20 December 2017

To: The Prostheses Reform Team, Department of Health
prosthesesreform@health.gov.au

REFORM OF PROSTHESES BENEFITS

This is a joint submission from the Australian Health Services Alliance (AHSA) and hirmaa in response to a request by Department of Health (the department) dated 29 November 2016 for sector input into prostheses model benefits-setting reform.

hirmaa is the national peak body for Australia's not-for-profit, member owned and community based health insurance funds.

The AHSA is a national service company established by small to medium Private Health Insurers.

Together these organisations represent 31 of the 36 Private Health Insurers across Australia.

Both organisations strongly believe that reform to prostheses regulation is an imperative to improving the value of private health insurance and alleviating cost pressures on consumers and the Government and we are pleased to outline our ideas for reform through this submission.

If you require further detail on any of the material contained within this submission, please do not hesitate to contact our offices on 03 9896 9372 (hirmaa) or 03 9813 5190 (AHSA).

Yours sincerely

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Executive summary

One of the key drivers of health inflation in the private healthcare system is the unsustainable cost of prostheses. Costs associated with prostheses are underpinned by poor government regulation and oversight, and the result is that prostheses prices in Australian private hospital setting are amongst the highest in the world, severely damaging the affordability of private health insurance and unnecessarily costing taxpayers hundreds of millions of dollars through the Australian Government Rebate.

In the 2013-14 financial year, $1.74 billion in benefits were paid for prostheses, representing 14.1% of all benefits paid. In 2015-16 this grew to almost $2 billion.

The AHSA and hirmaa acknowledge the need to fully accommodate legitimate growth utilisation for prostheses, however, the current regulatory pricing framework operated by the department through the Prostheses List is not set on a sound or equitable basis.

This pricing framework mandates fixed benefits for prostheses in the Private Hospital system that are not systematically assessed, nor set on value based principles or the principles of supply competition. Further, benefits are not subject to regular reviews that would reflect changes in relative performance of prostheses, advances or changes in health services and treatments, or advancements or lower manufacturing costs in the production of prostheses that typically drive cost reductions.

Pricing norms in the Australian public sector and internationally do not appear to have any correlation to the benefit level set for prostheses in the Australian private hospital setting under the current regulatory system. This is consistent with established evidence which shows that Australian consumers are being charged up to 300% more for some items than would be paid in comparable health jurisdictions overseas (See Appendix D).

Notably, this pricing mechanism is not mandated for Public Hospitals which are able to access identical classes and models of prostheses at lower prices by utilizing the open market and volume purchasing approaches.

The effect of the Prostheses List is such that the difference between projected benefits that will be paid for prostheses for privately insured patients in 2016-17 and what would have been the case if public sector rates had of been utilised is estimated at $882,743,381.

For holders of the 5,512,365 hospital treatment health policies across Australia, this represents an average difference in cost of $160.

On the current projections, this is expected to exceed $1 Billion in 2018-19, representing an average difference in cost of $181.

The AHSA and hirmaa welcome initial reform efforts undertaken by the current Minister for Health, however firmly believe that more needs to be done.

Specifically, we believe that the current system is unsustainable and requires significant reform to increase transparency and accountability to ensure the equitable setting of benefits for prostheses.

We submit that the existing Pharmaceutical Benefits Scheme (PBS) serves as a template for effective reform incorporating mandatory price disclosure, value based pricing and high quality economic analysis to deliver best value for the consumer.

Such a model would be supported by a National Prostheses Purchasing Authority which could leverage the economies of scale to maximize value for money.

We also believe that these systems should be underpinned by a program of reference pricing and coupled with reform to the '25% market share rule' to encourage the entry of new competitors into the marketplace.

With the percentage of Australians holding private health insurance falling for the first time in 15 years due to affordability pressures driven by service provider costs, the AHSA and hirmaa believe that there is no time to waste in implementing meaningful prostheses benefits-setting reform.

