Price regulation associated with the Prostheses List Framework

MTAA Supplementary Submission – March 2017

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

MTAA Supplementary Submission Title on price regulation associated with the Prostheses List Framework – 30 March 2017

Level 12, 54 Miller St, North Sydney
NSW 2060 Australia
PO Box 2016 North Sydney
NSW 2059 Australia
P (02) 9900 0600
E mtaa@mtaa.org.au

www.mtaa.org.au

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Executive Summary

The Medical Technology Association of Australia (MTAA) wishes to submit additional information to the Senate Committee to assist in its deliberations and clarify the testimony given by MTAA and other stakeholders during the course of the public hearings.

There is significant complexity surrounding the issues associated with reforms of the Prostheses List (PL) and it is imperative that careful consideration of reforms proposals occurs to avoid the policy failures of the past which have required Government intervention to rectify. These failures included patients having no certainty about whether their insurer would cover the cost of their prosthesis or where the cost of prostheses increased rapidly when insurers became able to negotiate on the price of prostheses directly with device sponsors.

MTAA seeks the Committee's support of the current reforms process initiated by Government. MTAA did not publically campaign against the cuts to benefits in February 2017 as it was perceived that to do so could potentially hamper meaningful and collaborative progress towards a transparent, evidence-based reform agenda.

However, these arbitrary cuts have already had an adverse impact on many suppliers, particularly Australian companies. In an effort to avoid an impact on patients arising from the cuts, companies have opted to lay off staff, recruitment activities have been frozen and investment in research and development has reduced.

MTAA would like to ensure the recommendations of the Committee allow the Government to continue its important work to bring meaningful reform to the PL system.

Key Issues

The key issues we would like to clarify for the Committee are as follows:

1. **Ancillary services**

Ancillary services are support services provided by medical device suppliers as a risk-management tool to optimise both short and long-term patient outcomes. A limited number of prostheses are associated with ancillary services.

Ancillary services are variable – they may occur only in the private sector or similar services may be provided to both the public and private sector but type and frequency may vary. These differentials will have an influence on the cost of a prosthesis – the greater the service burden for a supplier, the greater the differential in prosthesis cost.

2. **PHA claim of $800 million per annum savings from the Prostheses List**

This claim is flawed given the choice by PHA of a biased and extremely small sample size that would not render any statistically meaningful results. The price of 41 items from over 10,000 items on the PL has been erroneously used by the private health insurance industry to argue for an annual cut of $800 million.

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Based on the report commissioned by private insurers, it appears that the methodology did not adjust for the difference in prices due to differences in the type and frequency of ancillary services provided across sectors.

The extrapolation of the price reductions should not have flowed on to the many products on the PL that are not sold in the public sector.

Of all the informed stakeholders who have contributed to the debate on the PL reform, only the private health insurance industry has claimed the potential level of savings is $800 million per annum. Not even the Department of Health supports this claim, describing it as akin to 'putting up a wet finger in the air'. It is also important to reflect on other stakeholder inputs such as Shaun Gath who describes the $800 million as 'insurer fantasy'.

3. Company representatives in theatre

Company representatives in theatre are an essential component of support provided by suppliers for their devices and this has been recognised in international best practice guidelines associated with specific device types.

These services have been more in demand as the nursing workforce becomes more transient meaning that training of nursing staff in particular procedures or with particular devices is not cost-effective for hospitals.

Despite misleading claims by the private health insurance industry during the public hearing that supplier support services only began with the introduction of the PL arrangements in 2005, historical evidence confirms this is false and such services were established well before 2005.

Should the services of a representative not be required, a physician can decline these.

4. Use of international pricing and public hospital pricing for pharmaceutical benefits

Despite the misconception by many parties at the Committee's hearing, the Pharmaceutical Benefits Scheme (PBS) does not use international or pubic hospital pricing for setting pharmaceutical benefit levels or for price disclosure. This is clear in the legislative provisions that underpin price disclosure.

These should not be used for setting or reviewing PL benefits as the markets are non-comparable and is like comparing apples with oranges and would lead to unintended consequences for patients.

5. Claims existing PL benefit levels are inflated

There have been claims made by other stakeholders that exiting PL benefits are inflated as a consequence of the initial benchmark being set artificially high following a spike in the average PL benefit between 2001-2005. However, analyses reveal that the average PL benefit is lower today than it would have been if the PL growth had continued at the pace it was at just before the amendments were made to the PL in 2001.

