement (CRIS), as consistent with the Australian Government Charging Framework and the whole-of-Government Cost Recovery Guidelines (CRGs). It is anticipated that the CRIS will provide finalised cost recovery fee amounts. This will occur in the second quarter of 2023 and prior to the commencement of proposed new cost recovery provisions on 1 July 2023.

The Department will also continue to consult with stakeholders on the draft legislation for further amendments to the *Private Health Insurance Act 2007* as well as related legislative instruments (rules and regulations) that will incorporate compliance and data sharing provisions.

Further changes to the cost recovery proposal, including the implementation of the cost recovery levy on 1 July 2024 and associated legislation, will be subject to consultation prior to commencement.

For more information related to completed and published consultations and outcomes, please refer to the Prostheses List Reform page on the Department of Health and Aged Care website which provides all relevant information. The Department welcomes feedback from all stakeholders on this consultation paper through the consultation platform Citizen Space.

Overview of first-tranche legislation changes and associated subordinate legislation

In the first tranche of reform legislation, the following Bills were drafted:

- Private Health Insurance (National Joint Replacement Register Levy) Amendment (Consequential Amendments) Bill 2022
- Private Health Insurance (Prostheses Application and Listing Fees) Amendment (Cost Recovery) Bill 2022
- Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill 2022

The first-tranche legislation will allow for the development of the subordinate legislation as detailed in Table 1.

Table 1: Subordinate legislation relating to cost recovery of the Prescribed List of Medical Devices and Human Tissue Products (PL)

Title of subordinate legislation	Authorising Act	Amending Bill	Proposed start date	Purpose in plain English
Private Health Insurance (Medical Device and Human Tissue Product) Rules	*Private Health Insurance Act 2007*	Private Health Insurance (Prostheses Application and Listing Fees) Amendment (Cost Recovery) Bill 2022	1 July 2023	To set out the details for the charging of cost recovery fees

Title of subordinate legislation	Authorising Act	Amending Bill	Proposed start date	Purpose in plain English
Private Health Insurance (Medical Devices and Human Tissue Products Levy) Rules	*Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007 and formerly, the Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*	Private Health Insurance (Prostheses Application and Listing Fees) Amendment (Cost Recovery) Bill 2022	1 July 2024	To set out the details for the charging of cost recovery levies
Private Health Insurance (Medical Devices and Human Tissue Products Levy) Regulations	*Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007* and formerly, the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*	Private Health Insurance (Prostheses Application and Listing Fees) Amendment (Cost Recovery) Bill 2022	1 July 2024	To set out the fee amounts to be charged in the financial year for cost recovery levies
Private Health Insurance (Levy Administration) Rules	*Private Health Insurance Act 2007*	Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill 2022	1 July 2024	To amend overarching levy rules which apply to all Private Health Insurance levies to incorporate the new proposed cost recovery levy
Private Health Insurance (National Joint Replacement Register Levy) Rule	*Private Health Insurance (National Joint Replacement Register Levy) Act 2009*	Private Health Insurance (National Joint Replacement Register Levy) Amendment (Consequential Amendments) Bill 2022	1 July 2023	To reflect the changes in other primary and subordinate legislation for consistency and accuracy

It is standard practice that the details of cost recovery are specified in the subordinate legislation. These details are presented in this consultation paper. Further information about any subsequent tranches of changes to legislation required to enact the Prostheses List Reforms will be the subject of future consultation papers.

Revocation of previous legislative instruments

The previous instrument, Private Health Insurance (Prostheses Application and Listing Fee) Rules 2018, contains provisions for the current application fees. These application fees are legislated as taxes rather than cost recovery fees. These taxes were set as fixed amounts which had not been adjusted since 2009. This is inconsistent with the Australian Government Charging Framework, which mandates that cost recovery levies must reflect the efficient costs of providing the service to industry (see section on the Australian Government Charging Framework below).

With the introduction of cost recovery provisions to align with the Charging Framework in the new Private Health Insurance (Medical Devices and Human Tissue Products) Rules, the previous instrument Private Health Insurance (Prostheses Application and Listing Fee) Rules 2018 will be revoked.

The Private Health Insurance (Medical Devices and Human Tissue Products) Rules will be either remade or varied when amendments to the cost recovery fees are required.

