Regulation Impact Statement (RIS)

Improving the Private Health Insurance Prostheses List

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# Background

The Prostheses List (the PL) is the schedule to the *Private Health Insurance (Prostheses) Rules* that helps ensure privately insured patients have access to safe and clinically effective medical devices. Under Section 72-1 of the *Private Health Insurance Act 2007* (the PHI Act), private health insurers must pay at least the minimum benefit accorded to each prosthesis listed on the PL:

* 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 prosthesis.

Medical device sponsors and suppliers (collectively referred to as ‘sponsors’) apply to list prostheses on the PL so the listed item may be reimbursed by private health insurers.

Prostheses include surgically implanted prostheses, human tissue items and other medical devices. Typical devices funded through the PL are hip and knee replacements, pacemakers and vascular and cardiac stents.

The *Private Health Insurance (Prostheses) Rules* (as made from time-to-time) is a legislative instrument made under the *Private Health Insurance Act 2007*. Schedule 1 of the Rules is known as the Prostheses List or PL.[[1]](#footnote-2) The PL sets out the minimum benefits (or payments) a private health insurer must pay a hospital for listed, generally surgically implanted, medical devices (or prostheses) when provided to someone with appropriate private health insurance (PHI) as part of hospital or hospital-substitute treatment, where there is a Medicare benefit payable for a service associated with the use of the product.

The PL is in three parts:

* Part A—prostheses that satisfy the criteria for listing agreed by the Prostheses List Advisory Committee (PLAC) and approved by the Minister.
* Part B—human tissue (includes products that are substantially derived from human tissue where the tissue has been subject to processing or treatments, and whose supply [however described, including trade, sell, give or gift] is governed by state or territory law). Unless explicitly identified, human tissue products are not addressed in this guide.
* Part C—prostheses that satisfy the criteria for listing on Part C. These criteria specify that a prosthesis will be listed in Part C if it is

i. insulin infusion pump;

ii. implantable cardiac event recorder; cardiac home/remote monitoring system

iii. a cardiac ablation catheter;

iv. a mapping catheter for cardiac ablation; or

v. a patch for cardiac ablation.

The PL is updated three times per year (1st March, 1st July and 1st November). There are approximately 11,000 items listed on the PL, with the majority of these being in Part A. Based on the current grouping scheme, there are 1,700 possible groupings for devices on the PL. The current listing process can take up to seven months if an application is successful. The Department processes approximately 1,500 applications to the PL per year (new and amendment applications.

While the Government administers the PL and its arrangements, it is not a direct funder of PL benefits. In 2015-16, there were approximately 2.5 million prostheses used in the private system, at a cost to insurers of approximately $1.9 billion. By 2019-20, over 3.1 million prostheses were used in the private system, at a cost to private health insurers of approximately $2.1 billion. Despite the average cost per prostheses used reducing over time, from $789.46 in 2015-16 to $673.18 in 2019-20, total expenditure has continued to grow.[[2]](#footnote-3)

## History

The PL was introduced in 1985 to regulate the price of prostheses paid by patients with PHI and reduce public hospital waiting lists for procedures involving surgically implanted prostheses. From 1999-2001, in response to concerns raised by the PHI industry about the rate of increase of benefits, prostheses benefits were deregulated.[[3]](#footnote-4) Under these arrangements, there was still a defined list of products for which insurers had to pay a benefit, but insurers and medical device companies were responsible for negotiating prices. PL benefits almost doubled between 2000‑01 and 2002-03.[[4]](#footnote-5)

In response, new arrangements were announced in April 2003, which came into effect on 31 October 2005.[[5]](#footnote-6) These arrangements ensured independent clinical advice would be part of determining the clinical effectiveness of a device. Further changes have been made to the administrative arrangements since this time.

## Role of Government

The Minister for Health and Aged Care has the authority to decide which products should be included on the PL, the benefit associated with that listing and any other conditions which may apply. The Minister has delegated these responsibilities to a number of people within the Department of Health (the Department).

The Department has responsibility for administering the PL. This includes managing applications from medical device companies (sponsors), setting benefits for prostheses, administering the legislative framework associated with prostheses and supporting the relevant advisory bodies, in particular, the eight Clinical Advisory Groups (CAGs) and the PLAC. The PLAC is a non-statutory committee with responsibility for advising the Minister for Health and Aged Care (or delegate) on the appropriate listing and benefits of prostheses on the PL, taking into account any advice received from CAGs.

The CAGs (and the Panel of Clinical Experts for those areas of the PL where no CAG exists) assess applications, with a particular focus on the criteria for listing and appropriate groupings. The CAGs are expected to advise PLAC on the clinical effectiveness of each product, as compared to other products used for the same or similar purposes.

One of the considerations PLAC and the Minister take into account when considering whether a product should be listed is whether the product is listed on the Australian Register of Therapeutic Goods (ARTG). The ARTG is a database of therapeutic goods within which medicines and medical devices must be entered as ‘registered’ or ‘listed’ goods before they may be supplied in, or exported from, Australia. The ARTG is administered by the Therapeutic Goods Administration (TGA) who has responsibility for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products. This includes consideration of safety aspects of devices.

Further information on the current listing process and the roles and responsibilities can be found on the *Prostheses List: Guide to listing and setting benefits for prostheses*.[[6]](#footnote-7)

Other government agencies, such as the Department of Veterans’ Affairs and Defence may have an interest in the PL arrangements, but do not have a direct role in the administration of medical devices.

## Reviews and Reforms

The PL has been reviewed on a number of occasions, including:

* an independent review of the prostheses arrangements in October 2007, the Review of the Prostheses List Arrangements (Doyle Review);
* Review of Health Technology Assessment in 2009 (HTA Review);
* Industry Working Group on Private Health Insurance Prostheses Reform (PHIIWG) in 2016; and
* The 2017 Senate Inquiry into Price Regulation Associated with the Prostheses List Framework (Senate Inquiry).

Many of these reviews have indicated the need for reform, particularly noting the rising cost of PHI premiums, but there has been little consensus between stakeholders on how reforms should be made.[[7]](#footnote-8)

In 2017, the Australian Government entered into a Strategic Agreement with the Medical Technology Association of Australia (MTAA Agreement). This agreement aims to:

* support a stable and sustainable medical devicesector;
* reduce the time to market for medical devices;
* ensure Australians have access to safe and cost effective medical devices in the private sector; and
* improve the PL arrangements.

