MTAA Submission to the Australian Competition and Consumer Commission (ACCC): Report to the Senate on Private Health Insurance

April 2016

Medical technology for a healthier Australia

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MTAA Medical Technology ASSOCIATION OF AUSTRALIA

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1. Executive Summary

The Medical Technology Association of Australia (MTAA) welcomes the opportunity to provide comment to the Australian Competition and Consumer Commission (ACCC) Report to the Senate on Private Health Insurance (PHI) covering the period 1 July 2013 to 30 June 2014. MTAA notes that the ACCC report provides a review of the PHI industry, with a particular focus on information provision, including the transparency, accuracy and consistency of information about policies and the impact this has on consumer behaviour. While the report addresses issues specific to the reporting period, it also gives broader consideration to the enduring impact of these issues on consumers.

The report also highlights the complexity of the PHI system, and its impact on consumers, which was a frequent theme of submissions to the ACCC from both consumer and industry bodies. A range of factors contribute to this complexity, including regulatory settings, the large number of policies available, the range of potential policy benefits and exclusions, preferred provider arrangements, policy variations and differing terminology between funds which makes comparison difficult.

The medical technology industry's involvement in the PHI sector has been predominantly in the acute care setting providing medical technology to support privately insured patients in both private and public hospitals. From the provision of consumable medical devices to the supply of capital equipment and hi-tech medical devices used in surgical procedures, the MedTech industry has a symbiotic relationship with hospitals and Private Health Insurers in supporting the health needs of privately insured patients. The reimbursement of surgically implanted prostheses is the only medical technology area covered by PHI, which is subject to government regulation and this will be covered in detail below. With the rapid changes in technology capability, this involvement does not need to be limited to the acute care sector.

In respect of recent PHI consultations conducted by the federal Department of Health, MTAA made several recommendations focusing on the consumer at the centre of deliberations identifying reforms needed to enhance the value of PHI for Australians:

- Amend unnecessary or inefficient regulation and policies
- Improve access to innovative medical technology
- PL as the best PHI regulatory system.

In this submission, MTAA focuses on these recommendations and welcomes the ACCC approach to take into account the Department of Health's Private Health Consultations 2015-16.

MTAA acknowledges its commitment to supporting the value proposition of PHI for consumers and patients based on the following key principles:

- Privately insured patients have a right to access innovative medical technology, regardless of where they live: rural, remote or urban locations.
- Fair and sustainable benefit determination and review processes must support the value of PHI in terms of patient access to treatment options and products available. Where medical technology is essential to the performance of a procedure covered by Medicare, a funding pathway must facilitate its availability to patients.
- The continuation of the PL, or a contemporary medical device reimbursement list, is the best regulatory measure to ensure patient access and surgeon choice to the most clinically appropriate medical technology. MTAA supports a robust but sustainable benefit determination process. MTAA recommends that the Prostheses List Advisory Committee (PLAC) should have available a group benefit review process that is accessible and open to applications from both PHIs, and MedTech manufacturers and distributors (sponsors) whereby benefits applying to specific product groups identified as having pricing discrepancies may be reviewed to address claims of inappropriate benefit levels. (Note that the Government's Industry Working Group on PHI Prostheses Reforms has been considering this issue and has reported separately to the Minister for Health who is considering its recommendations).

MTAA Recommendations to the Australian Government on the PHI Consultation and the value proposition of PHI

- The Federal Government to commit to the continuation of the PL as the best regulatory system to ensure patient access and surgeon choice to the most appropriate medical technology.
- Regulation of the reimbursement of medical technology includes non-implantable medical technology that meets agreed eligibility criteria, as well as continuing to cover surgically implanted prostheses.
- When an episode of in-hospital treatment, for which a Medicare benefit is payable for the associated professional service, is available in a private hospital, a PHI policy should facilitate access to the relevant medical technology necessary to support the treatment.
- Patients should be provided access to subsidised, clinically and cost-effective sub-acute care products that are essential for their care in the out-of-hospital and in the home and community settings.
- Appropriate and consistent coverage to be provided for an integrated and well-coordinated approach for delivering care across primary, community and specialist care services.
- Deliberations on PL expenditure are balanced by consideration of the factors underpinning growth in utilisation and the longer term impact on PHI.
- The Prostheses List Advisory Committee (PLAC) should have available a group benefit review process that is accessible and open to applications from both PHIs, and MedTech manufacturers and distributors (sponsors) whereby benefits applying to specific product groups identified as having pricing discrepancies may be reviewed to address claims of inappropriate benefit levels.
- Regulatory changes be implemented to encourage PHI funds to become more innovative, and provide greater value for consumers, by linking Government rebates to fund performance indicators such as the provision of:
  - transparent policies with fewer exclusionary products
  - innovative and cost-effective services focused on the prevention and management of chronic disease, including telehealth and remote monitoring services.

2. About the Medical Technology Association of Australia

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community. Member companies cover a broad spectrum of the industry in Australia, from subsidiaries of major multinational medical technology companies to independent distributors and small and medium sized Australian innovator companies.

Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from consumable items such as bandages and syringes, to high technology implantable devices such as cochlear implants, cardiac defibrillators and orthopaedic joints, to diagnostic imaging and operating theatre equipment, to products which incorporate biological materials or nanomaterials. The industry is characterised by a high level of innovation, resulting in short life cycles for many products. Medical technology innovation is characteristically incremental in nature. Many medical devices undergo constant development based on feedback from medical practitioners and advances in other sciences relevant to medical technology.

3. Introduction

MTAA welcomes the opportunity to provide comment to the Australian Competition and Consumer Commission (ACCC) Report[1] to the Senate on Private Health Insurance (PHI) covering the period 1 July 2013 to 30 June 2014 – see **Annex 1** for the ACCC Feedback Questions. MTAA notes that the ACCC report provides a review of the PHI industry, with a particular focus on information provision, including the transparency, accuracy and consistency of information about policies and the impact this has on consumer behaviour. While the report addresses issues specific to the reporting period, it also gives broader consideration to the enduring impact of these issues on consumers. This approach aligns with the ACCC's 2015 Compliance and Enforcement Policy.

The report also highlights the complexity of the PHI system, and its impact on consumers, which was a frequent theme of submissions to the ACCC from both consumer and industry bodies. A range of factors contribute to this complexity, including regulatory settings, the large number of policies available, the range of potential policy benefits and exclusions, preferred provider arrangements, policy variations and differing terminology between funds which makes comparison difficult.

4. MTAA involvement in Private Health Insurance Consultation

The medical technology industry's involvement in the PHI sector has been predominantly in the acute care setting providing medical technology to support privately insured patients in both private and public hospitals. From the provision of consumable medical devices to the supply of capital equipment and hi-tech medical devices used in surgical procedures, the MedTech industry has a symbiotic relationship with hospitals and Private Health Insurers in supporting the health needs of privately insured patients. The reimbursement of surgically implanted prostheses is the only medical technology area covered by PHI, which is subject to government regulation and this will be covered in detail below. With the rapid changes in technology capability, this involvement does not need to be limited to the acute care sector.

In respect of recent PHI consultations conducted by the federal Department of Health, MTAA made several recommendations focusing on the **consumer at the centre of deliberations identifying reforms needed to enhance the value of PHI for Australians**:[2]

1 ACCC 16th annual report to the Senate on private health insurance: Available at: https://consultation.accc.gov.au/ipil/phireport-2014.

2 MTAA Submission to the Private Health Insurance Consultation - December 2015. Available at: www.mtaa.org.au/docs/submissions/mtaa-submission-to-the-private-health-insurance-consultation-final-w-attachments.pdf?sfvrsn=2.

- **Amend unnecessary or inefficient regulation and policies**, as these add costs (out of pocket expense) for consumers – resulting in consumer 'bill shock'.

- **Improve access to innovative medical technology** to build a reimbursement system that enables equitable patient access to innovative medical technologies, regardless of the geographic location of the patient. Generally, a benefit from a private health insurer will only be paid for an item listed on the Prostheses List (PL). Access and uptake of non-implantable devices as well as those used for remote monitoring are inconsistently covered (if at all) and the benefits of innovative medical technologies in providing improved health outcomes for private patients. In addition the submission addressed the disparity between privately insured patients in urban and rural and remote areas.