Matthew Koce, CEO, hirmaa

Andrew Sando, CEO, AHSA

How the current prostheses benefits-setting system works

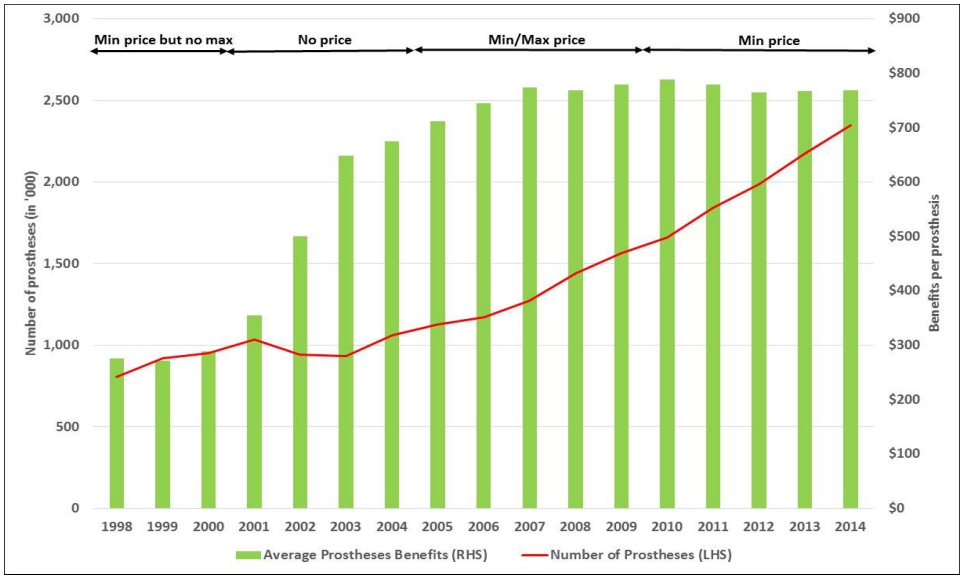
The *Private Health Insurance (Prostheses Rules)* and the *Private Health Insurance Act 2007*, requires private health insurers to pay mandatory benefits for a range of prostheses items where a Medicare benefit is payable for the associated hospital service.

The Minister for Health sets prices for prostheses through the 'Prostheses List' based on the advice from the Prosthesis List Advisory Committee (PLAC) which is comprised of a range of industry representatives and experts and is aligned with the Department of Health.

When a device sponsor seeks to add an additional item to the Prostheses List an application must be lodged and reviewed by the PLAC. As part of the assessment process, the item will be allocated to a group/sub-group (comprised of prostheses of similar type and clinical effectiveness) on the Prostheses List. With the exception of prostheses carrying a 'superior clinical performance' suffix, prostheses grouped together each have the same benefit level.

However, the premise upon which benefit levels are determined for the more than 10,000 products on the Prostheses List is unclear.

From 2001 to 2005, partial deregulation of benefits-setting for prostheses (insurers were allowed to negotiate benefit levels with hospitals and device sponsors with a condition on the benefit being that patients could not have an out-of-pocket expense) resulted in significant average benefit level inflation and individual benefit amounts set for each item on the Prostheses List (which was administratively complex, time consuming and costly). The underlying basis upon which the benefit amounts were negotiated and determined is unknown. It can reasonably be assumed that device sponsors were advantaged by the conditions placed on needing to arrive at a benefit level for each prosthesis which would eliminate out-of-pocket expense exposure for patients and on needing to have benefit levels set for all qualifying prostheses.



Source: Trends on hospital accommodation, medical services and prostheses: Private Health Insurance Administration Council, Chart 1 (PHIAC)

In 2005, the benefits-setting arrangements were re-regulated, which stemmed but did not reverse the inflation. Minimum and maximum benefit levels for each prosthesis were grand parented from the period of partial deregulation. PLAC's predecessor body, the Prostheses and Devices Committee (PDC) set about the task of systematically reviewing all the benefit levels. Prostheses of similar type and clinical effectiveness began to be grouped and benefit negotiations with device sponsors were undertaken to reduce variances in benefit levels within each group. As with the preceding period, the underlying basis upon which the benefit amounts were negotiated and determined is unknown.