This ensures that outdated provisions will no longer exist, and that legislative instruments will reflect the new cost recovery arrangements to be implemented. It is consistent with normal practice that Rules are regularly remade whenever there should be amendments to cost recovery fees. It is likely that the Rules will be remade at a minimum of once annually. For cost recovery purposes, this will reflect increases and decreases of costs associated with the services the Department provides, as calculated through the Activity Based Cost Model. All such changes will be consulted on (at a minimum) through the CRIS.

Overview of key implications for cost recovery due to first-tranche legislation change

The Australian Government Charging Framework

The Australian Government Charging Framework (the Charging Framework) is a policy of the Australian Government. The Charging Framework covers activities where the government charges the non-government sector for a specific government activity such as regulation, goods, services, or access to resources or infrastructure.

The Charging Framework applies to all non-corporate Commonwealth entities and selected corporate Commonwealth entities, where the Finance Minister has made a 'government policy order' that applies the Charging Framework. Non-corporate and corporate entities are defined under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act).

The Charging Framework applies to all new and existing charging activities and relates to:

- regulatory charging activities
- charging activities involving access to public resources, infrastructure and/or equipment
- commercial charging activities, including the sale of goods and services and acceptance of advertising and sponsorship payments.

Accountable authorities are responsible for the application of requirements and principles of the Australian Government Cost Recovery Guidelines (the CRGs) to regulatory charging activities.

More information is available at the Department of Finance website.

As the Government's administration of the Prostheses List (current terminology), constitutes regulatory activity, it is appropriate that the Charging Framework, and the supporting CRGs, apply to activities and services provided in relation to the Prostheses List.

The CRGs puts in place robust principles which govern the work of government departments in developing cost recovery. This provides safeguarding of the cost recovery process. Three principles that must be applied across all stages of the cost recovery process:

- efficiency and effectiveness
- transparency and accountability
- stakeholder engagement.

Under the CRGs, this guidance primarily means that, for both cost recovery fees and cost recovery levies, there must be a relationship between the charges and costs. This is termed **efficiency** and refers to whether the costs of administering a cost recovery activity appropriate to proposed charges and revenue from the activity. Reflecting **efficient costs** of an activity or service undertaken by the Department means that the revenue generated from the activity or service is approximately equal to the expenses generated by the Department in providing the activity or service. In the case of proposed cost recovery for the Prostheses List, this means that the cost recovery fees that an applicant is liable to pay is directly related to the cost of delivering the services that the applicant requires. For example, applications which do not require advice from external committees will not be required to pay for any part of the committees' costs (which are counted as expenses on the part of the Department).

All cost recovery fees and levies require a **statutory authority** to charge. For a cost recovery levy to be implemented, a **taxation act** is required. The statutory authority for charging is broadly outlined in Table 1. Note that for the purposes of being able to charge a levy, the *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007* will be a **taxation act**.

The Department remains committed to stakeholder engagement on the cost recovery proposal, primarily through the larger Prostheses List Reform program and the regular consultation and publication of the CRIS (this must happen at least twice annually and whenever there are significant changes to the charging activities).

Cost recovery implications of changes to primary legislation

Current state

Prior to the introduction of first-tranche legislative amendments, the *Private Health Insurance Act 2007* provided for three fees (Table 2). These were fixed fees without relation to the level of health technology assessment (HTA) and administrative services required by the individual application. The fee amounts were specified in Private Health Insurance (Prostheses Application and Listing Fee) Rules 2018.

Table 2: Current Fee Amounts

Legislation reference	Fee amount
Section 72-10 paragraph 3(b) provided for an application fee imposed under the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007* to accompany any application	$600
Section 72-10 paragraph 5(b) provided for an initial listing fee imposed under the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007* within 14 days of a Minister's decision to grant an application for listing	$200

Section 72-15 paragraph 2 provided for an ongoing listing fee imposed under the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*.	$200

Although these were described as **fees**, they did not meet the requirements of the definition for cost recovery fees under the Charging Framework. These charges had been introduced prior to the adoption of the Charging Framework and the CRGs. Both the legislation and the fee amounts had not been subsequently amended to then align with the Charging Framework and the CRGs. As a result, the amounts of the charges did not reflect the costs of the regulatory program to the Department. In addition, **these fee amounts have not been updated since 2009.**

Proposed reforms – future state

Under this cost recovery proposal, the first-tranche Prostheses List Reform legislative amendments will allow for the payment of cost recovery fees which meet the requirements of the Charging Framework. Importantly, these amendments introduce the safeguard from the Charging Framework that all cost recovery charges should reflect **efficient costs**.