In addition to agreement on a series of benefit reductions, a number of Industry Working Groups (IWGs) were established to consider various options for reforming the PL. The Revised Benefit Setting & Review Framework IWG (BSRIWG) was tasked with considering alternative benefit setting and review arrangements. The BSRIWG met eight times between 2018 and mid-2020, discussing many options for reform, their merits and potential downsides. During 2020, the University of Sydney prepared a report[[8]](#footnote-9) based on the discussions of the BSRIWG, outlining possible options for reform. The proposal builds on this earlier reform work and review activities, and the work of the BSRIWG.

In addition to the formal consultation processes associated with the aforementioned reform and review activities, the Department has sought broad stakeholder agreement through a recent consultation process (see Attachment A for the consultation paper).

Further the Department regularly meets with stakeholders to discuss PL issues, including through targeted, one-on-one consultations.

## Stakeholder Perspectives

As outlined in the Senate Inquiry Report, the framework within which benefits for prostheses paid through PHI is complex, opaque and involves multiple stakeholders.

### Consumers

For the most part, consumers have two choices in the prostheses reimbursement space; they choose the level of PHI coverage they purchase and they choose the clinician who will be implanting the device into them. Few consumers actively contribute to the decision-making process around choice of devices accepting their specialist is best placed to determine the device necessary. Consumers, however, bear the burden of high prostheses cost through higher PHI premiums.

### Clinicians

Clinicians are primarily responsible for choosing the appropriate device to use. There is no financial impact on the clinician as a result of the choice of the device used. While choice of device is often considered the key component in PHI’s value proposition, a recent Australian Orthopaedic Association National Joint Replacement Registry (AOA NJRR) report shows that choice of device does not always lead to the best clinical outcome.[[9]](#footnote-10) The choice of device may be influenced by a number of factors including clinical evidence and the training a clinician has had with a particular device.

### Hospitals

Aside from providing the infrastructure and health services for the episode of hospital care and the relevant medical procedure, the hospital’s primary role in the PL arrangements is to purchase the device(s) the clinicians have chosen to use from the medical device company. The hospital may not have control over which device is used. Following supply, the hospital seeks reimbursement from the private health insurer. Hospitals generally purchase devices at an amount equivalent or lower to the PL benefit, making prostheses costs a ‘pass through’ cost for the hospital.

Hospitals procure other medical supplies that are not subsidised through the PL and for these products, normal procurement processes apply, operating within a competitive market (although market distortions can occur because of rebate arrangements that are discussed below).

As part of the private hospital sector, there are 357 private day hospitals across Australia, accounting for 22 per cent of separations in the private hospital sector,[[10]](#footnote-11) some of which are able to specialise in certain procedure types, such as ophthalmology or gastroenterology.

### Medical Device Companies

Medical device companies manufacture and/or distribute the prostheses used in medical procedures and sell these to hospitals. In the context of the PL, medical device companies are often called ‘sponsors’ and apply to the Department to list their products on the PL. Application and listing fees apply. Following assessment, the product is allocated to one of approximately 1,700 groupings, each group being a group of similar (or interchangeable) products that will attract the same PL benefit. For new or novel products where there is no existing comparator on the PL, and hence no applicable group, a more detailed Health Technology Assessment (HTA) will be undertaken to determine clinical and cost-effectiveness and thus the PL benefit. Sponsors may choose not to list the device with that benefit if they believe it is not viable for them to do so.

Although arrangements between the hospital and the device companies are generally commercial-in-confidence, it is recognised that the PL benefit is the nominal purchase price for many devices and there may be in some instances little negotiation on price between hospitals and suppliers. However, there is concern that rebate arrangements exist whereby the PL benefit is returned, in part, to the hospital by the device company when agreed volumes are met or other products are purchased. Other stakeholder groups have accused device companies of gaming the system to maintain profit margins.[[11]](#footnote-12)

### Private Health Insurers

Private health insurers are obliged to pay the minimum benefit amount listed on the PL for a prosthesis provided to one of their policy holders, during an insured episode of hospital or hospital substitute care. The insurer has no control over the process in which a device is selected by the clinician and/or private hospital and will be required to pay for prostheses even where cheaper or more effective alternatives were available.

### Government

As outlined above, the Department is not directly involved in the purchasing, supply or reimbursement of prostheses. The Department administers the PL in accordance with the legislative framework, but has little to no visibility of the commercial arrangements which may be in place between the various stakeholders, and little or no authority to mediate disputes between hospitals and insurers, for example.

The Department of Veterans’ Affairs (DVA) is akin to an insurer in that it funds medical devices through its support for veterans. It is understood DVA hospital contracting arrangements reference the PL benefit amounts.[[12]](#footnote-13)

# RIS Question 1: What is the policy problem you are trying to solve?

Increasing medical costs, increasing utilisation of health services (particularly by older people and people with chronic disease) and declining participation rates (particularly by younger Australians) is challenging the affordability and long-term sustainability of the PHI sector.

The cost of prostheses on the PL has been identified as a factor in the rising price of PHI premiums for consumers, including through the aforementioned reviews. In 2019-20, over 3.1 million prostheses on the PL were supplied at a cost to private health insurers of approximately $2.1 billion.[[13]](#footnote-14) Expenditure on prostheses accounts for 14 per cent of PHI hospital benefits paid annually.

There is evidence that benefits paid through the PL are often inflated when compared to average prices paid for equivalent devices internationally or compared with Australian public hospitals. For example, the price of some drug eluting cardiac stents is up to five times higher on the PL relative to New Zealand ($2,484 versus $525). It is agreed by all stakeholders that prices paid in the public hospital sector in Australia are, on average, lower than private hospital prices and the PL benefits paid by insurers. The Independent Hospital Pricing Authority’s (IHPA) December 2019 report *Prostheses Costs in the private and public sector* (not published) estimates that for 2017‑18 this gap was 130 per cent. Further analysis in 2019-20 indicates the gap was up to 145 per cent for some devices.

A likely cause of the disparity in pricing is that the minimum benefits set through the PL act as a floor price. There is little incentive for price negotiation between hospitals and device companies. Instead, there is incentive to move as many items on to the PL as possible because of the mandated benefits for listed items. This can lead to a number of market distortions including preferential use of PL items over equally effective and lower cost non-PL items or equipment.

Through the 2017 MTAA Agreement, a series of one-off benefit reductions were introduced over four years (2017-2020). The reductions were estimated to save insurers a total of $1.1 billion. While this action reduced the average benefits paid for devices listed on the PL (from $775 in 2017-18 to $670 in 2018-19), over the same period utilisation grew above average (8.6 per cent in 2018 versus forecast 5.7 per cent), eroding any reduction on prostheses costs to insurers.