6. 25% rule for establishing original PL prices

There appeared to be significant confusion around the 25% rule during evidence provided to the Committee. MTAA understands the 25% rule was a once off methodology used to establish existing PL benefits and as such the effects of the rule live on where a product is added to an existing group.

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However the rule itself is not used to determine benefits for new groups and therefore is no longer an active consideration when setting benefits for new groups.

MTAA would appreciate the Department publishing information to clarify this on its website as well as information on whether companies can apply for a benefit lower than the benefit that applies to others in the same group.

7. Reforms proposals – tendering, DRGs, Japanese system

Some options for reform have been put forward for consideration by the Committee based on DRG based payment models in the private sector. The key concern with this is that this encourages the pursuit of the lowest cost product as opposed to the highest value product (in terms of the contribution to the patient's health outcome). This will reduce the number of innovative products available in the private sector and eventually erode the value of private insurance to consumers, which, based on a Government survey from 2015 was already a significant concern.

The concept of tendering proposed by some stakeholders is also likely to have the same outcome.

In identifying the Japanese system as a potential model for prosthesis price setting, private insurers have failed to acknowledge that this system is only viable because patients are required to pay 30% of the prosthesis cost as an out of pocket expense. In contrast, Australian patients currently incur no out of pocket expense for prostheses.

Conclusion:

The PL framework is complex and a considered and thoughtful process for reform is required to avoid unintended consequences that cannot be reversed.

This submission shows that:

- The PL has worked well and has been excellent at containing the growth of the PL;
- Public and international pricing comparisons are inappropriate;
- No credence can be place on the PHA claims of savings of $800 million - the limited sample size that selectively used products which require ancillary services (and therefore where a public price to PL benefit was inappropriate) renders this methodology unusable; the extrapolation of savings to apply to PL products that do not even supply to the public sector is fundamentally flawed;

MTAA hopes the Committee will continue to support the reform work commenced by Government to ensure that meaningful and sustainable reform can be achieved.

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1. Ancillary services

Issue

It appears that the Committee required clarification in relation to the provision of supplier supported ancillary services and MTAA would like to clarify this in writing as this is a complex issue.

MTAA response

Ancillary services are required for some types of devices, for example between joint implants, cardiac active implantable cardiac devices and intraocular lenses (IOLs). Ancillary services are used to reduce adverse events during the implant procedure and to optimize long-term patient outcomes.

The type and frequency of ancillary services provided by medical device suppliers to public and private hospitals varies considerably across Australia. This variability is a manifestation of a multitude of factors, including:

- Volume and nature of services required by the hospital,
- Capacity of individual suppliers to meet the demand for support services,
- Contract arrangements between supplier and hospital,
- Geographic location of the hospital (urban/rural),

The sections below provide examples of the differences in ancillary services and highlight why it is important that any reform to the PL take these into account.

Services for cardiac devices

Around 90% of products listed in the cardiac category of the PL relate to implantable cardiac defibrillators (ICDs) or pacemakers and require ancillary support through technical support during implantation and through post-implantation support.

Industry employed allied professionals (IEAPs) predominately provide support to private hospitals only as public hospitals employ cardiac technicians trained to provide theatre and peri-procedure support. In general IEAPs do not support public hospitals except in occasional circumstances at the public hospital's request.

The types and frequency of IEAP services required are underpinned by best practice evidence based on guidelines published by the American and European cardiac associations[1]. It is therefore inappropriate to conclude that these support services are unnecessary and unsolicited. Some of these activities have been outlined by MTAA at a high level in its submission and testimony at the public hearing.

However, the largest component of cost burden to suppliers lies in the provision of post-implantation support, details of which have been provided to the Committee previously. MTAA would like to clarify for the Committee the role of remote monitoring of cardiac devices as this was raised by Senator Griff. Remote monitoring may replace some in-office follow-up visits, however patients are still required to have periodic in-office visits.

[1] HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices: Description of Techniques, Indications, Personnel, Frequency and Ethical Consideration; Europace (2008) 10 707-725 doi:10.1093/europace/eun122

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These costs are not visible to the private hospital or private health insurers as their involvement ceases once the patient has received the implant. These costs are significant and are therefore included in the cost of the prostheses in the private sector and contribute to the price differential observed across the public and private sector.