The *Private Health Insurance Act 2007* will be amended to provide the Commonwealth with powers for the charging of cost recovery fees aligned with the Charging Framework. The amended primary legislation will specify in the new section 72-15 that cost recovery fees cannot amount to taxation. This addresses the constitutional limitation on the imposition of a tax.

Legislative instruments will be made to specify further matters relating to the cost recovery fees. The rest of this consultation paper will outline the proposed matters to be set out as part of the Private Health Insurance (Medical Devices and Human Tissue Products) Rules.

The Private Health Insurance (Prostheses Application and Listing Fees) Act 2007 will be amended to allow for a cost recovery levy to be charged. Like the new cost recovery fees, there will be a safeguard in place in section 4 paragraph 4, such that the Minister must be satisfied that the amount of the levy in each financial year 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.

Legislative instruments, including the Private Health Insurance (Medical Devices and Human Tissue Products Levy) Rules, may be made to specify further matters relating to the cost recovery levy. To ensure a smooth transition to the new cost recovery arrangements, a levy will not be payable in the financial year 2023-24 while the transition to the new cost recovery arrangements occur and reforms are ongoing. However, a cost recovery levy will apply from 2024-25. This means from a legislative perspective, that rules and regulations relating to the cost recovery levy will be in place before 1 July 2024. The amount of the cost recovery levy will also be finalised closer to the commencement and communicated to stakeholders through the CRIS process. **Therefore, while matters relating to the levy will not be covered in this consultation paper, it will be consulted upon at a later date. Stakeholders will be provided with the opportunity to provide feedback.**

More information regarding the legislative changes is available through published Explanatory Memorandum documents at the website of the Australian Parliament at:

- ParlInfo - Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill 2022 (aph.gov.au)
- ParlInfo - Private Health Insurance (Prostheses Application and Listing Fees) Amendment (Cost Recovery) Bill 2022 (aph.gov.au)
- ParlInfo - Private Health Insurance (National Joint Replacement Register Levy) Amendment (Consequential Amendments) Bill 2022 (aph.gov.au)

Appendix A provides further details regarding what cost recovery powers the Minister currently has and compares this to the future state following the enactment of the proposed cost recovery arrangements and legislation.

Overview of cost recovery in relation to the new application pathways

From 1 July 2023, applications for new and amended listings to the Prescribed List of Medical Devices and Human Tissue Products (PL) must be made under three categories of application (Tiers). For the purposes of cost recovery, these Tiers can be described as the following:

- Tier 1: Departmental Assessment Pathway
- Tier 2a: Focused HTA Pathway (Clinical Assessment only)
- Tier 2b: Focused HTA Pathway (Clinical Assessment and Health Economic Evaluation)
- Tier 3: Full HTA (Medical Services Advisory Committee (MSAC)) Pathway.

The Tier of application is initially selected by the applicant (sponsor) when they submit an application in the 'approved form'[1] for the application. It is expected that the relevant requirements of the Tier in which the application is made are met as set out in the **Prescribed List of Medical Devices and Human Tissue Products (PL) Guide**.

It is expected that the 'approved form' of the application will be provided through the online submission portal and the online form which each application will be required to fill out. This submission portal is the Health Products Portal. Each application must be accompanied by relevant documents which provide evidence to support the application, as outlined in the **Prescribed List of Medical Devices and Human Tissue Products (PL) Guide**. The online application system (Health Products Portal) will support the sponsor to provide the relevant documents, as part of the approved form for the application.

For the purposes of cost recovery, these Tiers will be designated using the level of HTA required for each application. The evidence requirements and other relevant information which should be included by Sponsors for the Tier in which the application is made will form part of the **Prescribed List of Medical Devices and Human Tissue Products (PL) Guide**.

Each of the Tiers are characterised by different levels and different kinds of HTA and evaluation required to assess the application, including Departmental assessment, clinical assessment, and economic evaluation.

These different levels and different types of assessment and evaluation are associated with different requirements for advice, including from HTA groups who develop health economic evaluations, and clinical advice from the currently named Prostheses List Advisory Committee (PLAC) and its subcommittees, currently named the Clinical Advisory Groups (CAGs) and Panel of Clinical Experts, and MSAC and its subcommittees. The PLAC will be renamed to the Medical Devices and Human Tissue Advisory Committee (MDHTAC) and its subcommittees will be renamed to the Expert Clinical Advisory Groups (ECAGs).

As the different levels and types of assessment and/or evaluation are associated with different application services required, this results in different levels of:

- administrative effort required on the part of the Department,
- consideration for advice (from expert HTA committees), and
- need to contract external experts (HTA groups).