- **PL as the best PHI regulatory system** - as its independence ensures private patient access to the most appropriate medical technologies, not the technologies that the PHI funds are willing to pay for. However, the PL criteria is outdated and need to be expanded to improve patient access to advancements in technology, including non-implantable medical technologies, which are not currently covered.

In this submission, MTAA focuses on these recommendations and welcomes the ACCC approach to take into account the Department of Health's Private Health Consultations 2015-16.

5. What is the 'Value' of Private Health Insurance for Australians?

Almost one in two Australians hold a PHI policy for all or part of their hospital treatment costs.[3] PHI represents a significant financial investment for many consumers and their families. One of the main reasons that consumers take out private health cover is so they or a family member do not have to wait for surgery in the event of an urgent in-hospital medical treatment and so they are able to choose their own medical specialist. However, there is increasing evidence to suggest Australians are becoming unsatisfied with the services available to them under their PHI cover. The Private Health Insurance Ombudsman released its yearly State of the Health Funds[4] report, in April 2015 demonstrating a **34% increase in complaints about exclusions and restrictions on levels of cover compared to the previous year**. According to Private Healthcare Australia 1,576,409 policies were dumped and 985,281 were downgraded between February 2012 and December 2014.[5]

In this context there is ongoing debate about what the role of PHI should be and what policy and regulatory changes should be made to ensure consumers get value for money from their cover. Furthermore, premiums continue to rise due to an ageing population and increasing onset of chronic disease, which then result in consumers paying higher premiums and receiving lower benefits.

a. Policies and Regulations – Factors that cause high out of pocket expenses and consumer 'bill shock'

The Private Health Insurance Rebate

- The PHI rebate was introduced as an incentive to encourage more Australians to take out PHI by making it more affordable. It has been suggested that the cost of the PHI rebate is greater than the flow-on savings to the public hospital system and that large savings could be achieved by removing the rebate altogether, which could then be used to fund more public hospital beds for the chronically ill, as well as reduce public hospital elective surgery waiting times.

- Recent data show the PHI rebate is growing at 6% per year and reached $5.56 billion in 2012-13. It can be argued that the rebate sustains a viable PHI industry, which supports private hospitals,

3 Private Health Insurance Administration Council (PHIAC). Operations of the Private Health Insurers Annual Report 2013–14, p .30.

4 State of the Health Funds Report, Private Health Insurance Ombudsman, Australian Government. Available at: http://www.phio.org.au/publications/publications/state-of-the-health-funds.aspx

5 Private Healthcare Australia Stats. Available: http://www.privatehealthcareaustralia.org.au/category/stats-data/

patient choice and relieves pressure on the public system by those who can afford to contribute to their healthcare costs.

- In February 2015, the Minister for Health, Sussan Ley explained that the increase was due to the fact that the benefits funds were paying to their members had increased by 7.4% over the previous year. Private health funds cite increases in individual technologies supplied by manufacturers and distributors of medical technologies as the primary cost driver. **What is not emphasised to consumers (general public) is the fact that growth in expenditure on prostheses is being driven largely by underlying growth in utilisation, not growth in the price of actual prostheses (Annex 2 - MTAA Factsheet)**.

- The discontinuation of the PHI rebate is one of five Government funding reform options outlined in the Department of Prime Minister and Cabinet's Reform of the Federation 2015 Discussion Paper.[6] Specifically, the Green Paper includes an option (Option 2) where the Commonwealth would redirect funds that would have been used for the rebate, to establish an MBS-style hospital benefit scheme to fund a proportion of the cost of each hospital procedure, with the States and Territories asked to cover any gap between the benefit and the service cost. As the paper acknowledges, the impact of adopting this option on the PHI market would need to be carefully considered, including the impact on consumers through changes to premiums. MTAA is concerned that the adoption of such an option would have other undesirable consequences, including for patient access to innovative medical technology.

- As more consumers discontinue their PHI following the discontinuation of the rebate, it will become more difficult for them to access new and innovative medical technologies in a bundled contractual environment in the public hospital system.

- Currently, in Australia there is a lack of a timely mechanism for the integration of new medical technologies into the classification and costing systems of public hospital services. **Therefore, rather than discontinuing the PHI rebate, another option would be to link the rebate to specific performance indicators that funds would have to meet in order to continue to have their premiums subsidised with public money.** This would reward funds that provide greater value for consumers, through more transparency in policies with fewer exclusionary products, and may incentivise them to provide more innovative and cost-effective services focused on the prevention and management of chronic disease, such as telehealth and remote monitoring services.

Increase in exclusionary products

- Over the last few years there has been an increasing trend for private health insurers to offer exclusionary hospital policies which do not provide members with cover for medical treatment for a range of acute or chronic health conditions **(Box 1)**. Furthermore, the list of medical services that have been subject to exclusions has expanded to include a much larger list of services. Some of these newly excluded services include spinal fusion, scoliosis treatment, gastric banding and related services, access to insulin pump therapy, cochlear implant surgery and bone anchored hearing devices, and ear, nose and throat procedures **(Annex 3)**. **It should be noted that exclusion of these particular services is not based on lack of clinical evidence or effectiveness -** raising the question of whether the growing use of exclusionary products is a de facto mechanism for PHIs to exclude patients that are considered to be high-risk.

- Issues causing the increasing trend:

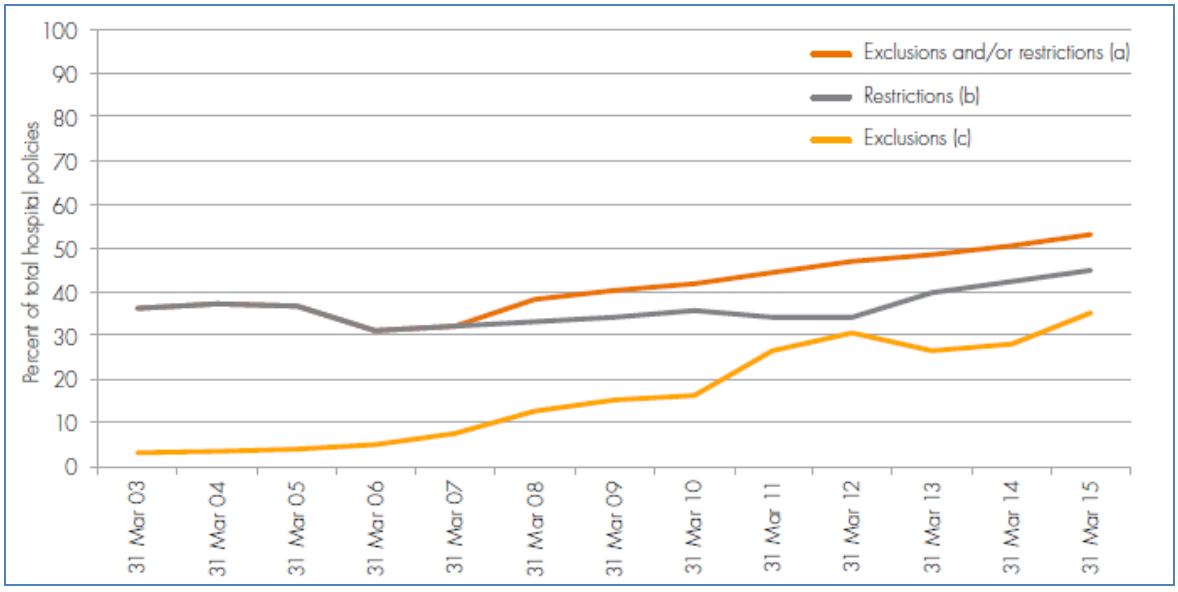
    - **Consumers do not understand the exclusions in their polices,** which results in increasing numbers of patients arriving in hospital unaware that they are not covered for the procedure they are about to have. Research conducted by PHIAC indicates that policies issued in recent years are more likely to include an exclusion or restriction than the broader population of policies already issued in the market. Hence, **new policy holders are more likely to take out an exclusionary policy from the outset than existing policy holders are to downgrade their cover.**

6 The Reform of the Federation Discussion Paper 2015. Department of the Prime Minister and Cabinet. Canberra.

- **Complexity of information**. Newly excluded services (with the exception of gastric banding) are not referred to in the Standard Information Statements alongside the services that may have been typically excluded in the past. Instead, if other services are excluded, the Statement uses other services (see insurer for details) to inform the member, which defeats the purpose of providing this Statement to members annually. It is also difficult for doctors and their patients to understand which specific procedures are excluded by their private health insurer, as they all use different interpretations of what services are not covered under the broad headings e.g. *Cardiac and cardiac related services* or *Pregnancy and birth related services*. **If private health insurers are to offer products with excluded services then this information should be clear and made available to doctors and patients (including specific MBS items that are not covered), so the consumer is aware of their options as early as possible.**

- **Additional premiums.** Exclusionary products force members to pay additional premiums for the highest level of cover or else join extensive public hospital waiting lists to receive treatment they need for the health condition - the latter, is inconsistent with the policy objective of PHI in easing the burden on public hospitals. This also raises questions around equity of access and improper discrimination.