Services for orthopaedic products

In the orthopaedic sector, suppliers provide similar support to public and private hospitals. Specifically, the services provided are training, technical support during surgery and the provision of loan kits to accompany every surgery across every hospital around Australia.

Technical support is also provided both pre and post intraoperatively to assist surgeons with the many trays of complex equipment and dozens of implant size choices required. This requires a good knowledge of the product for correct selection before and during the operation. Technical support is also provided to assist with the many trays of complex equipment that require inherent familiarity of the hospital staff with a particular implant's bespoke instrumentation used to prepare, size and insert the device (loan kits).

This support service manages the fact that nursing turnover is frequent and so consistent presence of an expert in all aspects of the product and instrumentation ensures that what is always a complex operation, is precise, accurate and timely for the benefit of both the surgeon and the patient.

While the provision of training and technical support may vary at the discretion of the surgeon or hospital, the provision of loan kits does not. They accompany every hip or knee implant provided to a hospital, public or private, for every surgical case.

These are significantly bulky and heavy items (can weigh around one tonne) to transport for every surgical case. Suppliers bear these transportation costs which varies based on the location of the hospital.

Private hospitals purchase prostheses on an individual case basis when required by a surgeon which makes it difficult for suppliers to have enough certainty of supply to obtain efficiencies from streamlining logistics arrangements. There is a larger volume of surgeries for hip and knee implants in the private sector compared to the public sector effects logistical costs.

Services for IOLs

Public hospitals routinely use monofocal lenses which are the most basic lenses, require no ancillary services and are therefore less costly.

Private hospitals generally use the more complex lenses (toric and multifocal). These devices require supplier support as they require a high degree of insertion precision that the more basic lenses do not. Services provided by suppliers include technical support with pre-surgical eye measurements, lens selection and technical support during implantation. These costs are built into the PL benefit for the lenses.

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2. PHA analysis of the $800 million p.a. savings from the PL

Issue

The methodology used by PHA to reach the claim that there are savings in the order of $800 million per annum to be made from adjustments to benefits on the PL was significantly flawed and is grossly exaggerated.

MTAA response

The overall methodology used in the PHA analysis looked at pricing differentials across Western Australia (WA) tender data for 41 items across 3 categories of PL products and compared them to the PL benefit. These differences were weighted for volume with a determination that there was a 45% differential across public and private prices. This difference was then extrapolated across all 10,000 plus items on the PL.

MTAA would like to clarify the methodological flaws in the analysis which made it inappropriate to extrapolate the pricing data across all PL benefits, including those that:

- have ancillary services included;
- have ancillary services and no public market; and
- have no ancillary services and no public market.

Methodological flaws:

1. The sample size was exceptionally limited – the 41 items selected for analysis represents only 0.4% of the items included in the PL. The average public/private price difference for this restricted sample was then extrapolated across the remaining 99.6% or products. This is not a statistically significant sample size given the variation in the number of different product types on the PL. This variation was not reflected in the 41 items that were selected.

2. An average price differential was derived for products comprising 0.4% of the PL and applied to all products, irrespective of whether they have a public market or not. Not every device on the PL has a public market, even if in some instances, other products in the same group do. These should not have been included for the purposes of calculating the level of savings.

3. The 3 categories of devices chosen were those with products most likely to be associated with ancillary services (cardiac, ophthalmic and orthopaedic prostheses) and therefore more likely to be associated with a variation in the level of service support by the supplier across the public and private sectors. Differences in the type and frequency of service support are associated with greater public/private price variation.

4. At a very minimum, the analysis would have required the following adjustments to be made to remove the inherent bias in the product sample selection:

    - A larger sample size that properly reflected the PL
    - An adjustment should have been made to account for the significant differentials in levels of supplier service across public and private hospitals for cardiac devices meaning the price differentials would also be significant.

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- An adjustment should have been made for the variability in the cost of providing loan kits by orthopaedic suppliers due to the differences highlighted earlier in this document.
- An adjustment should have been made for the orthopaedic product price comparisons to reflect the differences in the costs of service provision for products that do not have a public market at all but incur the costs of providing ancillary services. These products should have been excluded from the extrapolation of the benefit reduction.
- The analysis should not have extrapolated the findings to products that are not supplied in the public sector at all.

