Proposed legislation on listing criteria and cost recovery arrangements

Prostheses List Reform

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Questions and feedback

Questions and feedback can be posted at any time during the webinar.

Questions will be answered after our presentation.

Questions not related to the topics discussed today will not be addressed.

Webinar materials

This webinar is being recorded.

A link to the recording and copy of the slides will be sent to attendees after the webinar.

What to expect from this webinar

1. Introduction – legislative instruments and amendments

2. Overview of the proposed listing criteria for Parts A, B and C of the Prescribed List

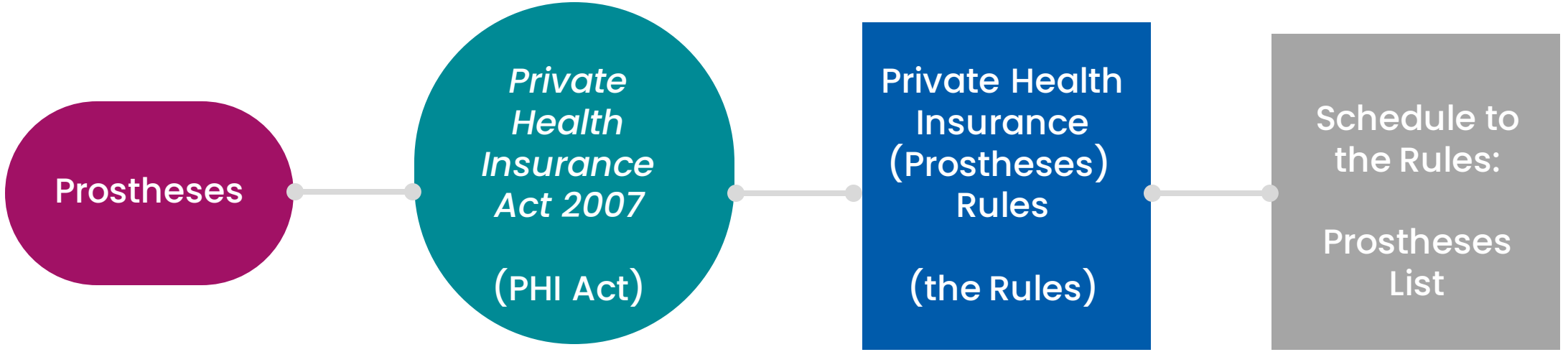
3. Overview of the proposed cost recovery arrangements (including planned cost recovery legislation)

4. Opportunity for stakeholders to ask questions or provide feedback on the proposed legislation.

Australian Government
Department of Health and Aged Care

1. Introduction – legislative instruments and amendments

Current legislative instruments and definitions



This is the Act that regulates private health insurance products.

Legislative instruments made under the PHI Act, that include specific requirements for private health insurance products.

The mechanism for the reimbursement for prostheses as part of the private health system in Australia.

The Prostheses List specifies a set benefit amount for each benefit group.

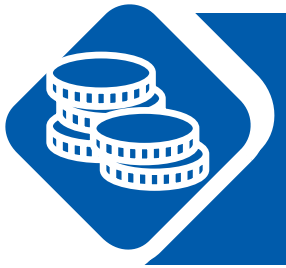
Legislative amendments – Tranche 1

Enacted

Amendments to the *Private Health Insurance Act 2007* and other legislation were enacted on 16 March 2023 and will commence from 1 July 2023. These amendments include:

A change of name from 'Prostheses' to 'Medical Devices and Human Tissue Products'