There is growing concern that the scope of the PL lacks specificity, meaning there are no obvious limits on what is included in the PL. The lack of a legislated definition of a ‘prosthesis’ potentially allows items to be listed which could be better funded by other avenues, or are already funded through other means (‘double funded’). This can be seen primarily in the General Miscellaneous category of the PL. This category includes items such as infusion pumps and haemostatic devices which, while being clinically useful products, may not meet the general understanding of what a ‘prosthesis’ is in terms of the PL.

The ill-defined scope of the PL has also led to an increase in complexity. Since 1997, the number of items on the PL has expanded nearly tenfold. In 2021, there are over 11,600 billing codes and over 1,700 unique groupings.

The activities associated with assessing applications are cost-recovered activities and have remained largely the same since they were introduced in 2007. Currently, there are three fees payable with respect of prostheses applications (with the exception of items listed on Part B):

* a $600 application fee for each new application (excluding amendments, deletions of listings, or duplications, expansions, compressions or transfers of existing billing codes;
* a $200 initial listing fee payable when a product is first listed on the PL (excluding products that were listed as a result of duplicating, expanding, transferring or compressing existing billing codes); and
* an ongoing listing fee of $200 per billing code, paid twice a year (excluding those that were added to the most recent PL as a result of an application to list a new prosthesis).

The current arrangements do not reflect the current Australian Government Charging Framework, nor do they reflect the complexity with some applications, particularly amendment applications.

# RIS Question 2: Why is government action needed?

As outlined above, the Australian Government has intervened in this market since 1985. The period of deregulation in 1999-2001, where PL prices significantly increased, showed that government intervention in this market is needed in some form.

The reforms intend to align the prices that are paid by private health insurers for prostheses (medical devices) used in privately insured hospital treatment to the prices for prostheses in the public hospital system. This will put downward pressure on PHI premiums and, in turn, improve the affordability and attractiveness of PHI for consumers.

The PL has been the subject of multiple reviews, all of which identified the need for reform. The MTAA Agreement introduced a series of benefit reductions (between 2017 and 2020) and established three IWGs to consider various options for reforms.

The reductions were estimated to save insurers a total of $1.1 billion. While this reduced the average benefits paid for devices listed on the PL (from $775 in 2017-18 to $670 in 2018-19), over the same period utilisation grew above average (8.6 per cent in 2018 versus forecast 5.7 per cent), eroding any reduction on prostheses costs for insurers.

Given the complexities in the relationship between the various stakeholders, it has historically proven difficult to reach consensus on specific issues relating to the PL and its administration. A change that benefits one stakeholder may negatively impact one or more of the other stakeholder groups. Government action is needed to help balance the changes across the stakeholder groups.

It should be noted, however, that the success of any government action will depend on factors outside the government’s control, including factors such as changes in patterns in utilisation of devices, the timely provision of appropriate data from states and territories, and cooperation from other stakeholder groups. While this is an identified concern, the Department will put steps in place to minimise the risk associated with these wherever possible. These concerns do not outweigh the need for government action.

After contributing to the reform process for many years, stakeholders expect reforms to be forthcoming. Failure to act would further entrench the existing inefficiencies and inflated prices that are supported through the current PL arrangements.

# RIS Question 3: What policy options are you considering?

Through the IWGs established under the MTAA Agreement, a number of possible benefit setting and review arrangements were considered. Building on these, three options are being put forward.

There are two key principles that the Department is keen to ensure are maintained, regardless of which approach to reform is taken:

1. No out of pocket costs for prostheses for patients; and
2. Maintained choice of devices for clinicians and patients.

## Option 1 – Maintain the Status Quo

This option would maintain the status quo. Medical device companies would continue to submit applications to the Department to have their products listed on the PL in one of 1,700 possible groupings. Regardless of the complexity of the application, it would continue to be subject to internal departmental triaging, assessment by clinicians and CAGs and consideration by PLAC. Following a PLAC recommendation, the Minister (or Minister’s delegate) would continue to decide whether a product is suitable for listing and the Prostheses List Rules are updated to reflect the new listing.

There is currently no certainty around the definition of a prosthesis and the listing criteria are somewhat opaque. As such, in maintaining the status quo, opportunities for scope creep of items on the PL will continue.

PL benefits would continue to be set at rates significantly higher than the public prices, linked to the current benefit amounts which, for the most, were not set using HTA principles, i.e. the PL benefit may not reflect a cost-effective price.

The ‘set and forget’ model of benefit setting would be maintained, and there would be little changes to PL benefits over time. This would place increased pressure on PHI premiums and erode the value proposition of PHI for consumers.

No formal review or compliance functions currently exist and as such there will continue to be limited scope for monitoring the clinical or cost effectiveness of devices and their appropriate use after they are listed.

While this option would maintain the status quo, some changes would still be required. Through a linked proposal (Streamlining Health Products Digital Pathways), the IT system platform would be adapted to be used to administer PL applications. Similarly, given the PL cost recovery arrangements do not align with the current Australian Government Charging Framework, the cost recovery model will need to be updated to ensure fees reflect the services provided to individual organisations. Current application fees, which have not changed since 2007 will likely increase.

## Option 2 – Transfer administration of the PL to the Independent Hospital Pricing Authority, using an activity-based funding approach

This option would provide for the Independent Hospital Pricing Authority (IHPA) to set the prostheses benefit and cease the Department’s current administrative processes associated with the PL benefit setting and listing process. The prostheses benefit would be set by IHPA using an activity-based funding approach. Around 400 Diagnosis Related Groups (DRGs) (more if necessary) would replace the 1,700 PL groups. IHPA and the Department have previously advised stakeholders that additional DRGs could be developed if needed.

The DRGs currently developed, managed and used by IHPA to determine funding amounts for public hospital episodes of treatment, including prostheses costs, would be used to regulate prices for prostheses used in the private sector.

Currently, public hospital funding is based on grouping services into one of about 700 DRGs, with about half involving the use of prostheses.

There would be no need for medical device companies to apply to list a product on the PL, rather it would be automatically eligible for reimbursement when it is listed on the Australian Register of Therapeutic Goods (ARTG), that is, when it can be legally supplied in Australia.

The main functions of the Independent Hospital Pricing Authority (IHPA) are:

* to determine the national efficient price for health care services provided by public hospitals where the services are funded on an activity basis;
* to determine the efficient cost for health care services provided by public hospitals where the services are block funded; and
* to publish this, and other information, for the purpose of informing decision makers in relation to the funding of public hospitals.