3. Company representatives in theatre

Issue

During the public hearing, issues were raised as to the requirement to have company representatives in theatre. It was also stated that these services were introduced after 2005, inferring that the inflation which occurred in 2001-2005 was used to create and fund a demand for company representatives that was not already in existence prior to 2005.

MTAA response

Role of representatives in theatre:

For cardiac devices, the role and responsibilities of company representatives in theatre are underpinned by international guidelines[2]. Critically, the guidelines state the following about the company representatives:

- Their role in the clinical environment is to provide technical expertise on the implant, its use and the operation of the proprietary equipment specific to their company;
- If they are trained in sterile techniques, they may participate in the implant procedure but as a rule they should not enter the sterile field;
- Technical support tasks should only be performed under the direct supervision of the physician; and
- When working in a hospital, they must abide by the hospital specific policies that may pertain to their presence and clinical activity.

These guidelines specifically state that *"the industry employed allied health professional is an invaluable technical resource for physicians and their allied health care providers attempting to deliver high quality healthcare in the most cost-effective manner to patients with electronically complex arrhythmia".*

Based on MTAA's understanding, company representatives for orthopaedic devices and IOLs also operate in the manner described in these guidelines. If they are not required by the hospital or the physician, they will not be present during surgery.

These have been requested and provided for at least a decade or more prior to 2005. It is the nursing staff who more directly benefit from the guidance as to the order and choice of instruments prior to and during operations, but of course the surgeon (and patient) do also due to the resulting smoothness and streamlining of the operative procedure.

[2] Heart Rhythm Society Policy Statement Update: Recommendations on the role of the industry employed allied professionals 2008 Published by Elsevier Inc on behalf of the Heart Rhythm Society doi:10.1016/j.hrthm.2008.09.023

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Role of representatives prior to 2005

Company representatives in theatre have been present since before 2005 and are not an artifact of the PL arrangements as was implied by the PHA during the Committee's hearing.

4. Use of international pricing and public hospital pricing for pharmaceutical benefits

Issue

Several submissions and evidence at the public hearing indicate many stakeholders do not understand how pharmaceutical benefit arrangements around price referencing or price disclosure operate. This needs to be corrected for the record as it is critical to reform discussions going forward.

MTAA response

Pharmaceuticals are listed on the Pharmaceutical Benefits Scheme (PBS) following an assessment by the Pharmaceutical Benefits Advisory Committee (PBAC) of whether a pharmaceutical achieves the same or better health outcomes or improved economic value compared to other available therapies, including other PBS listed products.

The PBAC will recommend whether the pharmaceutical will be listed at the same equivalent price per outcome as other products on the PBS or they will recommend that a product is cost-effective at a specific price. This sets the basis of pricing negotiations with sponsors. Pricing comparisons against public and international prices are irrelevant – it is about the value per health outcome for a new pharmaceutical against existing products or therapies. This advice was provided recently verbally by the Department in conversations with the MTAA late last year and early this year and confirms MTAA's understanding about the arrangements.

In relation to PBS price disclosure, public and international pricing are excluded from the calculations. Public prices are explicitly excluded as an input into price disclosure in the text of the relevant regulatory provision (Part 6A of the National Heath Act Regulations, Subdivision 3).See *Attachment 1*.

While the text does not specifically exclude international pricing, there are no legislative provisions in the Regulations which provide for methodology to adjust the data collected to account for international differences and convert to Australian prices. By virtue of this omission, the price disclosure calculations do not allow for international pricing to be an input into the process.

5. Clarification of the claims existing PL benefit levels are inflated

Issue

Claims have been made by other stakeholders that existing PL benefits are inflated as the effect of the inflation between 2001-2005 has not been reversed.

MTAA response

MTAA undertook an analysis of what the average PL benefit would be today if the average inflation rate that applied in 1999 and 2000 had continued for 16 years – i.e. that the inflation in 2001 and 2005 had never occurred and the rate of growth of the PL was 1.74% per quarter over a 16 year period. The actual average benefit level today is lower ($794) than it would have been had the pre-2001 inflation rate continued to apply ($860). See *Attachment 2.*

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This can be explained by the fact that in recent years the average growth in PL benefit has been negative when adjusted for CPI (see *Attachment 3*) and reforms to the grouping arrangements for PL benefits in 2012 resulted in significant price reductions for many products.

This means that the PL provides better value now than it did 10 years ago.