Box 1. Increasing trends in exclusions and restrictions in PHI policies[7]



Note the significant increase in exclusionary products in March 2011 relative to March 2010 is partly due to a re-classification of policies between exclusions and restrictions by some insurers.

Furthermore, there is a break in the excess and co-payment data in June 2007 due to a change in the definition used. While the data on exclusionary products pre and post March 2011 and the data on excess and payments pre and post June 2007 is not strictly comparable, the data over the entire period can be taken as a proxy for the overall trend.

(a) This includes hospital policies with exclusions and restrictions, with exclusions but no restrictions, and with restrictions but no exclusions.

(b) This includes hospital policies with restrictions with or without exclusions.

(c) This includes hospital policies with exclusions with or without restrictions.

7 PHIAC. Risk sharing in the Australian private health insurance market. Available at: www.apra.gov.au/PHI/PHIAC-Archive/Documents/Risk-Sharing_June-2015.pdf.

'Empty' and 'Junk' Policies: Increasing trend of private patients being treated in public hospitals

- While the **Government provides incentives to encourage the purchase of PHI,** there is no requirement for it to be used, and approximately a quarter of people with PHI choose to use the public system rather than the private system.[8] Between 2005-06 and 2010-11 the number of private patients treated in public hospitals increased by 50% (an average increase of 8.5% per annum), and by 2010-11, 10% of all patients in public hospitals were private patients, compared with 7.8% in 2005-06.[9]

- Many insurers offer policies that only cover patients for treatment in a public hospital. However, these policies make sense in areas where access to private hospital services is limited, such as in rural and remote communities. The increasing trend of private patients in public hospitals is driven by these factors:
    - **High out of pocket cost - an important factor.** Increasing number of privately insured patients are faced with significant out of pocket costs following treatment in a private hospital.
    - **Better and more coordinated care in a large public hospital compared with a private hospital.** Depending on the nature of the condition for which the patient is seeking treatment, a patient may in fact receive better, more coordinated care in a large public hospital compared with a private hospital. This is due in part to the team-based model of care provided in large public hospitals, which places an importance on nursing and allied health services.

- In the PHI Consultation, MTAA made the recommendation to the Australian Government to work with the States and Territories to address the financial and other incentives that are driving the growth in private patients in public hospitals. **It is important that the Government carefully consider the value of continuing to subsidise 'empty' or 'junk' PHI policies, particularly those that exclude treatment within private hospitals, and are thus unable to reduce the pressure on the public hospital system.**

Limited coverage of non-admitted hospital procedures

- **PHI does not routinely cover medical services that are provided out-of-hospital.** There are also inconsistencies in coverage of private patients receiving certain procedures, for example renal dialysis **(Box 2)**. Therefore, many private hospitals are not willing to admit patients needing dialysis care. Some of these services were previously provided to admitted hospital patients, but due to developments in clinical practice can now be provided in outpatient, community or home settings.

- **Many sub-acute care medical products needed by patients for appropriate clinical care** (and in some cases, survival) **out-of-hospital are not covered by PHI**. In general, these items are consumable, single-use, non-implantable medical products, together with the hardware that are important for appropriate clinical care, particularly for patients requiring cancer treatment (radiation therapy and medical oncology), and chronic disease treatment and management e.g. chronic kidney disease, chronic wounds and diabetes **(Box 2)**. Examples of sub-acute care medical products include:
    - oxygen supplies/consumables
    - compression hosiery, bandages and garments for lymphoedema
    - continence products
    - sleep apnoea devices
    - renal (home) dialysis devices, consumables and set-up costs.

- **Some products are provided currently at no cost to patients by healthcare practitioners** who understand the need of the patient for the benefit that can be gained from use of a particular product.

8 MTAA Submission to the PHI.

9 King D. 2013. Private Patients in Public Hospitals. Sponsored by the Australian Health Service Alliance and the Australian Centre for Health Research.

Box 2. PHI needed for medical technologies that are essential for the care of non-admitted patients in the home and community settings

Renal dialysis

Some PHI funds cover renal dialysis in a private haemodialysis unit, which can be at a stand-alone haemodialysis unit or part of a private hospital, or at a public hospital (private-in-public). However, there is inconsistency in the coverage provided by PHIs and/or the private hospitals.

Currently funds do not cover private patients in a private hospital for peritoneal dialysis (PD) and thus not many private hospitals are willing to admit PD patients.

Further, for private patients on home renal dialysis, PHI does not support home dialysis services being delivered by the private clinics i.e. nurses to visit patients in their homes to help with home dialysis and also train patients and provide the equipment for home dialysis, in which there is coverage for public patients.

Diabetes

There are over 1 million Australians living with diabetes. However, there are currently no price weights for non-admitted patients, despite the fact that self-management and structured care of patients with diabetes provided by multidisciplinary teams are crucial for improved health outcomes. Further, data from most current insulin pumps can be downloaded and shared between the person with type 1 diabetes and their healthcare team, which allows easier self-management of diabetes (particularly overnight) for patients, especially children and adolescents.

Modern wound care devices (MWCDs)

MWCDs such as wound closure devices, negative pressure wound therapy and antimicrobial wound dressings, offer many clinical and economic benefits over traditional or conventional treatments such as 'wet' or 'dry' gauze. MWCDs are associated with greater ease of application, reduced pain and anxiety for patients at dressing change, and reduced infection rates and procedural complications. As a result, MWCDs reduce the economic burden of chronic wounds in Australia by reducing hospitalisations and length of stay, reducing GP visits, enabling patients to remain in their own homes and avoiding residential aged care.

Despite the significant clinical and economic benefits of MWCDs, access is limited, with patients and their families usually paying for these devices, where they can afford to since PHI do not reimburse MWCDs.

Radiation therapy (RT)

RT in Australia is mainly provided by private providers (clinics). The majority of patients receiving RT however, incur considerable out-of-pocket expenses as PHIs do not provide cover.

PHI coverage of outpatient RT would improve access to RT services in Australia – where currently only 1 in 3 cancer patients in Australia receive RT as part of their cancer treatment – lower than the reported 50% of cancer patients receive RT treatment in curative, adjuvant, or palliative setting.[10,11]

10 National Cancer Institute Fact Sheet, US National Institute of Health. 2004. Available at: http://www.cancer.gov/cancertopics/factsheet/Therapy/radiation

11 MTAA Submission on the 2016 Review of the Radiation Oncology Health Program Grants (ROHPG) Scheme - March 2016. http://mtaa.org.au/docs/submissions/mtaa-submission-to-the-radiation-oncology-health-program-grant-response-.pdf?sfvrsn=2.

b. Improving access to innovative medical technology

- For 30 years the PL (the PL was previously called Schedule 5) has ensured that privately insured Australians have had access to innovative surgically implanted prostheses, chosen by their physician and based on what their physician assessed to be the best clinical outcomes for their patient. MTAA believes that this contributes to the value proposition for consumers whereby it is a patient's surgeon rather than his or her health fund that controls such personal clinical decisions through financial levers. Two examples illustrating the benefits for privately insured patients with regard to access to innovative surgically implanted prostheses are outlined in **Box 3**.

- MTAA believes that without the PL, consumers' access to innovative medical technology would be unpredictable and not assured. MTAA bases this on the observation that when PHIs may exercise their prerogative to fund proven, clinically effective innovative medical technology that is not implanted in the body (and therefore not on the PL), the funds do not reliably or consistently choose to do so. This is particularly disappointing for consumers when the technology may provide better health outcomes and is immediately cost-saving **(Box 4)**. Some examples that demonstrate this recalcitrance are:
  - Drug Eluting Balloons (DEB)
  - Fractional Flow Reserve (FFR) guided Percutaneous Coronary Intervention (PCI)
  - Catheter ablation for atrial fibrillation, an MBS listed procedure
  - Custom made 3D printed devices.