These considerations are reflected in the cost recovery fees payable.

Applications are to be submitted by a deadline that is specified by the Department (Table 3). The deadlines are set to allow applications to be considered for a particular update or remake of the Rules. These are currently set out to be Midnight (Canberra time) of the first Sunday in each of January, May and September in each calendar year to align with updates to the Rules in July, November and March (respectively) of each year.

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[1] Note that 'approved forms' are detailed in subsection 333-10 of the *Private Health Insurance Act 2007*. Proposed cost recovery arrangements will not give rise to changes in relation to this subsection.

These deadlines are only a guide for sponsors for submission times and the targeted listing date in the case that the application is granted.

Table 3: Application submission deadline and targeted listing date annual cycles

Application submission deadline	Targeted listing date if application granted
January	July
May	November
September	March

Sponsors should refer to the **Prescribed List of Medical Devices and Human Tissue Products (PL) Guide** for further information about the requirements of each Tier and other administrative information relating to applications.

Provisions proposed to be included in the Private Health Insurance (Medical Device and Human Tissue Product) Rules

The following sets out the proposed provisions to be included in the Private Health Insurance (Medical Device and Human Tissue Product) Rules. Each section below will be followed by a short paragraph explaining the purposes of the provisions that are proposed to be included in the new subordinate legislation.

Applications which are within scope of cost recovery fees

1. Applications to list a medical device or human tissue product in the Rules, specifically the Prescribed List of Medical Devices and Human Tissue Products (the Schedule to the Rules), applications to vary a listed medical device or human tissue product in the Rules, and applications to revoke (remove) a listed medical device or human tissue product in the Rules will be within the scope of cost recovery fees.
2. Transfer applications and deletion applications will be characterised as 'List Management Applications'.
    - A transfer application is when only the sponsor details of a listed medical device or human tissue product is changed.
    - A deletion application is when a listed medical device or human tissue product is revoked (removed) and no other change.

All other applications will fall under one of the categories (Tiers) of applications. All applications, including transfer applications and deletion applications, will be subject to cost recovery fees.

Fees payable for each Tier of application

1. Fees are based on the level of assessment that must be undertaken.

The following table provides the fees (according with the kinds of assessments) which is generally associated with applications of each Tier.

Table 4: Indicative fee categories payable for each Tier of application under the cost recovery proposal

Tier	Payable Fee Category	Additional Payable Fee Category	Additional Payable Fee Category
Tier 1	Non-Refundable Application Fee		
Tier 2a	Non-Refundable Application Fee	Clinical Assessment Fee	
Tier 2b	Non-Refundable Application Fee	Clinical Assessment Fee	Economic Evaluation Fee
Tier 3	Non-Refundable Application Fee	Full HTA (MSAC) Pathway Assessment Fee	
List Management Application	List Management Application Fee – Deletion application; or List Management Application Fee – Transfer application		

Description of Fees

1. List Management Application Fee – Removal or revoking of a listing (deletion application)
    - The application is in relation to a medical device or human tissue product; and
    - The application only relates to the removal of that listed medical device or human tissue product.
2. List Management Application Fee – Transfer of a listing (transfer application)
    - The application is in relation to a medical device or human tissue product; and
    - The application only relates to a change from one sponsor to another sponsor for a listed medical device or human tissue product.

The proposed Rules will provide that List Management Applications will be available to sponsors in very limited circumstances which are clearly defined. The List Management Applications are defined as such because unlike other applications, they do not require the same level of HTA and clinical advice as other applications. This means that for the purposes of cost recovery, these applications only require administrative action on the part of the Department.

3. Non-Refundable Application Fee
    - The applicant must pay a fee for an application which requests the Minister to make a decision with regard to a medical device or human tissue product that is not in relation to a decision relating to a transfer application or a deletion application.
    - The applicant must have paid this fee before their application is considered by the Department.

The proposed Rules will provide that for all relevant applications which are not transfer applications and deletion applications, there must be a non-refundable application fee paid. This fee will be payable before the Department commences undertaking work on the application. The non-refundable application fee, for the purposes of cost recovery, reflects the level of health technology assessment (and the associated services provided by the Department) which is required in the consideration of each application.