This better value can be accentuated by the fact there have been incremental improvements to technologies but in many cases, there has been no subsequent increase in price to reflect the value of these improvements in the last 10 years. In effect, there have been PL benefit decreases since that time.

For example, improvements to the battery technology for ICDs since 2005 result in the devices lasting a few years longer so the time between surgery for battery replacement is longer and the impact on the patient is reduced. The associated savings to the healthcare sector of this technological advance is estimated to be around $900 million over 15 years[3].

6. 25% rule for establishing original PL prices

Issue

During evidence provided to the Senate Inquiry there appeared to be confusion around the "25% rule", why it existed and how it worked and why it is not in place any more.

MTAA response

Prior to the inception of the PL there were no clinical groupings of products. Schedule 5 was simply a list of rebate codes, with no way of knowing which items were similar. The major reform of the PL at that time was to create a detailed clinical grouping and sub grouping structure, so that like for like products could be compared alongside each other. This process took several years. Once complete, it was clear that there was a wide range of prices with the same clinical groups. As a result, a decision was made by the Department of Health to set one benefit level per sub group. How would that sub group benefit be calculated? The 25% rule was introduced as the methodology for calculating that benefit.

Products were listed from the highest to lowest benefit. A cumulative utilization would then be calculated starting from the lowest benefit product and working up until the **combined** utilisation reached 25%. The benefit for the product at that point became the new group benefit. So in fact the formula **included** the lowest, and even least utilized product within that calculation.

Here is an example:

	Benefit level	Utilisation	Cumulative % of utilization
Product 1	$100	100	100%
Product 2	$80	200	90%
Product 3	$75	450	70%
Product 4	**$70**	**120**	**25%**
Product 5	$65	80	13%
Product 6	$50	50	5%
		1000	

[3] Economic value of improved ICD and CRT-D battery longevity in devices with a 1.7-2.0 Amp Capacity and Li?MnO2 Chemistry in Australia – Priest VL; Haddrick N; Denman R; Hammill E; Simmonds MR; Canobbio M

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Product 6 only represents 5% utilization. Products 5 and 6 combined represent 13%. 4, 5 and 6 combined represents 25%. So, Product 4 becomes the 25% utilization product that sets the new price.

The Group price became $70, for every Product. Product 1 went from $100 to $70. Product 3, the most commonly used product would go from $80 to $70.

So the 25% rule, implemented by the Department Of Health in 2005, was used to determine a price for a clinical grouping where there was a wide range of existing prices. It succeeded in lowering prices on the PL. Even though it is no longer used for new groupings, it never did, nor does not, discriminate against a small company, or exclude a company with a lower price.

7. Reform proposals - tendering, Diagnosis-Related Groups (DRGs), and pricing comparison against Japan

Issue

Several issues were raised as part of proposed reforms proposals. MTAA would like to provide additional information to assist the Committee in its deliberations.

MTAA response

Tendering

Reform proposals whereby private sector procurement would be undertaken by different entities were proposed, including one where the purchasing power was given to private insurers.

Based on previous experience, deregulation of the PL arrangements to allow insurers to control the types of devices they paid for or allowing them to negotiate the price, required Government intervention to correct these policy failures.

Setting history aside, many countries are introducing the concept of value-based procurement whereby purchasing is not based on the lowest price but on the value of the technology with respect to health outcomes. This means that other countries, including Sweden and America, are trying to introduce a PL type of assessment into their tender processes.

Adopting a procurement based approach just on price for the private sector in Australia will be counter to international moves to incorporate the consideration of the health outcome value of technologies such as that afforded by the PL arrangements. For example, Japan is considering moving to an evidence-based approach to setting prices for their prostheses.

The use of tendering for PL items will mean that there will be limited device choice for patients (and their treating physician) and the value proposition of PHI will be diminished. Essentially, it will offer very few benefits over the existing public system whilst being impacted by significant implementation and maintenance costs.

Incorporation of the prostheses price into the DRGs

This has been a reform proposal which is inherently very complex. A key consideration with incorporating the price of prostheses into DRGs is that private hospitals will be incentivised to use the lowest cost prosthesis (that may not provide the best long term value for the patient or our overall health dollar) which will diminish the value of PHI to consumers and impact on choice.

Additionally, the current DGR process does not have a way of dealing with innovative products accessing the market. This would become an issue for the private health insurance industry if

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Government decided to go down this route as it would put further pressure on the value proposition of health funds.