- In July 2014, the Federal Parliament's Community Affairs References Committee Inquiry into 'Out-of-pocket costs in Australian health care' was advised of the practical difficulties created by the reluctance of health funds to cover the costs of the above technologies, some of which are:[12]
  - Cost shifting private patients to the public sector
  - Not providing optimal clinical care for private patients
  - Uncertainty for private patients at a vulnerable time.

12 MTAA Submission to the Private Health Insurance Consultation December 2015- Attachment 5 A transcript of Dr Jepson's evidence. Available: www.mtaa.org.au/docs/submissions/mtaa-submission-to-the-private-health-insurance-consultation-final-w-attachments.pdf?sfvrsn=2

Box 3. The value proposition for private patients

Intra-ocular lenses (IOLs)

Intra-ocular lenses (IOLs) are implanted inside the eye to replace the eye's natural lens when it is removed during cataract surgery and provides a relevant case study.

In the public sector usage of standard 'low cost' IOLs (standard monofocal) predominate as they address the hospital's budgetary constraints whilst providing the intended outcome of cataract surgery i.e. the IOL treats the cataract and improves visual clarity and quality. Standard monofocal IOLs however, do not provide spectacle independence vision at near, intermediate and far distances as vision is monofocal and does not correct other vision problems, such as presbyopia and astigmatism.

In the private sector privately insured patients can access optimal refractive outcomes, and both monofocal IOLs and advance technology IOLs (i.e. multifocals, which promote spectacle independence and Astigmatism-correcting IOLs that reduce the need for glasses/contact lens for distance vision) are used.

Implantable cardiac devices (ICDs)

Range
Private patients have access to a greater range of devices with higher energy levels, timing and shock algorithms, battery and transmission capacities plus more lead options. All devices are accessible (made available through representatives' stock holdings) to the surgeon at the time of implantation to make sure that the right device and leads are available as per the surgeon's determination according to patient anatomy. Public hospitals have a limited range of devices and leads which do not have the full range of operating algorithms available.

Implantation testing
Private patient devices are supplied with all the materials and tooling to implant the device tested at implantation by the manufacturer to ensure the system is working correctly. Such resource needs to be supplied by general trained hospital technicians in public hospitals.

Lifetime device testing
As ICDs are active devices they require regular testing for the life of the device. For private patients a representative of the manufacturer attends each and every follow-up visit for the life of the device to make sure that the device remains optimally tuned for that particular patient under his changing disease conditions. This support is not provided to public hospitals unless requested as part of a tender process.

Remote/home monitoring
With the recent introduction of remote monitoring devices on the Prostheses List, all private patients have access to such leading 21st century technology which has the benefit of ensuring that cardiac events are picked up even between doctor's visits. In addition, clinical trials have shown that remote monitoring can potentially extend the device battery life meaning less exposure to replacement surgery for private patients. Remote monitors are usually supplied on a limited basis in public markets, if at all.

Box 4. Medical technologies that are not included on the PL and which are routinely not reimbursed by PHI funds

Drug Eluting Balloons (DEB)

While Drug Eluting Stents (DES) are included on the PL, Drug Eluting Balloons (DEB) are not. Despite being more clinically appropriate for the patient in some circumstances as an alternative to a DES, and supplied at a lower cost, PHI funds have been reluctant to provide ex-gratia payments to cover the discrepancy. Without intervention by the fund, the use of a DEB will be a cost against the private hospital while any savings from DES not used will benefit the health fund.

Fractional Flow Reserve (FFR) guided Percutaneous Coronary Intervention (PCI) (pressure wires)

FFR measured with a pressure wire during angiography measures blood flow in diseased coronary arteries and determines where coronary stents should be placed. It has been demonstrated that 30% of implanted stents are unnecessary and that better outcomes are achieved with fewer stents. There is financial disincentive to use a pressure wire in the private sector. In the private system, PHI funds either do not or only partially cover the cost of the pressure wire. Private hospitals do not routinely receive any additional benefit – no incentive – for the cost savings associated with the use of pressure wire. Medicare item number for coronary angiography with use of a pressure wire pays less than the item number for PCI and stent(s).

Catheter ablation for atrial fibrillation

Catheter ablation for atrial fibrillation is a case in point where appropriately insured patients may receive PHI benefits for hospital accommodation and medical services, but not for the critical ablation catheters which are not a prostheses and therefore not eligible for listing on the PL. With the current PL criteria, ablation catheters are not included on the PL and PHI covers only the patient's hospital stay, theatre time and professional fees but not ablation catheter – leading to inconsistent funding required to perform these procedures. Catheter ablation is one of the key examples to show that the MBS fails to support delivery of best value and quality healthcare.[13]

MTAA believes that when an episode of in-hospital treatment, for which a Medicare benefit is payable for the associated professional service, is available in a private hospital, a PHI policy should facilitate access to all elements necessary to support the treatment. If private patients are denied access to these procedures, they may be forced to seek treatment in the public health system. This will invariably add to the existing burden on public hospital waiting lists.

Patients' perspectives: [14]

"Finding out that you have AF can be a sobering experience, but it needn't necessarily be a life sentence. AF can be fixed in many of us."

"AF was beginning to seriously affect my life to the point where I felt compelled to retire several years early. Sometime after that I finally heard about and underwent a completely successful ablation procedure, after which my quality of life was completely restored. Had I known about ablation before I retired, I would have been able to continue working for some years."

"AF was beginning to seriously affect my life until I finally heard about and underwent ablation, after which my AF completely disappeared."

Custom made 3D printed devices

Custom made devices (CMDs) are not eligible for listing on the PL because the medical device regulations specifically state that CMDs do not require inclusion on the Australian Register for Therapeutic Goods (ARTG). CMDs are still required to fulfil all relevant Essential Principles for safety and effectiveness, but are not required to be included on the ARTG. While technically possible to list a CMD on the ARTG, the investment of time and money to do so in respect of a CMD for each individual patient would be prohibitive and makes this an unpractical solution because CMDs are by their very nature customised, one-off devices. In practice, CMDs are usually funded in the private sector through PHI approved ex-gratia payments – see **Annex 5**.

This case study exemplifies the red tape involved in authorisation of CMDs for private patients that can by ameliorated by adopting the Proposed Criteria for Reimbursement of Innovative Technologies.[15] 3D printing of devices is another method of manufacturing CMD and will increasingly be utilised to provide bespoke devices in circumstances where greater anatomical precision is required than can be provided by off the shelf devices.[16] **Note that MTAA believes that custom made technologies must be subject to HTA to confirm clinical suitability of technologies for patients.**

See **Annexes 4 and 5** for clinical evidence and costing issues for each of these technologies.

13 MTAA Submission to the Medicare Benefits Schedule Review Taskforce Consultation Paper - 9 November 2015. Available at: http://www.mtaa.org.au/docs/submissions/mtaa-submission-to-the-medicare-benefits-schedule-review-taskforce.pdf?sfvrsn=2

14 Value of Technology. Inequitable patient access to clinically and cost effective medical technology: Catheter ablation for atrial fibrillation. Poster presented at the MTAA Annual Conference: MedTech 2015.

15 MTAA Submission to the PHI Consultation Attachment 6.

16 MTAA Submission to the PHI Consultation Attachment 7.

c. Importance of the Prostheses List to ensure certainty of patient access to innovative medical technology

- Since 2005 the PL processes have also conducted health technology assessment (HTA) on all applications to list new products. HTA has either been conducted by a Clinical Advisory Group (CAGs) of clinicians or two clinicians from a large panel of clinical experts. This product review is in addition to that provided by the TGA, the Australian regulatory gatekeeper for use of surgically implanted prostheses. The current PL includes over 10,000 products in 444 product groups, 739 product sub-groups with the option of an additional 342 product suffixes (denoting further clinical difference) providing a full range of clinician choice to clinically reviewed products.