4. Clinical Assessment Fee

- The clinical assessment fee must be paid if the application needs a clinical assessment. The application requires a clinical assessment (and the clinical assessment fee applies) if:
    - The application is an in-vitro diagnostic (IVD) or an active implantable medical device (AIMD), or Class III medical device under the Therapeutic Goods (Medical Devices) Regulations 2002, or
    - A clinical assessment applies as per the Guide on the Operation of the Prescribed List of Benefits for Medical Devices and Human Tissue Products (the Guide); the main reasons an application will need a clinical assessment include:
        - The application is for a new medical device or human tissue product to be listed; or
        - The application is to vary a listing of a medical device or human tissue product in the PL if the variation would change the listed item's grouping or increase the benefit.

The proposed Rules will provide that for all applications which require a clinical assessment, the clinical assessment fee applies. The proposed Rules will not specify the circumstances whereby the clinical assessment fee is payable, however, these will be set out in the Guide.

5. Economic Evaluation Fee

- The economic evaluation fee must be paid if the application needs an economic assessment.
    - The application requires a Focused HTA Assessment (economic evaluation) (and the Focused HTA Assessment Fee applies) if an economic evaluation applies as per the Guide; the main reasons an application will need an economic evaluation include:
        - The application is for a new kind of medical device or human tissue product of a different grouping with a higher benefit than the comparator;
        - The application is to vary a listed medical device or human tissue product and this would change the listed item's grouping or increase the benefit.

The proposed Rules will provide that for all applications which require an economic evaluation, the economic evaluation fee applies. The proposed Rules will not specify the circumstances whereby the economic evaluation fee is payable, however, these will be set out in the Guide.

6. Full HTA (MSAC) Pathway Assessment Fee

- The application requires an MSAC Assessment (and the fee applies) if:
    - The application is for a medical device or human tissue product and there is no Medicare Benefits Schedule (MBS) item for the professional service associated with the application, or
    - The medical device or human tissue product is first in class technology (meaning that there is no comparator for that medical device or human tissue product).
- This fee is payable when the applicant is invoiced for the fee.
- Exemption from fees for Full HTA (MSAC) Pathway Assessment Fee for when the application has completed a clinical assessment and economic evaluation.
    - The Minister (or the Minister's delegate) may waive, or refund in whole or in part, a fee specified in the Rules in relation to an application if:
        - The application has already undergone a clinical assessment and economic evaluation; and
        - The application needs MSAC evaluation; and
        - the Minister has information relating to the medical device or human tissue product that enables the evaluation of the application to be abridged.
    - The Full HTA (MSAC) Pathway Assessment Fee may be waived in whole or in part.

The proposed Rules will provide that for all applications which are associated with an MSAC assessment, the full HTA (MSAC) pathway assessment fee applies. The Rules will not specify the circumstances whereby the full HTA (MSAC) pathway assessment fee is payable, however, these will be set out in the Guide. The proposed Rules also identifies that in practice, there may be situations where the application may not be recognised from the outset as requiring a full HTA (MSAC) pathway assessment. In the example case where an application might have undergone a clinical assessment and/or and economic evaluation prior to having been identified as requiring a full HTA (MSAC) pathway assessment, then for cost recovery purposes, the full HTA (MSAC) pathway assessment fee may be exempted on the basis that the applicant should not be required to pay for services provided a second time.

Note that these provisions only relate to the services provided for the assessment of the medical device or human tissue product. Any services provided by the Department in relation to the MSAC application are not included in the calculation of these fee amounts. Similarly, the proposed fee exemption would not apply to those services.

Fee waivers

1. Fee waivers

    - No fee is payable if the application made by a sponsor is made in regard to a listing of a human tissue product in the Rules (which would be in Part B of the Schedule to these rules). This can be either for an application for a new listing or for amendments to a listing or removing a listing.

The proposed Rules will provide for a fee waiver (i.e. no cost recovery fee will be payable) in relation to an application relating to a product in Part B of the Schedule to the Rules. This aligns with current arrangements in the *Private Health Insurance (Application and Listing Fees) Act 2007* which sets the application and listing fees for those in Part B of the Schedule to these Rules at zero.

Administrative matters relating to the payment of fees

1. Payment of fees – Timings
    - For the non-refundable application fee: The invoice is generated upon the submission of a completed application.
        - All sponsors (applicants) will pay the non-refundable application fee at the time the application is made.
        - The Department will not commence services on the application until the non-refundable application fee is paid and the application submitted.
    - For all other cost recovery fees: the fee must be paid within 28 days.
2. Payment of fees if the Minister decides not to grant the application
    - No refunds will be made if the Minister (or Delegate) has decided not to grant the application.
3. Unpaid fees in relation to applications
    - Note that sections 72-20, 72-25 and 72-27 of the amended PHI Act will be relevant in the case of unpaid fees or debts to the Commonwealth.