As part of its functions, IHPA collects information on prostheses costs in the public sector and can undertake some analysis on the differences prostheses costs in the public and private sectors. As part of this option, IHPA would be well placed to monitor patters of use (utilisation and expenditure) for prostheses costs. The data collected could also be used to inform reviews if there were identified concerns.

The Department acknowledges the feedback received from stakeholders that the existing DRGs do not reflect the complexity of the ophthalmic procedures performed in the private sector. For novel, high cost medical devices not readily accommodated in existing DRGs (or for procedures such as ophthalmic procedures), it would be possible to create a new DRG. It is envisaged the initial benefit for these new DRGs could be set through a HTA undertaken by the Medical Services Advisory Committee. After an agreed period of usage, this item would then be subject to the regular benefit reviews as other DRGs.

Issues around the scope of the PL would be considered when defining what is eligible for inclusion in a DRG. Once set, the ongoing scope creep would no longer be an issue. This option allows for benefits to be set and continually reviewed using IHPA’s well developed administrative processes.

## Option 3 – Retain the Prostheses List with Significant Redesign

This option would retain the PL as a list of regulated prices for prostheses, but with significant redesign to reduce the number of separate device groups and benefits, and align PL benefits with the prices paid for devices in the public hospital sector. Medical device companies would continue to apply to list their product on the PL with the application process enhanced and streamlined supported by more intuitive application forms and guidance material. A review will be undertaken to determine whether most assessments could be undertaken by Departmental staff supported by clinical advice. Cost recovery fees would be applied to align with the current Australian Government Charging Framework.

Like Option 2, this option would see the scope of the PL better defined with a view to funding high value specific purpose medical devices used in medical procedures (e.g. hip prostheses, pacemakers and stents) through this mechanism, complementing other payments made by insurers to hospitals for the balance of an insured patient’s hospital care. As a consequence of clarifying the scope, general use items used in a range of surgeries and in-hospital care (e.g. drug delivery and skin closure devices) would be removed from the PL and funded through existing case-based payments.

The current PL would be streamlined and consolidated using an agreed methodology so that devices with similar intended use and/or health outcome would be grouped together and attract the same benefit. This would support a benefit setting model where the price of the PL items would be benchmarked to public hospital pricing, using advice from IHPA who would have an active role in benefit setting and ongoing benefit reviews.

Formal review and compliance functions would be introduced, supported by legislation. In total, up to five pieces of primary legislation and at least that many pieces of subordinate legislation would need to be updated to give effect to this measure.

# RIS Question 4: What is the likely net benefit of each option?

## Option 1 – Maintain the Status Quo

Maintaining the status quo would maintain the inequitable stakeholder relationships that currently exist in the market. Private health insurers and consumers will continue to be impacted by the current prices of medical devices on the PL. There is unlikely to be any impact on hospitals, medical device companies or clinicians. Apart from revising cost recovery arrangements, there is no benefit to the Department in administering the PL.

Responses to the recent consultation paper released by the Department indicates general agreement from the sector on the need for reform. While there was no consensus on a preferred option for reform, stakeholder are unlikely to support no reform action being taken.

If no changes are made to the current PL and its management, the gap between private and public prices for medical devices will be maintained and likely increase. This in turn, is likely to put further pressure on PHI premiums adding to the issue of affordability of PHI for consumers. However, as this option maintains the status quo, there will be no changes to the regulatory burdens associated with the PL process.

#### Health

There are no anticipated health impacts associated with this option. Consumers and clinicians could still have access to the entire range of prostheses currently listed on the PL. There will be no change to clinical outcomes.

#### Economic

There are no direct economic impacts associated with this option, with the exception of revised cost recovery model fees, to align with the Australian Government Charging Framework. The high PL benefit price will continue to place pressure on insurers, and therefore may have broader economic impacts as the viability of insurers is threatened.

As previously identified, even maintaining the status quo would require updates to the current cost recovery model with medical device companies would see an increase in the fees payable with the listing (and ongoing listing) of devices on the PL. The quantum of such changes would be identified through standard cost recovery processes.

#### Changed Behaviour in Market

There are no anticipated impacts on existing market behaviour as a result of this option on hospitals, insurers, medical device companies, clinicians or consumers.

## Option 2 – Transfer administration of the PL to the Independent Hospital Pricing Authority, using an activity-based funding approach

The DRGs currently developed, managed and used by IHPA to determine funding amounts for public hospital episodes of treatment, including prostheses costs, can be used to regulate prices for prostheses used in the private sector with administrative efficiency. The implementation process for this option would not be onerous as it uses an existing grouping structure and does not require significant IT changes for government. Beyond the legislative timing, timing for this option would need to take into account PHI premium round cycles, PL application cycle timeframes, and would need to allow sufficient time to re-negotiate hospital contracts.

Medical device companies would no longer have to apply and pay an application fee to be listed on the PL. This administrative burden would ceases entirely. Following TGA approval, devices would automatically be eligible for reimbursement when it is listed on the ARTG. Private hospitals, clinicians and consumers would continue to access prostheses as they do now.

This option was canvassed in the public consultation and was opposed by the Consumers Health Forum, clinicians, private hospitals and medical device companies. They are concerned about the unintended consequences of a move to averaged pricing which they believe will limit clinician choice and increase the likelihood of out of pocket costs for patients. The Department notes these concerns, however, while there may be a push for more lower cost devices to be used, the most appropriate device from the patient and clinician’s point of view will still be paramount.

There is a high risk of stakeholder push back with this option, however the costs to implement this option are less than Option 3 outlined below.

This option may require consultation with states and territories regarding any new functions conferred on IHPA. While IHPA currently has the authority to provide advice to Government on prostheses costs in the public and private sector, the Department needs to explore what legislative changes would be required to invest IHPA with sufficient authority to administer prostheses benefit setting arrangements. It is anticipated that up to five pieces of primary legislation and at least that many pieces of subordinate legislation would need to be updated to give effect to this measure.

#### Health

There are no anticipated health impacts associated with this option. Despite concerns expressed by stakeholders, consumers will continue to have access to devices that suit their clinical needs, as chosen by clinicians. The Australian Government is committed to ensuring consumers have access to safe, clinically effective and cost effective prosthetic items, chosen by their clinicians. In this context, it is important to remember that the PL is a reimbursement mechanism, but there is nothing to prevent something that has a lower benefit than the purchase from being used if it is appropriate for the clinical needs of the patient (assuming it can be legally supplied in Australia).

#### Economic

By referencing to average public hospital prices, PHI outlays for medical devices will be reduced, with positive impacts on PHI premiums. Revenues for medical device companies for in‑scope devices will be reduced.