- The PL owes its origins to the need for patient access to the most clinically appropriate implantable medical technology prescribed by physicians, and the need to manage the growth in benefit levels. However, consumers rely on healthcare professionals with expert knowledge to advise them on the most appropriate course of action to address their healthcare need. A recent survey released in 2014 reported that 90% of Australians aged 14 or over rate nurses as the most ethical and honest profession, closely followed by Doctors at 86%.[17] This finding shows that **consumers rely on a healthcare system where a healthcare professional with expert knowledge is in a position to recommend and utilise the most appropriate healthcare service available on the market.**

- MTAA believes that without regulated reimbursement of prostheses, private hospitals will face additional funding pressures from PHIs, which MTAA expects will bundle MedTech into case payments and contracts based on restrictive product group values. It is expected that this pressure will also be shared by surgeons drawn into accommodating such arrangements, especially if their clinical choice of product is compromised.

- PHIs' behaviour in recent times indicates that deregulation of access to prostheses would be problematic. Examples of recent health fund behaviour include:
  - the increase in exclusions in health fund coverage for health fund members without top hospital cover
  - decline of ex-gratia approvals for clinically proven and cost saving non-implantable medical technologies
  - health funds not covering for patient complications and readmissions.

Box 3. The genesis of regulated reimbursement

The PL had its origins in 1984 when access by orthopaedic surgeons to the most clinically appropriate joint replacements for their private patients was inconsistently supported by PHIs. This issue of access was subsequently addressed in 1985 by government regulation through the establishment of a reimbursement list known as Schedule 5. Schedule 5 listed benefits (or a "charge"), as well as the prosthesis. Due to concerns over the rate of increases in benefit levels, Schedule 5 was varied from February 2001 when the benefit to be paid in respect to listed prostheses was to be negotiated by insurers; however, patients were not to be charged out of pocket costs. The February 2001 changes did not satisfactorily address benefit growth leading to the implementation of the PL in 2005, which has been reviewed twice (the Doyle Review in 2007, and the Health Technology Assessment Review 2009 and implemented through to 2012) leading to its relatively mature state now, a decade later.

17 Roy Morgan 'Image of Professions Survey' April 2014.

The Prostheses List – the appropriate mechanism to contain the inflation of benefits and PHI healthcare expenditure

- Over the 10 years of operation of the PL:[18]
  - The growth in total benefits paid has been 8.5%; while
  - The growth in average benefit per item has been 1.25%; whereas
  - The growth in average benefit per item over the last five years (2010-15) has been 0%.

- With regard to hospital insurance outlays by PHI funds last year, **prostheses benefits are the lowest at 14.3%** followed by medical benefits 15.8% and hospital accommodation benefits 69.9%.[19] These statistics are provided in more detail in the MTAA Fact Sheet **(Annex 2)** with the following conclusions being drawn:
  - Inflation in individual benefits has been effectively contained.
  - Growth in overall expenditure on the PL is being driven by increased utilisation or by more private patients accessing medical technology through their PHI policies.

- MTAA believes that **any debate on PL expenditure would best be informed by not misrepresenting or confusing product benefit growth with overall growth in expenditure**:

  - In a report on factors causing increases in Hospital Table Benefits, by Dr Brian Hanning of the Australian Health Services Alliance (AHSA), an alliance of over 20 health funds, the foreword notes:
    "concern that public understanding of the growth in health fund spending is so simplistic as to seriously detract from the industry's efforts to improve health services"[20]

    In reflecting on the complex issue of underlying factors contributing to annual increases in benefits paid, the foreword also notes that:
    "These four factors make it clear that 'inflation', is a minor factor in the whole picture and illustrates the nonsense involved when journalists and others attempt to compare movements in benefits paid or indeed health fund premiums with inflation when the greatest reason for the increase in benefits is an increase in the number of hospital episodes"[21]

    MedTech companies are not the main drivers behind growth in prostheses expenditure. The AHSA paper further noted that:
    "…older populations need more health care and obviously have a larger number of admissions to hospital than younger populations, but we also know that as medical technology enables more conditions to be treated and keeps people alive longer and cure people who otherwise would have died, there are more procedures to be performed."[22]

- Regardless of official data, **health funds have not publicly acknowledged the PL's achievement in containing inflation on benefits**:
  - As recently as 23 November 2015, Private Healthcare Australia in a press release **reflected confusion between prostheses expenditure and costs** in stating that:
    "The annual premium increase is necessary to ensure Funds can continue to provide members with access to quality medical treatment by covering the increasing costs of health care services, for example in the year ending September 2015 the annual increase in prostheses costs was 8.9% compared with the average annual premium increase of 6.18%".[23]

  - In hirmaa's media release dated 24 November 2015, CEO Mr Matthew Koce unmistakably identifies his concerns regarding individual benefits:

    "Manufacturers are operating under a broken regulatory system that allows them to profiteer off of (sic) Australian private health insurers, resulting in massive prices for basic

18 The Australian Prudential Regulation Authority (APRA), previously the Private Health Insurance Administration Council (PHIAC).

19 MTAA Factsheet. Available at: http://mtaa.org.au/docs/access/mtaa-prostheses-expenditure-factsheet.pdf?sfvrsn=2.

20 P3, Hanning B, Dr, Factors Causing Increases in Hospital Table Benefits paid by Health Funds Retrospective Analysis and Projections to 2013-2014 Prepared by Brian Hanning Australian Health Service Alliance January 2010 for the Australian Centre For Health Research Limited (ACHR)

21 Ibid Page 6.

22 Ibid Page 5.

23 Private Healthcare Australia Press Release "PHI: Value and Choice for Members", 23 November 2015. 8.9% is the annual increase in PHI expenditure on prostheses.

prostheses. This pushes up premiums and hurts the hip pocket of ordinary Australians."…"This issue should be investigated by regulators and needs to be front and centre as part of the Federal Government's review of private health insurance."[24]

- **MTAA supports a robust but sustainable benefit determination process. MTAA recommends that the Prostheses List Advisory Committee (PLAC) should have available a group benefit review process that is accessible and open to applications from both PHIs, and MedTech manufacturers and distributors (sponsors) whereby benefits applying to specific product groups identified as having pricing discrepancies may be reviewed to address claims of inappropriate benefit levels. (Note that the Government's Industry Working Group on PHI Prostheses Reforms has been considering this issue and has reported separately to the Minister for Health who is considering its recommendations).**

- The PL process and mechanism is complex. However, **public (consumer) information on PL expenditure should be accurately represented, particularly in relation to product benefit growth with overall growth in healthcare expenditure.**

6. Summary and Recommendations

In addition to the PHI Consultation, the Australian Government is currently undertaking a number of reviews aimed at ensuring consumers are able to access affordable, quality and timely health services into the future, including reviews of primary healthcare and the MBS. The patient journey involves many people, organisations and processes as part of its flow, which includes the medical and allied health professions, Federal and State and Territory funding of services, and industry - to ensure that patients have access to clinically and cost-effective medical technologies and receive appropriate, co-ordinated clinical care. Australian consumers with PHI, particularly those living in rural and remote regions, and Aboriginal and Torres Strait Islander people are not currently getting value from their PHI cover. **It is imperative to note that if consumers pay to be privately insured they must receive value for money.**

MTAA supports the ACCC's view that *'consumer information and awareness is critical in ensuring that products with less than comprehensive coverage are fully understood at the time of purchase and beyond'. 'Consideration is given to applying the government incentives to participate in private health insurance only to products that contain no excluded services. Exclusionary and restricted benefit products result in an increased administrative burden for hospitals as they introduce added complexity to claiming, billing and payment collection process. Hospitals are also exposed to additional financial risk particularly if it cannot be foreseen and confirmed whether a patient's policy will provide adequate cover.'*

MTAA acknowledges its commitment to supporting the value proposition of PHI for consumers and patients based on the following key principles:

- **Privately insured patients have a right to access innovative medical technology, regardless of where they live: rural, remote or urban locations.**
- **Fair and sustainable benefit determination and review processes must support the value of PHI in terms of patient access to treatment options and products available. Where medical technology is essential to the performance of a procedure covered by Medicare, a funding pathway must facilitate its availability to patients.**
- **The continuation of the PL, or a contemporary medical device reimbursement list, is the best regulatory measure to ensure patient access and surgeon choice to the most clinically appropriate medical technology.**

24 hirmaa Media Release "hirmaa calls for private health review to address a broken market for prostheses" dated 24 November 2015.