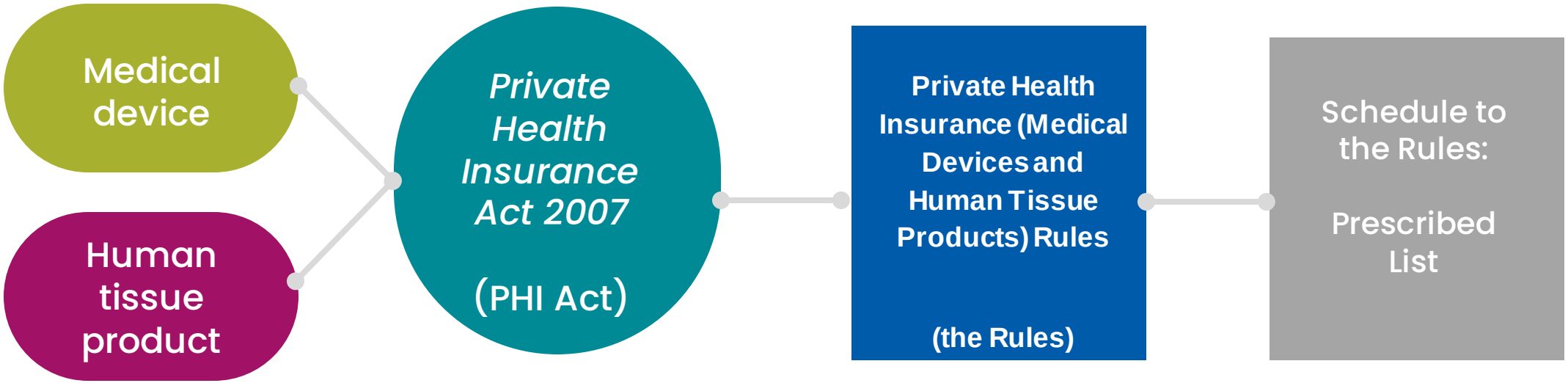
new definitions for 'medical device' and 'human tissue product' that are aligned with those in therapeutic goods legislation



establishing the authority for new fee for service cost recovery arrangements that are consistent with the Australian Government Charging Framework.

Stakeholders were consulted on these changes between September and November 2022, via Consultation Papers 4(a) and 4(b), and three webinars (stakeholder feedback report is available from our website) followed by an exposure draft of each Bill and the explanatory memorandum prior to introduction in December 2022.

Legislative instruments and definitions commencing on 1 July 2023



From 1 July 2023, the PHI Act provides for the Rules (legislative instrument) to specify benefits that must be paid for medical devices and human tissue products. These benefits will be prescribed for each benefit group with medical devices or human tissue products listed in a Schedule to the Rules.

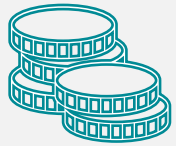
Legislative amendments – Tranche 2

Under consultation (Consultation Paper 6(a) and 6(b))

Amendments to the Private Health Insurance (Medical Devices and Human Tissue Products) Rules to specify:

1. Listing criteria for Parts A, B and C of the Prescribed List

2. Cost recovery arrangements



Australian Government
Department of Health and Aged Care

2. Overview of the proposed listing criteria for Parts A, B and C of the Prescribed List

Why are we making these amendments?

The PHI Act provides for the Rules to set out listing criteria. These criteria must be satisfied for an application to be granted. Our goal in making these amendments is to:

communicate criteria that are aligned to the purpose of the list and are as objective and clear as possible

include the criteria in a legislative instrument rather than guidance material to strengthen its standing and increase scrutiny

preserve the three parts of the current Prostheses List (Parts A, B and C)

align the criteria with the current administrative practices used for listing items