Medical device companies are not universally supportive of this model, however, they would benefit from reduced ‘time to market’ by removing the need to apply to list their product on the PL, potentially allowing them access to the private hospital market earlier than anticipated (immediately following listing on the ARTG).

Unlike Options 1 and 3, it is likely that this option would see a significant reduction to the fees and charges that would be payable by medical device companies, though some levies may still be payable particularly with respect to the National Joint Replacement Registry (NJRR). The reduction in fees is primarily is due to the fact that they would no longer need to apply to be listed on the PL and there would be no application requiring assessment.

Feedback from the recent consultation process (not published) indicated there might be an element of shifting the risk of increased costs from insurers to hospitals, who would still be required to purchase the device required by the clinician, regardless of whether it costs more than the DRG benefit. Conversely, hospitals would benefit if their purchase price was lower than the DRG‑derived benefit. Because of the ‘give and take’ involved in this process, it is not anticipated that there will be an impact on out of pocket costs for consumers.

A submission to the Senate Inquiry[[14]](#footnote-15) discussed the medical device market. This submission noted that in a real market, a supplier may lower its price, reducing its profit margin on existing sales, however, it does so in the hopes of increasing sales volumes to generate profits over a larger number of markets. In the already regulated environment of the PL, there is no incentive for a sponsor to seek a lower benefit than its competitors and the choice of which product is used is generally made by someone (a clinician) who has no financial interest in the transaction. This option would introduce genuine competition in the market, as device companies would be encouraged to provide competitive prices or higher quality products. For this reason, this option is not likely to lead to device companies leaving the market, nor will it act as a deterrent to entering the market in the first place.

#### Changed Behaviour in Market

Currently, not all hospitals regularly negotiate prices for prostheses, rather private hospitals often see devices as a ‘pass through’ cost. That is, the hospital purchases the prostheses at an amount equivalent to the PL benefit. The hospital does not get a choice in the type of device used, as the clinician is responsible for this choice. As the clinician is the customer for both the hospital and the medical device company, practically, there is little incentive in the current practice for hospitals and device companies to negotiate device prices.

Moving to a DRG model should incentivise hospitals to negotiate prices for devices. Many hospitals, particularly the smaller day hospitals, have advised they do not have sufficient bargaining power to negotiate with large device companies, nor do they have sufficient staff or IT systems to support this model. While it may be true that some smaller private hospitals might not have sufficient bargaining power on their own, this does not take into account that some belong to groups of private hospitals (increasing the volume of devices purchased), or the specialisation that can occur in the smaller facilities (allowing for negotiation on a smaller range of products, rather than needing to negotiate across the entire PL). The Department and IHPA had previously identified that support may need to be provided to assist with the data capabilities for smaller hospitals, particularly in the day hospital sector.

## Option 3 – Retain the Prostheses List with Significant Redesign

As with Option 2, this option would achieve the objective of reducing the disparity between public and private prices and would therefore, have a positive impact for private health insurers and consumers. Private health insurers will benefit from lower benefits (prices) for medical devices which they have committed to pass on to savings to consumers.

While this option is also intended to reduce the price disparity between public and private hospitals, it was the preferred option of many stakeholders, excluding private health insurers. The risk of stakeholder push back is less than that for Option 2, however the costs to implement this option are higher.

This option will impact all stakeholders within the sector, specifically:

* Consumers in relation to lower the PHI premiums;
* medical device companies will transition to more streamlined administrative processes and revised fees;
* private health insurers will see a decrease on PHI premiums while still providing a value proposition to consumers;
* private hospitals will need to review future contract arrangements for medical devices; and
* the Department will administer a more efficient and streamlined PL application process.

This option may require consultation with states and territories regarding any new functions conferred on the IHPA. Regulation will be reduced over time by reviewing and reducing the requirement for all listing changes to be considered by the PLAC, and by reducing the number of groups and different prices through simplification of the PL.

#### Health

There are no anticipated health impacts associated with this option. Consumers will continue to have access to devices that suit their clinical needs, as chosen by clinicians. As previously identified, as the PL is a reimbursement mechanism, there is nothing that prevents a prostheses from being used even if the benefit and purchase price do not align.

#### Economic

By referencing to public hospital prices, the PL benefit will reduce over time, reducing the pressure on PHI premiums. Revenues to medical device companies for devices listed on the PL will be reduced.

Medical device companies are more supportive of this model than Option 2. As the goal is similar to Option 2 (reduce the gap between public hospital and private sector pricing) the impact on revenues will be similar. The administration of the list by the Department will be enhanced, with increased scrutiny of devices ahead of listing and regular post market review. Hence the regulatory burden for medical device companies will be increased. The additional Departmental resources will be funded by industry through increased fees and charges. It should be noted that the MTAA Agreement anticipated changes to the cost recovery model. Anecdotally, it has been suggested that device companies would generally accept the higher fees providing they could see efficiencies or improvements in the listing process. Smaller device companies would likely notice the impact of the increased fees more than the larger, multinational companies. This will be considered in the development of the revised cost recovery model.

Private hospitals, particularly day hospitals, have expressed concern about a revised scope for the PL which would see many general use (consumable) items ineligible for PL benefits. Hospitals and insurers will need to cover the shifted cost of these, through revising existing payment contracts and case-based payment arrangements. Discussions about appropriate compensations are underway. It should be noted that these changes would not prevent these items from being used in a procedure, rather it would just change the mechanism by which they are reimbursed.

There would be minor impacts on public hospitals when providing care to privately insured patients, as public hospitals currently benefit from the higher prices on the PL (and hence benefits paid) relative to the actual public hospital purchase price. Feedback from the recent consultation process (not published) indicated there might be an element of shifting the risk of increased costs from insurers to hospitals, who would still be required to purchase the device required by the clinician, regardless of whether it costs more than the reduced PL benefit, though this was raised primarily with respect to Option 2. However, it is anticipated the purchasing arrangements will continue to be a pass through system.

#### Changed Behaviour in Market

Unlike Option 2, this model is largely aligned with the status quo, so there will be little changed behaviour in the market. Hospitals may choose to negotiate prices as they would benefit from doing so if they can retain the margin between the mandated PL benefit and the purchase price.

Like Option 2, this option would incentivise private hospitals to provide additional information to IHPA. IHPA will work with affected hospitals to promote and encourage the provision of data, particularly for day hospitals. This could have a regulatory impost.