Recommendations

MTAA Recommendations to the Australian Government on the PHI Consultation and the value proposition of PHI

- The Federal Government to commit to the continuation of the PL as the best regulatory system to ensure patient access and surgeon choice to the most appropriate medical technology.
- Regulation of the reimbursement of medical technology includes non-implantable medical technology that meets agreed eligibility criteria, as well as continuing to cover surgically implanted prostheses.
- When an episode of in-hospital treatment, for which a Medicare benefit is payable for the associated professional service, is available in a private hospital, a PHI policy should facilitate access to the relevant medical technology necessary to support the treatment.
- Patients should be provided access to subsidised, clinically and cost-effective sub-acute care products that are essential for their care in the out-of-hospital and in the home and community settings.
- Appropriate and consistent coverage to be provided for an integrated and well-coordinated approach for delivering care across primary, community and specialist care services.
- Deliberations on PL expenditure are balanced by consideration of the factors underpinning growth in utilisation and the longer term impact on PHI.
- The Prostheses List Advisory Committee (PLAC) should have available a group benefit review process that is accessible and open to applications from both PHIs, and MedTech manufacturers and distributors (sponsors) whereby benefits applying to specific product groups identified as having pricing discrepancies may be reviewed to address claims of inappropriate benefit levels.
- Regulatory changes be implemented to encourage PHI funds to become more innovative, and provide greater value for consumers, by linking Government rebates to fund performance indicators such as the provision of:
  - transparent policies with fewer exclusionary products
  - innovative and cost-effective services focused on the prevention and management of chronic disease, including telehealth and remote monitoring services.

Annex 1 – ACCC Report to the Senate on Private Health Insurance: Stakeholder Submission Questions

- In addition to complying with the legislative requirements, are you aware of or do you undertake any additional steps to inform consumers of policy changes?
- Do you think there are any problems with the way in which policy changes are communicated to consumers e.g. are they being communicated effectively?
- Are you aware of specific examples where policy changes have not been communicated to consumers in a clear and transparent way? Please provide details.
- Are you aware of practices where policy changes have not been communicated to consumers at all? Please provide details.
- Are you aware of practices where the information provided by insurers relating to policy changes has resulted in consumers experiencing 'bill shock'? Please provide details.
- Are you aware of practices where the information provided by insurers relating to policy changes has resulted in inadequate policy coverage for consumers?
- Are you aware of any common practices or methods for communicating policy changes to consumers that you consider 'poor practice', or that insurers should not be doing?
- Do you have any suggestions for how the provision of policy change information can be simplified or made more accessible to assist consumers to understand any changes to the terms and conditions of their policies?
- What do you consider to be 'best practice' principles for communicating policy changes to consumers, and when should this communication occur? Are there other industries which may provide an example of a 'best practice' approach?

Data

- Are these complaints changing over time and if so how?
- If you are a health insurer provider or consumer organisation, could you provide us with information about complaints and/or concerns you receive relating to the communication of policy changes to consumers, including:
    - The number or frequency of such complaints
    - The main causes of these complaints
    - How you address these complaints.

Annex 2 - MTAA Factsheet

Medical Technology
ASSOCIATION OF AUSTRALIA

MTAA FACTSHEET

What is Driving Increased Expenditure on Prostheses?

Recently, the private health insurance industry has suggested that there is a need for reform of prostheses pricing under the Prostheses List (PL) arrangements, citing the growth in prostheses expenditure over the last 20 years. The purpose of this factsheet is to identify what factors are driving this increase in prostheses expenditure by health funds.

The Australian Prudential Regulation Authority (APRA) is an independent statutory authority that regulates the private health insurance industry in Australia, and MTAA has drawn on its statistical collections to produce this factsheet, providing information on trends in the three components of hospital treatment supported by private health insurance, including prostheses. Specifically, the factsheet presents information on trends in the benefits paid by health funds and the volume of prosthetic devices used in hospital treatment.

As PL arrangements reflecting both the listing and benefit amount for prostheses began in November 2005, statistical data covering the new arrangements has been used. As outlined in Table 1, since 2005 a greater proportion of total hospital benefits have been paid for hospital accommodation and medical services, compared with prostheses.

Table 1: Hospital accommodation, medical and prostheses benefits as a proportion of total hospital treatment benefits

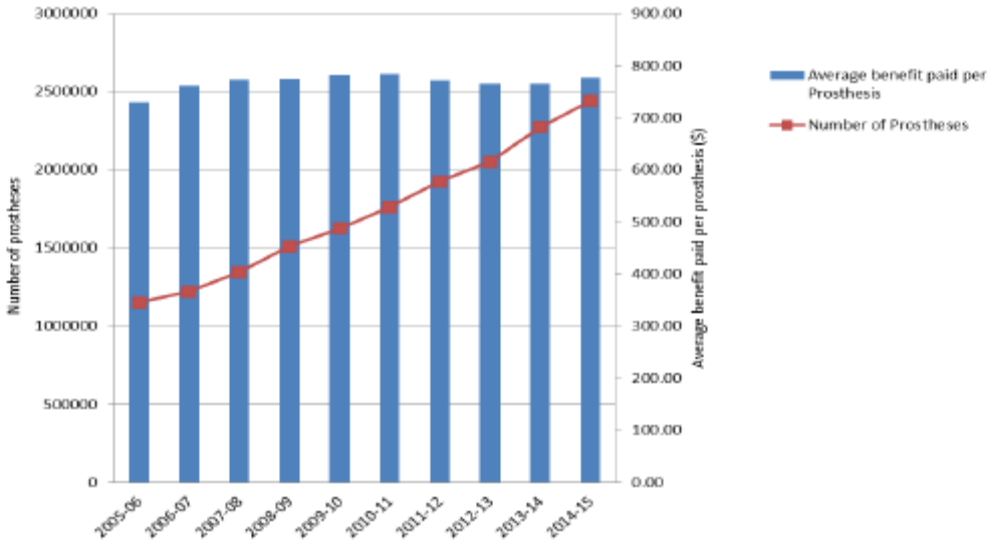
	Hospital accommodation benefits	Medical benefits	Prostheses benefits
2005-06	70.7%	15.6%	13.7%
2009-10	70.1%	15.7%	14.2%
2014-15	69.9%	15.8%	14.3%

Source: Australian Prudential Regulation Authority

The average benefit paid by insurers for prostheses increased steadily between 2005 and 2007; however, there has been little growth in average prostheses benefits since 2007 (Figure 1). The number of prostheses paid for by insurers (volume) has been growing steadily since 2005.

The growth in the volume of prostheses items, average price per item and total prostheses benefits paid since 2005 is shown in Table 2.

Figure 1: Number of prostheses used and average prostheses benefit paid (2005 – 2015)



Source: Australian Prudential Regulation Authority

Between 2005 and 2015 the average annual growth in the volume of prostheses used was 7.4% per annum. Over the same period, the average annual growth in the average benefit paid per item increased by 1.2% per annum, compared with 2.7% per annum for the CPI All Groups and 4.7% per annum for the CPI Health Component. Between 2010 and 2015 there was no growth in the average cost per item, suggesting that prices for prostheses may be falling in real terms. This suggests that the growth in expenditure on prostheses is being driven largely by underlying growth in volume (utilisation) rather than growth in the price of prostheses.

Table 2: Average annual growth rates for prostheses

	Growth in average benefit per item (price)	Growth in volume (number of items)	Growth in total benefits paid
2005 to 2015	1.2%	7.4%	8.5%
2005 to 2010	2.5%	7.0%	9.4%
2010 to 2015	0.0%	7.8%	7.7%

Source: Australian Prudential Regulation Authority

CONCLUSION

- PL arrangements have limited growth in individual benefits to a level below inflation
- Growth in overall expenditure by health funds on prostheses is due to increased volume (utilisation)

Annex 3. Example of exclusions and restrictions in PHI policies[25]

HCF

Basic Hospital

Key Features	
Excess options (per person per calendar year)	$250 or $500
No excess for kids	✔
No excess for accident related treatment	✔
Available without extras cover	Yes

Examples of what's covered - Includes accommodation, operating theatre, intensive care, Australian Government approved prostheses, pharmaceuticals (excluding experimental and high cost non PBS drugs) and physiotherapy as part of your covered admission at a HCF participating private hospital.	
Emergency ambulance	✔
Accident related treatment after joining	✔
Removal of tonsils, adenoids, appendix	✔
Surgical treatment of a hernia	✔
Removal of kidney stones and gall stones	✔
Digestive disorder procedures (e.g. bowel surgery)	✔
Cancer related services (e.g. chemotherapy)	✔
Heart surgery including diagnostic and therapeutic cardiac procedures	✖
Spinal surgery (other than surgery related to spinal scoliosis)	✖
Surgery related to spinal scoliosis	✖
Cochlear implant surgery and bone anchored hearing devices^	✖
Insulin pump treatments*	✖
Care involving dialysis for chronic renal failure	✖
Rehabilitation	▲
Psychiatric services	▲
Gastric banding and obesity surgery	✖
Assisted reproductive services (e.g. IVF, GIFT)	✖
Pregnancy and birth related services	✖
Joint investigations and reconstructions	▲
Joint replacements and revisions (e.g. hip replacements, knee replacements)	✖
Cataract and other lens related surgery	✖
Sterilisation	✖
Elective cosmetic surgery	✖
Podiatric surgery by an accredited podiatrist	✖
All other in-hospital services where a Medicare benefit is payable	✔

^ Includes associated speech and sound processors including upgrades.
# Certified Type C procedures and certified overnight Type C procedures for the treatment of diabetes.