consider issues previously raised about the criteria

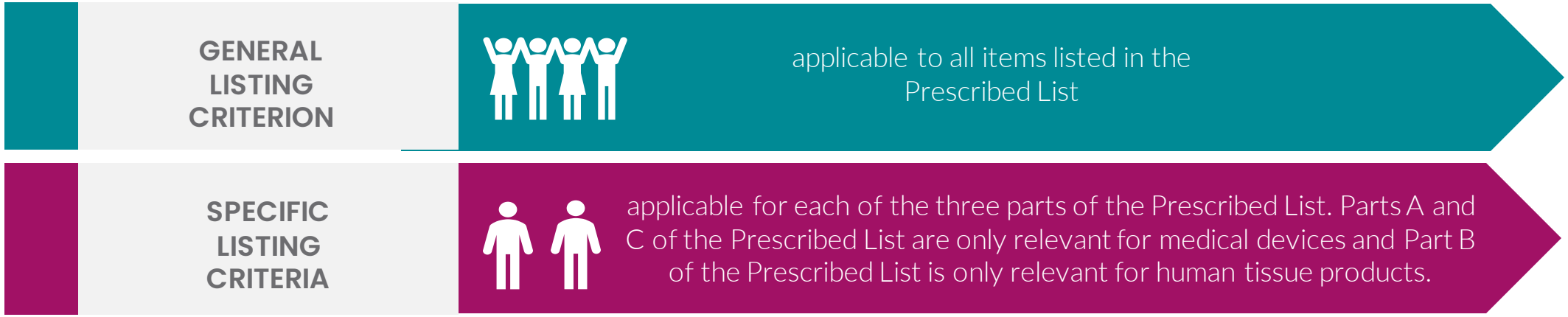
ensure the criteria are consistent with measures in the PHI Act.

Listing criteria

The definitions in the PHI Act and the listing criteria in the Rules operate together to define the kinds of medical devices and human tissue products that are eligible for inclusion in the Schedule to the Rules. Private health insurers will be required to pay benefits for medical devices and human tissue products that are included in the Schedule to the Rules (the Prescribed List):

- for which an insured person has appropriate cover;
- that are provided as part of an episode of hospital treatment or hospital-substitute treatment; and
- for which a Medicare benefit is payable for the professional service associated with the provision of the medical device or human tissue product.

The proposed listing criteria do not and cannot alter this requirement. The listing criteria includes:



General Listing Criterion (Part A, B and C)

#	Criterion	Notes	Current
1	It is a listing criterion for listing in the Rules that a medical device or human tissue product must be included in the Australian Register of Therapeutic Goods (ARTG), within the meaning in section 3 of the *Therapeutic Goods Act 1989* (TG Act).	A medical device or human tissue product needs to be included in the Australian Register of Therapeutic Goods (ARTG) to be listed in the Prescribed List.	✓

Part A – Medical devices

#	Criterion	Notes	Cur-rent
1	It is a listing criterion that the medical device must be:		✓
	a. An implantable medical device designed to: i. replace an anatomical body part; or ii. combat a pathological process; or iii. modulate a physiological process; **OR**	• 'modulating a physiological process': this term can include blocking or facilitating a process Example • A pacemaker to regulate heartbeat or sacral nerve stimulators to improve bladder and bowel function	
	b. essential to and specifically designed as an integral single-use aid for implanting a medical device in (a) above, which is only suitable for use with the patient in whom the medical device is implanted; **OR**	• single-use: once used; the product cannot be used again and may only be discarded. If the product can be reused or has a purpose that is not specific to the implanted product then the criterion is not met. Examples • A preloaded coronary stent that is supplied fixed on a balloon catheter that is needed for positioning and implanting the stent. Without the balloon catheter, the stent is unable to be satisfactorily implanted. The catheter is specific and integral to the particular stent. • A screwdriver is of a general nature and not specific, and does not meet the criterion	
	c. critical to the continuing function of the surgically implantable medical device to achieve (a) (i), (ii) or (iii) above and which is only suitable for use by the patient in whom the medical device is implanted.	• surgically: the term conveys the intention that the product be provided through an interventional process • implanted: this term conveys that the interventional process breaches the interface (or integument) between the body and the outside world (i.e. the skin or other epithelial surfaces, such as the rectal mucosa)	

Associated products

This criterion is also for associated products that are essential and manufactured specifically to enable the delivery of a product that meets the criteria above. Associated products (as opposed to equipment) are only for use once in a patient, have a unique and direct connection to the product and are integral to implanting the product into the patient.

Part A – Medical devices (cont.)