As with Options 1 and 2, if a medical device company chooses not to list a product with the reduced benefit amount, they can choose not to engage with the PL. There is a possibility that device companies may inflate public hospital prices to influence the revised benefit amounts. This is not considered to be a significant risk given the competitive tender arrangements that underpin hospital procurement in the public sector.

As formal review and compliance activities will be introduced, there may be an increased regulatory burden associated with this option. While all identified stakeholders may be required to contribute to this process which may have a time and cost impact, it is not anticipated this will significantly change day-to-day arrangements for industry, other than to ensure greater cooperation and compliance.

# RIS Question 5: Who did you consult and how did you incorporate their feedback?

As earlier identified, the PL has been reviewed on several occasions, most of which have had a component of stakeholder consultation. Key stakeholders, including the Australian Medical Association, MTAA, Private Healthcare Australia (PHA), consumer groups/representatives and private hospitals have all been involved in our consultations. Feedback from a broad range of earlier consultation was also considered in drafting the Consultation Paper released on 18 December 2020, which closed for comment on 15 February 2021. The paper sought feedback about better defining the scope of the program, reducing prices and consolidating the PL. It offered Options 2 and 3, outlined above, for reform.

Eighty submissions were received in response. There is broad agreement that reform is needed. However, opinion remains divided about which option would work best. Most support using reference pricing to the public sector to close the gap between average prices paid in the public sector and average PL prices. There is also strong support for a clearer definition of scope for the PL and many agree that some items have been incorrectly listed. There was less feedback about consolidating the PL. Those stakeholders that did comment generally supported a less complex grouping structure. Consumers provided little technical input but want to be assured that any change won’t impact adversely on patient out of pocket expenses. Neither option has this intention or likely outcome.

In developing the options, consideration was given towards all issues raised in the submissions noting that each option proposed provides varying degree of impact and benefit for each of the stakeholder groups.

Additional consideration of stakeholder views is outlined below:

* The proposal to retain but consolidate the PL and introduce a price setting model based on public sector reference pricing was preferred by the MTAA, private hospitals and clinician groups.
* Private hospitals and device companies generally oppose confining the scope of the PL.
* Private health insurers are strongly supportive of moving prostheses funding to a bundled payment model administered by IHPA and based on the AR-DRG classifications. Many insurers already use this system in negotiating hospital contracts for the non-prostheses and non-medical aspects of hospital funding.
* Through PHA, insurers have offered to put safeguards in place to maintain clinician choice if this is the model implemented. As outlined in media articles,[[15]](#footnote-16) PHA has suggested that where a more expensive device than the average model is required, the devices could be subject to increased reimbursement where a clinician makes a declaration form. Such safeguards would not be needed if Option 3 is implemented as there will still be a defined list of products that can be used and reimbursed.
* PHA has also offered to compensate hospitals for the perceived loss of revenue from removing general use items from the PL, which could take place under both Options 2 and 3. As the timing, quantum and mechanism for any compensation associated with the removal of general use items is dependent on implementation of Government’s preferred option, the details of this are still being finalised.
* The medical devices industry argue that PHI buys choice for consumers and many responses to the consultation paper raised concerns that Option 2 would limit clinician choice of devices (in that they would be encouraged or required to use lower cost products equal to or lower than the DRG amount, even when it may not be the most clinically appropriate).

It should be noted, however, that there is no evidence that greater choice of devices leads to improved clinical outcomes. Evidence from the AOA NJRR demonstrates that for hip and knee replacements, patient outcomes are better in public hospitals where choice may be more limited than private hospitals. Public hospitals use ‘proven performers’ over new, unproven prostheses that may be preferred by private sector clinicians. This indicates that in some cases, greater choice can lead to negative health outcomes.

The Department regularly meets with stakeholders about the PL, including PL reforms. While not explicitly captured in the above, these discussions have assisted the Department in explaining and clarifying the two reform options to stakeholders, and to better understand and address the concerns raised. Feedback from these meetings have been incorporated into the design and implementation plans for both reform options.

# RIS Question 6: What is the best option from those you have considered?

Based on the existing inefficiencies and financial impacts associated with maintaining the status quo, Option 1 is not feasible and should not be considered as an option moving forward.

Both Options 2 and 3 aim to close the gap between public and private sector pricing in three to four years, however stakeholder opposition for progressing Option 2 is less likely to receive support of stakeholder and is not feasible in the short term. Based on the analysis of the options outlined above, Option 2 is likely to offer the highest net benefit in the longer term. However, most stakeholders are opposed to the DRG model at this time (with only insurers clearly supporting this model). Stakeholder opposition means that progressing option two (DRG) is not feasible in the short term. Therefore, Option 3 may offer a greater net benefit in the short-term.

While more complex to implement and administer, implementation of Option 3 could commence from February 2022, and achieve the aim of closing the gap between public and private sector pricing in three to four years. Therefore, Option 3 can be considered the best option of those considered, noting that further investigation of Option 2 should continue to occur.

Should Option 3 be implemented, the Department has proposed to continue exploring the DRG option, particularly through a review at year three of this reform process. This review would be intended to explore whether Option 3 has achieved its stated aims particularly with regards to benefit reductions. Based on this review, the Department will revisit whether DRGs would be a more desirable approach for government and stakeholders, and may provide further advice to government at that time.

# RIS Question 7: How will you implement and evaluate your chosen option?

Implementation would commence following Government decision, with concurrent activities would include the following elements:

1. better defining the scope of the PL and removing ineligible products;
2. reducing the gap between PHI prices and public sector prices for the same prostheses, over a maximum of four years, with a review of revised arrangements in year three to update the Government on the progress of the reforms;
3. streamlining listing of new devices by reviewing whether the PLAC and its sub‑committees can be ceased, moving the assessment process to the Department;
4. improving the administration of the PL, by consolidating the existing grouping structure using an agreed methodology so that devices with similar intended use and/or health outcomes would be grouped together and attract the same price (benefit);
5. improve administration of the PL by reviewing the functions and membership of PLAC;
6. improving post‑listing scrutiny including an enhanced program of utilisation reviews and the establishment of a compliance program;
7. updating cost recovery arrangements;
8. amending legislation to give effect to the changes;
9. supporting implementation of the Government decision by developing a high-level principles-based multilateral agreement endorsed by all stakeholders to reflect the commitment of all parties to work together towards long-term sustainability of the PL and PHI.

Implementation will be undertaken by a dedicated internal Taskforce led by the Department, which will coordinate reforms and improvements over a four year period (see Attachment B, Tab 1 for additional detail on the implementation).