Following recommendations from the Doyle report, the grouping process was accelerated and a single benefit level was established for each group/sub-group on the Prostheses List (from 2010). Each group's benefit level was set at a benefit amount which aligned with the benefit amount for a product or average benefit amount for products which, at the time the group benefit was established, commanded a minimum of 25% of volume share for that group of prostheses. This was an expedited process to eliminate the costly, labour and time-intensive process of negotiating benefit levels with device sponsors for each listed prosthesis. However, this process further locked in and muddied the opaque basis upon which benefit levels were determined during the precedent years.

Thus, the benefit levels set for the items on the Prostheses List (especially items grand parented from the period of partial deregulation and items listed since then with benefit levels predicated on the grand parented items) were likely not established on value-based principles nor through exercise of competitive levers (including through the years when benefit levels were determined through a process of negotiation with device sponsors).

Furthermore, since 2010, the benefit levels for the more than 10,000 products on the Prostheses List have not been regularly or systematically reviewed to reflect changes in relative clinical effectiveness, changes in relative cost effectiveness and efficiencies associated with innovations in prostheses design and/ or manufacturing.

For example, if a new device sponsor makes available a cheaper version of a device already on the list, there is no incentive for the sponsor to offer a lower price than the benefit set by the current benefits-setting process.

There is, however, an incentive for device sponsors to engage in activities directly with private hospitals to influence decision making, such as offering volume discounts and rebates, none of which is passed along to the payer (insurers) to relieve premium pressures.

These perverse incentives appear to have been acted upon as outlined by prostheses and medical devices supplier Applied Medical which noted in a submission to the Australian Governments Competition Policy Review released in March 2015 that:

> *Customers have explicitly stated to Applied Medical that unless it also provides such hidden rebates or kickbacks, there is no incentive for the hospital to use its products.*[1]

and:

[1] 'Applied Medical, Submission to Draft Report, 'Competition Policy Review', 2014, pg 11,

the current structure significantly impedes the ability of a supplier reluctant to engage in hidden rebating…[2]

The current prostheses benefits-setting system is inequitable

Following the establishment of the Prostheses List in 2005 a significant distortion in the prostheses pricing market has developed, and widespread price disparities paid by different health entities for the same prosthesis device is well established, particularly with respect to price differences between public and private hospitals.

In early 2016 the Department of Health established an Industry Working Group on Private Health Insurance Prostheses Reform (IWG) to examine opportunities for reform in the arrangements governing prostheses and other medical devices access and benefits. As part of the group's work the Chair of the IWG, Emeritus Professor Lloyd Sansom AO requested submissions relating to these price disparities between public and private hospitals.

In his final report, the Chair noted that "the responses received clearly indicated that a price differential exists between public and private sectors"[3].

Public versus Private hospital data

The findings of the IWG are clearly observable when comparing private cost and volume data sets for prostheses in the public and private hospital settings for the 2013-14 year (the most recent publicly available data).

The analysis at Attachment A compares the top 20 Diagnosis-Related Groups (DRG's) between public and private hospitals in terms of both volume and unit price, overall the analysis finds that private hospitals paid approximately $1.17 billion for devices in the top 20 DRG prostheses category while public hospitals paid approximately $683.2 million.

Critically, Private Hospitals paid more than Public Hospitals over all DRGs with the cost difference exceeding 200% in several instances with a total average cost differential, when weighted for casemix, being approximately 71.6%. Put another way, if private hospital prostheses benefits by DRG were equivalent to public hospital costs by DRG over the same period prostheses benefits would reduce by 41.3%.