#	Criterion	Notes	Cur-rent
2	It is a listing criterion that the medical device must be a medical device that is not used solely for diagnosis, prediction or prognosis.	The definition of 'medical device' may already exclude devices used for the purposes of diagnosis but the criterion makes that clear. The definition of 'medical device' includes devices used for prognosis or prediction but this listing criterion would exclude the devices from inclusion in the Prescribed List if they are used solely for prediction or prognosis.	✓
3	It is a listing criterion that the medical device must be for a specific treatment and indication.	Devices used for multiple kinds of treatment or in multiple circumstances (general use items) would not be eligible for inclusion in Part A. General items will be funded by an alternative funding arrangement for a transitional period. Examples • Fibrin sealants: ineligible as they can be used in multiple procedures where there is a risk of internal bleeding. • Specific sealants (e.g. vascular sealants): eligible as they are for a specific indication or specific treatment. • Coronary stents: eligible because they are designed for coronary vessels, and treat the condition coronary artery disease which causes vessel narrowing and occlusion.	✓

Part A – Medical devices (cont.)

#	Criterion	Notes	Cur-rent
4	It is a listing criterion that: a. the medical device must have been compared to either of the following: i. alternative devices listed in the Schedule to the Rules; or ii. alternative treatments; **AND**	This criterion is included with the intention that comparative clinical effectiveness and relative cost be considered. • 'alternative treatments': this term allows for entirely new products or technology to be compared with current treatments for the same clinical condition, as not all products to be considered will have an existing counterpart on the Prescribed List. Examples • When Cochlear implants were first introduced, the comparator would have been a conventional hearing aid or no hearing assistance at all • When pins and plates were introduced to treat fractured femurs, the comparator would have been use of an external splint and bed rest for 10 weeks. The alternative treatment is generally expected to be the current standard of care for the condition or indication. A product's cost should be compared to alternative treatments and considered in relation to its clinical benefits.	✓
	b. the comparison specifies: i. the medical device is no less clinically effective than the alternative devices or treatments; and ii. the benefit amount for the medical device is proportionate to the clinical effectiveness of that device.	• 'no less clinically effective': this term is used because products are rarely identical and a range of factors may need to be balanced against each other when comparing clinical effectiveness.	

Part B - Human tissues products

#	Criterion	Notes	Cur-rent
1	It is a listing criterion that a human tissue product must be human tissue. Human tissue includes but is not limited to: a. human tissue that is substantially derived from human tissue that has been subjected to processing or treatments; and b. human tissue for which the supply (however described, including trade, sell, give or gift) is regulated by state or territory law.	Product must be derived from human tissue, and has to be regulated by state or territory law	✓

Part C – Medical devices

#	Criterion	Notes	Cur-rent
1	It is a listing criterion that the medical device must be a medical device that does not meet all the criteria for listing in Part A of the Schedule to the Rules (i.e. ineligible for listing in Part A of the Schedule to the Rules).	A device that is ineligible for listing in Part A.	✓
2	It is a listing criterion that:		
	a. the medical device must have been compared to either of the following: i. alternative devices listed in the Schedule to the Rules; or ii. alternative treatments; **AND**	This criterion is included with the intention that clinical effectiveness and relative cost be considered. • 'alternative treatments': this term allows for entirely new products or technology to be compared with current treatments for the same clinical condition, as not all products to be considered will have an existing counterpart on the Prescribed List. The alternative treatment is generally expected to be the current standard of care for the condition or indication. A product's cost should be considered relative to alternative products or treatments, and relative to its clinical effectiveness compared with those alternative products or treatments.	✓
	b. the comparison specifies: i. the medical device is no less clinically effective than the alternative devices or treatments; and ii. the benefit amount for the medical device is proportionate to the clinical effectiveness of that device.	• 'no less clinically effective': this term is used because it is impossible to state that one product is exactly 'equal' to another product when considering clinical effectiveness.	

Part C – Medical devices (cont.)