An initial preparatory and transition period will commence from May 2021 and will continue until the end of the MTAA Agreement in February 2022. This includes the establishment of a Departmental Taskforce, and necessary preparatory work, including a range of legislative changes. Subject to the passage of legislation, changes to PL prices will be implemented in stages. Concurrently, the Taskforce will develop an improved grouping structure and conduct a review of the functions and membership of PLAC.

The Taskforce will be supported by IHPA and clinical experts. IHPA will manage the data collection, price setting and price review process. The current listing arrangements, managed by the Department of Health would continue alongside the Taskforce reform work.

Reducing the disparity between the costs for devices in public and private hospitals (as assessed by IHPA) and the continued viability of PHI (as assessed by the Australian Prudential Regulation Authority) would be indications the reforms were having a positive influence.

### Consultation

Consultation with internal and external stakeholders will be ongoing throughout the preparatory and implementation phase of the reforms.

This will include:

* a new multi-lateral framework to guide the reform work (MTAA, PHA, Australian Medical Association, and the private hospital sector);
* Steering committee with relevant portfolio agencies (up to 4 per year);
* Stakeholder workshops (up to 2 per year); and
* Consumer forum.

The Department will continue one on one targeted consultation with those stakeholders impacted by these reforms. Further details are provided at Attachment B, Tab 1and Appendix 2.

### Legislation

Both Options 2 and 3 will require significant legislative amendments (additions, amendments, repeals), including to the following:

* *Private Health Insurance Act 2007*
* *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*
* *Private Health Insurance (National Joint Replacement Register Levy) Act 2009*
* *National Health Reform Act 2011*
* *Private Health Insurance (Prostheses) Rules*
* *Private Health Insurance (Prostheses Application and Listing Fees) Rules*
* *Private Health Insurance (National Joint Replacement Register Levy) Rules*
* *Private Health Insurance (Complying Products) Rules*
* Administrative Arrangements Orders
* PHI Delegations

The legislative arrangements will need to give effect to, among other things:

* Legislative authority for IHPA to undertake data collection activities relating to PL benefit setting;
* Definitional issues about which products are eligible for reimbursement;
* Revised cost recovery arrangements in line with the current Australian Government Charging Framework; and
* Appropriate data sharing arrangements to give effect to these processes.

In addition, Option 3 will require a legislative framework to support the review and compliance functions, and a more prescribed listing and de-listing process.

# Status of the RIS at each of the major decision points

This RIS was prepared concurrently with the advice provided to government when direction and authority was being sought on the future of the PL. There have been no major decision points leading up to the development of advice to government, therefore the RIS was not used to inform key decisions prior to government consideration of the options contained herein. However, information used to prepare the RIS (in particular the referenced documents outlined below) has been provided in various forms to the Minister for Health and Aged Care, and his office, throughout the policy development process.

An announcement is possible immediately following government decision, at which point the RIS will be considered final.

# Attachments

Attachment A: December 2020 Consultation Paper

Attachment B: Regulatory Costing Table

# Appendixes

## Appendix 1

### Regulatory Burden Estimate (RBE) Table

The below RBE’s have been calculated on the maximum costs associated with undertaking the required tasks. That is, it assumes the time associated with certain activities is at the higher end of the scale, and that 100 per cent of medical device companies or sponsors would contribute to any process. The actual RBE is therefore likely to be significantly lower than the figures outlined below.

Further, consistent with the Regulatory Burden Measurement Framework, the regulatory costs below do not include any changes to the quanta of fees and charges as a result of changing cost recovery arrangements, nor any indirect costs that may result from changes in market behaviour.

#### Option 1 – Status Quo

No change in annual regulatory costs as a result of maintaining the status quo.

|  |
| --- |
| **Average Annual Regulatory Costs (from business as usual)** |
| **Change in Costs ($ million)** | **Business** | **Community Organisations** | **Individuals** | **Total change in cost** |
| **Total by Sector** | $- | $- | $- | $- |

As this option maintains the status quo, there will be no changed to the regulatory burden associated with this option. The lengthy application process will be maintained. There will be no change in data requirements and no change to review or compliance activities.

A revised cost recovery approach may still need to be introduced even though the status quo would be unchanged. This is due to the fact the current cost recovery arrangements are not consistent with the Australian Government Charging Framework.

#### Option 2 – Transfer administration of the PL to the Independent Hospital Pricing Authority

This option will see a decrease in regulatory burden associated with the removal of the current application process, both a saving in terms of time completing the form and a reduced time to market. These changes will benefit the medical device sector. No review or compliance activities will be introduced. Private hospitals may notice changed requirements for data processing arrangements.

|  |
| --- |
| **Average Annual Regulatory Costs (from business as usual)** |
| **Change in Costs ($ million)** | **Business** | **Community Organisations** | **Individuals** | **Total change in cost** |
| **Total by Sector** | **$0.99** | $ | $ | **$0.99** |

Calculations and assumptions are documented in further detail in the attached excel document.

While it does not factor into the RBE, it should be noted that cost recovery arrangements may not be applicable if this option is implemented. If the Australian Government Charging Framework applies to some or all of the activities associated with Option 2, it is anticipated this will be much less than that proposed in Option 3.

#### Option 3 – Retain the PL but with significant redesign

There are some minor savings associated with the efficiencies in the application and listing process for medical device companies, but these are offset by enhanced health technology assessment for novel devices and other innovation, increased data provision requirements for hospitals and increased compliance and review costs.

|  |
| --- |
| **Average Annual Regulatory Costs (from business as usual)** |
| **Change in Costs ($ million)** | **Business** | **Community Organisations** | **Individuals** | **Total change in cost** |
| **Total by Sector** | **$1.81** | $ | $ | **$1.81** |

Calculations and assumptions are documented in further detail in the attached excel document.

While not included in this section, it should be noted that the activities associated with this option would remain cost recovered. It is anticipated, but not yet quantifiable, that this option would attract a higher rate of cost recovered fees than Options 1 and 2. This increase would be as a result of several factors, including:

* Increased administrative effort for the Department in processing applications and listing devices;
* Updates to the cost recovery model to align with the Australian Government Charging Framework; and
* The introduction of formal review and compliance activities.

No offsets have been found for the regulatory impacts associated with this option. While this option almost doubles the regulatory burden of Option 2, this is the preferred option for the majority of stakeholders, including hospitals who will notice the increased cost associated with increased data reporting.

## Appendix 2

### Stakeholder Map

The below is a high level stakeholder map provided for illustrative purposes only. It does not include all stakeholders nor all engagement types. It is anticipated the level of influence and impact will change throughout implementation.