The data also clearly shows that Private Hospitals generate greater volume, in terms of prostheses use, than public hospitals, with there being more private sector cases in all but three of the top twenty private sector DRGs by prostheses charge.

Greater volume typically translates into lower prices. If normal economics applied the relative volume would indicate significantly lower prostheses charges in the private sector, especially for those DRGs related to hip and knee replacements where the volume in Private Hospitals is much higher than in Public Hospitals. This is clearly not occurring within

[2] ibid
[3] Sansom AO, Industry Working Group on private Health Insurance Prostheses Reform – Final Report, 2016, pg 8

the current market setting and is a clear and compelling sign of regulatory and market failure.

The estimated cost between prostheses benefits paid to Private Hospitals compared to what they would have been paid in the public system for the 2015-16 year is $824,338,607 (Attachment B.)

Noting that the combined private health insurance industry manages 5,512,365 hospital treatment health policies this would have translated into an average reduction in the cost of an average hospital treatment policy by $149.50.

Also of particular note is the fact that the failure to relieve premium pressure through prostheses reform has cost the Commonwealth Government approximately $672,026,626 through the Australian Government Private Health Insurance Rebate over the last three years.

On the current trend, the cost disparity between prostheses in the private sector versus the public sector is projected to be $882,743,381 in 2016-17, representing a $160 cost burden to the average hospital treatment policy. This is expected to increase to $1 Billion in 2018-19, representing a $181 cost burden to the average hospital treatment policy (Appendix C).

Projected Prostheses benefits			
Year	Current prices	If public price parity*	Difference
2016-17	$2,137,393,174	$1,254,649,793	$882,743,381
2017-18	$2,288,828,473	$1,343,542,314	$945,286,159
2018-19	$2,450,993,034	$1,438,732,911	$1,012,260,123
* based on 2013-14 data, a 41.3% reduction in prostheses benefits is projected if the private sector charges reflected public sector costs			

See Appendix C: Projected Prostheses benefits

Who benefits?

With the existing market for prostheses and medical devices lacking transparent price disclosure, the precise nature of payment arrangements between Private Hospitals and medical device sponsors (being device manufacturers and distributors) is hidden. Despite this, there is strong evidence pointing to the existence of hidden rebates and kickback arrangements.

Private Hospital Groups and device manufacturers are the key beneficiaries of inflated prostheses benefit levels generated by the current. Private Hospital Groups are able to secure volume discounts and rebates from device sponsors below the listed benefit levels. The benefits to device sponsors in the current system are not as well-known and it is essential that the precise nature of payment arrangements between Private Hospitals and device sponsors be discussed and documented.

It should be noted that for the 12 months to June 30, Ramsay Health Care reported a 16.8 per cent lift in net profit to $450.3 million while Healthscope reported an 18.9 per cent lift in net profit to $182.8 million.

Medical device sponsors

The importance of transparency in the prostheses system, and the need for the precise nature of payment arrangements between Private Hospitals and device sponsors to be discussed and documented, is particularly noteworthy given the questionable behaviour of several multinational device manufacturers in the global prostheses market.

In December of 2016 device manufacturer Medtronic was investigated and fined US $17.20 million by China's National Development and Reform Commission for "monopolistic behavior with its distributors and local partners to fix prices and set lower limits on the resale price to hospitals"[4].

In March 2015 device manufacturer Olympus was investigated and agreed to a US $623 million fine to settle charges with the US Department of Justice (DoJ) relating to claims that it bribed doctors and hospitals to buy its medical devices as part of a scheme that generated more than $600 million in sales[5].

In April of 2015, device manufacturer Health Diagnostics Laboratory Inc. was investigated and agreed to pay a US $47 million fine to the DoJ to settle allegations of kickback payments[6].

In July 2015, device manufacturer NuVasive was investigated and agreed to a US $13.5 million fine to settle charges with the DoJ in a decision that the DoJ claimed "further resolves allegations that NuVasive caused false claims by paying kickbacks to induce physicians to use a product offered by the company[7].