#	Criterion	Notes	Cur-rent
3	It is a listing criterion that there must be exceptional circumstances for listing of the medical device. Exceptional circumstances include that the medical device is or does any of the following: a. is less invasive than the alternative device or treatment; or b. delivers better care to patients than the alternative device; or c. improves patient access to beneficial therapies; or d. is a significantly lower cost than the alternative device; or e. improves access or acceptability of treatment for a patient group.	This criterion refers to exceptional circumstances for including medical devices. The matters specified in paragraphs (a) to (e) are not exclusive but merely indicative of the kinds of circumstances where inclusion in Part C may be appropriate. The specified matters in paragraphs (a) to (e) should not be seen as the only circumstances where including a medical device for exceptional circumstances should be exercised.	

Specifications

- These criteria must be satisfied for an application to be granted. The Minister must not grant a listing application if any applicable listing criteria are not satisfied in relation to the application.
- From 1 July 2023, the listing criteria would also apply for a medical device or human tissue product that is already included in the Prescribed List. If the listing criteria are no longer satisfied this would form the basis to remove the kind of device or product from the Prescribed List.
- The PHI Act does not provide for an application to be made to the Administrative Appeals Tribunal for the review of a decision to remove a kind of medical device or human tissue product from the Prostheses Rules. This includes removing a device product from the Prescribed List because of unpaid listing fees.
- From 1 July 2023 a new section provides that the Minister may refuse to carry out or direct a person not to carry out specified activities until unpaid fees or levies are paid. The Minister must have regard to:
    - whether the exercise of these powers would be detrimental to the interests of insured persons (patients); and
    - whether the exercise of these powers would significantly limit the professional freedom of medical practitioners (clinicians) to identify and provide appropriate treatments.

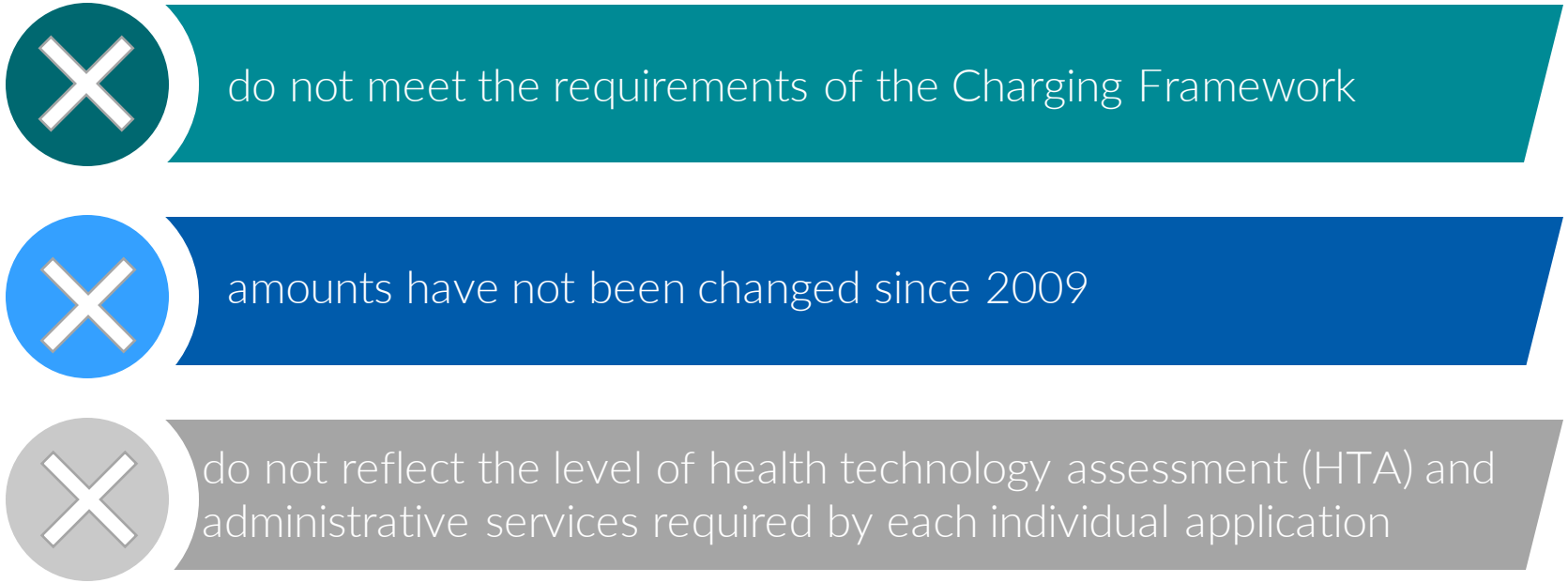
3. Overview of the proposed cost recovery arrangements (including planned cost recovery legislation)

Why are we changing cost recovery arrangements?