Japanese pricing system
The Japanese system was identified as a potential model for prostheses price setting. However, there are some key issues which need to be taken into account as they were not explained to the Committee:

- Japan is reviewing its current arrangements and is considering implementing the Australian model for evaluation to include a product on the PL to set its device prices.
- In Japan, all hospitals, whether public or private, are under the same National Health Insurance fee schedule, including for the reimbursement of medical devices;
- There is no private market in Japan;
- Japanese patients pay a co-payment that is equal to 30% of the cost of the prostheses;
- The Japanese equivalent of the PL includes non-implantable prostheses such as ablation catheters which are not on the PL;
- Premiums are awarded for innovation (up to 100%) and early introduction to the Japanese market;
- Prices in Japan are allowed to be higher than in international jurisdictions (up to 1.5 times greater of a basket of international jurisdictions that includes Australia); and
- Products without clinical evidence can obtain a price premium if they have a high probability of cost-effectiveness (this is not the case in Australia).

Conclusion

As can be seen from this submission, the complexity of the PL system has been significantly under-represented by private health insurers.

The impact of any reform proposals must take into account the key features of the current operating environment.

The claim by PHA that savings of $800 million can be achieved is fundamentally flawed, incorrect and unachievable. There would be significant risks to patient access to medical technology, the viability of the industry and the value of private health insurance if PL reform was based on such a spurious claimed savings.

MTAA hopes that the Committee will support a continuation of Government's reform agenda for the PL arrangements to improve the existing arrangements as outlined in MTAA's first submission to this Inquiry.

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Attachment 1

Extract from National Health (Pharmaceutical Benefits) Regulations 1960.
Subdivision 3—Price disclosure requirements

37T Price disclosure requirements

(1) This regulation is made for subsection 99ADC (1) of the Act.

Prescribed information

(2) The responsible person must provide the following information in relation to the supply of a brand of a pharmaceutical item, **other than the supply to a public hospital:**

a) the start and end dates of the period to which the information relates;
b) the name of the brand;
c) the name of the responsible person;
d) the name of the drug in the pharmaceutical item;
e) the form of the drug, including its strength;
f) the manner of administration of the form of the drug;
g) the number or quantity of units in a pack (the number of tablets in a pack, for example);
h) the number of packs sold;
i) the revenue from sales of the brand, excluding GST;
j) if any incentive is given in relation to the brand:
    (i) the kind of incentive; and
    (ii) the value of the incentive, excluding GST.

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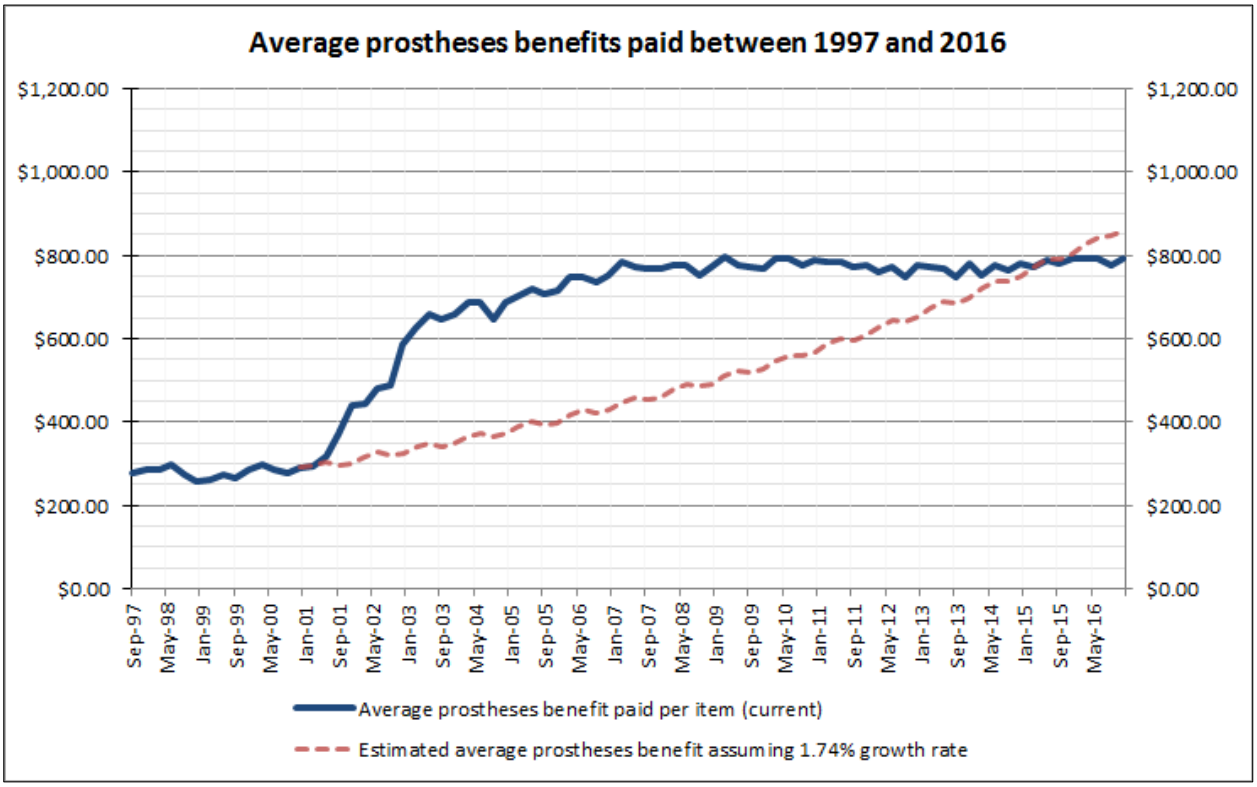
Attachment 2