In January of 2014 device manufacturer Carefusion was investigated and fined US $11.6 million by the DoJ for paying kickbacks of $11.6 million to a doctor who was then the co-chair of the Safe Practices Committee at the National Quality Forum, in order to secure that doctor's endorsement of a product[8].

The appalling behaviour of these large multinational device manufacturers is particularly concerning given that they operate in the Australian prostheses market and have been found guilty of criminal activity, or settled to avoid further prosecution, in overseas jurisdictions.

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[4] Reuters, article , China says fines Medtronic local unit $17.2 million for price fixing, 7 December 2016.
[5] Media release, DoJ, Medical Equipment Company Will Pay $646 Million for Making Illegal Payments to Doctors and Hospitals in United States and Latin America, 1 March 2016
[6] Medical Device and Diagnostic Industry (website), '5 highest fines in medtech'
[7] Media release, DoJ, Medical Device Manufacturer NuVasive Inc. to Pay $13.5 Million to Settle False Claims Act Allegations, 30 July 2015
[8] ibid

Reforming the prostheses benefits-setting system

The effective and equitable reform of the prostheses benefits setting system is long overdue with both Government and the Department of Health unable to explain or justify the costs set for prostheses under the current regulatory model, or set a dynamic price structure.

Recent actions of the current Minister for Health do, however, show that the Government is listening to concerns from the sector and that the current Government recognises that the current regulatory system is unsustainable and in need of significant reform. Recent reform actions are a step in the right direction and have included:

- The reconstitution of the Prostheses List Advisory Committee and its:
  - Increased focus on pricing;
  - Collaboration with the Medical Services Advisory Committee (MSAC), Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Advisory Committee (PBAC).
  - Increased resourcing by the Government.
- The October 2016 announcement of $86 million a year in savings by reducing the cost artificial knees, hips, intra-ocular lenses and cardiac devices as set by the Prostheses List.

<u>Setting a sustainable model for prostheses benefits</u>

Comprehensive, meaningful and sustainable reform of the prostheses benefits-setting system needs to reflect the foundation principles of the successful Pharmaceutical Benefits Scheme (PBS), specifically:

- Mandatory Price Disclosure (Legislated)
- Value based pricing (Legislated)
- High quality economic analysis

Consideration of a PBS equivalent as a national price-setter of prostheses. The role of this body would include determining national maximum benefits for all devices provided across all hospitals – public and private.

This model has proven highly effective at analyzing supply chains and delivering pharmaceutical products to Australian patients at significant price reductions.

Significantly, the department has investigated this option and presented an overview of the Pharmaceutical Benefits Scheme (PBS) price disclosure arrangements, noting its potential applicability to prostheses, to the IWG[9].

The IWC, in turn, surmised that:

In the longer term, price disclosure would ensure that lower prostheses prices

[9] ibid, pg 6

achieved through competition are reflected in private health insurance benefits, with the potential for premiums to be lower than they would otherwise be. Under price disclosure, sponsors would be required to provide the Department with information relating to their selling price, the cost of sales incentives and volume sold in both the private and public sectors. Price disclosure has been successful in achieving price reductions for the Pharmaceutical Benefits Scheme.[10]

To encourage greater competition, innovation and savings to consumers future benefits should be set as a maximum benefit as opposed to a minimum benefit.

National Prostheses Purchasing Authority

At present, several state jurisdictions operate central procurement agencies/ authorities which exist to maximize price advantages derived from the bulk acquisition of commonly used goods and services.

For example, in Victoria, the Health Purchasing Victoria (HPV) is responsible for managing contracts totaling $776.9 million on behalf of 27 participating health services[11].
HPV's purpose is to improve the collective purchasing power of Victorian public health services and hospitals through achieving 'best value' outcomes in the procurement of health-related goods, services and equipment across 48 contract categories, and in the 2015-16 year was able to leverage $96.2 million in benefits (incorporating cost reduction, cost avoidance and further opportunities)[12].