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 existing fees:



Legislative amendments for cost recovery

These reflect amendments to the Rules and Regulations, which will be implemented following the Tranche 1 amendments to the PHI Act (explained earlier in this presentation).

As the levy will not be imposed until 2024-25, the Rules and Regulations for the levy will be in place later.

Title of Rules and Regulation (subordinate legislation)	Proposed start date	Purpose in plain English
Private Health Insurance (Medical Device and Human Tissue Product) Rules	1 July 2023	To set out the details for the charging of cost recovery **fees**
Private Health Insurance (Medical Devices and Human Tissue Products Levy) Rules	1 July 2024	To set out the details for the charging of cost recovery **levy**
Private Health Insurance (Medical Devices and Human Tissue Products Levy) Regulations	1 July 2024	To set out the **levy amount** to be charged in the financial year (cost recovery levy only)
Private Health Insurance (Levy Administration) Rules	1 July 2024	To amend overarching levy rules which apply to all Private Health Insurance levies to incorporate the proposed cost recovery levy
Private Health Insurance (National Joint Replacement Register Levy) Rule	1 July 2023	To reflect the changes in other legislation for consistency and accuracy

What will the Rules include?

The proposed Rules will include administrative details of:

- **Names and amounts of fees**
- **Fee waiver**
- **Fee exemption**
- **Timing for payment of fees**
- **Withdrawal and remaking of applications**
- **Refunds in the case of administrative error**

No fees will be payable for applications associated with human tissue products (Part B)

Some fees can be exempted, in the potential scenario where an application has already undergone clinical and economic assessment and is found to require MSAC evaluation, the applicant would not be required to pay again for clinical and economic assessment.

The non-refundable application fee will be payable immediately.
All other fees will be invoiced, with 28 days terms of payment.