## Appendix 3

### Referenced Documents

1. October 2007, the Review of the Prostheses List Arrangements (Doyle Review);
2. Review of Health Technology Assessment in 2009 (HTA Review), https://www1.health.gov.au/internet/main/publishing.nsf/Content/AF68234CE9EB8A78CA257BF00018CBEB/$File/hta-review-report.pdf
3. Industry Working Group on Private Health Insurance Prostheses Reform (PHIIWG) in 2016, Industry Working Group on Private Health Insurance Prostheses Reform (PHIIWG) in 2016
4. 2017 Senate Inquiry Report, Price regulation associated with the Prostheses List Framework, <https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/ProsthesesListFramework/Report>
5. 2017 Strategic Agreement with the Medical Technology Association of Australia, https://www.health.gov.au/resources/publications/agreement-between-the-government-and-the-medical-technology-association-of-australia
6. Independent Hospital Pricing Authority’s December 2019 report Prostheses Costs in the private and public sector (Not published)
7. Harris et al. Outcomes of hip and knee replacement surgery in private and public hospitals in Australia. ANZ J Surg 89 (2019) 1417–1423. doi: 10.1111/ans.15154
8. *Prostheses List: Guide to listing and setting benefits for prostheses*, [www.health.gov.au/resources/publications/prostheses-list-guide](http://www.health.gov.au/resources/publications/prostheses-list-guide)
9. December 2020, Report of the Menzies Centre for Health Policy, University of Sydney, on proceedings of the Prostheses List Revised Benefit Setting & Review framework Industry Working Group (BSRIWG) and options for reform, https://www.health.gov.au/resources/publications/options-for-a-revised-framework-for-setting-and-reviewing-benefits-for-the-prostheses-list-report
10. APRA Statistic, *Private health insurance prostheses report*, June 2020 (released 18 August 2020
11. December 2020 Discussion Paper, Options for Reforms and Improvements to the Prostheses List (Attachment A).
12. 30 March 2021, *Medibank says reform of device pricing 'essential'*, Health Dispatch, <https://healthdispatch.com.au/news/medibank-says-reform-of-device-pricing-essential>
13. Commonwealth Ombudsman, Health Insurance Premium Increases Fact Sheet, <https://www.ombudsman.gov.au/publications/brochures-and-fact-sheets/factsheets/all-fact-sheets/phio/health-insurance-premium-increases>
14. *Groups issue joint call for 'practical reform' of Prostheses List*, February 23, 2021, <https://healthdispatch.com.au/news/joint-statemen> t

## Appendix 4

### List of Defined Terms

| **Defined Term** | **Meaning** |
| --- | --- |
| AOA NJRR | Australian Orthopaedic Association National Joint Replacement Registry |
| ARTG | Australian Register of Therapeutic Goods |
| BSRIWG | Revised Benefit Setting & Review Framework Industry Working Group |
| AR-DRG | Australian Refined Diagnosis Related Groups |
| CAG / CAGs | Clinical Advisory Group(s) |
| Department, the | The Department of Health, unless otherwise stated |
| Doyle Review | The Review of the Prostheses List Arrangements |
| DRG | Diagnosis Related Groups |
| DVA | Department of Veterans’ Affairs |
| HTA | Health Technology Assessment |
| HTA Review | Review of Health Technology Assessment in 2009 |
| IHPA | The Independent Hospital Pricing Authority |
| IWG / IWGs | Industry Working Group(s) |
| MTAA | Medical Technology Association of Australia |
| MTAA Agreement | Government’s Strategic Agreement with the MTAA |
| PHI | Private Health Insurance |
| PHIIWG | Industry Working Group on Private Health Insurance Prostheses Reform |
| PL | Prostheses List |
| PLAC | Prostheses List Advisory Committee |
| Senate Inquiry | 2017 Senate Inquiry into Price Regulation Associated with the Prostheses List Framework |

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All information in this publication is correct as at April 2021.

1. Available at [www.health.gov.au/resources/publications/prostheses-list](http://www.health.gov.au/resources/publications/prostheses-list) [↑](#footnote-ref-2)
2. Analysis of APRA Data, refer Attachment B. [↑](#footnote-ref-3)
3. Pg. 9, Senate Inquiry Report, *Price Regulation Associated with the Prostheses List Framework*, 11 May 2017, referencing the Department of Health’s submission to the inquiry. [↑](#footnote-ref-4)
4. Ibid. [↑](#footnote-ref-5)
5. Ibid, pg. 10. [↑](#footnote-ref-6)
6. [www.health.gov.au/resources/publications/prostheses-list-guide](http://www.health.gov.au/resources/publications/prostheses-list-guide) [↑](#footnote-ref-7)
7. Ibid, pg. 17. [↑](#footnote-ref-8)
8. Report of the Revised Benefit Setting & Review Framework Industry Working Group, [www.health.gov.au/resources/publications/revised-benefit-setting-and-review-framework-industry-working-group-meeting-communiques](http://www.health.gov.au/resources/publications/revised-benefit-setting-and-review-framework-industry-working-group-meeting-communiques) [↑](#footnote-ref-9)
9. Harris et al. Outcomes of hip and knee replacement surgery in private and public hospitals in Australia. ANZ J Surg 89 (2019) 1417–1423. doi: 10.1111/ans.15154 [↑](#footnote-ref-10)
10. Day Hospitals Australia, Infographics, https://www.dayhospitalsaustralia.net.au/wp-content/uploads/2019/07/Day-Hospitals-Australia-Infographic-3.pdf [↑](#footnote-ref-11)
11. For example, *Medibank says reform of device pricing 'essential'*, Health Dispatch, 30 March 2021, https://healthdispatch.com.au/news/medibank-says-reform-of-device-pricing-essential [↑](#footnote-ref-12)
12. Commonwealth Ombudsman, Health Insurance Premium Increases Fact Sheet, https://www.ombudsman.gov.au/publications/brochures-and-fact-sheets/factsheets/all-fact-sheets/phio/health-insurance-premium-increases [↑](#footnote-ref-13)
13. APRA Statistics, *Private health insurance prostheses report*, June 2020 (released 18 August 2020) [↑](#footnote-ref-14)
14. Pg. 2, Applied Medical, Submission to the Senate Inquiry into Price Regulation Associated with the Prostheses List, https://www.aph.gov.au/Parliamentary\_Business/Committees/Senate/Community\_Affairs/ProsthesesListFramework/Submissions [↑](#footnote-ref-15)
15. For example, *Groups issue joint call for 'practical reform' of Prostheses List*, February 23, 2021, https://healthdispatch.com.au/news/joint-statement [↑](#footnote-ref-16)