There is an opportunity to utilise such an entity on a national scale to drive even greater savings in the prostheses and medical devices market by combining the market power of both Public and Private Hospitals.

Such a national entity would incorporate best practice standards derived from existing examples from Australia and internationally, and could be established and supported by a federation model of health jurisdictions or centrally by the Commonwealth Government.

Given the anticipated volume of devices purchased by a national authority, covering public and private sectors, it would be reasonable to assume a significant reduction in prices across both sectors. Additionally, the present administrative burden of both private and public hospitals would be reduced substantively.

The work of a National Prostheses Purchasing Authority sould also adopt a reference pricing mechanism to facilitate international benchmarking.

[10] ibid, pg 3-4
[11] Health Purchasing Victoria – Annual Report 2015-16, pg 13
[12] Ibid, pg 1

Introducing Reference Pricing

Reference pricing is not a part of the current prostheses benefits setting model, however significant evidence exists in the public realm to show that such a requirement would result in a reduction in the cost of prostheses while enhancing transparency through the establishment of international benchmarks.

In 2015 hirmaa compared various items from the prostheses list with prostheses pricing in France. The analysis found significant price variances on a product versus product basis, with several items on the Prostheses List priced over 300% more than in France[13] (see Attachment D).

Reference pricing was a prominent issue investigated by the IWG which agreed "that reference pricing, taking into account domestic and relevant international prices, be considered as a mechanism to set the PL [Prostheses List] benefit"[14].

Additionally, reference pricing would be of value in circumstances where price disclosure mechanisms would be of limited effect (e.g., single device sponsor device markets).

Such a model would necessitate a minimum fixed period for review, which we suggest should be not more than three years.

Modifying the 25% market share rule

The existing market structure for prostheses and medical devices requires a 25% market share, or 'utilization rate' to set the minimum benefit limit for a sub-group as a whole. The AHSA and hirmaa believe that this model provides an unfair advantage to existing entities within the market and serves as a barrier against new entrants and the innovation, that can be achieved through enhanced competition.

In its submission to the Australian Government's Competition Policy Review released in March 2015 prostheses and medical devices supplier Applied Medical noted that:

> *…the 25% utilization rate threshold actually acts to prevent innovation amongst suppliers to supply prostheses at lower costs to Australian patients*[15]

and that

> *This also means that the ability of an innovative, ethical competitor, willing to supply at a much lower benefit level, to influence the group benefit level, is severely restricted. Instead, the current structure, particularly the use of a 25% utilization rate*

[13] Media release, hirmaa, hirmaa calls for private health review to address a broken market for prostheses, 24 November 2015
[14] Sansom AO, op.sit, pg 1
[15] Applied Medical, op.sit, pg 12

drawn from sales within the very same regulatory framework, serves to protect incumbents[16].

The 25% market share rule should be amended to benefit those who are *able* to meet the 25% threshold as opposed to those already there. Such a change would ensure that large manufacturers with the infrastructure at hand to generate the requisite supply are able to better compete in the space and facilitate the addition of further innovation and cost competition in the sector.

General

Prohibiting rebates and kickbacks

As noted in the previous section of this submission, the combination of a PBS equivalent for the prostheses market and a National Prostheses Purchasing Authority would drive significant savings across the health system in both public and private settings.

It is, however, acknowledged opportunities can often be created to manipulate the purpose and intent of the Prostheses List. The use of rebates and like activities to facilitate financial benefits between a device sponsor and hospitals should be prohibited under law.

Inventory

The establishment of a reimbursement mechanism for the maintenance of inventory is an issue that has been raised by Private Hospitals in various forums.

Such a mechanism would be negligible in terms of its financial impacts to Private Hospitals owing to several factors including:

- The fact that volume tends to be higher in Private Hospitals and work is more likely to be elective, thus minimizing inventory levels; and
- Private Hospitals are more likely to be located in major population centers from which they can arrange direct access to prostheses with little notice.