The proposed Rules will provide that the non-refundable application fee must be paid when the application is submitted. For all other fees, the fee must be paid within 28 days of an invoice being issued by the Department. The proposed Rules will provide that if the application is not granted, there will be no refund provided. For cost recovery purposes, this reflects that the applicant had received the services associated with the application. The proposed Rules will include a note referring to powers relating to subsections 72-20, 72-25 and 72-27 in the *Private Health Insurance Act 2007* in the case of unpaid fees.

Administrative matters relating to withdrawal and remaking of applications

1. Withdrawal of applications, excluding List Management Applications
    - Applications may be withdrawn at any point in the application process by written notice to the Department.
    - Withdrawn applications may be resubmitted in same or amended form, however, any relevant fee under this instrument will be payable as though the resubmitted application is a new application.
2. Withdrawal of List Management Applications
    - A List Management application may be withdrawn by written notice given to the Department. The application must be withdrawn before the application is completed (which will happen at the next regular making of the Rules including all new, amended and revoked (removed) items).

- No refunds will be made when a List Management application has been withdrawn.

3. Remaking the application
    - A person who has made an application may remake the application in the same or amended form; this application can be made to the same or a different category (Tier).
    - The Rules should apply to the remade application as if it were a new application.
    - This means, for example, that a remade application will attract a new non-refundable application fee.

The proposed Rules will provide that withdrawals of applications will be possible. There is no time frame for the withdrawal of applications which are not transfer applications or deletion applications. For transfer applications or deletion applications however, these will need to be withdrawn prior to the applications being completed.

While applications can be withdrawn as per the above, a refund of cost-recovery fees will not be provided. For cost recovery purposes, this reflects that the service which the applicant has paid for would commence immediately and would have been completed.

If an application is withdrawn, or if an application has not been granted, the application may be remade. The proposed Rules will specify that this application may be made to the same or a different category (Tier). In practice, this would mean that if an application made in Tier 1 has not been granted, the person who made the application may choose to remake the application in Tier 2. In remaking the application, a new non-refundable application fee will be payable as this application will be treated as a new application for the purposes of cost recovery.

Refund due to administrative error

1. Refund due to administrative error
    - In the circumstance where all the following apply:
        - an administrative error has occurred in the evaluation of the application; and
        - the Department has made the administrative error in the evaluation of the application; and
        - as a result of the administrative error, the value of the services received by the applicant is less than that of the fees paid by the applicant for the application.
    - The Minister (or Delegate) must refund to the applicant an amount equal to the difference between the fees paid by the applicant and the cost for the evaluation of the application.

The proposed Rules will allow the Department to provide refunds in appropriate circumstances where administrative error on the part of the Department means that the value of the services received by the applicant is less than the amount of fees paid by the applicant in relation to that service. An example of such an administrative error may be that an application is submitted with the appropriate non-refundable application fee, however, IT failure means that the Department does not commence work on it before the next making of the Rules.

Indicative fees and high-level description of service

Table 5 shows the fees for each fee category and a broad description of the services that is provided by the Department for the payment of each fee.

Note that the fees at this stage remain indicative and are not final. Stakeholders will be provided with the opportunity to comment on final fees when the CRIS is released for consultation. Changes you may notice in this version of indicative fees will have resulted from changes to the underlying activity-based cost model. Changes to the cost model may have resulted from, for example:

- New estimates of committee costs, which might have been due to changes in remuneration to committee members; or
- Changes in estimated supplier costs.

Costs included in the Activity Based Cost Model

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

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

Indirect costs: cannot be easily linked or where tracking this outweighs the benefits. Indirect costs are allocated as overheads for staff directly involved in performing the activities using the Department of Finance's approved costing methodology. Indirect costs include staff training and development, workers compensation premium, human resources support, organisational services, desktop ICT services and property operating expenses.

Other costs: IT system costs associated with the Prescribed List of Medical Devices and Human Tissue Products listing processes. This includes depreciation associated with necessary IT systems and ongoing support costs.

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;
- Relevant committee 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 is calculated on the total number of submissions in previous financial years;
- Supplier costs were based on relevant contracts; and
- Staff costs/overheads include salaries as recommended by the Department of Finance.