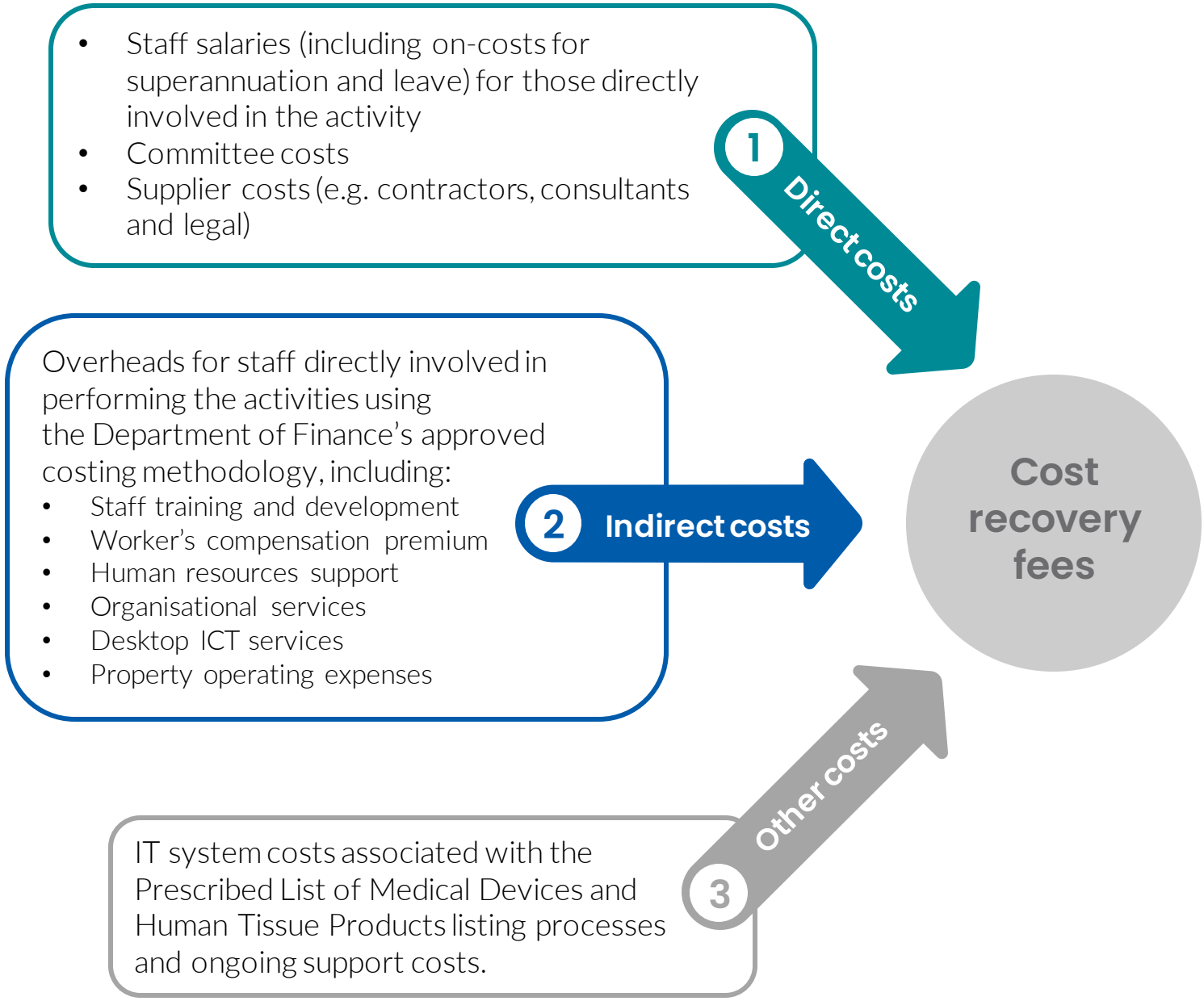
Applications in Tiers 1-3 can be:

- withdrawn at any time; there is no refund of fees.
- resubmitted if a listing is not granted; this can be in the same or different Tier.

If an error by the Department has resulted in the value of services received being less than the fees charged, there must be a refund of fees.

How are cost recovery fees calculated?

Calculation of cost recovery fees is completed via an activity-based costing model.



Indicative Cost Recovery Fees

The Cost Recovery fees are calculated in line with the Australian Government Charging Framework. The fees reflect the efficient costs of the services which are included in each step.

Tier	Payable Fee Category	Additional Payable Fee Category	Additional Payable Fee Category	Total indicative fees payable per application in tier
Tier 1	Non-Refundable Application Fee Indicative amount: $1,370	N/A	N/A	Indicative total amount: $1,370
Tier 2a	Non-Refundable Application Fee Indicative amount: $1,370	Clinical Assessment Fee Indicative amount: $5,460	N/A	Indicative total amount: $6,830
Tier 2b	Non-Refundable Application Fee Indicative amount: $1,370	Clinical Assessment Fee Indicative amount: $5,460	Economic Evaluation Fee Indicative amounts: $14,400 (standard) $22,540 (complex) $33, 400 (other)	Indicative total amount: $21,230 (standard) $29,370 (complex) $40,230 (other)
Tier 3	Non-Refundable Application Fee Indicative amount: $1,370	Full HTA (MSAC) Pathway Assessment Fee Indicative amount: $4,670	N/A	Indicative total amount: $6,040
List Management Application	List Management Application Fee: • Deletion application • Transfer application Indicative amount: $105	N/A	N/A	Indicative total amount: $105

Next steps for cost recovery arrangements

The Department will consult on the Cost Recovery Implementation Statement (CRIS) in May 2023 – the fee amounts for 2023-24 are expected to be final at that time.