As such, a rationale does not exist for such a fee mechanism when similar arrangements are not in effect in the public system.

Further, the provision of prostheses devices is a core business function of a Private Hospital offering this service, and the provision of a new fee mechanism is likely to be clouded and difficult to negotiate and administer.

[16] ibid

Handling fees

In the early 2000's hospitals were paid a handling fee with respect to prostheses of approximately 10% the prostheses value. This handling fee was abolished in favour of rates at comparable increments.

Similar to 'inventory fee's' discussed above we believe that the provision of prostheses devices is a core business function of a Private Hospital offering this service, and that the maintenance of a built-in fee for the handling of items directly associated with core business function is entirely without merit or justification.

The AHSA and hirmaa are not aware of any equivalent public sector equivalent for the subsidization of general business overheads and believe that any financial arrangements beyond the immediate costs of purchasing and installing a medical device adds unnecessary complication to financial arrangements and is unjustifiable from a health economy perspective.

Summary points

- The current prostheses market was established in response to failed deregulation efforts in 2001 which saw the price of prostheses grow exponentially.
- The establishment of the Prostheses List has locked in categories of pricing for Private Hospitals that are significantly more than most Public Hospitals with several DRG's showing cost differences of over 200%.
- In 2016-17 the total cost differentiation between prostheses devices in Public and Private Hospital settings is estimated to be over $882 million, translating into an average cost burden of $160 for every hospital treatment private health policy.
- If this cost differentiation between prostheses devices in public and private hospital settings didn't exist the Commonwealth Government would have paid approximately $680,000,000 less to the Australian Government Private Health Insurance Rebate over the last three years.
- There appears to be no justification for cost differientation between prostheses devices in public and private hospital settings offered by Government or the Department Health.
- The current system requires comprehensive reform, and the Pharmaceutical Benefits Scheme (PBS) can serve as an effective template, particularly the foundation principles of:
    - Mandatory Price Disclosure
    - Value based pricing
    - High quality economic analysis.
- A National Prostheses Purchasing Authority could complement the work of the reformed prostheses pricing market in ensuring equitable prostheses costs for both Public and Private hospitals by leveraging economies of scale.
- The '25% rule' should be modified to allow the entry of prostheses manufacturers able to meet the demands of 25% of the market in order to drive competition and innovation.

- Financial or in-kind transactions such as rebates or kickbacks between sponsors and hospitals relating to the acquisition of prostheses products should be probibited under law.

Conclusion

Existing government regulations on prostheses are significant drivers of health inflation within the private hospital setting, impacting affordability of private health insurance premiums for consumers and putting the sustainability of the private health insurance system at risk if reform in not undertaken as a priority.

The AHSA and hirmaa are not aware of any justification from the Department of Health for mandating benefit levels for prostheses in Private Hospitals that are significantly higher than what is paid for the same or similar items within the Public System, or in comparable overseas countries.

The regulatory settings for the current benefit arrangements for items on the Prostheses List is based on the market context of 2005, when it was first established, and little has been done since then to review the appropriateness of benefit levels .

As a result, the difference between projected benefit levels for prostheses devices utilised in Private Hospitals in 2016-17, and what would have been the case if public sector rates had been utilised, is estimated at $882,743,381.

For holders of the 5,512,365 hospital treatment health policies across Australia, this represents an average cost of $160.

On the current projections, this is expected to grow to exceed $1 Billion in 2018-19, representing a $181 cost burden to the average hospital treatment policy.

With utilization growing, the current prices set for prostheses is financially unsustainable. However, existing health models with proven benefits that are based on efficient regulation, such as the PBS, reference pricing, and group purchasing arrangements are readily applicable to this sector and should be urgently explored and adopted as a means of ensuring greater equity, transparency, accountability, and financial sustainability.