Table 5: Proposed fee category, description of service and indicative fee amounts

Item	Fee category	Description of service	Fee ($)
1	Non-Refundable Application Fee	The following activities are included: • Department assessment of application. • Administrative processing of the request following application submission through HPP. • Departmental preparation of relevant legislation. • Departmental invoicing for application cost recovery.	$1,370

Item	Fee category	Description of service	Fee ($)

2	Clinical Assessment Fee	The following activities are included:
		• Clinical and expert advice sought to assess the clinical aspects of the application.
		• Administrative processing of the request following application submission through HPP.
		• Departmental preparation of relevant legislation.
		• Departmental invoicing for application cost recovery.
		• Application assessment and recommendation by HTA committees:
		  ○ Expert Clinical Advisory Group
		  ○ Medical Devices and Human Tissue Advisory Committee (MDHTAC)
			$5,460

3	Economic Evaluation Fee	The following activities are included: • Development of an economic assessment. • Liaison between sponsor and the Department to inform the development of the economic assessment of an application. • HTA and expert advice (supplier costs). • Administrative processing of the request following application submission through HPP. • Departmental preparation of relevant legislation. • Departmental invoicing for application cost recovery.	$14,400 (standard) $22,540 (complex) $33, 400 (other)

Item	Fee category	Description of service	Fee ($)

4	Full HTA (MSAC) Pathway Assessment Fee*	The following activities are included:
		• 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.
		
		* Note that currently no part of this fee includes the costs of services provided as part of the Medical Services Advisory Committee (MSAC) application process. This indicative fee of $4,670 relates only to the services provided in relation to the administration and assessment of the application relating to the Prosthesis List.
			$4,670

5	List Management Application Fee – Deletion application	The following activities are included: • Assessment of the Deletion Application. • Administrative processing of the request if appropriate. • Notification to the sponsor when the request is completed; or notification to the sponsor if application is not granted. • Departmental preparation of relevant regulation and legislation. • Departmental invoicing for application cost recovery.	$105

Item	Fee category	Description of service	Fee ($)
6	List Management Application Fee – Transfer application	The following activities are included: • Assessment of the Transfer Application. • Administrative processing of the request if appropriate. • Notification to the sponsor when the request is completed; or notification to the sponsor if a different type of application is required. • Departmental preparation of relevant regulation and legislation. • Departmental invoicing for application cost recovery.	$105

Next steps

The Department will consider comments provided as part of this consultation.

The proposed cost recovery arrangements would then need to be considered by the Minister for Health and Aged Care, and if supported, will be included in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (the Rules).

The Rules are a legislative instrument and the making of this instrument and any amendments to this instrument are subject to Parliamentary Scrutiny under the *Legislation Act 2003*.

As outlined above, finalised details of proposed cost recovery arrangements, including fee amounts, will be consulted on through the CRIS prior to implementation.

What we invite you to do

We ask that stakeholders provide feedback on the proposed cost recovery arrangements via the consultation hub. This feedback will then be used to inform any other refinement of the cost recovery proposal.

The Department intends to publish the submissions so stakeholders should clearly identify commercial in confidence information preferably under a separate attachment, noting it may still be accessible under Freedom of Information processes.

Please consider the questions below and provide your responses:

1. Do you have any significant concerns with the proposed provisions regarding the new cost recovery arrangements? Please provide details of examples of situations which might be of concern.
2. Do you have any further comments on the cost recovery proposal?
3. Do you think these proposed arrangements will have a negative impact? Please provide examples.
4. Do you think these proposed arrangements will have a positive impact? Please provide examples.

This paper will close for consultation on 1 May 2023. Stakeholders are encouraged to attend an information webinar on 3 April if they have questions regarding this paper, where the

Department will be available to provide more information on Consultation Papers 6(a) and 6(b). Register here.

Appendix A – What cost recovery powers does the Minister have now (current state) and how is that different to the proposed future state?

This appendix details the current and proposed future state of cost recovery legislative powers relating to the management of the Prosthesis List.