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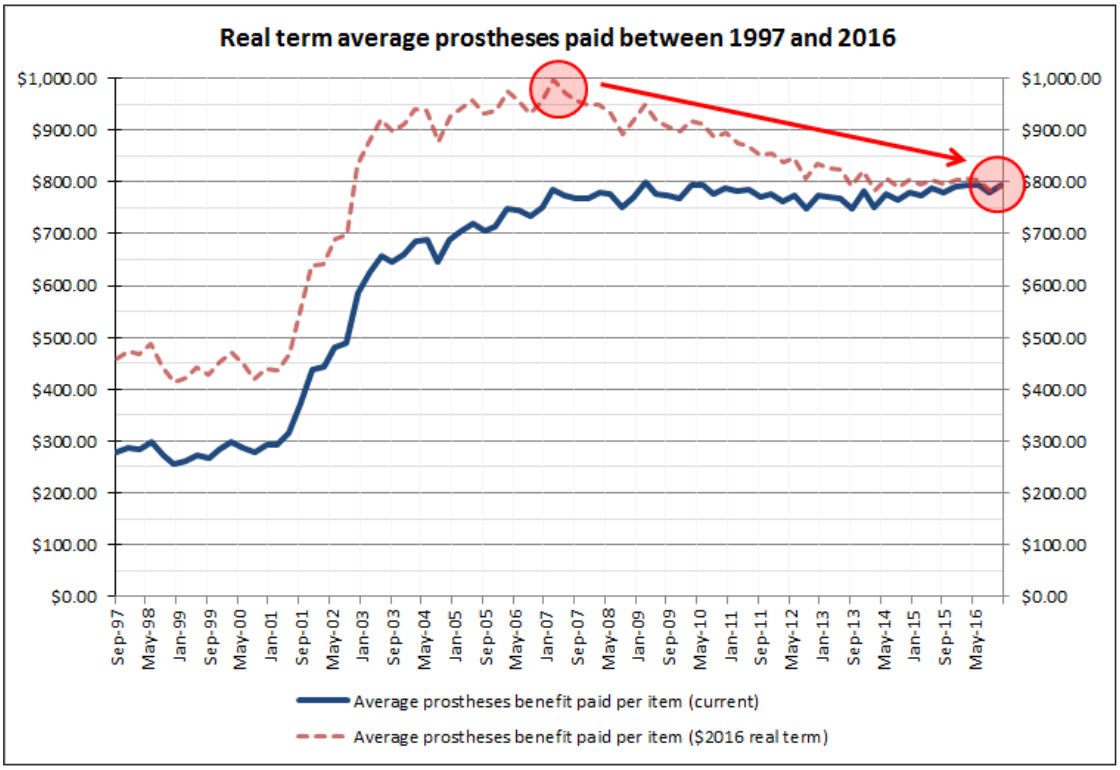
Attachment 3



Source: APRA, Private Health Insurance Statistical Trend