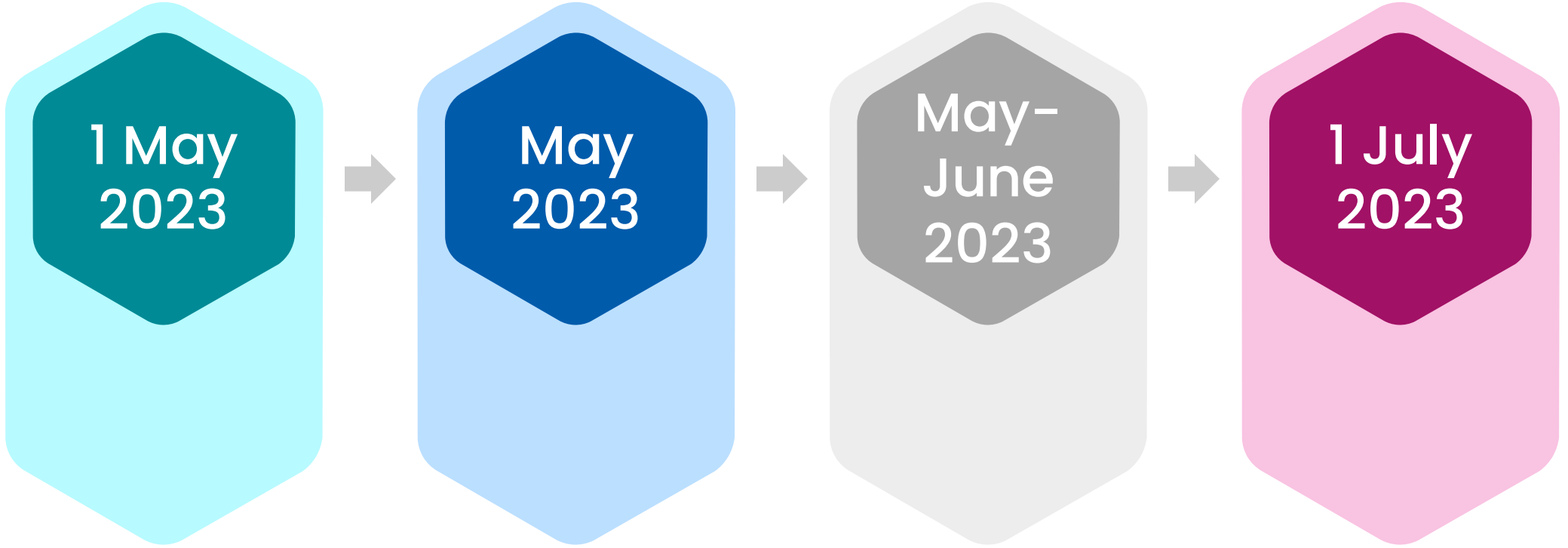
The CRIS will be updated annually at a minimum. This is required as the cost model is updated annually to reflect indexation of fees. The CRIS will also be updated for any major changes to the costing activities.

We will consult stakeholders and provide information on what the Levy will fund and the anticipated amount before the Levy is implemented.

We intend to undertake an independent review of all cost recovery activities around 24 months after implementation.

4. Opportunity for stakeholders to ask questions or provide feedback on the proposed legislation.

Next steps



Consultation on proposed legislation for listing criteria and cost recovery arrangements closes.

Stakeholder feedback will be considered and summarised on Consultation Hub.

Legislative instruments will be drafted and finalised.

For cost recovery arrangements, implementation prior to the invoicing of any fees.

For listing criteria: implementation

For cost recovery arrangements: invoicing of fees expected to commence on or around 1 July 2023.

Getting in touch with us

Prostheses List

Applications
prostheses@health.gov.au

Reforms (including Cost Recovery)
prosthesesreform@health.gov.au

Post-listing reviews
PLReviews@health.gov.au

Compliance
prosthesescompliance@health.gov.au

Health Products Portal (HPP)

hpp.support@health.gov.au

Bundling arrangements for General Use Items (IHACPA)

enquiries.ihacpa@ihacpa.gov.au

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