Excess

An excess means a nominated amount you elect to pay per person, per calendar year when admitted to hospital. If hospitalised, the total excess option you select will apply only once per person in a calendar year.

Hospital benefits and 'the gap'

Hospital benefits are payable to formally admitted hospital patients at the time of the service. If you are a private patient in a non-participating private hospital, you may face a large gap depending on the hospital charges. Prior to treatment, please check with your doctor to obtain Medicare item numbers and call HCF to clarify benefits payable.

Medical Gap: Medicare will cover 75% of the Medicare Benefits Schedule (MBS) fee for medical charges and HCF will cover the remaining 25%. Some doctors may choose to charge more than the MBS fee, which may result in additional expenses, known as the 'Medical Gap'.

HCF has no-gap arrangements to assist you in eliminating the gap. Always ask your doctor what your charge will be and if they'll participate in HCF's no-gap arrangement for your procedure. If you still have questions, call HCF on 13 13 34.

Pregnancy and birth related services

To be covered for pregnancy and birth related (obstetrics) services in hospital, make sure your cover includes full benefits for these services. If not, you may wish to upgrade to a more comprehensive cover 12 months before the planned date of birth to minimise your out of pocket expenses. If you're expecting, make sure you transfer to a family membership at least two months prior to the birth of the child to ensure the baby is covered from birth.

▲ Minimum Benefits

For procedures identified as Minimum Benefits, we will pay the rate set out by the Commonwealth as the minimum shared room benefit, and benefits for Government approved Prostheses List items, if applicable.

In a private hospital: These benefits would not be adequate to cover all hospital costs and are likely to result in large out-of-pocket expenses.

In a public hospital: In the event these benefits are less than what your chosen public hospital charges, you may have out-of-pocket expenses to pay.

✖ Exclusions

If you need treatment for any procedures listed as an Exclusion in your hospital cover, you won't receive any benefits from us and you may have significant out-of-pocket expenses. Please ensure you have reviewed the exclusions on this product, and always check with us to see if you're covered before receiving treatment.

1

25 HCF Basic Hospital PS 0515. Current as at May 2015. This product summary is created from the Health Fund Rules.

Annex 4. Patient access issues for catheter ablation, fractional flow reserve guided percutaneous coronary intervention, and drug coated balloons

A. Catheter ablation for the treatment of AF[26]

Catheter ablation procedures receive funding from the Australian Government through the MBS - through a non-specific MBS item to cover all ablation procedures, whereby catheter ablation procedures for AF makes up only 30% of this item (Figure 1). With the current PL (PL) criteria, ablation catheters are not included on the PL and PHI covers only the patient's hospital stay, theatre time and professional fees but not ablation catheter – leading to inconsistent funding required to perform these procedures. **Therefore, if private patients are denied access to these procedures, they may be forced to seek treatment in the public health system. This will invariably add to the existing burden on public hospital waiting lists** (Figure 2).

Avoidable AF-related stroke and costs

AF implicates around 15-25% of all ischaemic strokes and increases to 35% of strokes for those over 80 years old.[27] Stroke is one of the leading causes of death in Australia.[28] Avoidance of an AF-related stroke is likely to save the Australian healthcare system **at least $30,000 per patient for the first year**.[29] **Evidence shows that the risk of stroke after catheter ablation for AF can be reduced to that of the general population.**[30,31]

Figure 1. Catheter ablation for AF – 30% of all MBS ablation services

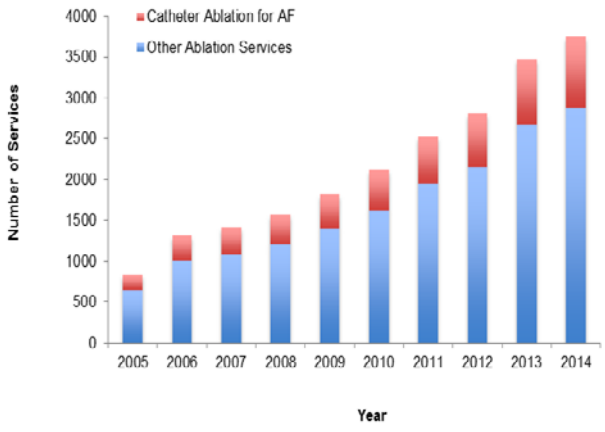
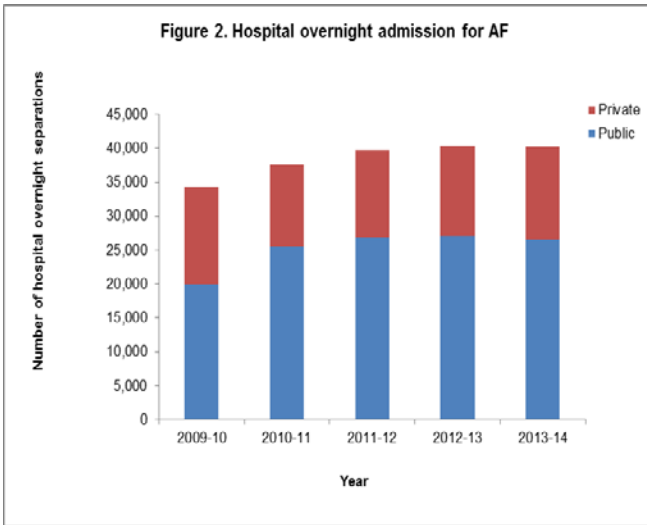


Figure 2. Hospital overnight admission for AF



26 Doolan *et al.* Poster presented at: 8th Asia Pacific Heart Rhythm Society Scientific Sessions, in conjunction with the 11th Asia Pacific Atrial Fibrillation Symposium; 2015 November 19-22; Melbourne, Australia.

27 Gattellari *et al.* 2011 *Cerebrovasc Dis.* 32(4):370–82.

28 ABS 3303.0 - Causes of Death, Australia, 2013.

29 Cadilhac *et al.* 2009. Stroke 40(3):915-21.

30 Hunter *et al.* 2012. *Heart.* 98(1):48-53.

31 Bunch *et al.* 2011. *J Cardiovasc Electrophysiol.* 22(8):839-45.

B. Fractional flow reserve (FFR) to diagnose and treat coronary heart disease[32]

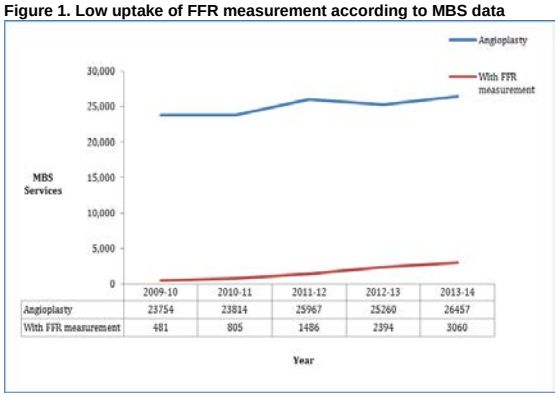
In Australia (as in other countries) most coronary lesions are revascularised based on their angiographic characteristics, often without knowledge of whether the lesion is causing ischaemia or not.[33] Assessment of ischaemia using FFR is associated with improved clinical outcomes and provides potential cost savings gained through:

- Shorter hospital stay
- Lower non-fatal myocardial infarction
- Lower repeat revascularisation[34,35]

Use of FFR measurement in the cardiac catheterisation lab saves money in both the public and private sector - where "*savings are seen over and above the improved patient care and outcomes which would have occurred with the better triage of patients for revascularisation*." [36] However, uptake of FFR is low (Figure). Despite costs incurred with the use of FFR - cost of $A1200 per wire (2010/11) - use of FFR saves money. Mean savings in the public sector were $1200 per patient and in the private sector the savings were $5000 per patient (Table 1).