Appendix A Table 1: Current and future state of cost recovery legislative powers in the *Private Health Insurance Act 2007*

Current State (cost recovery)	Proposed Future State (cost recovery)
Under the *Private Health Insurance Act 2007* subsection 72-10 paragraph 1-2, a person may apply to the Minister to have the Private Health (Prostheses) Rules list a prosthesis of the kind to which the application relates.	Under the amended *Private Health Insurance Act 2007*, a person may apply to the Minister to have the Private Health Insurance (Medical Devices and Human Tissue Products) Rules list the kind of medical device or human tissue product to which the application relates. • The key changes here reflect the new definitions to be used in the legislation.
Under the *Private Health Insurance Act 2007* subsection 72-10 paragraph 3, the application must be in the approved form, and accompanied by any application fee imposed under the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*.	Under the amended *Private Health Insurance Act 2007*, the application must be accompanied by any cost-recovery fee that the applicant is liable to pay at the time the application is made. Under subsection 72-15, these fees will be set out in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules. • The key changes here reflect that cost recovery fees will no longer be set out in the *Private Health Insurance (Prostheses Application and Listing Fees) Act* but be set out in Rules. • This also reflects that new charges will be cost recovery fees under the Charging Framework.
Under the *Private Health Insurance Act 2007* subsection 72-10 paragraph 5, there is an initial listing fee to be paid which is imposed under the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*, within 14 days of an applicant being informed of the Minister's decision to grant the application.	Under the amended Private Health Insurance Act 2007, there will be no initial listing fee payable if the Minister decides to grant the application. • This reflects that the new charges will align with the Charging Framework, in that the costs of providing the activity or service (in this case, administering applications) will be reflected in the charges generated. • These will be cost recovery fees as the service is provided to a specific individual or organisation (the applicant).

Current State (cost recovery)	Proposed Future State (cost recovery)
Under the *Private Health Insurance Act 2007* subsection 72-15, there is an ongoing listing fee which is payable for a prosthesis listed in the Private Health Insurance (Prostheses) Rules as a result of an application under subsection 72-10.	Under the amended *Private Health Insurance Act 2007*, there will be no ongoing listing fee payable. • This reflects that the new charges will align with the Charging Framework in that the costs of providing the activity or service (in this case, administering applications) will be reflected in the charges generated. • Services relating to maintaining newly renamed Prescribed List will be cost recovered as levies as the service is provided to a group of individuals or organisations (sponsors with medical devices or human tissue products listed on the Prescribed List). • Per the *Public Governance, Performance and Accountability Act 2013*, this levy will be set out in a separate taxation act. This taxation act where the new levy will be set out will be the amended *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007* which is the newly renamed *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*.
Under the Private Health Insurance Act 2007 subsection 72-20, the Private Health Insurance (Prostheses) Rules may, in relation to application fees, initial listing fees or ongoing listing fees imposed under the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*, provide for, or for matters relating to, any or all of the following: (a) methods for payment; (b) extending the time for payment; (c) refunding or otherwise applying overpayments.	Under the amended *Private Health Insurance Act 2007*, some of these have been moved to the primary legislation. The *Private Health Insurance Act 2007*, will now provide more specificity, including specifying that the cost recovery fee must be paid to the Commonwealth (new subsection 72-35) and must be paid at a time set out in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (new subsection 72-30). The legislation states that any fee that is payable may be recovered as a debt by action in a court of competent jurisdiction by the Commonwealth (new subsection 72-40). The legislation further makes provisions for other matters relating to cost recovery to be set out in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules. • These provisions support the new cost recovery arrangements and are largely standard provisions for imposing and dealing with cost recovery fees.

Current State (cost recovery)	Proposed Future State (cost recovery)
	• These replace the existing provisions dealing with the imposition of fees which are largely contained in the *Private Health Insurance (Prostheses Application and Listing) Fees Act 2007*.
Under the *Private Health Insurance Act 2007*, subsection 72-15 paragraph 3 specifies that if the applicant fails to pay an ongoing listing fee in accordance with requirements, the Minister may remove the kind of prosthesis from the list in the Private Health Insurance (Prostheses) Rules.	Under the amended *Private Health Insurance Act 2007*, the Minister will have specific and limited powers relating to delisting because of unpaid fees or levy (new subsection 72-20) and the Minister may direct that activities not be carried out (new subsection 72-25). These powers will be subject to new subsection 72-27 which will specify that the Minister must have regard to certain matters in deciding to exercise these powers. • The powers in 72-20 and 72-25 are discretionary, which means that the Minister or the Minister's delegate may choose to retain a listing in the case of a cost recovery fee or levy that is not paid, for example, where it is in the best interests of patients and clinicians. • Furthermore, 72-27 specifically notes that there are matters the Minister or the Minister's delegate must have regard to in exercising the powers in 72-20 and 72-25. The Minister must have regard to whether the exercise of the power would be detrimental to the interests of insured persons and whether it would significantly limit medical practitioners' professional freedom, within the scope of accepted clinical practice, to identify and provide appropriate treatments.