PHI funds may be expected to achieve significant savings by reimbursing the use of FFR.

Figure 1. Low uptake of FFR measurement according to MBS data



PRIVATE (n=120)		
ITEM	**FFR COST ($)**	**NO FFR COST ($)**
38218*	$0	$317,200
38246/38241*	$691,600	$0
38246/38306*	$0	$952,000
38246/38306/38241*	$360,500	$0
38306/38243*	$0	$131,500
CABG	$209,000	$323,000
O/N STAY	$31,475	$98,202
DAYSTAY	$71,345	$39,052
DES	$90,000	$296,250
BMS	$6,000	$16,000
PW	$159,900	$0
MIBI/SE	$0	$21,000
Clopidogrel^	$49,000	$78,000
Total	$1,668,820	$2,272,204
Cost savings gained through FFR use		$603,384
Cost savings gained per private patient with FFR use		$5028.20

Table 1. Costs associated with treatment of the patient with or without the use of FFR in private sector

Adapted from Murphy et al., 2014[35]

*MBS item numbers attached to theatre fees: 38218 diagnostic angiography, 38246 diagnostic angiography and coronary intervention/FFR, 38241 FFR 38306 stent placement, 38243 coronary intervention without diagnostic angiography.

^Clopidogrel treatment for one year was added after stenting when the patient was clinically stable and had not had any other coronary stents within the previous 12 months.

Abbreviations: BMS, bare metal stent; CABG, coronary artery bypass grafting; DES, drug-eluting stent; FFR, fractional flow reserve, MIBI/SE, MIBI scanning or stress echocardiography; O/N overnight; PCI, percutaneous coronary intervention; PW, pressure wire.

	Treatment of CHD patient without FFR	**Treatment of CHD patient using FFR**
Cost per stent	$3450[i]	$3450
Number of stents used per case[iii]	2.74	1.93
Total cost of stents used per case[iv]	$9453	$6658.50
Cost of pressure wire	0	$1360[ii]
Overall cost of stents and pressure wire per episode of care	**$9453**	**$8018.50**
Saving		**$1434.50**

Table 2. Economic analysis indicating that FFR measurement reduces costs due to reduction in stents implantation

Abbreviation: CHD, Coronary heart disease.

i Benefit paid by health funds for drug eluting stents is $3450.

ii Pressure wire costs $1360.

iii An average of 2.74 coronary stents is used per case. This is reduced to an average of 1.93 coronary stents per case if FFR is measured first with a pressure wire. Source: Tonino et al., 2009[37]

iv Cost of stents = cost per stent x number of stents used per case.

32 Value of Technology. Inequitable patient access to clinically and cost effective medical technology: Fractional flow reserve to diagnose and guide treatment of coronary heart disease. Poster presented at the MTAA Annual Conference: MedTech 2015.

33 Harper and Ko., 2011. *Med J Aust*. 194 (4): 186-9.

34 Park *et al*., 2013. *Eur Heart J*. 34:3353-61.

35 Pijls et al., 2007. *J Am Coll Cardiol*. 49(21):2105-11.

36 Murphy *et al.,. Heart Lung Circ*. 23(9):807-10.

37 Tonino *et al*, 2009. *N Engl J Med.* 360(3):213-24.

C. Drug-coated balloons

- Use of DCB has been determined to be **clinically and cost-effective treatment** option (Figures 1 and 2). However, unlike BMS and DES, DEB may not meet criteria for inclusion the PL because they are not permanently surgically implanted. This creates a persevere incentive to use a less clinically and cost-effective option because there is certainty of funding for devices on the PL.

- **Lack of a funding pathway for DCB could effectively preclude clinicians from accessing this therapy,** and could mean that **therapy choice is restricted/limited to those therapies that rely upon devices that are funded through inclusion on the PL rather than what is clinically appropriate for patients.**

- **Impact of no funding pathway**: current Commonwealth arrangements for assessing medical technology for reimbursement by Private Health Insurers are restricted to permanently implanted medical devices: **the clinical benefits for patients and predicted cost benefits to private health insurers from the use of DCB may not be realised unless an appropriate funding pathway is established.**

- The current fee-for-service models and reimbursement schemes create a financial disincentive for private hospitals to use DCB thus potentially **limiting the uptake of a treatment strategy that is beneficial for both the patients and the healthcare system.**

Figure 1. Clinical (Target Lesion Revascularisation) - 24 months estimates

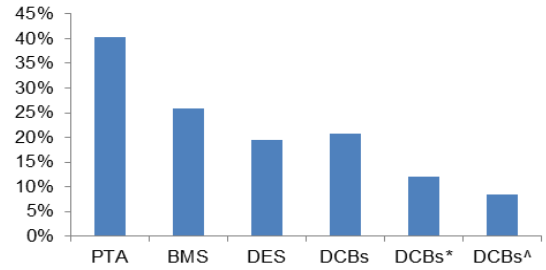
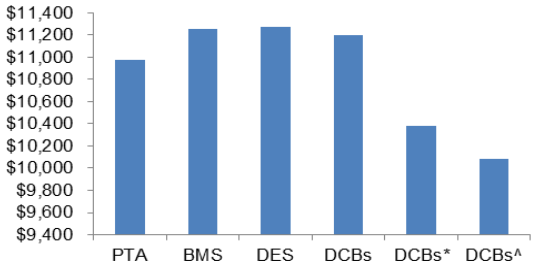


Figure 2. Economic - 24-month Budget Impact Estimates



Abbreviations: BMS, bare metal stent; DCB, drug coated balloon; DES, drug eluting stent; PTA, percutaneous balloon angioplasty.

Charts adapted from Pietzsch *et al.*, 2014[38,39]. DCBs* and DCBs^ - indicate new/advanced DCBs.

38 Pietzsch *et al.*, 2014. *Catheter Cardiovasc Interv.* 84(4):546-54.

39 MTAA internal data

Annex 5. Custom made devices

For convenience and to facilitate PHI approvals, the price of a custom made graft is based on the nearest off-the-shelf PL listed device. This may vary greatly depending on the clinical purpose of the device (e.g. an aortic aneurysm (AAA) main body graft PL benefit is $5,794 ranging to a benefit of $14,500 for a long thoracic graft).

However, while cost is an issue, the more pressing concern is the requirement to request an ex-gratia payment from the insurer which potentially slows down treatment of the private patient. Note, in the public system, it would normally just require the head of the vascular department to approve the payment. The following is an example of the approval process covering a CMD endo-vascular graft.

When a surgeon determines clinically that their patient is not suitable for treatment with a standard off-the-shelf device, the doctor will prescribe a custom made endovascular graft for a patient. The sponsor confirms to the surgeon that the graft is not on the PL and therefore the surgeon will need to request (on behalf of their patient) an ex-gratia payment for the device from the patient's PHI fund. Ex-gratia payments are discretionary payments for services not covered under the rules of the insurer. The surgeon will be required to clearly explain to the PHI fund the clinical scenario that necessitates the use of the CMD. Over the past 6-12 months, the sponsor has noticed an increased time to approval. While funds will generally approve these payments, review of the surgeon's request and the clinical documentation slows the approval process, resulting in delays to the manufacturing of the prosthesis.

As CMDs will often take 4-6 weeks to plan, design and manufacture, further delays due to approval issues with the private insurer often extends the date of surgery, increasing the time in which the patient remains untreated and potentially at risk from aneurysm rupture. Delays in treating aortic aneurysms can be life threatening and the uncertainty of payment and whether the procedure will be covered can be a cause of great anxiety. As these are bespoke products for the individual patient, as a commercial manufacturer, the sponsor cannot start to manufacturer the product until certain that the procedure will proceed.

In the public system, it is normally the responsibility of the director of Vascular Surgery to sign-off the payment for the custom made endovascular grafts. The relative ease for use of a CMD in the public system could be seen to create an inequity between public and private patients.